LAW, AGRICULTURE, AND BIOTECHNOLOGY

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I. Chapter One: Introduction to Agricultural Law

A. WHAT IS AGRICULTURE? REALITY AND IDEOLOGY

1. Public lawmaking and agricultural politics

To see how regulatory rationales, interest-group politics, and the breathtaking scope of agricultural policymaking combine in the making of agricultural public law, consider the following classic case. President Roosevelt had made agricultural reform a top priority of the New Deal. The Commodity Credit Corporation, Soil Conservation Service, Tennessee Valley Authority, Rural Electrification Administration, the Farmers Home Administration, and numerous other agricultural institutions all sprang to life during Roosevelt's first term. But the Supreme Court in 1936 had struck down the legislative centerpiece of the New Deal's agricultural agenda, the Agricultural Adjustment Act of 1933.1 Congress responded in part by enacting the Agricultural Adjustment Act of 1938.2 The constitutional battle that ensued revolutionized not only agricultural regulation, but also the very idea of law in America:

Wickard v. Filburn
Supreme Court of the United States
317 U.S. 111 (1942)

MR. JUSTICE JACKSON delivered the opinion of the Court.

The appellee filed his complaint against the Secretary of Agriculture of the United States, [seeking] to enjoin enforcement against himself of the marketing penalty imposed by the amendment of May 26, 1941, to the Agricultural Adjustment Act of 1938, upon that part of his 1941 wheat crop which was available for marketing in excess of the marketing quota established for his farm. He also sought a declaratory judgment that the wheat marketing quota provisions of the Act as amended and applicable to him were unconstitutional because not sustainable under the Commerce Clause or consistent with the Due Process Clause of the Fifth Amendment. . . .

The appellee for many years past has owned and operated a small farm in Montgomery County, Ohio, maintaining a herd of dairy cattle, selling milk, raising poultry, and selling poultry and eggs. It has been his practice to raise a small acreage of winter wheat, sown in the Fall and harvested in the following July; to sell a portion of the crop; to feed part to poultry and livestock on the farm, some of which is sold; to use some in making flour for home consumption; and to keep the rest for the following seeding. The intended disposition of the crop here involved has not been expressly stated.

1See United States v. Butler, 297 U.S. 1 (1936). This decision is excerpted in chapter 5. You may wish to skim that chapter's brief survey of the history of price and income regulation, which treats cases such as Butler and Filburn as emblems of the "agricultural moment" in American legal history.

252 Stat. 31.
In July of 1940, pursuant to the Agricultural Adjustment Act of 1938, as then amended, there were established for the appellee's 1941 crop a wheat acreage allotment of 11.1 acres and a normal yield of 20.1 bushels of wheat an acre. He was given notice of such allotment in July of 1940 before the Fall planting of his 1941 crop of wheat, and again in July of 1941, before it was harvested. He sowed, however, 23 acres, and harvested from his 11.9 acres of excess acreage 239 bushels, which under the terms of the Act as amended on May 26, 1941, constituted farm marketing excess, subject to a penalty of 49 cents a bushel, or $117.11 in all. The appellee has not paid the penalty and he has not postponed or avoided it by storing the excess under regulations of the Secretary of Agriculture, or by delivering it up to the Secretary. The Committee, therefore, refused him a marketing card, which was, under the terms of Regulations promulgated by the Secretary, necessary to protect a buyer from liability to the penalty and upon its protecting lien.

The general scheme of the Agricultural Adjustment Act of 1938 as related to wheat is to control the volume moving in interstate and foreign commerce in order to avoid surpluses and shortages and the consequent abnormally low or high wheat prices and obstructions to commerce. Within prescribed limits and by prescribed standards the Secretary of Agriculture is directed to ascertain and proclaim each year a national acreage allotment for the next crop of wheat, which is then apportioned to the states and their counties, and is eventually broken up into allotments for individual farms. Loans and payments to wheat farmers are authorized in stated circumstances.

The Act provides further that whenever it appears that the total supply of wheat as of the beginning of any marketing year, beginning July 1, will exceed a normal year's domestic consumption and export by more than 35 per cent, the Secretary shall so proclaim not later than May 15 prior to the beginning of such marketing year; and that during the marketing year a compulsory national marketing quota shall be in effect with respect to the marketing of wheat. Between the issuance of the proclamation and June 10, the Secretary must, however, conduct a referendum of farmers who will be subject to the quota to determine whether they favor or oppose it; and if more than one-third of the farmers voting in the referendum do oppose, the Secretary must prior to the effective date of the quota by proclamation suspend its operation.

On May 19, 1941 the Secretary of Agriculture made a radio address to the wheat farmers of the United States in which he advocated approval of the quotas and called attention to the pendency of the amendment of May 26, 1941, which had at the time been sent by Congress to the White House, and pointed out its provision for an increase in the loans on wheat to 85 per cent of parity. He made no mention of the fact that it also increased the penalty from 15 cents a bushel to one-half of the parity loan rate of about 98 cents, but stated that "Because of the uncertain world situation, we deliberately planted several million extra acres of wheat . . . . Farmers should not be penalized because they have provided insurance against shortages of food."

Pursuant to the Act, the referendum of wheat growers was held on May 31, 1941. According to the required published statement of the Secretary of Agriculture, 81 per cent of those voting
favored the marketing quota, with 19 per cent opposed.

The court below held . . . that the amendment of May 26, 1941, "in so far as it increased the penalty for the farm marketing excess over the fifteen cents per bushel prevailing at the time of planting and subjected the entire crop to a lien for the payment thereof," should not be applied to the appellee because as so applied it was retroactive and in violation of the Fifth Amendment; and, alternatively, because the equities of the case so required. Its judgment permanently enjoined appellants from collecting a marketing penalty of more than 15 cents a bushel on the farm marketing excess of appellee's 1941 wheat crop, from subjecting appellee's entire 1941 crop to a lien for the payment of the penalty, and from collecting a 15-cent penalty except in accordance with the provisions of § 339 of the Act as that section stood prior to the amendment of May 26, 1941. The Secretary and his co-defendants have appealed.

I.

[Omitted.]

II.

It is urged that under the Commerce Clause of the Constitution, Article I, § 8, clause 3, Congress does not possess the power it has in this instance sought to exercise. The question would merit little consideration since our decision in United States v. Darby, 312 U.S. 100 [(1941)], sustaining the federal power to regulate production of goods for commerce except for the fact that this Act extends federal regulation to production not intended in any part for commerce but wholly for consumption on the farm. The Act includes a definition of "market" and its derivatives so that as related to wheat in addition to its conventional meaning it also means to dispose of "by feeding (in any form) to poultry or livestock which, or the products of which, are sold, bartered, or exchanged, or to be so disposed of." Hence, marketing quotas not only embrace all that may be sold without penalty but also what may be consumed on the premises. Wheat produced on excess acreage is designated as "available for marketing" as so defined and the penalty is imposed thereon. Penalties do not depend upon whether any part of the wheat either within or without the quota is sold or intended to be sold. The sum of this is that the Federal Government fixes a quota including all that the farmer may harvest for sale or for his own farm needs, and declares that wheat produced on excess acreage may neither be disposed of nor used except upon payment of the penalty or except it is stored as required by the Act or delivered to the Secretary of Agriculture.

Appellee says that this is a regulation of production and consumption of wheat. Such activities are, he urges, beyond the reach of Congressional power under the Commerce Clause, since they are local in character, and their effects upon interstate commerce are at most "indirect." In answer the Government argues that the statute regulates neither production nor consumption, but only marketing; and, in the alternative, that if the Act does go beyond the regulation of marketing it is sustainable as a "necessary and proper" implementation of the power of Congress over interstate commerce.
The Government's concern lest the Act be held to be a regulation of production or consumption rather than of marketing is attributable to a few dicta and decisions of this Court which might be understood to lay it down that activities such as "production," "manufacturing," and "mining" are strictly "local" and, except in special circumstances which are not present here, cannot be regulated under the commerce power because their effects upon interstate commerce are, as matter of law, only "indirect." Even today, when this power has been held to have great latitude, there is no decision of this Court that such activities may be regulated where no part of the product is intended for interstate commerce or intermingled with the subjects thereof. We believe that a review of the course of decision under the Commerce Clause will make plain, however, that questions of the power of Congress are not to be decided by reference to any formula which would give controlling force to nomenclature such as "production" and "indirect" and foreclose consideration of the actual effects of the activity in question upon interstate commerce.

[The Court reviewed its previous commerce clause decisions.]

The Court's recognition of the relevance of the economic effects in the application of the Commerce Clause . . . has made the mechanical application of legal formulas no longer feasible. Once an economic measure of the reach of the power granted to Congress in the Commerce Clause is accepted, questions of federal power cannot be decided simply by finding the activity in question to be "production" nor can consideration of its economic effects be foreclosed by calling them "indirect." . . .

Whether the subject of the regulation in question was "production," "consumption," or "marketing" is, therefore, not material for purposes of deciding the question of federal power before us. That an activity is of local character may help in a doubtful case to determine whether Congress intended to reach it. The same consideration might help in determining whether in the absence of Congressional action it would be permissible for the state to exert its power on the subject matter, even though in so doing it to some degree affected interstate commerce. But even if appellee's activity be local and though it may not be regarded as commerce, it may still, whatever its nature, be reached by Congress if it exerts a substantial economic effect on interstate commerce and this irrespective of whether such effect is what might at some earlier time have been defined as "direct" or "indirect."

The parties have stipulated a summary of the economics of the wheat industry. Commerce among the states in wheat is large and important. Although wheat is raised in every state but one, production in most states is not equal to consumption. Sixteen states on average have had a surplus of wheat above their own requirements for feed, seed, and food. Thirty-two states and the District of Columbia, where production has been below consumption, have looked to these surplus-producing states for their supply as well as for wheat for export and carryover.

The wheat industry has been a problem industry for some years. Largely as a result of increased foreign production and import restrictions, annual exports of wheat and flour from the United States
during the ten-year period ending in 1940 averaged less than 10 per cent of total production, while
during the 1920's they averaged more than 25 per cent. The decline in the export trade has left a
large surplus in production which in connection with an abnormally large supply of wheat and other
grains in recent years caused congestion in a number of markets; tied up railroad cars; and caused
elevators in some instances to turn away grains, and railroads to institute embargoes to prevent
further congestion.

Many countries, both importing and exporting, have sought to modify the impact of the world
market conditions on their own economy. Importing countries have taken measures to stimulate
production and self-sufficiency. The four large exporting countries of Argentina, Australia, Canada,
and the United States have all undertaken various programs for the relief of growers. Such measures
have been designed in part at least to protect the domestic price received by producers. Such plans
have generally evolved towards control by the central government.

In the absence of regulation the price of wheat in the United States would be much affected by
world conditions. During 1941 producers who cooperated with the Agricultural Adjustment program
received an average price on the farm of about $1.16 a bushel as compared with the world market
price of 40 cents a bushel.

Differences in farming conditions, however, make these benefits mean different things to
different wheat growers. There are several large areas of specialization in wheat, and the
concentration on this crop reaches 27 percent of the crop land, and the average harvest runs as high
as 155 acres. Except for some use of wheat as stock feed and for seed, the practice is to sell the crop
for cash. Wheat from such areas constitutes the bulk of the interstate commerce therein.

On the other hand, in some New England states less than one percent of the crop land is devoted
to wheat, and the average harvest is less than five acres per farm. In 1940 the average percentage
of the total wheat production that was sold in each state as measured by value ranged from 29 per
cent thereof in Wisconsin to 90 per cent in Washington. Except in regions of large-scale production,
wheat is usually grown in rotation with other crops; for a nurse crop for grass seeding; and as a cover
crop to prevent soil erosion and leaching. Some is sold, some kept for seed, and a percentage of the
total production much larger than in areas of specialization is consumed on the farm and grown for
such purpose. Such farmers, while growing some wheat, may even find the balance of their interest
on the consumer's side.

The effect of consumption of homegrown wheat on interstate commerce is due to the fact that
it constitutes the most variable factor in the disappearance of the wheat crop. Consumption on the
farm where grown appears to vary in an amount greater than 20 per cent of average production. The
total amount of wheat consumed as food varies but relatively little, and use as seed is relatively
constant.

The maintenance by government regulation of a price for wheat undoubtedly can be
accomplished as effectively by sustaining or increasing the demand as by limiting the supply. The effect of the statute before us is to restrict the amount which may be produced for market and the extent as well to which one may forestall resort to the market by producing to meet his own needs. That appellee's own contribution to the demand for wheat may be trivial by itself is not enough to remove him from the scope of federal regulation where, as here, his contribution, taken together with that of many others similarly situated, is far from trivial.

It is well established by decisions of this Court that the power to regulate commerce includes the power to regulate the prices at which commodities in that commerce are dealt in and practices affecting such prices. One of the primary purposes of the Act in question was to increase the market price of wheat and to that end to limit the volume thereof that could affect the market. It can hardly be denied that a factor of such volume and variability as home-consumed wheat would have a substantial influence on price and market conditions. This may arise because being in marketable condition such wheat overhangs the market and if induced by rising prices tends to flow into the market and check price increases. But if we assume that it is never marketed, it supplies a need of the man who grew it which would otherwise be reflected by purchases in the open market. Home-grown wheat in this sense competes with wheat in commerce. The stimulation of commerce is a use of the regulatory function quite as definitely as prohibitions or restrictions thereon. This record leaves us in no doubt that Congress may properly have considered that wheat consumed on the farm where grown if wholly outside the scheme of regulation would have a substantial effect in defeating and obstructing its purpose to stimulate trade therein at increased prices.

It is said, however, that this Act, forcing some farmers into the market to buy what they could provide for themselves, is an unfair promotion of the markets and prices of specializing wheat growers. It is of the essence of regulation that it lays a restraining hand on the self-interest of the regulated and that advantages from the regulation commonly fall to others. The conflicts of economic interest between the regulated and those who advantage by it are wisely left under our system to resolution by the Congress under its more flexible and responsible legislative process. Such conflicts rarely lend themselves to judicial determination. And with the wisdom, workability, or fairness, of the plan of regulation we have nothing to do.

III.

The statute is also challenged as a deprivation of property without due process of law contrary to the Fifth Amendment, both because of its regulatory effect on the appellee and because of its alleged retroactive effect. The court below sustained the plea on the ground of forbidden retroactivity "or in the alternative, that the equities of the case as shown by the record favor the plaintiff." An Act of Congress is not to be refused application by the courts as arbitrary and capricious and forbidden by the Due Process Clause merely because it is deemed in a particular case to work an inequitable result.

Appellee's claim that the Act works a deprivation of due process even apart from its allegedly retroactive effect is not persuasive. Control of total supply, upon which the whole statutory plan is
WHAT IS AGRICULTURE?

based, depends upon control of individual supply. Appellee's claim is not that his quota represented less than a fair share of the national quota, but that the Fifth Amendment requires that he be free from penalty for planting wheat and disposing of his crop as he sees fit.

We do not agree. In its effort to control total supply, the Government gave the farmer a choice which was, of course, designed to encourage cooperation and discourage non-cooperation. The farmer who planted within his allotment was in effect guaranteed a minimum return much above what his wheat would have brought if sold on a world market basis. Exemption from the applicability of quotas was made in favor of small producers. The farmer who produced in excess of his quota might escape penalty by delivering his wheat to the Secretary or by storing it with the privilege of sale without penalty in a later year to fill out his quota, or irrespective of quotas if they are no longer in effect, and he could obtain a loan of 60 per cent of the rate for cooperators, or about 59 cents a bushel, on so much of his wheat as would be subject to penalty if marketed. Finally, he might make other disposition of his wheat, subject to the penalty. It is agreed that as the result of the wheat programs he is able to market his wheat at a price "far above any world price based on the natural reaction of supply and demand." We can hardly find a denial of due process in these circumstances, particularly since it is even doubtful that appellee's burdens under the program outweigh his benefits. It is hardly lack of due process for the Government to regulate that which it subsidizes.

The amendment of May 26, 1941 is said to be invalidly retroactive in two respects: first, in that it increased the penalty from 15 cents to 49 cents a bushel; secondly, in that by the new definition of "farm marketing excess" it subjected to the penalty wheat which had theretofore been subject to no penalty at all, i.e., wheat not "marketed" as defined in the Act.

It is not to be denied that between seed time and harvest important changes were made in the Act which affected the desirability and advantage of planting the excess acreage. The law as it stood when the appellee planted his crop made the quota for his farm the normal or the actual production of the acreage allotment, whichever was greater, plus any carry-over wheat that he could have marketed without penalty in the preceding marketing year. The Act also provided that the farmer who, while quotas were in effect, marketed wheat in excess of the quota for the farm on which it was produced should be subject to a penalty of 15 cents a bushel on the excess so marketed. Marketing of wheat was defined as including disposition "by feeding (in any form) to poultry or livestock which, or the products of which, are sold, bartered, or exchanged ..." The amendment of May 26, 1941, made before the appellee had harvested the growing crop, changed the quota and penalty provisions. The quota for each farm became the actual production of acreage planted to wheat less the normal or the actual production, whichever was smaller, of any excess acreage. Wheat in excess of this quota, known as the "farm-marketing excess" and declared by the amendment to be "regarded as available for marketing" was subjected to a penalty fixed at 50 per cent of the basic loan rate for cooperators, or 49 cents, instead of the penalty of 15 cents which obtained at the time of planting. At the same time there was authorized an increase in the amount of the loan which might be made to non-cooperators such as the appellee upon wheat which "would be subject to penalty if marketed"
from about 34 cents per bushel to about 59 cents. The entire crop was subjected by the amendment to a lien for the payment of the penalty.

The penalty provided by the amendment can be postponed or avoided only by storing the farm marketing excess according to regulations promulgated by the Secretary or by delivering it to him without compensation; and the penalty is incurred and becomes due on threshing. Thus the penalty was contingent upon an act which appellee committed not before but after the enactment of the statute, and had he chosen to cut his excess and cure it or feed it as hay, or to reap and feed it with the head and straw together, no penalty would have been demanded. Such manner of consumption is not uncommon. Only when he threshed and thereby made it a part of the bulk of wheat overhanging the market did he become subject to penalty. He has made no effort to show that the value of his excess wheat consumed without threshing was less than it would have been had it been threshed while subject to the statutory provisions in force at the time of planting. Concurrently with the increase in the amount of the penalty Congress authorized a substantial increase in the amount of the loan which might be made to cooperators upon stored farm marketing excess wheat. That appellee is the worse off for the aggregate of this legislation does not appear; it only appears that if he could get all that the Government gives and do nothing that the Government asks, he would be better off than this law allows. To deny him this is not to deny him due process of law.  

Reversed.

* * * * *

To the extent that he consumed his wheat on the farm, farmer Filburn argued, he was engaged in the putatively local act of wheat rather than the interstate (and regulated) act of marketing wheat. Ever since, jurists and constitutional law scholars have debated the extent to which seemingly trivial individual acts should be regarded as contributions to a mass market whose aggregate effects on interstate or international commerce justify congressional action. This sort of analysis is, by and large, agriculturally illiterate. It is impossible to debate the scope of Congress's authority to regulate wheat production in the abstract, to study precedent Filburn without studying farmer Filburn's agricultural practices. Like Old McDonald of lore, Old Man Filburn had a biologically diverse farm:

And on this farm he had some cows,  
Ee-eye-ee-eye-ooh.

---

*Compare, e.g., Laurence H. Tribe, American Constitutional Law § 5-5, at 310-11 & n.6 (2d ed. 1988) (noting that Filburn established the principle that "Congress has the power to regulate not only acts which taken alone would have substantial economic effect on interstate commerce, . . . but also acts which might reasonably be deemed nationally significant in their aggregate economic effect" (emphases in original)), with Hodel v. Virginia Surface Mining & Reclamation Ass'n, Inc., 452 U.S. 264, 310 (1981) (Rehnquist, J., concurring in the judgment) ("Some activities may be so private or local in nature that they simply may not be in commerce" (emphasis in original)).
A moo-moo here, a moo-moo there,
Here a moo, there a moo,
Everywhere a moo-moo . . . .

And on this farm he had some chicks,
Ee-eye-ee-eye-ooh.
A cluck-cluck here, a cluck-cluck there,
Here a cluck, there a cluck,
Everywhere a cluck-cluck.4

When Filburn consumed his wheat "at home," he most assuredly was not diverting wheat from the interstate market into his kitchen. He used the wheat from acres exceeding his allotment to feed the dairy cows and egg-laying chickens on his farm. In so doing, he converted an adversely regulated commodity (wheat) into forms of wealth (milk, meat, and eggs) that eluded the long arm of the Agricultural Adjustment Act. In a nation that produced its wheat on multi-use farms that integrated wheat fields with barnyard animals, so broad a "home consumption" loophole in the AAA's wheat program would have devastated any hope of bringing wheat prices and supplies under control.

Furthermore, farmer Filburn grew wheat, a commodity represented in many prototypical models of perfect competition. In that nirvana-like economic state, consumers retain all surplus, at the expense of marginal producers unable to keep their costs below the market-clearing price for the commodity in question. Why, then, did the Agricultural Adjustment Act undertake to raise wheat prices and to suppress wheat prices? We would expect no less from a price-gouging natural monopolist, but from the sovereign government of these United States? A pro-consumer perspective on the standard rationales underlying agricultural law and policy might assert that the law tends more to protect farmers as "price takers" than to shield consumers from the effects of price-gouging. Is there a case for protecting consumers from farmers as well as from agribusinesses? Why, despite the triumph of the consumer welfare model in virtually every other facet of American economic thought, does producer welfare dominate the making and analysis of agricultural policy in the United States?5

Bear in mind that agricultural public law in the age of National Broiler Marketing Association and Wickard v. Filburn is driven by legislative and administrative decisionmakers. Both farm and agribusiness interests are very well organized, especially relative to food consumers. The farm sector, the input sector, and the agribusiness sectors are all "minorities," at least in numerical terms, relative to the broader taxpayer and consumer classes. No one has seriously sought to confer political minority status on suppliers of nonfarm inputs or on agribusinesses. (Why not?)


opposite is true for farmers.\textsuperscript{6}

The legal profession's numerous aphorisms share one ironic characteristic: the more talismanic a particular maxim, the more misleading it is. All of you know the following adage, which lies firmly in the intellectual foundation on which the modern theories of constitutional law and judicial review are based:

\begin{quote}
[P]rejudice against discrete and insular minorities may be a special condition, which tends seriously to curtail the operation of those political processes ordinarily to be relied upon to protect minorities, and which may call for a correspondingly searching judicial inquiry.\textsuperscript{7}
\end{quote}

The "footnote four" principle can be generalized into a rationale for special legal treatment of a politically disfavored "discrete and insular" minority. Let's examine how well this principle applies to agriculture:

\textsuperscript{6}We need look no further than the title of a leading study on the American farmer. \textit{See} GILBERT C. FITE, AMERICAN FARMERS: THE NEW MINORITY (1981).

\textsuperscript{7}United States v. Carolene Prods. Co., 304 U.S. 144, 153 n.4 (1938).
United States v. Carolene Products Co.
Supreme Court of the United States
304 U.S. 144 (1938)

MR. JUSTICE STONE delivered the opinion of the Court.

The question for decision is whether the "Filled Milk Act" of Congress of March 4, 1923,\(^1\) which prohibits the shipment in interstate commerce of skimmed milk compounded with any fat or oil other than milk fat, so as to resemble milk or cream, . . . infringes the Fifth Amendment.

Appellee was indicted . . . for violation of the act by the shipment in interstate commerce of certain packages of "Milnut," a compound of condensed skimmed milk and coconut oil made in imitation or semblance of condensed milk or cream. The indictment states . . . that Milnut "is an adulterated article of food, injurious to the public health," and that it is not a prepared food product of the type excepted from the prohibition of the act. . . .

Appellee . . . complains that the statute denies to it equal protection of the laws, and in violation of the Fifth Amendment, deprives it of its property without due process of law, particularly in that the statute purports to make binding and conclusive upon appellee the legislative declaration that appellee's product "is an adulterated article of food, injurious to the public health, and its sale constitutes a fraud on the public" . . .

The prohibition of shipment of appellee's product in interstate commerce does not infringe the Fifth Amendment. Twenty years ago this Court held that a state law which forbids the manufacture and sale of a product assumed to be wholesome and nutritive, made of condensed skimmed milk, compounded with coconut oil, is not forbidden by the Fourteenth Amendment. The power of the Legislature to secure a minimum of particular nutritive elements in a widely used article of food and to protect the public from fraudulent substitutions, was not doubted; and the Court thought that there was ample scope for the legislative judgment that prohibition of the offending article was an

\(^1\) . . . "Section 61. . . . (c) The term 'filled milk' means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated."

"§ 62. . . . It is declared that filled milk, as herein defined, is an adulterated article of food, injurious to the public health, and its sale constitutes a fraud upon the public. It shall be unlawful for any person to . . . ship or deliver for shipment in interstate or foreign commerce, any filled milk" . . .
appropriate means of preventing injury to the public.

We see no persuasive reason for departing from that ruling here, where the Fifth Amendment is concerned; and since none is suggested, we might rest decision wholly on the presumption of constitutionality. But affirmative evidence also sustains the statute. In twenty years evidence has steadily accumulated of the danger to the public health from the general consumption of foods which have been stripped of elements essential to the maintenance of health. The Filled Milk Act was adopted by Congress after committee hearings, in the course of which eminent scientists and health experts testified. An extensive investigation was made of the commerce in milk compounds in which vegetable oils have been substituted for natural milk fat, and of the effect upon the public health of the use of such compounds as a food substitute for milk. The conclusions drawn from evidence presented at the hearings were embodied in reports of the House Committee on Agriculture and the Senate Committee on Agriculture and Forestry. Both committees concluded, as the statute itself declares, that the use of filled milk as a substitute for pure milk is generally injurious to health and facilitates fraud on the public.²

There is nothing in the Constitution which compels a Legislature, either national or state, to ignore such evidence, nor need it disregard the other evidence which amply supports the conclusions of the Congressional committees that the danger is greatly enhanced where an inferior product, like appellee's, is indistinguishable from a valuable food of almost universal use, thus making fraudulent

²The reports may be summarized as follows: There is an extensive commerce in milk compounds made of condensed milk from which the butter fat has been extracted and an equivalent amount of vegetable oil, usually coconut oil, substituted. These compounds resemble milk in taste and appearance and are distributed in packages resembling those in which pure condensed milk is distributed. By reason of the extraction of the natural milk fat the compounded product can be manufactured and sold at a lower cost than pure milk. Butter fat, which constitutes an important part of the food value of pure milk, is rich in vitamins, food elements which are essential to proper nutrition, and are wanting in vegetable oils. The use of filled milk as a dietary substitute for pure milk results, especially in the case of children, in undernourishment, and induces diseases which attend malnutrition. Despite compliance with the branding and labeling requirements of the Pure Food and Drugs Act, there is widespread use of filled milk as a food substitute for pure milk. This is aided by their identical taste and appearance, by the similarity of the containers in which they are sold, by the practice of dealers in offering the inferior product to customers as being as good as or better than pure condensed milk sold at a higher price, by customers' ignorance of the respective food values of the two products, and in many sections of the country by their inability to read the labels placed on the containers. Large amounts of filled milk, much of it shipped and sold in bulk, are purchased by hotels and boarding houses, and by manufacturers of food products, such as ice cream, to whose customers labeling restrictions afford no protection.
distribution easy and protection of the consumer difficult.\(^3\)

Here the prohibition of the statute is inoperative unless the product is "in imitation or semblance of milk, cream, or skimmed milk, whether or not condensed." Whether in such circumstance the public would be adequately protected by the prohibition of false labels and false branding imposed by the Pure Food and Drugs Act, or whether it was necessary to go farther and prohibit a substitute food product thought to be injurious to health if used as a substitute when the two are not distinguishable, was a matter for the legislative judgment and not that of courts. It was upon this ground that the prohibition of the sale of oleomargarine made in imitation of butter was held not to infringe the Fourteenth Amendment.

Appellee raises no valid objection to the present statute by arguing that its prohibition has not been extended to oleomargarine or other butter substitutes in which vegetable fats or oils are substituted for butter fat. . . .

_Reversed._

[Justice Black concurred in the result and in most of the opinion, including the portion excerpted here. Justice Butler concurred in the result. Justice McReynolds dissented. Justices Cardozo and Reed took no part in the consideration or decision of the case.]

* * * *

The obvious negative implication of _Carolene Products_\(^4\) footnote four was that the distributor of filled milk did not belong to a discrete and insular minority. As I noted at the beginning of this discussion, nonfarm players in agriculture – whether involved in supplying inputs or in processing, marketing, or distributing farm products – have not established a historical claim to favored political status. The food-consuming public (i.e., everyone) is simply too vast a group to qualify as a minority, much less a discrete and insular one. But note that the Supreme Court defended the Filled Milk Act as a consumer protection statute. Was this the likeliest explanation for the statute's enactment? It is true that by 1923, the modern phenomenon of unpaid consumer advocacy had emerged, spurred in large part by public revulsion to the meat-packing abuses depicted in Upton Sinclair's muckraking novel, _The Jungle_. Besides, how pro-consumer is a statute that bans voluntary purchases of filled milk for use in cooking, as a beverage, or in food processing? (Think of the

\(^3\)There is now an extensive literature indicating wide recognition by scientists and dietitians of the great importance to the public health of butter fat and whole milk as the prime source of vitamins, which are essential growth producing and disease preventing elements in the diet.

When the Filled Milk Act was passed, eleven states had rigidly controlled the exploitation of filled milk, or forbidden it altogether. Some thirty-five states have now adopted laws which in terms, or by their operation, prohibit the sale of filled milk. Three others have subjected its sale to rigid regulations.
market for nondairy creamers, cheese food products, and the like.) If Congress was truly concerned
with the lack of consumer information about filled milk, why didn't it simply strengthen the truth-in-
labeling provisions of the Pure Food and Drugs Act (now the Pure Food, Drugs, and Cosmetics
Act)? If labeling cannot protect consumers who buy filled milk after its use in other processed foods
such as ice cream, why not ban only filled milk sales for uses other than direct consumption?

On the other hand, filled milk processors were competing directly against dairy farmers, who
would have an obvious financial interest in banning filled milk. Wouldn't this sort of lobbying
simply implicate two different parts of the farm sector? No: the filled milk at issue in Carolene
Products was processed from coconut oil. Coconut farming has never really been a key domestic
industry. Even if oilseed producers could sell coconut substitutes to filled milk processors, the bulk
of the profits in the filled milk market would flow to agribusiness concerns, not to soybean farmers.
The deep, enduring irony of Carolene Products is the case never mentions the one sector within the
elaborate structure of the agricultural marketplace that played the greatest role in forging the disputed
legislation.\(^4\) In short, farmers constitute the one agricultural sector that repeatedly wins favored
legal treatment, and the case that originally established the legal basis for protecting "discrete and
insular" minorities never acknowledged farmers' privileged political status.

* * * * *

Geoffrey P. Miller
The True Story of Carolene Products
1987 Sup. Ct. Rev. 397, 421-22

The Filled Milk Act was justified by the contention that filled milk posed a threat to the dairy
industry, a vital institution essential to the national welfare. At bottom the argument was a thinly
disguised expression of self-interest. So interpreted, it was no doubt valid; filled milk did threaten
the dairy industry. Yet the argument at least purported to consider the broader public interest as well.

One oft-repeated assertion was that dairying preserved the "fertility of American soil." The
connection between dairying and the fertility of the soil was never spelled out, but it was obvious
to anyone who had ever walked across a cow pasture. So understood, the argument is easily seen
to be made of the same substance that gave such fertility to the soil. While the by-product of the
dairy cow was undoubtedly good fertilizer, it was no better, and considerably less convenient, than
other commercially available fertilizers. There was no evidence that the fertility of the soil would
suffer a whit by a marginal decrease in the number of dairy cows due to competition from the
"coconut cow" of the South Seas.

The "national interest" argument also incorporated disquieting ideas about the alleged

\(^4\)See Geoffrey P. Miller, The True Story of Carolene Products, 1987 Sup. Ct. Rev. 397, 422-
28 (formally analyzing the Filled Milk Act as an interest group measure).
superiority of milk-consuming cultures. [Nutritionist E.V.] McCollum, who was an odd blend of hard scientist, dairy huckster, and middleheaded racist, epitomized these attitudes. His grand scheme divided humanity into milk-drinking and vegetable-eating people. With breathtaking disregard of history he asserted that milk drinkers had always enjoyed cultural and physical superiority over their leaf-chewing cousins. Not a single plant-eating culture, he claimed, "has ever come to the front in a matter of human achievement in any field of activity." Take the Japanese. "These people . . . are the subjects or vassals; they are the peoples who multiply in considerable numbers, but whose life is short, who are inefficient, of low mentality, warped by peculiar religious prejudices which ruined them . . . . They are a failure from the standpoint of living a normal human life." Milk-drinking peoples, on the other hand, "become large, strong, vigorous people, who . . . have the best trades in the world, who have an appreciation for art and literature and music, who are progressive in science and in every activity of the human intellect." Unpleasant as it may now seem, this racial stereotype had considerable currency in the dairy districts of the country and in the Congress. Farmers of the "coconut cow" were portrayed as lazy, ignorant, dark-skinned natives who had nothing to do all day but run up a tree and shake down a few nuts. A milk industry cartoon showed Congress, as a large white American, booting filled milk, personified as a small dark-skinned savage, back to the South Sea islands from which he came, while an American dairy cow watched with evident satisfaction. . . .

* * * * *

To the extent the ban on filled milk dissuaded willing consumers from purchasing the processed foods they wanted, Carolene Products' irony carries a tragic dimension. The Filled Milk Act undoubtedly shifted wealth from filled milk processors and foreign coconut producers to domestic milk producers. In so doing, however, the statute probably altered consumer purchases for the worse. But the history of legislation motivated by dairy interests can virtually be summarized by the single principle: government should support local milk production at all costs, even if such support must be financed through higher retail food prices. By the 1970s, the anti-consumer impact of the Filled Milk Act was so apparent that a federal district court — in direct contravention of the holding in Carolene Products — actually invalidated the statute for want of a rational basis.

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116[Citing the remarks of Rep. Voigt:] "[T]he superiority of the white race is due at least to some extent to the fact that it is a milk-consuming race. Natives of tropical countries who use the products of the coconut are stunted in body and mind."


Whatever your views on the irony and tragedy of *Carolene Products*, you cannot deny that much of the traditional case for special legal treatment of agriculture rests on the notion of farming as a unique and superior way of life. This line of argument is open to attack on several fronts. Are farmers really unique, after all? Isn't this changing in an increasingly urbanized and industrialized America? And so what if farmers are a discrete and insular minority? There is respectable legal scholarship suggesting that this traditional justification for special legal treatment should warrant precisely the opposite response: legal distrust of a political interest group that is all the more effective in its efforts at self-dealing. 48 That distrust should be all the greater when the group at issue supports its case for special treatment with a claim to moral superiority. What is this mystique of farming as a way of life? Why does the "agricultural creed" continue to grip the American cultural imagination? 49 We now turn to a more thorough examination of that issue.

* * * * *

2. The agricultural creed: how do unspoken assumptions about agrarian virtues affect agricultural law and policy?

Recitation of the traditional rationales may be masking deeper assumptions about agriculture, farming, and the agrarian lifestyle itself. To what extent do these rationales rest on economically defensible grounds, such as a view of food production as a "public good"? Or is there an altogether different agenda, one seeking to promote a nostalgic, romantic vision of farming as an intrinsically good activity and farmers as intrinsically good people?

The romantic vision of the American farmer has persisted since the founding of the republic. Thomas Jefferson extolled the virtues of farming; even the urbanite Theodore Roosevelt wrote that "[n]o nation has ever achieved permanent greatness unless this greatness was based on the well-being of the great farmer class, the men who live on the soil; for it is upon their welfare, material and

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49 For an irreverent (and perhaps irrelevant) perspective on this issue, see United States v. Garth, 773 F.2d 1469, 1476 n.11 (5th Cir. 1985), cert. denied, 476 U.S. 1140 (1986):

[F]arming is not a constitutional right nor are farmers a suspect class. *But hear* W. Jennings & W. Nelson, "Mamas Don't Let Your Babies Grow Up To Be Cowboys," on *Waylon and Willie* side 1, track 1 (1978) (noting that "Cowboys ain't easy to love, and they're harder to hold. They'd rather give you a song than diamonds or gold.").
moral, that the welfare of the nation ultimately rests.\textsuperscript{50} This strain of "agricultural fundamentalism . . . – the idea that agricultural welfare was synonymous with national well-being\textsuperscript{51} – has at times commanded tremendous political support in America. The yearning for the virtues of a lost agrarian culture became more pronounced as industrialization, urbanization, and social change swept the American cultural landscape during the twentieth century. Consider the following excerpts from the unofficial manifesto of the South's leading agrarian movement,\textsuperscript{52} written on the eve of the New Deal:

\textbf{TWELVE SOUTHERNERS, I'LL TAKE MY STAND (1930)}


[We] all tend to support a Southern way of life against what may be called the American or prevailing way; and all as much agree that the best terms in which to represent the distinction are contained in the phrase, Agrarian \textit{versus} Industrial. . . .

Industrialism is the economic organization of the collective American society. It means the decision of society to invest its economic resources in the applied sciences. But the word science has acquired a certain sanctitude. It is out of order to quarrel with science in the abstract, or even with the applied sciences when their applications are made subject to criticism and intelligence. The capitalization of the applied sciences has now become extravagant and uncritical; it has enslaved our human energies to a degree now clearly felt to be burdensome. . . .

The regular act of applied science is to introduce into labor a labor-saving device or a machine. Whether this is a benefit depends on how far it is advisable to save the labor. The philosophy of applied science is generally quite sure that the saving of labor is a pure gain, and that the more of it the better. This is to assume that labor is an evil, that only the end of labor or the material product is good. On this assumption labor becomes mercenary and servile, and it is no wonder if many forms of modern labor are accepted without resentment though they are evidently brutalizing. The act of labor as one of the happy functions of human life has been in effect abandoned, and is practiced solely for its rewards. . . .

Religion can hardly expect to flourish in an industrial society. Religion is our submission to the

\textsuperscript{50}FITE, \textit{supra} note 6, at 37.

\textsuperscript{51}\textit{Id.} at 39.

\textsuperscript{52}\textit{I'll Take My Stand} was a collection of essays by twelve leading men of letters of the early twentieth century American South. The volume contained the manifesto for a group that was to become known as the Agrarians. Several of the Agrarians – including the renowned Southern writers John Crowe Ransom, Robert Penn Warren, and Allen Tate – also belonged to the allied literary group called the Fugitives.
general intention of a nature that is fairly inscrutable; it is the sense of our rôle as creatures within it. But nature industrialized, transformed into cities and artificial habitations, manufactured into commodities, is no longer nature but a highly simplified picture of nature. We receive the illusion of having power over nature, and lose the sense of nature as something mysterious and contingent.

Opposed to the industrial society is the agrarian, which does not stand in particular need of definition.\textsuperscript{53} An agrarian society is hardly one that has no use at all for industries, for professional vocations, for scholars and artists, and for the life of cities. Technically, perhaps, an agrarian society is one in which agriculture is the leading vocation, whether for wealth, for pleasure, or for prestige—a form of labor that is pursued with intelligence and leisure, and that becomes the model to which the other forms approach as well as they may. But an agrarian regime will be secured readily enough where the superfluous industries are not allowed to rise against it. The theory of agrarianism is that the culture of the soil is the best and most sensitive of vocations, and that therefore it should have the economic preference and enlist the maximum number of workers.

This much is clear: If a community, or a section, or a race, or an age, is groaning under industrialism, and well aware that it is an evil dispensation, it must find the way to throw it off. To think that this cannot be done is pusillanimous. And if the whole community, section, race, or age thinks it cannot be done, then it has simply lost its political genius and doomed itself to impotence.\textsuperscript{[From Herman Clarence Nixon, \textit{Whither Southern Economy?}, pp. 176-200:]}\par

Southern economic life is at the crossroads. Its agrarian predominance in fact and spirit is seriously threatened by the rising tide of industrial growth and aspiration, if not exploitation.\ldots I have no intention to oppose Southern industrialization as a moderate fact\ldots. But there seems strong ground for apprehension over the inner and articulate spirit of industrialism that is claiming so much for itself in the South today.

It is deplorable that the South's agricultural philosophy is imperiled by a non-philosophical pattern of society in which the highest aim in life is success in industry. It is deplorable that this spread of the Southern worship of industrial gods after the World War, comparable to the Northern tide after the Civil War, is taking place at the time when dollar-chasing industrialism is being weighed in the balance and found wanting in America and Europe\ldots. It is questionable policy to consider scrapping old-fashioned economic ways for new-fashioned ways that are already in disrepute.\ldots

The South's greatest activity is that of cotton-growing, and this agricultural pursuit is the basis for cotton-milling, the South's greatest manufacturing enterprise.\ldots The South is the leading section of the country in the manufacture and use of fertilizer on account of agricultural needs, and

\textsuperscript{53}Ed. note – But cf. supra part I.A and cases excerpted therein.
this industry is partly based on cottonseed. Southern manufacturing may be considered as largely agrarian manufacturing, physically decentralized and not necessitating an excessive urbanization. The most highly industrialized Southern state of North Carolina contains only small-sized cities. . . . Southern commerce and banking are largely built around agriculture. . . .

Cotton and the South distinguish each other. . . . [M]uch which is significant in Southern life "has developed as a kind of complex around the cotton plant . . . . "In the Belt – Black, Cotton, or Bible . . . cotton is Religion, Politics, Law, Economics, and Art" . . . .

The chief activity of the negro since slavery has been in agriculture, and his chief place in agriculture has been in cotton production. . . . The writer can testify personally to the difficulty of urging a negro "cropper" with a mule to the successful production of anything but cotton. Southerners owe praise to Booker T. Washington for the persistency with which he urged his people to get more land and keep it and grow something besides cotton. . . .

Industrialization in the South has become greater as a fact, and industrialism has become greater as a social force, . . . with the hopes of a Southern-Western agrarian protest much weaker than in the days of [Thomas] Jefferson or [William Jennings] Bryan. The decline of the farmer seems to be taken as a matter of course as the South goes through "a remarkable industrial development," thanks in part to a newer and larger economic invasion from the North. . . . Perhaps something of a crusade is required to secure an equable public treatment as between industry and agriculture in the South, to preserve the agrarian group from industrial exploitation.

Southerners in strategic or public positions should take warning against the evils of a discriminatory encouragement of rapid industrialization in their section. They can profit by recalling that the decline of the Roman Empire was accompanied by the neglect of agriculture and the growth of an idle urban proletariat of unwieldy proportions. . . . With industry facing a giant break-down, it is no disservice to be different from the common trend and to consider the superior power of a healthy agricultural civilization to endure an economic crisis over a long period of time. . . .

For the South agriculture is much more important than industry, in view of the contributions that it makes to industry and commerce and in view of its unrecorded contributions to rural subsistence. It may be confidently said that the physical operations of agriculture will continue in the South, just as certain process of industry are expected to continue in the South. But the human civilization now based on Southern agriculture is in no little peril, and industrial civilization under the capitalistic system does not offer a satisfying substitute in human values. If Southern farmers can be saved from exploitation and serfdom, it is possible for the South, which has had experience with slavery, to subordinate industrial processes to the status of slaves, not masters, and, thus escaping industrialism, to exemplify a cultural emergence from a too acquisitive society. The South is no longer conquered territory, not quite conquered, but a protest, articulate and constructive, is needed against another conquest, a conquest of the spirit. From a dull industrialism Southern civilization should be preserved with its supporting agrarian economy.
In 1933, agriculture ("the farm sector") contributed $4.6 billion to the gross domestic product of $55.5 billion, or 8.3%. In 1982, the farm sector contributed $74.8 billion to the total gross domestic product of $3,012 billion, or only 2.5%. Moreover, the U.S. farm population decreased from 32.4 million, 25.8% of the total population, in 1933 to 6.9 million, 3.0% of the total population, in 1981. A revised definition of farm population, however, reduced the 1981 estimate to 5.6 million, 2.4% of the total population.

Depression and political revolution were destined to sweep away the Agrarians. But did the agricultural creed nevertheless survive? Consider the following pair of perspectives:

Harold F. Breimyer
Agricultural Philosophies and Policies in the New Deal
68 Minn. L. Rev. 333, 333-34 (1983)

In the frequently innovative social-program atmosphere of the New Deal 1930s, agriculture was not a bystander or even an incidental happenstance participant. Although agricultural programs ranged from crude improvisation to sophisticated social design, they were very much a part of the New Deal activity and, perhaps surprisingly, attracted some of the brightest minds in the New Deal constellation.

Agriculture's participation in New Deal programs began immediately. Agriculture was a major concern of initial New Deal programs -- the Roosevelt administration enacted a new farm law in its famous first one hundred days.

Unrest in the countryside, including instances of violence, partially explained Roosevelt's and Congress's prompt attention to agricultural problems. Equally significant was the era's political arithmetic -- agriculture comprised a larger fraction of the economy in the 1930s than it does today, and numerous influential senators and representatives promoted agricultural concerns.

Farm policy debates had already been underway in the 1920s, and facilitated the quick attention New Dealers gave to agriculture. A sharp decline in prices of farm products that occurred just after the end of World War I was followed by only a partial recovery -- agriculture did not share fully in the industrial prosperity of the 1920s. Throughout this period restive political leaders and creative scholars filled both the countryside and the halls of Congress with calls for "farm relief." As a result, the Roosevelt administration entered office in 1933 with a portfolio of plans for relieving agricultural distress.

The sequence of events leading to New Deal legislative programs, however, can mask the underlying forces. New Deal innovations in agriculture attest to a reweighing of one of the most basic balances in any economy -- the balance between the rural-agrarian and the urban-industrial
sectors. The New Deal erased for all time the rural-agrarian heritage of a circumscribed role for government, not only in agriculture but in the economy. By the mid-1930s the economy and its agricultural portion had been converted to an urban-industrial commercial conceptualization and policy design.

* * * * *

DON PAARLBERG

Some time ago a friend asked me, "What is the most important event that has happened in agriculture during your lifetime?" . . . I told him, "The most important event is that agriculture is the process losing its uniqueness" . . .

Many years ago agriculture was basically different from other occupations; it was more a way of life than a business. Farmers were self-sufficient. They bought and sold little; they took to market only what was in excess of their family needs. Despite regional differences, there was a generally recognizable rural culture, tradition, and life-style. Farmers were readily distinguishable from other people by speech, dress, and manner.

Farmers had much lower cash incomes than nonfarmers, and they had fewer conveniences. But these disadvantages were not so much the subject of indvidious comparisons as accepted attributes of a special way of life.

Farmers were considered uniquely worthy. The Jeffersonian ideal was of a nation of family farm operators producing food, the most needed product of all. Farmers were considered good God-fearing citizens, stalwart defenders of the republic, and a stabilizing element in the society. Those who grew up in the country did not need to be taught these values; they absorbed them through their pores. This set of ideas was known . . . as agrarianism, or agricultural fundamentalism, or the agricultural creed. . . .

From early times, the economy was delineated into farm and nonfarm sectors. If someone was born into agriculture and left it, the important thing was not whether he became a tradesman or a laborer, but that he became a nonfarmer; and usually there was some stigma associated with the change.

The farm/nonfarm delineation of the society was a logical grouping . . . . Farmers were different. They were unique, and worthily so. They knew it, and so did everyone else.

This uniqueness manifested itself in many ways, not least in the political process. Farmers were the most numerous group in the economy. Their spokesmen held the political initiative and controlled the farm policy agenda.
There were few public policy issues about food as such. The assumption, based on the teaching of classical economics, was that producers responded automatically to the needs of the consumer through the mechanism of the marketplace. If the country saw to the needs of the producers, consumer well-being would follow as the night the day. Consumers needed no advocate of their own.

Since farmers were unique, the country set up a group of unique institutions to serve them: a Department of Agriculture, a Homestead Act, a land grant college system, a network of Agricultural Experiment Stations, an Agricultural Extension Service, a Rural Electrification Service, a Rural Electrification Administration, and a Bureau of Reclamation. Farmers were given preferred access to land and water. We voted price and income supports for farmers, but not for automobile manufacturers or hardware merchants.

When general social legislation was enacted, we often excluded agriculture because of its uniqueness.

Preferred treatment having been achieved, the attitude in farm circles was to treat it not as an indication of political favor, but as a form of deserved differentiation from the nonfarm sector. A farm leader or a farm politician would deny with his last breath that agriculture had received any preference. The strategy has been to focus attention on those areas that showed agriculture at a disadvantage, to contrast the existing situation with some ideal, and to claim from government full redress of the disparity. If the claim of agriculture's uniqueness would help in this objective, it was invoked.

A powerful body of rhetoric developed in support of agriculture's unique worthiness. Here are the articles of the agricultural creed:

Farmers are good citizens and a high percentage of our population should be farmers.
Farming is not only a business but a way of life.
Farming should be a family enterprise.
The land should be owned by the man who tills it.
It is good to "make two blades of grass grow where only one grew before."
Anyone who wants to farm should be free to do so.
A farmer should be his own boss.

So we had, until fairly recent times, a coherent, mutually reinforcing agricultural policy, based on the concept of agriculture's uniqueness. There was a body of belief, a set of unique institutions, and the political power to defend the system.

And it worked. In America, agriculture became productive and efficient perhaps to a greater degree than anywhere else in the world. Farm families achieved a social status unknown in most other countries. All of this powerfully supported the policy postulates underlying the structure.
But change was coming. . . .

* * * * *

Let us return to a question suggested by earlier readings. Did agricultural law undermine agrarianism by adopting the sort of "urban-industrial commercial conceptualization and policy design" that the Twelve Southerners decried? Or did the agricultural creed plant the seeds of its own destruction through too much success — political, economic, and otherwise? As Paarlberg suggests (without serious dispute from other writers), American farmers have, until recently, gotten exactly the sort of special legal treatment they wanted without really having to explain why. How well do the laws that sprung from the golden age of agricultural fundamentalism fit a reshaped society in which urban and industrial concerns now reign supreme and in which agriculture must defend its legal uniqueness on grounds other than its intrinsic virtues, its social and cultural uniqueness?

Answers to these questions cannot emerge without consideration of the dramatic economic and demographic changes in the agricultural sector.

* * * * *

3. The impact of industrial and demographic changes

Recall that Old Man Filburn, the law-evading farmer whose Supreme Court defeat inaugurated the modern era in American constitutional law and American agricultural law alike, kept wheat, dairy cows, and laying hens together on the same farm. In economic terms, Filburn also symbolized the end of an era. Soon after World War II, the economically self-contained farm would pass into the deep recesses of American history. American agriculture had died; American agribusiness was born in its stead. By 1957, the changes had become so apparent that two leading observers felt moved to propose a new vocabulary:

JOHN H. DAVIS & RAY A. GOLDBERG
A CONCEPT OF AGROBUSINESS 1-2, 4-6 (1957)

The concept of agriculture as an industry in and of itself or as a distinct phase of our economy was appropriate 150 years ago when the typical farm family not only raised crops and livestock but also produced its own draft animals, tools, equipment, fertilizers, and other production items; processed its own food and fiber; and retailed in the community most of the excess above family needs. Then virtually all operations relating to growing, processing, storing, and merchandising food and fiber were a function of the farm. This being the case, it was appropriate to think of all such things as within the scope of the meaning of the word "agriculture." . . .

[Along with the technological revolution has come a narrowing of the function of the farm. Basically, farming has changed from a subsistence to a commercial status in that now the progressive
farm family consumes only a fraction of what it grows – the balance being sold to feed the 88% of the population employed off the farm. The modern farmer is a specialist who largely confines his operations to growing crops and livestock. The functions of storing, processing, and distributing food and fiber have been transferred in large measure to off-the-farm business entities. These enterprises, too, have become highly specialized operations. Complementing this development has been the creation of still another array of specialized off-the-farm functions—the manufacture of farm supplies, including implements, tractors, trucks, tractor fuels, fertilizers, feed supplements and mixed feeds, insecticides, and weed controllers, plus a host of other items. Today, the combined off-farm functions are considerably larger in magnitude than is the total operation of all our farms.

Despite the changes that have taken place, the functions of manufacturing farm supplies and storing, processing, and merchandising farm commodities still are closely related to agricultural production. Our farms could not operate for one week if they were cut off from these services. And, by the same token, the business firms which serve agriculture rely on farmers for their markets and for some of their supplies. There is a two-way interdependence with businessmen and farmers in the dual roles of suppliers and purchasers. Yet, in general, we tend to think of agriculture and business as separate entities. So true is this that our language contains no word to describe their interrelated functions. Presently, the only means of expressing such an idea is to write a paragraph or a page explaining it. Our vocabulary has not kept pace with progress.

To enable us to think more precisely in this field, the authors suggest a new word to describe the interrelated functions of agriculture and business — the term *agribusiness*. By definition, agribusiness means the sum total of all operations involved in the manufacture and distribution of farm supplies; production operations on the farm; and the storage, processing, and distribution of farm commodities and items made from them. Thus, agribusiness essentially encompasses today the functions which the term agriculture denoted 150 years ago. . . .

**Agricultural Self-Sufficiency**

In the year 1800 it was appropriate to think of agriculture as more or less a self-contained industry, in that a farmer could operate successfully cut off from other industries. The typical farm family produced its own food, fuel, shelter, draft animals, feed, tools, and implements and even most of its clothing. Only a relatively few necessities had to be bartered for or purchased from off the farm. For the economy to operate on this basis required that 80% of our total labor force be engaged in farming; otherwise there would have been a deficiency of food and fiber to sustain the population.

The significant fact . . . is that this type of agriculture involved the performance by the farm family of virtually all operations pertaining to the production, processing, storage, and distribution of farm commodities.

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1A word first used publicly by John H. Davis in a paper presented at the Boston Conference on Distribution, October 1955.
WHAT IS AGRICULTURE?

TECHNOLOGICAL REVOLUTION ON THE FARM

Near the very end of the eighteenth century, the vanguard of a new technological era appeared on the agricultural horizon in the form of new mechanical devices designed to perform old tasks in less time and with less labor. Particularly prophetic of the spirit of this new era were such inventions as the cotton gin and the cast iron plow—both making their appearance in the 1790's.

During the first three decades of the nineteenth century, numerous inventions appeared, few of which were significant except as stepping stones to the future. In general, these devices proved cumbersome, fragile, or defective, with the result that few of them were put to general use. Then about 1830 agricultural mechanization gained new momentum—a characteristic it has retained ever since. With the settling of the virgin lands of the frontier and improved transportation, first by water and then by rail, new incentives appeared to speed the adoption of labor-saving devices. In the decade of the 1830's John Lane, John Deere, and William Parlin pioneered in the development of a steel mouldboard plow which was to revolutionize the process of preparing soil for planting. Simultaneously, McCormick, Manning, and Hussey concentrated on devices for cutting grass and grain by means of a reciprocating knife passing through bladed guards. This led the way to rapid procession of improvements in the form of mowers and reapers.

Each important new development called forth others by creating bottlenecks in allied operations. Thus, the plow necessitated improved methods of harrowing, seeding, and cultivating. The reaper advanced the bottleneck of harvesting to the process of winnowing, thus creating the need for a mechanicalresher. But with each new need, inventors came forward to meet the challenge. By 1860 a host of new machines had appeared in the form of plows, harrow, planters, discs, stalk cutters, bailing presses, feed grinders, "straddle row" cultivators, mowers, reapers, and threshers.

Farmers, having tasted of the advantages and benefits of such new devices, became increasingly ready to try the next one. The task of improving old types of equipment and inventing new types has continued, gaining additional momentum and acceleration with each passing decade. The adaptation of the steam engine, the internal combustion engine, and the electric motor as sources of power on the farm has ushered in successive new eras of progress in terms of mechanized farming. Of all such developments, doubtless the internal combustion engine has proved most revolutionary in terms of farming methods. For not only has it made available a more powerful and convenient source of draft power; it has also made possible an array of companion implements, such as field cutters, loaders, ditchers, and harvesters, which would not have been feasible in a horsedrawn era.

Simultaneous to the mechanization of agriculture has been the application of research to other phases of farming, including plant and animal breeding, plant and animal nutrition, soil and water management, disease and insect control, animal housing, and commodity storage. Here, too, the rate of discovery has mounted decade by decade. Particularly notable in terms of advancing the scientific side of farming were the Morrill Act of 1862 creating land grant college systems; the establishment of the United States Department of Agriculture the same year; the Hatch Act of 1887 giving impetus
to state experiment stations; the Smith-Lever Act of 1914 authorizing the Extension Service; and the Smith-Hughes Legislation of 1917 promoting vocational agriculture as a subject in secondary schools.

TECHNOLOGICAL REVOLUTION OFF THE FARM

Accompanying the technological revolution on the farm has been a companion revolution, related to food and fiber, off the farm. One important phase of this revolution has been the development of commercial facilities for handling, storing, processing, and distributing farm commodities and products made therefrom.

The textile industry led the way in this field, progressing for several decades even well ahead of farm mechanization. As early as 1800 the basic processes essential to the mechanical production of textiles were established. With this development, weaving in the home began to decline and then gradually disappeared. In general, off-farm processing of food developed much later than the industrial production of textiles – being closely related to the release of workers from agriculture and the migration of population to industrial centers. This concentration of population in industrial centers created a corresponding need for moving food from the farm to urban areas. The magnitude of this feeding problem increased constantly with each decade. In 1957, agriculture employed about 12% of the working force in contrast to 72% in 1820 and 59% in 1860.

Paralleling this change has been the development of a commercial food processing and distributing industry which not only has fed urban people as well as their farmer ancestors fared, but actually has improved the national diet in terms of quality, variety, and nutrition. In fact, today, the farm population itself depends in large measure upon the food industry for its daily needs. In other words, the modern farmer finds it more satisfactory to have industry process much of his own food than to process it on the farm.

To meet the food requirements of a constantly increasing urban population, a technological revolution has taken place with respect to methods of handling, preserving, and distributing food. Here, too, the tempo of progress has accelerated with passing years. Not only have older techniques such as drying, salting, canning, and preserving been improved, but new processes of dehydrating, concentrating, quick-freezing, pre-cooking, and handling fresh products have been developed. Related to these changes have been improvements in transport, refrigeration, grading, packaging, sanitation, etc. Simultaneously with these improvements has come the evolution of the food chain and the supermarkets as techniques for mass merchandizing. Also, the growth of public eating

1The principal exception was the milling of grain, which was well advanced in colonial days. Early milling was done generally with stone burrs, driven by water power. Following the Civil War flour milling was revolutionized by the introduction of the moller mills method. This, together with the rapid expansion of wheat production in the West, led to larger milling units, concentrated at strategic locations.
establishments to meet the needs of urban dwellers and to serve an increasingly mobile population has been significant.

A second phase of the off-the-farm technological revolution has evolved from the increasing tendency of farmers to utilize production supplies originating from off the farm. This tendency got an early impetus from agricultural mechanization. Farmers themselves had neither the means nor the skills to manufacture the more complex machines; hence they purchased them from industrial firms. Thus there developed alongside of agriculture a farm machinery industry which grew as mechanization advanced and as the country grew.

Supplementing this growth related businesses developed, such as binder twin factories, belt factories, implement stores, and repair shops. With the invention of the farm tractor, the petroleum industry expanded to meet the farmer's needs. The change-over from steel to rubber tires on tractors called on the rubber manufacturer for a new product. The electrifying of farm homes created need for a host of industrial items, such as motors, milking machines, mild coolers, pumps, waterers, heaters, welders, and power tools, all of which are a part of the modern farm.

As scientific knowledge as to the type and quality of soils improved, the farmer demanded more and better fertilizers to replenish the nutrients taken from his soil. Industry responded to this need with the rapid development of a commercial fertilizer industry. Also accompanying the improvement if farming methods came the incentive for better seeds and better livestock. This intern led to specialized seed production and artificial insemination. To keep pace with improved livestock, farmers felt the need for better feeding practices, and industry responded by producing feed supplements, minerals and mixed feeds. This tendency of farmers to shift to production supplies originating off the farm has grown with increasing tempo until today they are purchasing roughly half of all the supplies they use.

**AGRIBUSINESS — A PRODUCT OF THE DISPERSION OF FUNCTIONS**

The significant point of the preceding discussion is this – during the past 150 years the food and fiber segment of our economy has evolved from a status of self-sufficiency to one of intricate interdependency with great segments of our industrial economy. Succinctly stated, it has evolved from an *agricultural* to an *agrribusiness* status. In some cases, whole new industries have come into being to supply the needs of modern agriculture. Illustrative of these are, for instance, the farm implement companies, the meat packers, the food canners, and the food freezers. In other cases, established industries, such as rubber, chemicals, and pharmaceuticals, have expanded to create new products to meet the farmer's needs.

The present agribusiness economy has come about by the gradual dispersion of functions from agriculture to business, particularly those relating to the manufacture of production supplies and the processing and distribution of food and fiber products. This has continued to the point where today agriculture retains primarily the function of producing crops and livestock.
It is important to keep in mind that modern agribusiness is the result of a combination of forces actively at work for a century and a half and with roots running back even deeper into history. In no sense is it the result of a preconceived plan or design being carried to completion. Rather, it is the product of a complex of evolutionary forces more or less spontaneously at work without central guidance or direction. In fact, so gradual has been the development of agribusiness that students of agriculture and business largely have failed to recognized its significance.

Agribusiness has no center of control or direction. It has no president, no board of directors, and no central office. Instead, it consists of several million farm units and several thousand business units—each an independent entity, free to make its own decisions. In addition, there are hundreds of trade associations, commodity organizations, farm organizations, quasi-research bodies, conference bodies, and committees, each largely concentrating on its own interests. In general, these groups function in the area of education, promotion, coordination, and lobbying. They possess little or no direct power of determination over the business decisions of their members. The United States Government, also, is a part of agribusiness, to the degree that it engages in research, regulation of food and fiber operations, or the ownership and trading of farm commodities. The land grant colleges with their teaching, experiment stations, and extension functions also are an integral part of agribusiness. In brief, today agribusiness exists in a vast composite of decentralized entities, functions, and operations relating to food and fiber.

The evolution of agribusiness has brought with it innumerable benefits in the form of reduced drudgery, the release of workers for nonagricultural endeavors, better quality of foods and fibers, greater variety of products, improved nutrition, increased mobility of people, and so on. At the same time it has brought with it numerous problems of imbalance and maladjustments—problems which to a large extent reflect the unevenness of the evolutionary progress which has taken place. The complex problems, mentioned earlier, relating to commercial farming and low-income families are, to a large degree, of such origin.

Now reconsider our initial question, "What is agriculture?" in light of the changes that have swept across the landscape of American agriculture:

Neil D. Hamilton
Feeding Our Future:
Six Philosophical Issues Shaping Agricultural Law

II. What Is Agriculture?

The question may seem odd because we all have well developed views of what agriculture is
WHAT IS AGRICULTURE?

and even perhaps what it is not. But different legal definitions of agriculture are found in various laws, depending on the issue. An increasingly important issue may be whether some food producing operations lose their status as agricultural if they reach a certain size or are organized in certain ways. Two related developments make the issue more than just a simplistic theoretical question – first the rapidly advancing industrialization of American agriculture and second the sharply declining number of farmers and the related structural shifts in the agricultural system. These developments may redesign the shape and appearance of agriculture and in so doing, drastically alter how the public views farming.

A. Industrialization of American Agriculture

American agriculture is changing rapidly – becoming more concentrated, more technically advanced, and more integrated with the input and marketing sectors. In other words, American agriculture is rapidly becoming industrialized. Thomas Urban, president of Pioneer Hi-Bred International, Inc. of Des Moines, Iowa, the world's largest supplier of hybrid seed, describes industrialization as the process whereby the production of goods is restructured under the pressure of increasing levels of capital and technology in a manner which allows for a management system to integrate "each step in the economic process to achieve increasing efficiencies in the use of capital, labor and technology." He has this to say about the change:

Production agriculture in the Western World is now entering the last phase of industrialization – the integration of each step in the food production system. The production segment is rapidly becoming part of an industrialized food system.

While not advocating the changes, Urban views the development optimistically, noting it will maximize uniformity and predictability in agricultural production allowing for branding of food and marketing of "identity preserved" products, a development his plant breeders are actively pursuing. He believes it will attract capital to agriculture and lead to more rapid adoption of new technologies. He is also optimistic it will create new opportunities – possibly giving rise to a new family farm – one that is "dependent as much on financial management skills and contract marketing as on production and agronomy know-how" – a "super farmer" who will respond quickly to new opportunities to increase income and reduce risk. It is this person who will be part of the industrialization of agriculture.

Of course the movement to an industrialized agriculture is not without critics who identify concerns about the economic and social health of family farms and rural communities, the stewardship of the land, and the effect on the cost and quality of our food. Regardless of conflicting opinions on the issue, the signs of the industrialization of American agriculture are all around. Consider these developments:

– the movement toward contract production of swine in the Midwest, following the example of the large integrators who dominate the poultry sector;
— continued trends towards larger, confined animal feeding facilities with operations shifting
between states in search of lower environmental standards;

– the prospect of commercialization of biotechnology, on the horizon for years but now becoming reality as products, such as Calgene's Flavr Savr tomato, near the table;

– increased efforts to develop markets and technology for producing "industrial" crops to create new uses for agricultural production; and

– increased concentration in the food processing industry with vertical integration into production by food processors and marketers.

Each of these trends raises fundamental legal issues which will challenge both the farming community and agricultural lawyers. For example, increased use of contract production for hogs will raise questions both about the fairness of the contracts offered producers and the economic effect of integration on the swine industry. Some states, such as Minnesota, have responded by regulating agricultural contracting to protect producers who enter such agreements. The development has also triggered controversies over the Iowa ban on packer feeding of livestock, on the location and construction of new large-scale swine facilities, and even on the appropriate relation between cooperatives and their members. When Farmland Foods decided to compete with its members by producing pigs under contract through local cooperatives, the Iowa legislature considered a bill to require a cooperative's decision to use contracting be voted on by the members.

The movement to large scale livestock facilities may tempt courts and lawmakers to re-examine the very issue of what is agriculture, for example, as the appropriateness of offering "right to farm" protections to large operations becomes controversial. Whether courts will view large scale livestock operations as part of agriculture is not an idle concern. Twenty-two years ago the Iowa Supreme Court concluded concentrated poultry production on a small tract without accompanying crop activity was not agriculture and refused to apply an agriculture exemption from county zoning. Similar questions will no doubt be raised whenever the planned construction of a large animal feeding operation generates local opposition.

The development of specialty crops and industrial uses raise the potential for greatly expanded marketing opportunities and greater diversity in the mix of crops raised. But legal issues of producer access to contracting opportunities and the role of specialty crop production in spurring concentration of production are real. One direct result of agricultural industrialization may be the need for farmers to consider collective action to negotiate fair contracts on a parallel with organized labor's practices. Urban recognized this:

We may even see farmers organize with like members of a system, or systems, as labor did at the turn of the century, to protect their interests in the face of contracts perceived to be unfair. They will certainly ask for, and receive, legislative protection at state and federal

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21Farmegg Prod., Inc. v. Humboldt County, 190 N.W.2d 454 (Iowa 1971) [excerpted supra in part I.A.1. and discussed in Neil D. Hamilton, Freedom to Farm! Understanding the Agricultural Exemption to County Zoning in Iowa, 31 DRAKE L. REV. 565 (1981).]
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levels as labor has done in the past.

In recent years broiler producers throughout the South have organized to combat both the unequal bargaining strength of integrators and cases of fraudulent weighing. In 1991 the 11th Circuit Court of Appeals upheld an Alabama federal court jury award of $13.6 million to 268 chicken producers who sued ConAgra, Inc. for fraudulently misweighing their birds. In January 1991, the 11th Circuit affirmed a Florida district court's injunction to prevent Cargill from retaliatory termination of contracts with a grower who complained about deceptive practices and who was organizing other growers. The experiences of farmers who live under industrialized integrated production contract systems indicate Urban's prediction may be on point, meaning collective bargaining will join the growing field of agricultural law.

The industrialization of agriculture has also raised concerns about the control and location of the mechanisms for making domestic policy on food and agriculture issues. One major change in U.S. agriculture in the last twenty years is the increasing reliance on export markets. This reliance has led to major changes in federal farm programs so U.S. farm policies do not interfere with the ability to sell products overseas. Increased reliance on international markets has led to conflicts with major Western allies, such as the European Community over the impact of domestic agricultural policies on world trade. A bitter impasse over agricultural trade has blocked completion of the Uruguay round of GATT trade talks and threatens progress on world trade in all economic fields.

B. Declining Farm Numbers and Related Structural Issues

The 1990 Census data contained startling news for agriculture and agricultural lawyers, reflecting the body count of declining farm numbers inflicted by the farm financial crisis of the 1980's. For example, Iowa lost twenty-five percent of its farmers, with those who describe farming as their primary occupation declining from 125,763 in 1980 to only 93,780 in 1990. Only 7% of Iowa's work force now farms, meaning there are more school teachers, health care workers, or business executives and managers in the state than farmers. The farm population in the Midwest declined even more rapidly than did farm numbers. In the 1980's Iowa's farm population dropped by 34% with nearly 135,000 people leaving the countryside, with similar or steeper declines in Illinois, Minnesota, and Missouri. Today only 9% of the Iowa population is classified as rural while 61% is urban. The reports show a steeper decline in the number of young farmers, which combined with an aging farm population sets the stage for continuing and perhaps even steeper drops in farm numbers and more wrenching changes in rural communities.

The implications of changing demographics are clear – fewer farms, larger operations, and concentrated land ownership. Legal challenges which may accompany these trends include:

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increased farm tenancy and separation of land ownership from management, meaning an issue of historical legislative concern in connection with land stewardship may assume even greater significance in years ahead;

– creating systems to link older and retiring landowners with young farmers who want a start in agriculture. Several midwestern states operate beginning farmer loan programs which have successfully financed a small crop of new farmers, but states are now looking at methods for more direct and aggressive linkages.

– continued division of American agriculture into two segments, large scale commercial farms producing most of our grain, meat and fiber and a larger sector of small and part-time farms, which will require laws and policies sensitive to the differing needs of each.

– a changing farm labor market has led to increased use of seasonal and migrant labor to perform functions, such as detasseling seed corn, traditionally performed by local youth. The use of seasonal and migrant labor brings with it the obligation to comply with the regimen of federal and state labor laws protecting workers. The application of these laws has already resulted in litigation in the Midwest and creates a multitude of risks for any farm operation failing to comply.

The changing demographics of agriculture and the industrialization now underway are clearly linked. A major part of the linkage is the role of technology and how it is employed in farming. A direct result of increased industrialization and use of new technologies such as genetic engineering is that an ever smaller share of economic activity from agriculture is being contributed by the farming sector. Determining whether the linkage is cause and effect or merely symptomatic of larger economic and social forces is not as important as is recognizing the significant legal dimension of these forces. Declining farm numbers will impact the agricultural law community, as reflected in the recent closing of the farm division of the Iowa Attorney General's office, the first such office in the nation. The forces also create opportunities for lawyers to perform valuable services for farm and agricultural clients who must adjust to the changes.

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B. Public Support for Agricultural Research

1. Public subsidies for agricultural research

Earl Heady has argued that "United States agricultural policy revolved around" the subsidization of "public agricultural research" as a "major socialized program to increase the supply and maintain a lower real price for a [farm] production resource." During the "developmental" era of American agricultural law, the federal government subsidized agricultural production by disbursing wealth from its public lands, often in the form of free land, cheap water, and favorable grazing rights. Likewise, certain types of agricultural finance, especially when designed for farmers unable to obtain

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credit through ordinary banking channels, subsidized even more production at the margin of an already overloaded agricultural market.

Whereas most economists condemn those programs as inefficient failures, some observers actually laud the education and research programs. Although Heady believed that "the private sector would have eventually supplied" the agricultural research generated by the land grant universities, other agricultural economists have defended the educational subsidies:

Policies oriented toward providing public goods, such as the Land Grant Universities and publicly sponsored agricultural research, extension services, and regulatory agencies, also have continued and proliferated. In contrast to the coupled commodity programs, public sponsorship of these activities is generally economically efficient. Rather than creating distortions in the allocation of resources, these policies are designed to help society overcome the distortions that would arise in the absence of collective action. These policies are also potentially pareto improving and welfare enhancing from a societal perspective. These are policies that make society more economically productive. They are policies that do not create incentives to expend valuable resources unproductively in competition for program benefits.\(^3\)

Such high praise for educational subsidies must be viewed with some suspicion, since most publicly employed agricultural economists and some agricultural law professors owe their jobs to those subsidies.\(^4\) Is this particular public good program an undiluted success? Even if we assume that publicly supported agricultural research will spur the development of new farm technologies, how will scientific advances affect the delicate economic policies aimed at structuring agricultural markets?\(^5\) Before we engage in a fuller debate over the normative implications of public support for agricultural research, let us examine the actual statutory authorization for federal fiscal support of

\(^2\)Id. at 612 n.10.


agriculturally oriented research and education:

**Selected statutes supporting agricultural research and education**

**Morrill Land-Grant College Act of 1862, 7 U.S.C. §§ 301-329**

§ 301. Land Grant Aid of Colleges

There is granted to the several States, for the purposes hereinafter mentioned in this subchapter, an amount of public land, to be apportioned to each State a quantity equal to thirty thousand acres for each Senator and Representative in Congress to which the States are respectively entitled by the apportionment under the census of 1860: Provided, That no mineral lands shall be selected or purchased under the provisions of this subchapter.

§ 302. Method of Apportionment and Selection; Issuance of Land Scrip

The land aforesaid, after being surveyed, shall be apportioned to the several States in sections or subdivisions of sections, not less than one-quarter of a section; and whenever there are public lands in a State subject to sale at private entry at $1.25 per acre, the quantity to which said State shall be entitled shall be selected from such lands within the limits of such State, and the Secretary of the Interior is directed to issue to each of the States in which there is not the quantity of public lands subject to sale at private entry at $1.25 per acre, to which said State may be entitled under the provisions of this subchapter, land scrip to the amount in acres for the deficiency of its distributive share; said scrip to be sold by said States and the proceeds thereof applied to the uses and purposes prescribed in this subchapter, and for no other use or purpose whatsoever: Provided, That in no case shall any State to which land scrip may thus be issued be allowed to locate the same within the limits of any other State, or of any Territory of the United States, but their assignees may thus locate said land scrip upon any of the unappropriated lands of the United States subject to sale at private entry at $1.25, or less, per acre: And provided further, That not more than one million acres shall be located by such assignees in any one of the States . . . .

§ 304. Investment of Proceeds of Sale of Land or Scrip

All moneys derived from the sale of lands as provided in section 302 of this title by the States to which lands are apportioned and from the sales of land scrip provided for in said section shall be invested in bonds of the United States or of the States or some other safe bonds; or the same may be invested by the States having no State bonds, in any manner after the legislatures of such States shall have assented thereto and engaged that such funds shall yield a fair and reasonable rate of return, to be fixed by the State legislatures, and that the principal thereof shall forever remain unimpaired: Provided, That the moneys so invested or loaned shall constitute a perpetual fund, the capital of which shall remain forever undiminished (except so far as may be provided in section 305 of this title), and the interest of which shall be inviolably appropriated, by each State which may take and
claim the benefit of this subchapter, to the endowment, support, and maintenance of at least one college where the leading object shall be, without excluding other scientific and classical studies and including military tactics, to teach such branches of learning as are related to agriculture and the mechanic arts, in such manner as the legislatures of the States may respectively prescribe, in order to promote the liberal and practical education of the industrial classes in the several pursuits and professions in life.

SMITH-LEVER ACT OF 1914, 7 U.S.C. §§ 341-349

§ 341. COOPERATIVE EXTENSION WORK BY COLLEGES

In order to aid in diffusing among the people of the United States useful and practical information on subjects relating to agriculture, uses of solar energy with respect to agriculture, home economics, and rural energy, and to encourage the application of the same, there may be continued or inaugurated in connection with the college or colleges in each State, Territory, or possession, now receiving, or which may hereafter receive, the benefits of subchapters I and II of this chapter, agricultural extension work which shall be carried on in cooperation with the United States Department of Agriculture: Provided, That in any State, Territory, or possession in which two or more such colleges have been or hereafter may be established, the appropriations hereinafter made to such State, Territory, or possession shall be administered by such college or colleges as the legislature of such State, Territory or possession may direct.

§ 342. COOPERATIVE AGRICULTURAL EXTENSION WORK

Cooperative agricultural extension work shall consist of the development of practical applications of research knowledge and giving of instruction and practical demonstrations of existing or improved practices in agriculture, uses of solar energy with respect to agriculture, home economics, and rural energy and subjects relating thereto to persons not attending or resident in said colleges in the several communities, and imparting information on said subjects through demonstrations, publications, and otherwise and for the necessary printing and distribution of information in connection with the foregoing.

HATCH ACT OF 1887, 7 U.S.C. §§ 361a-361i

§ 361a. CONGRESSIONAL DECLARATION OF PURPOSE

It is the policy of Congress to continue the agricultural research at State agricultural experiment stations which has been encouraged and supported by the Hatch Act of 1887, the Adams Act of 1906, the Purnell Act of 1925, the Bankhead-Jones Act of 1935, and Acts amendatory and supplementary thereto, and to promote the efficiency of such research by a codification and simplification of such laws.
§ 361b. Congressional statement of policy; researches, investigations and experiments

It is further the policy of the Congress to promote the efficient production, marketing, distribution, and utilization of products of the farm as essential to the health and welfare of our peoples and to promote a sound and prosperous agriculture and rural life as indispensable to the maintenance of maximum employment and national prosperity and security. It is also the intent of Congress to assure agriculture a position in research equal to that of industry, which will aid in maintaining an equitable balance between agriculture and other segments of our economy. It shall be the object and duty of the State agricultural experiment stations through the expenditure of the appropriations hereinafter authorized to conduct original and other researches, investigations, and experiments bearing directly on and contributing to the establishment and maintenance of a permanent and effective agricultural industry of the United States, including researches basic to the problems of agriculture in its broadest aspects, and such investigations as have for their purpose the development and improvement of the rural home and rural life and the maximum contribution by agriculture to the welfare of the consumer, as may be deemed advisable, having due regard to the varying conditions and needs of the respective States.

Bankhead-Jones Act of 1935, 7 U.S.C. §§ 427, 427i

§ 427. Agriculture research; declaration of policy; duties of Secretary of Agriculture; use of existing facilities

It is declared to be the policy of the Congress to promote the efficient production and utilization of products of the soil as essential to the health and welfare of our people and to promote a sound and prosperous agriculture and rural life as indispensable to the maintenance of maximum employment and national prosperity. It is also the intent of Congress to assure agriculture a position in research equal to that of industry which will aid in maintaining an equitable balance between agriculture and other sections of our economy. For the attainment of these objectives, the Secretary of Agriculture is authorized and directed to conduct and to stimulate research into the laws and principles underlying the basic problems of agriculture in its broadest aspects, including but not limited to: Research relating to the improvement of the quality of, and the development of new and improved methods of the production, marketing, distribution, processing, and utilization of plant and animal commodities at all stages from the original producer through to the ultimate consumer; research into the problems of human nutrition and the nutritive value of agricultural commodities, with particular reference to their content of vitamins, minerals, amino and fatty acids, and all other constituents that may be found necessary for the health of the consumer and to the gains or losses in nutritive value that may take place at any stage in their production, distribution, processing, and preparation for use by the consumer; research relating to the development of present, new, and extended uses and markets for agricultural commodities and byproducts as food or in commerce, manufacture, or trade, both at home and abroad, with particular reference to those foods and fibers for which our capacity to produce exceeds or may exceed existing economic demand; research to encourage the discovery, introduction, and breeding of new and useful agricultural crops, plants, and
animals, both foreign and native, particularly for those crops and plants which may be adapted to utilization in chemical and manufacturing industries; research relating to new and more profitable uses for our resources of agricultural manpower, soils, plants, animals, and equipment than those to which they are now, or may hereafter be, devoted; research relating to the conservation, development, and use of land, forest, and water resources for agricultural purposes; research relating to the design, development, and the more efficient and satisfactory use of farm buildings, farm homes, farm machinery, including the application of electricity and other forms of power; research and development relating to uses of solar energy with respect to farm buildings, farm homes, and farm machinery (including equipment used to dry and cure crops and provide irrigation); applied research to develop agricultural, forestry, and rural energy conservation and biomass energy production and use; research relating to the diversification of farm enterprises, both as to the type of commodities produced, and as to the types of operations performed, on the individual farm; research relating to any other laws and principles that may contribute to the establishment and maintenance of a permanent and effective agricultural industry including such investigations as have for their purpose the development and improvement of the rural home and rural life, and the maximum contribution by agriculture to the welfare of the consumer and the maintenance of maximum employment and national prosperity; and such other researches or experiments bearing on the agricultural industry or on rural homes of the United States as may in each case be deemed advisable, having due regard to the varying conditions and needs of Puerto Rico, the respective States, and Territories. In effectuating the purposes of this section, maximum use shall be made of existing research facilities owned or controlled by the Federal Government or by State agricultural experiment stations and of the facilities of the Federal and State extension services. Research authorized under this section shall be in addition to research provided for under existing law (but both activities shall be coordinated so far as practicable) . . . .

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_The black land grant colleges._ In 1890, the second Morrill Act authorized states to use their land grant funds to establish "separate but equal" agricultural colleges for "white and colored students":

No money shall be paid out under this subchapter to any State or Territory for the support and maintenance of a college where a distinction of race or color is made in the admission of students, but the establishment and maintenance of such colleges separately for white and colored students shall be held to a compliance with the provisions of this subchapter if the funds received in such State or Territory be equitably divided . . . .

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^6 Ed. note – So in original. Probably should be "deemed."

^7 Act of Aug. 30, 1890, ch. 841, § 1, 26 Stat. 417.

^8 7 U.S.C. § 323.
The resulting network of seventeen historically black agricultural colleges, all located in Southern or Border states, continues to vex a legal system that supposedly repudiated the noxious doctrine of "separate but equal" forty years ago. Deciphering the legal status of the "1890 institutions"—as the black land grant colleges are euphemistically called—which prescribes the measures that states must take to remedy historical de jure segregation of public colleges, with Metro Broadcasting, Inc. v. FCC, which adopts an intermediate level of equal protection scrutiny for "benign race-conscious measures mandated by Congress." A realistic solution to this legal problem requires an effort to "combat [the] vestiges" of segregation that does not destroy the very "institutions that sustained blacks during" the ascendancy of Jim Crow. This monstrous legal knot, which no one has ever tried to unravel, is gnarled further by the virtual impossibility of proving that Congress had a benign intent in authorizing the segregation of land grant colleges in 1890, six years before Plessy v. Ferguson first sanctified the phrase "separate but equal."

Meanwhile, Congress has granted land grant college status to 29 post-secondary educational institutions that serve American Indians. The newly recognized "1994 institutions" have received (among other benefits) an initial $23 million endowment, annual appropriations of $50,000 per college, and their share of an annual $5 million appropriation that will fund cooperative programs with land grant colleges established under the original Morrill Act of 1862.

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Fordice, 112 S. Ct. at 2746 (Thomas, J., concurring).

163 U.S. 537 (1896). For an introduction to the voluminous literature on the black land grant colleges, see William Payne, The Negro Land-Grant Colleges, 3:2 Civil Rights Dig. 12 (Spring 1970), and Symposium, Anachronisms or Rising Stars: The Black Land Grant System in Perspective, 9:1 Agric. & Human Values 1 (Winter 1992).


2. Legal limits on the use of public research funds

Public support for the land grant college system and other venues for agricultural research and education has sparked a fierce debate over the very desirability of technological advances in agriculture. If one opposes the application of newer, more expensive, and arguably immoral forms of technology to farming, the public sector *a fortiori* should not subsidize agricultural research. At the very least, some critics argue that public spending for agricultural research should be tempered with the sort of substantive policymaking conditions that we encountered in the context of the homesteading, reclamation, and grazing laws. The next passage, by J.W. Looney, outlines the debate and describes one particular dispute over the use of public research funds. The California courts' final resolution of that dispute follows immediately.

**J.W. Looney**

*The Changing Focus of Government Regulation of Agriculture in the United States*


Agricultural research is credited with improving both U.S. agricultural production and agricultural productivity primarily through the development of new technologies. The beneficiaries of research efforts are not only the farmers who adopt the new technologies but consumers who benefit from lower costs and improved quality as well as increased choices. For example, the typical supermarket now has available between 11,000 and 39,000 food items compared to only 1500 items less than fifty years ago.

And, the dramatic changes in technology of the past may well pale by comparison with what is to come from "science power" in the future. Along with other advances, significant increases in agricultural productivity are projected from the application of biotechnology. In the livestock and meat sector alone, genetic technologies, when combined with developments in animal health and nutrition and processing and marketing improvements, will likely result in major increases in production of milk and meat products.

In approximately ten years, meat production per cow and per sow is projected to increase by twenty-five percent; milk production per cow by forty percent; production per sheep or goat by thirty-five percent; broiler production efficiency by thirty percent; and, catfish weight efficiency by twenty percent. By 2030 these increases may be as high as sixty percent per cow and sow; seventy percent per sheep and goat and two hundred percent for catfish.

The future of agricultural research, and particularly that related to biotechnology, raises important political, social, economic, ethical, and legal questions not only for the agricultural sector but for society generally. The successful history of agricultural research since World War II, and the
rapid changes brought about in recent years by the application of biotechnology to agriculture, make projections for future production increases appear somewhat frightening. Increased production of agricultural products, unless accompanied by increased demand, must be viewed in light of the trends already evident in U.S. agriculture – what might be called food-system consolidation. Further economic consolidation, fewer farmers, fewer suppliers, and fewer processors, may well continue, driven in part by the application of the new technologies. Consequences for the environment, such as pesticide and chemical effects, soil and water consumption, and safety concerns from biotechnology, raise similar concerns.

These potential changes in agriculture and the application of biotechnology raise suggestions that the regulation of the scientific pursuit of knowledge might become necessary or desirable. If scientific inquiry is to be regulated, then certain other questions immediately arise. Who will regulate? What issues will be addressed in any such regulation? What criteria will be used to assess the safety and health concerns? Is there an argument that scientific pursuit of knowledge should not be regulated? These questions have not been fully addressed, but they have been raised in recent years as agricultural science researchers have found themselves embroiled in political and legal challenges to their research efforts.

For example, tomato harvester research is at the center of a major lawsuit filed against the University of California challenging its entire agricultural research effort. Plaintiffs were identified as a public interest organization and nineteen individually named agricultural workers who alleged that each was directly threatened economically by the commercial mechanization research projects conducted by the University. Plaintiffs contended that the University had as a basic policy goal the development of machines and other technology to reduce the use of labor as a means of agricultural production. Plaintiffs alleged this policy was implemented by the undertaking of the development of preharvest and postharvest production practices, the use of genetically modified varieties of crops, experimentation with growth and maturation control chemicals for cultivation, and methods of handling, transporting, and processing crops for machine harvest.

The lower court found that the Hatch Act funding amounted to only three percent of the total budget for the California Agricultural Experiment Station, but that the University had no process designed to ensure consideration of the legislatively expressed interests, primarily those of the small family farmer. The court found that the legislative history of the Act and its subsequent amendments and the cognate terms and legislative history of the Morrill Act of 1862 and the Smith-Lever Act require the experiment station, when approving of and allocating Hatch funds, to "consider the extent to which the interests of all of the Congressionally intended beneficiaries will be favorably or unfavorably served by its agricultural research projects, and require that in that process, primary consideration shall be given to the interests of the small family farmer."

The court found that the University was administering the funds in violation of the Hatch Act because it had no process designed to ensure consideration of each legislatively expressed interest ("promoting a sound and prosperous agriculture and rural life," the "improvement of rural life," and
The California Agrarian Action Project is self-described as a project to aid small family farmers, promote farmers' markets and to "provide relief to the poor, distressed and disadvantaged people of rural California.

To "contribute to maximizing the welfare of the consumer"). The court applied the same conclusions to state funding as well because these funds were to be expended in pursuit of or in compliance with the federal law.

The University, along with supporters among various agricultural groups, answered the appeal in a vigorous denial of the assertions, both factual and legal, of the plaintiffs. They likened plaintiffs' efforts to those of the Luddites, who in England in the early years of the nineteenth century were involved in machine-breaking activities as protests against mechanization, automation, and the adoption of labor saving devices. Even agriculture was not immune because the notorious "Captain Swing" was credited with the breaking of threshing machines in southern England in 1830.

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California Agrarian Action Project, Inc. v. University of California
California Court of Appeal

LOW, Presiding Justice.

We reverse the judgment declaring the University of California in violation of the federal Hatch Act of 1887. The University of California is not required to establish an administrative process to ensure that Hatch Act funds for agricultural research are expended so as to give primary consideration to the needs of the small family farmer.

The California Agrarian Action Project and 19 farm workers (hereafter collectively referred to as the Project) sued the regents and individuals affiliated with the University of California (hereafter collectively referred to as the University) alleging a violation of state and federal laws, including the Hatch Act. The Project's complaint alleged that the University's agricultural research program emphasized farm mechanization, which favored the interests of large agricultural business, to the detriment of the small farmer and consumer. Much of the litigation has been disposed of in pretrial proceedings and is not before us on appeal. We are concerned only with the Project's third cause of action which alleged the University had failed to act in accordance with the purposes for which the Hatch Act was promulgated. The Project asserted that the University's mechanization research projects have harmed the interests of small family farmers, laborers, consumers and California's rural population. The trial court never made a finding that Hatch Act funding was used to conduct research that was injurious to small farmers or any other group. Nevertheless, after receiving factual stipulations, judgment was awarded to the Project on this cause of action; and the University was ordered to "establish and supervise an administrative process" to ensure that Hatch Act funds "are

1The California Agrarian Action Project is self-described as a project to aid small family farmers, promote farmers' markets and to "provide relief to the poor, distressed and disadvantaged people of rural California."
expend in a manner which affords consideration for each of the legislatively intended beneficiaries, with primary consideration for the small family farmer." The University acknowledges that such an administrative process does not presently exist.

We must determine whether Congress has required such a review process in the funding of the University's agricultural research. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." The type of procedure ordered by the trial court is not required by the express terms of the statute nor is it part of the administrative construction of the statute by the United States Department of Agriculture. The term "small family farmer" is not found in the Hatch Act or in its legislative history. The Project maintains, however, that notwithstanding this lack of an express provision, the requirement of such a procedure is implicit within the broad policy objectives of the Hatch Act.

The Hatch Act provides funding to support agricultural research conducted at state agricultural experiment stations. The University of California has been designated the California state agricultural experiment station and receives federal appropriations annually. The university-sponsored agricultural experiment station has three major branches at its campuses in Berkeley, Davis and Riverside. During the course of this litigation, the experiment station had from 1,000 to 1,400 formally approved research projects underway. Federal appropriations, including those pursuant to the Hatch Act, comprise 3 percent of the station's total budget.

The Hatch Act seeks "to promote the efficient production, marketing, distribution, and utilization of products of the farm," to promote "a sound and prosperous agriculture and rural life," and "to assure agriculture a position in research equal to that of industry, which will aid in maintaining an equitable balance between agriculture and other segments of our economy." (7 U.S.C. § 361b.) To serve those purposes, the act authorizes funds to assist state agricultural experiment station research "bearing directly on and contributing to the establishment and maintenance of a permanent and effective agricultural industry of the United States," including "researches basic to the problems of agriculture in its broadest aspects, and such investigations as have for their purpose the development and improvement of the rural home and rural life and the maximum contribution by agriculture to the welfare of the consumer . . . ." (7 U.S.C. § 361b.) Congress did not expressly state a preference for agricultural research that would benefit the small family farm.

The Hatch Act is administered by the Department of Agriculture, which makes grants pursuant to the formula prescribed by the act to state agricultural experiment stations to carry out this research. The Secretary of Agriculture has the authority to approve projects and to determine whether federal
funds have been properly used. The Secretary is also directed to "furnish such advice and assistance as will best promote the [congressional] purposes" and "from time to time to indicate such lines of inquiry as to him seem most important."

The Secretary has issued an administrative manual which establishes the procedures for obtaining approval of research projects, of which we take judicial notice. The manual outlines the permissible research under the Hatch Act, including: "research on all aspects of agriculture, including soil and water conservation and use; plant and animal production, protection, and health; processing, distributing, marketing, and utilization of food and agricultural products; forestry, including range management and range products, multiple use of forest and rangelands, and urban forestry; aquaculture; home economics, including human nutrition and family life; and rural and community development." The manual gives the state agricultural experiment stations the primary responsibility for determining the need for and the scientific feasibility of the projects proposed. It directs the director of such stations to develop a procedure, to be approved by the department, for project documentation, scientific review, and project selection. The manual does not require agricultural experiment stations to develop an administrative procedure to consider whether congressionally intended beneficiaries will be favorably or unfavorably served by its agricultural research projects, nor does it require that primary consideration be given to the interests of the small family farmer.

The University has developed a procedure under which each proposed research project is reviewed and approved at several levels of administration. The University does not claim to have an administrative process designed to assess the consequences of its research on any particular group. The University's review procedures have received approval by the Department of Agriculture. After a project is reviewed and approved for scientific merit within the University, a written project proposal is reviewed by the Department of Agriculture for compliance with the Hatch Act. All agricultural research conducted by the University receiving Hatch Act funding was reviewed both within the University and by the Department of Agriculture, and each determined the research was consistent with the purposes of the Hatch Act.

Nothing in the legislation or in its administrative interpretation by the agency charged with its implementation requires an administrative process which gives primary consideration to the small family farmer. Nevertheless, the Project contends that the Secretary's interpretation and the University's guidelines are at variance with congressional directives found in several other statutes which foster and encourage the family farm system of agriculture in this country. Specifically, the Project relies on expressions of concern for the small farmer in the statutory terms and legislative history of the Morrill Act of 1862; the Smith-Lever Act of 1914; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. § 3101 et seq.). The Project argues that these enactments should be read in pari materia with the Hatch Act because together they constitute the agricultural policy of the United States; and, when read together, Congress intended the University to conduct its research under the Hatch Act to primarily benefit the small family farmer.
The Project principally relies on a provision of the Food and Agriculture Act of 1977 which sets forth congressional policy applicable to federal agricultural programs generally. That section reads:

It is neither the policy nor the intent of Congress that agricultural and agriculture-related programs be administered exclusively for family farm operations, but it is the policy and the express intent of Congress that no such program be administered in a manner that will place the family farm operation at an unfair economic disadvantage.

(7 U.S.C. § 2266(a).) The Project argues that this congressional declaration of policy contemplates the need for some type of administrative process to ensure that Hatch Act research be conducted in such a way as to primarily benefit the small family farmer. There has been no effort to legislatively implement this section by imposing additional procedural requirements on existing agricultural research programs. The statute itself simply requires the Secretary of Agriculture to submit to Congress, on an annual basis, a written report which includes "information on how existing agricultural and agriculture-related programs are being administered to enhance and strengthen the family farm system of agriculture in the United States . . . ." This report must also contain "identification and analysis of new food and agricultural production and processing technological developments . . . and evaluation of the potential effect of such developments on . . . the economic structure of the family farm system." "Thus, a mere reading of the Act itself demonstrates that Congress desired nothing more than an assessment of the effect of federal policies and programs on the family farm."

Congress enacted the Rural Development and Small Farm Research and Education Act (7 U.S.C. § 2661 et seq.) which endeavors to "expand small farm research and extend training and technical assistance to small farm families . . . ." (7 U.S.C. § 2661(a)(4).) To carry out this goal, the Secretary of Agriculture is authorized to conduct small farm research programs in coordination with colleges and universities. "Small farm research programs" consist of programs "to develop new approaches for initiating and upgrading small farm operations through management techniques . . . to develop new enterprises that can use labor, skills, or natural resources available to the small farm family; or that will help to increase the quality and availability of services and facilities needed by the small farm family." Therefore, Congress has chosen to enact separate legislation to foster agricultural research designed to address the special needs of the small farmer rather than narrowing the broad scope of permissible agricultural research under programs such as the Hatch Act.

The University argues that research projects should be selected solely on the basis of scientific merit; and that if it is required to design research projects to benefit small farmers or other special interest groups, academic freedom would be paralyzed. The Project argues that the intent and purposes of the Hatch Act are being ignored by the University, and a procedure to ensure that research benefits the small family farmer would inevitably inure to the benefit of agriculture in this country. The judiciary is not the forum to debate national farm policy or to develop administrative procedures for enforcing the Hatch Act. Because the Hatch Act is silent as to the necessity for such a procedure, our task is to determine whether the agency's construction of the statute is a "reasonable
policy choice for the agency to make." ... 

We conclude that nothing in the Hatch Act or the regulatory mandate under which the University operates its agricultural experiment station requires the University to develop a procedure to see that funds authorized by the Hatch Act are "expended in a manner which affords consideration for each of the legislatively intended beneficiaries, with primary consideration for the small family farmer." Reversed.

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3. The political debate over subsidized agricultural research

Although the University of California prevailed in the California Agrarian Action Project litigation and was free to conduct its federally subsidized agricultural research without the restrictions sought by the public interest activists and tomato harvesting workers, Looney warns:

[T]his litigation provides an example of the serious questions that are being raised about the outcomes of agricultural research. And, it is not just those willing to litigate who are beginning to question research outcomes. A report from the congressional Office of Technology Assessment ("OTA") suggests that new technologies could profoundly affect the future of farming, perhaps more than chemicals did in the past. The developments in biotechnology have caused farmers themselves to question the wisdom of research that could have a detrimental effect on their own futures.17

The debate represented by California Agrarian Action Project comes at a critical moment for the land grant system and for publicly supported agricultural research generally. Despite its illustrious history of technological triumph,18 the public agricultural research system cannot expect to continue receiving the levels of financial support that it has historically enjoyed.19 Fiscal constraints aside, public agricultural research is coming under increasing scrutiny for its contribution to the structural transformation of agriculture. Perhaps the pioneers of the land grant system should have expected educational and research subsidies to fuel agriculture's economic engine, but their agrarian successors seem not to have anticipated the system's role in industrializing farm production. Hell has no fury like a duped agrarian.

19 See generally Vernon Ruttan, Agricultural Research Policy (1982).
From the traditional agrarian perspective, agricultural research poses a serious dilemma. Who could possibly oppose better information, better education? Aren't these the underpinnings of improved life in rural America? Who could complain when research at land grant colleges enhances farm productivity, boosts farm income, and enriches rural life? Actually, many of the descendants of the original agrarian activists who secured the land grant legislation have the most to fear and to decry. Improved farm technology got farmers much of what they wanted: additional production. But enhanced production merely increases aggregate supply, which in turn depresses prices. The drop in prices then increases the pressure to push production even more, with resort to even more advanced technology and even greater reliance on borrowed capital. Throughout, whatever benefits bestowed by this technological push fall unevenly throughout the agricultural economy generally and within the farm sector itself. New technology deepens individual farmers' reliance on high-cost inputs. Ever thirstier for capital and more vulnerable to risk, farmers seek the capital and the contractual certainty that agribusiness can supply. Vertical integration proceeds apace, while marginal producers drop out of farming. The nonfarm input and agribusiness sectors thus tighten their grip on farm production. If the land grant system is not fuel for the agricultural treadmill, it is surely a strong catalyst.

Land grant colleges, agricultural research stations, and the extension service — the collective legacy of legislation supporting agricultural research and education — have deeply wounded the agrarian agenda. To critics, the land grant college system has become more of a complex, the agrarian equivalent of the military-industrial complex. Publicly supported agricultural research and technological progress in farming have facilitated and, indeed, accelerated the industrial and demographic transformation of American agriculture. To watch the land grant system help agribusiness and contribute to rural upheaval is vilest treachery in the family farming ethos. Consider the following excerpts:

**JIM HIGHTOWER, HARD TOMATOES, HARD TIMES: THE FAILURE OF THE LAND GRANT COLLEGE COMPLEX 33-67 (1972)**

It is practically impossible to talk with anyone in the land grant college complex . . . without getting a mindful of the staggering achievements wrought by agricultural research. From the Secretary of Agriculture right down to the most junior instructor of agricultural economics, the entire land grant community enthusiastically recites the litany:

— the farmer [in 1972] is able to produce food and fiber for himself for 45 others, up from the 11 others that he could provide for in 1940
— because of the farmer's increasing productivity, millions of other Americans are freed from farming and able to pursue other occupations

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20 To be truly cold-hearted, one would have to qualify this sentence with the observation that most descendants of pre-New Deal agrarians no longer live on farms or work in agricultural production.
— the consumer receives an abundant and steady supply of more food products than ever before
— ... the American consumer pays a mere 16 percent of his disposable income on food, the lowest rate in the world
— ... the farmer is the major contributor toward a favorable balance-of-payments position for his country
— American agricultural technology and know-how stands as a final bulwark against world-wide famine.

Every one of those points can be conceded. ... The land grant community has every right to boast of its achievements along these lines.

But the question is whether the achievements outweigh the failures, whether benefits are overwhelmed by costs. In short, land grant college research is not the bargain that has been advertised. ... 

What is purchased with [the public's] research expenditure? ... The answer is, "more revolution." Overwhelmingly, agricultural research continues to be committed to the technological and managerial needs of the largest-scale producers and of agribusiness corporations, and it continues to omit those most in need of research assistance. ... 

The original rationale for public support for agricultural research was that farming was not big business. That has changed. Agriculture today is the country's biggest business, and it is an industry that is dominated by relatively few huge-scale producers and by giant processing, marketing and exporting corporations. ... 

The experiment stations at land grant colleges exist today as tax-paid clinics for agribusiness corporations, while others who need publicly-supported research either benefit only incidentally, are not served at all, or actually are being harmed by land grant research.

Land grant researchers are preoccupied with machinery, chemicals, systems and other gadgetry designed to assist agribusiness and to eliminate the human element from farming. The research focus is warped by the land grant community's fascination with technology, integrated food processes and the like. Efficiency is the goal, not people. ... 

[I]n mechanization research ... one can draw a relatively sharp line between who is helped and who is hurt by land grant college research. ... 

Mechanization means more than machinery for planting, thinning, weeding and harvesting. It also means improving on nature's design; i.e., breeding new food varieties that are better adapted to mechanical harvesting. Having built machines, the land grant research teams found it necessary to build a tomato that is hard enough to survive the grip of mechanical "fingers" ... If it cannot be
done by manipulating genes, land grant scientists reach into their chemical cabinet. . . . Genetically redesigned, mechanically planted, thinned and weeded, chemically readied and mechanically harvested and sorted, food products move out of the field and into the processing and marketing stages – untouched by human hands. . . .

Who is helped by this research and development? More significant, who is hurt?

It is agribusiness that is helped. In particular, the largest-scale growers, the farm machinery and chemical in-put companies and the processors are the primary beneficiaries. . . . Obviously, farm machinery and chemical companies are direct beneficiaries of this research, since they can expect to market products that are developed. . . . Even a farm machinery company not involved directly in land grant research will profit directly from the resulting increase in machinery use. With more and more crops being mechanized, there is more and more machinery to be sold. . . .

Large-scale farming operations, many of them major corporate farms, also are directly in line to receive the rewards of mechanization research. In the first place, it is these farms that hire the overwhelming percentage of farm labor, thus having an economic incentive to mechanize. Secondly, these are the massive farms, spreading over thousands of acres. This scale of operation warrants an investment in machinery. Thirdly, these are heavily capitalized producers, including processing corporations, vertically-integrated in-put industries and conglomerate enterprises. Such farming ventures are financially able and managerially inclined to mechanize the food system.

Mechanization has been a key element in the cycle of bigness: enough capital can buy machinery, which can handle more acreage, which will produce greater volume, which can mean more profits, which will buy more machinery. . . .

Then there are the victims of mechanization – those who are directly hurt by research that does not consider their needs. If mechanization research has been a boon to agribusiness interests, it literally has been a bane to millions of rural Americans. The cost has been staggering.

Farm workers have been the earliest victims. It is outrageous that those who have been brutalized so badly by mechanization have been used as the excuse for mechanization. Again and again there are references in land grant research materials to the scarcity, unreliability and cost of farm labor as the factor requiring mechanization. . . . [M]echanization is perceived as an essential, tactical step within the land grant community's broad strategy of making agriculture strictly efficient. . . . Why mess with a union, make payroll deductions and wrestle with a whole range of worker problems when you can turn to machinery?

The turn to machinery has a snowball effect. As one crop is mechanized, there is less work in the area; as two or three crops are mechanized, there is not work in the area to make a living, so the farm worker hits the road. Then there is a "scarcity of labor," so other crops are mechanized. . . .
Independent family farmers . . . also have been victimized by the pressure of mechanization, and their needs also have been largely ignored by the land grant colleges . . . . [Land grant research] ha[s] narrowed [family farmers'] choices to two: either get with the new production efficiency technology as we are developing it, or get out of farming business. These are not very inspiring alternatives.

The rapidly-increasing cost of farming, in combination with perennially low farm prices, is driving farmers off the land. Mechanization is a major contributor to that skyrocketing cost of doing business. . . . The fact is that the land grant colleges are expending their resources on mechanization that primarily is useful to the highest income growers, focusing attention exclusively on those producers with the necessary acreage, capital and management to achieve economies of scale. . . . America's massive corporate farms . . . . are the "farmers" who are welcome in the land grant research labs. They bring grants and equipment [and,] more importantly, a shared vision of assembly-line food production. In turn, they get research to implement that vision. These huge growers are more than clients of the land grant system; they are colleagues. . . .

The public subsidy for mechanization has actually weakened the competitive position of the family farmer. Taxpayers . . . have given corporate producers a technological arsenal specifically suited to their scale of operation and designed to increase their efficiency and profits. The independent, family farmer is left to strain his private resources to the breaking point in a desperate effort to clamber aboard the technological treadmill.

Mechanization has not been pressed by the land grant colleges as an alternative, but as an imperative. The fact that his corporate and well-to-do neighbors are rushing pell mell into agricultural technology means that the independent operator must either "adapt or die" . . . .

As farms collapse, small town businesses follow, and small towns begin to die. Rural America is changing radically, irrevocably and for the worse. All America is affected. . . .

The land grant community would insist that all of its research is targeted toward the consumer . . . . [T]hat assertion is at least questionable. It is true that the consumer enjoys an abundance of a wide variety of food products, and that he enjoys those products at a relatively cheap market price. But the connection between the price of tomatoes and the tomato harvester is a bit strained. Assuming that there are cost savings on mechanized production, and assuming that the producer's savings are passed on to the processor or marketer, it is unlikely that the savings comes intact from there to the consumer. . . .

To this must be added the cost that the consumer pays for mechanization. The assembly line is neither gentle nor particularly concerned with quality. . . . Mechanized crops are bred for the machine, not for the consumer. Mechanized crops require sizeable doses of chemicals to regulate their growth. Mechanized crops are harvested, sorted and packaged by machine. . . . The genetical [sic] and chemical aspects of mechanization raises [sic] unanswered questions of carcinogenic effects. And chemicals raise unanswered questions of ecological impact. . . .
If economies of scale, integrated food systems and assembly-line efficiency are products of mechanization research at land grant colleges, so are hard tomatoes and hard times. . . . Indeed, in terms of wasted lives, depleted rural areas, choked cities, poisoned land and maybe poisoned people, mechanization research has been a bad investment. . . . The land grant college community, working too intimately with its agribusiness colleagues, is accountable for that failure.

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Everyone, it seems, has some sort of grievance with the land grant system. The College of Natural Resources at the University of California, Berkeley, has endured a bloody battle between traditionalists who wish to keep directing public research funds at problems facing production agriculture and "new agenda" researchers who seek to tackle broader environmental challenges.21

Suppose that the production agriculture traditionalists win this battle. Would the farm sector as a whole benefit? Probably. How about individual farmers? A much more difficult question. Especially if focused on production-enhancing research, a prolific land grant system fuels the agricultural treadmill of cost- and labor-saving (albeit frequently capital-intensive) technological advancement. Every improvement in agricultural efficiency purges farmers at the margins. To some, having public money fuel such changes in the structure of agricultural markets and the organization of agricultural industries is particularly objectionable, especially if publicly supported universities are not releasing their discoveries into the public domain, but rather licensing them commercially.22

To the extent that they agree with Jim Hightower, farmers themselves must bear some of the responsibility for the evolution of the land grant system. If indeed agricultural research wounded the farm sector, it was at least in part a self-inflicted wound:

What were the forces behind the great changes on America's commercial farms? One of the most obvious influences, of course, was the cumulative effect of changes that had been going on for many years. But beyond this was the fact that farmers themselves wanted to increase their efficiency and production to improve their incomes. Farm families wanted to enjoy the same standards of living as people in


nonfarm employment. They wanted to modernize their homes, to buy household appliances, to educate their children, and to take vacations like town and city folks. These things required more income. Since farm income was determined by units of production times price, farmers believed they could make more money by increasing their efficiency. This meant producing more crops and livestock in relation to the inputs of capital and labor . . . .

The USDA, the colleges of agriculture, agricultural experiment stations, and the cooperative extension services all played a significant role in helping farmers achieve their goal of increased production . . . . Their influence before World War II had been modest. Farmers had resisted "book farming," and relatively few producers looked to the agricultural colleges and experiment stations for help and advice. As farming operations became increasingly complex, more and more commercial farmers turned to scientists, engineers, economists and other specialists at these institutions. Wheat farmers on the Southern Plains looked to Kansas State University for information on the best varieties of seed, methods for disease and rust controls, proper fertilizer applications and other matters. Cotton growers in the South depended on the work of [publicly subsidized] engineers and plant breeders . . . to develop a cotton plant and machinery which together would permit fully mechanized production. At the Tifton, Georgia, experiment station, extensive research on the peanut . . . resulted in farmers doubling their production per acre. Farmers no longer ignored the information streaming from the agricultural colleges.23

In short, to the extent land grant colleges betrayed agrarian interests by intensifying the role of technology and capital in farming, they did so at farmers' prodding. Farmers seeking a better life for themselves and their families sought the land grant system's help. To liberate future generations from "the drudgery of farming" in the labor-intensive tradition of the past,24 farmers and their rural neighbors sent their children to the land grant colleges in Fargo, Brookings, St. Paul, Ames. They got precisely what they wanted. Rampant industrialization and rural depopulation were among the consequences of that decision. "[I]ncreas[ed] affluence" through enhanced agricultural productivity necessarily spells "the social and economic decline of rural communities and small towns dependent on agriculture."25 *Volenti non fit injuria.*

Agricultural research, especially in capital-intensive farm technology, reflects the fundamental problem in agricultural policymaking. Research promises progress. But progress means change.


24**Hiram M. Drache, Beyond the Furrow: Some Keys to Successful Farming in the Twentieth Century** 430 (1976).

25**Marion Clawson, America's Land and Its Uses** 109 (1972).
And change leaves somebody behind. If the difference between the agrarian and the industrial perspectives on agriculture could be reduced to a single pair of sentences, the following two would suffice. The industrialist worships the prospect of progress. The agrarian laments the loss of markets for traditional labor, the loss of lifestyles associated with a slower rate of economic growth. Simply to adopt one perspective and to seek legal remedies consistent with that perspective, however, cannot guarantee "desirable" results. The story of land grant colleges proves as much. Beginning with the Morrill Act of 1862, agrarian activists got ample public support for agricultural research and education. Eleven decades later, an agrarian voice wonders how the land grant college system could have transmogrified itself into a complex. Getting your wish is sometimes the fastest way to a curse.

While the political titans of agricultural public lawmaking have confounded themselves over the consequences of research subsidies, the agricultural economists and scientists who benefit most directly from public support may have known all along that trying to give farmers is frequently the surest way to hurt them:

It does not require very sophisticated economic logic to show that technology provided directly to farmers can actually reduce farm incomes and the demand for farm labor when demand is inelastic, while public sector provision of new technology in the post-harvest agribusiness sector is likely to increase farm incomes and the demand for farm labor even in the presence of imperfect competition. Technology that lowers farm input prices may have different effects, of course, but, in general, such technology is also likely to benefit farmers more than the technology of the traditional kind.

We have now achieved a consensus of perspective on the general productivity and effectiveness of agricultural research programs. We have not achieved consensus on the distributive consequences of productivity change and on the agribusiness role in the process.26

If this agricultural economist's insight is correct, economically astute farmers should have known that asking for technology directly enhancing farm output would inexorably fuel an agricultural treadmill that runs on cycles of increasing productivity and falling commodity prices. Even more ironically, this economist suggests that public research flowing in the first instance to agribusiness – not unlike George Washington Carver's research into the uses of processed peanut products – would eventually but unequivocally benefit farmers by enhancing agribusiness demand for farm products. Political pressures being what they are, land grant colleges are probably likelier to be accused of collaboration with agribusiness if they direct their research toward the sort of post-

harvest technology that agribusiness (but not farmers) can immediately exploit. Research reducing input costs, such as improvements in plant and animal genetics, has less predictable effects. As it happens, such research will provide the predominant backdrop for the remainder of this chapter.  

Suffice it to say that lack of consensus may be the only consensus we can have. Let us leave this debate and turn without further delay to one of the most controversial types of agricultural research — plant and animal genetics — and its use on the farm.

27 For a thorough overview of the issues raised in this subchapter, see INDUSTRIAL POLICY FOR AGRICULTURE IN THE GLOBAL ECONOMY (S.R. Johnson & S.A. Martin eds. 1993).
II. Chapter Two: Intellectual Property Rights in Living Matter

Although we have had trouble defining agriculture, certain aspects are irreducible. Human beings must eat, and they must eat other living things. Other claims to the distinction notwithstanding, food production is the oldest profession. From the very beginning, family farming specialized either in plant cultivation or in animal husbandry. 28 A primitive barter economy obviates the need for finance, and a farmer can rely exclusively on personal or family labor, but no one can begin farming without either plants or animals.

The astonishing pace and scale of changes in technology enabling biological manipulation of plants and animals have thrust biotechnology into the forefront of the new agricultural agenda. 29 This chapter marks a critical pivoting point within that new agenda. After exploring public support for agricultural research, this chapter considers three separate ways in which consumers and the farm sector have responded to the fruits of that research: agricultural intellectual property; animal rights; and the interplay between animal rights, consumer protection, and economic regulation of agriculture.

Several factors lend a unique passion to discussions of agricultural biotechnology. The emergence of a highly capitalized, information-intensive biotechnology industry takes direct aim at

28See Gen. 4:2 ("And Abel was a keeper of sheep, but Cain was a tiller of the ground."); Fidler v. Zoning Bd. of Adjustment, 468 Pa. 260, 182 A.2d 692, 695 (1962); see also Gen. 9:3 ("Every moving thing that liveth shall be meat for you; even as the green herb have I given you all things."). Whether horticulture or animal husbandry was the earlier basis of primitive human civilization is currently the subject of fierce anthropological debate. Recent archeological research suggests, contrary to conventional wisdom, that foragers in northerly climates such as Turkey may have settled down and established agriculture in order to raise pigs. See Constance Holden, Bringing Home the Bacon, 264 SCIENCE 1398 (1994); cf. Graeme O'Neill, Cemetery Reveals Complex Aboriginal Society, 264 SCIENCE 1403 (1994) (challenging the traditional belief that complex civilization began when agriculture replaced foraging as the predominant human food supply).

29For a discussion of how biotechnology fits within this new agenda, see WESLEY D. SEITZ, GERALD C. NELSON & HAROLD G. HALCROW, ECONOMICS OF RESOURCES, AGRICULTURE, AND FOOD 353-54, 357-65 (1994). A recent congressional publication on the new agricultural technology is indispensable reading. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE (OTA-F-474, Aug. 1992). This report describes emerging plant and animal technologies, id. at 37-95, their impact on agricultural production and management, id. at 133-76, food safety and quality issues, id. at 275-385, intellectual property issues, id. at 389-405, and institutional changes within the land grant college system, id. at 409-26.
traditional plant breeding and animal husbandry, two of the most time-honored activities within the classically agrarian notion of farming as a "way of life." "The greatest service which can be rendered any country is to add a useful plant to its culture," wrote Thomas Jefferson. Yet Jefferson as agrarian visionary probably never envisioned a world in which the principal manipulators of genetic resources would not be farmers. The battle over plant and animal genetic in agriculture is thus a microcosm of the larger clash over all the terms by which players from conflicting social and economic classes will struggle to feed and clothe a world of increasingly scarce resources.

An even grander struggle is that of the human against an uncaring, even hostile natural environment. All the agroecological romanticism in this world – a commodity in chronic oversupply – cannot change certain cold equations about the place of Homo sapiens sapiens in a constantly evolving ecosystem. Human beings do not live "in harmony" with nature as though they were the favored children of the Earth Mother; rather, their very existence hangs by a mere thread, the gossamer strand that separates Earth's top predator from an ignominious fate as food or fertilizer for other species. Biotechnology promises deliverance from famine and pestilence, and it often delivers. Nevertheless, as an act of human aggression against plant parasites and food competitors generally, biotechnology may well backfire if it disrupts the fragile ecosystem that sustains human life.

Every living organism on earth must compete with others for nourishment and manage to reproduce itself as successfully as possible within a limited lifespan. All too often, the realms of competition and colonization are not mutually reinforcing, and a species that excels in securing food is frequently unable to reproduce at an adequate pace when new predators and parasites enter its ecosystem. In manipulating biotechnology, human society often faces two grim choices: (1) expand food production to forestall famine at the risk of falling victim to novel plant viruses and other agricultural pests, or (2) take measures against exposing agricultural production to devastating blights and diseases at the risk of using food rationing or compulsory birth control to allocate diminished food supplies on an overpopulated planet.

In this Darwinian world, there are two and only two forces that matter. One is food. The other is sex. Paradoxically, the seed is both. "It is both means of production and, as grain, the product." As the first step toward understanding agricultural biotechnology, let us examine what public support for agricultural education and research actually buys.

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A. AGRICULTURAL INTELLECTUAL PROPERTY: AN INTRODUCTION

*The Congress shall Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . .

− U.S. Const., art. I, § 8, cl. 8

* * * * *

Almost if by reflex, lawyers react to a new development by asking about rights and duties. However expansively one chooses to view the notion of "rights" in civilized society, recognizing and protecting intangible rights attaching to products of the human mind represents one of the most difficult (and perhaps one of the most necessary) legal projects imaginable. The Constitution's succinct "twenty-seven words . . . which give Congress the power to legislate copyrights and patents" − the foundations of a comprehensive system of intellectual property − "contain the only use of the right in the main body of the Constitution."² The most legally intriguing "inventions" in agriculture may arise from human intervention in the quintessentially natural process of plant and animal reproduction. In nature, new plant varieties and animal species emerge as a matter of biological evolution. Does any other type of human activity more strikingly show how "knowledge of good and evil" renders men and women "as gods" without conferring the full attributes of divinity?³

On the farm and in the agricultural research center, new life forms appear as a matter of deliberate human manipulation of biology. It arguably requires superhuman suspension of the senses to ignore the philosophical and ethical implications of this activity. We will nevertheless try. In its initial proprietary phase, the rights-based approach to law focuses exclusively on defining

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¹ Compare, e.g., John Rawls, A Theory of Justice (1971) (describing the legal enterprise as beginning in the establishment of certain rights inherent in a societal "original position") with Michael Sandel, Liberalism and the Limits of Justice (1982) (arguing that a liberal conception of the state as creator and protector of rights wrongly divorces citizens' conception of self from notions of community and common values).


³ Gen. 3:5 (The Serpent: "For God doth know that the day ye eat [of the tree of the knowledge of good and evil], then your eyes shall be opened, and ye shall be as gods, knowing good and evil.); cf. Gen. 2:17 (God: "But of the tree of the knowledge of good and evil, thou shalt not eat of it: for in the day that thou eatest thereof thou shalt surely die.").
entitlements, on identifying rights, privileges, and duties, on discerning powers and immunities. Only in a later reconciliatory phase does the legalistic perspective consider the broader consequences — both material and metaphysical — of the initial assignment of rights. Although I by no means endorse this approach to law, the remainder of this chapter will address biotechnology from this perspective. First, after presenting a brief introduction to fundamental principles of intellectual property, I will describe the assorted types of legal protection for new plant varieties and animal species. The legal doctrines I present follow a progression dictated by biology, by positive law, and by economic realism. Federal law has created separate schemes for protecting asexually and sexually reproduced plant varieties. I will then turn to one of the rare instances in which "agricultural law" constitutes the mere application of general law to an agricultural activity: patenting plants and animals under the general patent laws. I then conclude our tour of agricultural intellectual property with a brief look at trademarks, trade secrets, and privately developed protections for biotechnology. Only then will I turn to the issues arising from the use of legally protected biotechnology (with a specific focus on animal rights, intensive production methods, and food labeling and safety).

* * * *

1. What is intellectual property?

The task at hand, however, is to understand fundamental principles of intellectual property and how they operate in the agricultural context. This is no easy task, for agricultural and other biological materials fall in a twilight zone between well established "paradigms" for analyzing intellectual property. The law of intellectual property frequently invokes agrarian analogies, perhaps the most celebrated being the admonition that one should not reap where another has sown. We will now see whether the law of intellectual property has anything of value to contribute to agricultural law.

(i) Types of intellectual property. Whenever "intellectual property" exists or can be debated, as many as five distinct types of property may come into play:

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4 See generally J.H. Reichman, Legal Hybrids Between the Patent and Copyright Paradigms, 94 Colum. L. Rev. 2432 (1994).

1. Patent: A patent gives its owner the exclusive right to copy and to use an invention. Independent creation is no defense to an allegation of infringement. Because of a patent's potency, the law imposes relatively high hurdles that an inventor must clear before receiving a patent. The law also places a fairly strict time limit on patents.

2. Copyright: A copyright gives its owner the exclusive right to copy, but not an exclusive right to use. Unlike a patent, which requires that an invention be novel (that is, never imagined before), a copyright vests upon merely original creation. In other words, independent creation satisfies the requirements for receiving a copyright and insulates an alleged infringer from liability. The Constitution requires that federal copyright protection be limited in time. Although most agricultural "inventions" fall outside the scope of the Copyright Act, you should mind the distinction between a patent-like right to copy and to use and a more limited right to copy without an exclusive right of use.

3. Trade secret: One disadvantage of the federal patent and copyright laws is that the creator must disclose the knowledge underlying his or her creation in exchange for temporary legal protection. If a creator chooses instead to keep that knowledge wholly secret, state law provides trade secret protection for commercially valuable, confidential information. Trade secrets protected under state law are regarded property for purposes of federal constitutional law.

4. Trademark: At the opposite extreme is a creator's commercial interest in the public's association of a certain word, phrase, design, or picture with the creator's product. A word or picture

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7See id. § 154 ("Every patent shall contain . . . a grant to the patentee . . . of the right to exclude others from making, using, or selling the invention . . . .").


10See RESTATEMENT OF TORTS § 757 (1939).


may become so readily (and exclusively) associated with a particular source of goods that the word or picture itself develops commercial value as a informational shortcut for consumers. A supplier of nonfarm inputs has an interest in distinguishing its products from its competitors; a producers' cooperative may wish to induce brand loyalty by nurturing a famous trademark and a corresponding consumer image of quality. Think, for example, of the trademark value that enables Land O' Lakes to command a higher retail price for butter, a virtually fungible food product. Trademark protection endures indefinitely unless a mark becomes generic and consumers no longer associate the mark with a particular seller of a product.

5. Chattel: Intellectual property is by definition intangible. But intangible intellectual property rights must attach to a tangible piece of personal property. Always be careful to distinguish the intellectual property interest from the chattel to which the interest attaches. For instance, buying a seed from a supplier entitles a farmer to plant the seed, but not necessarily to reproduce the plant that grows from the seed by reaping seeds from that plant.

(ii) Natural law vs. positive law. One further issue bears notice: Are intellectual property rights essentially statutory projections of legal imagination, delimited by positive law, or do they originate in the natural right of an inventor to master his or her creation? The positive law/natural law debate within intellectual property law is fierce, but most legal doctrines tend to track the Supreme Court's resolution of the tension in the following case:

Graham v. John Deere Co.
Supreme Court of the United States
383 U.S. 1 (1965)

Mr. Justice Clark delivered the opinion of the Court.

. . . At the outset it must be remembered that the federal patent power stems from a specific constitutional provision which authorizes the Congress "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." The clause is both a grant of power and a limitation. This qualified authority, unlike the power often exercised in the sixteenth and seventeenth centuries by the English Crown, is limited to the promotion of advances in the "useful arts." It was written against the backdrop of the practices – eventually curtailed by the Statute of Monopolies – of the Crown in granting monopolies to court favorites in goods or businesses which had long before been enjoyed by the public. The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated

\(^{13}\) Cf. 17 U.S.C. § 109(a) (enabling a purchaser of a particular copy or phonorecord of a copyrightable work to dispose of that copy or phonorecord); id. § 202 (providing that the sale of a particular copy or phonorecord does not of itself transfer the copyright in the work); Forward v. Thorogood, 985 F.2d 604 (1st Cir. 1993).
constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of . . . useful Arts." This is the standard expressed in the Constitution and it may not be ignored. . . .

Within the limits of the constitutional grant, the Congress may, of course, implement the stated purpose of the Framers by selecting the policy which in its judgment best effectuates the constitutional aim. This is but a corollary to the grant to Congress of any Article I power. Within the scope established by the Constitution, Congress may set out conditions and tests for patentability. It is the duty of the Commissioner of Patents and of the courts in the administration of the patent system to give effect to the constitutional standard by appropriate application, in each case, of the statutory scheme of the Congress.

Congress quickly responded to the bidding of the Constitution by enacting the Patent Act of 1790 during the second session of the First Congress. . . . Thomas Jefferson . . . might well be called the "first administrator of our patent system." He was not only an administrator of the patent system under the 1790 Act, but was also the author of the 1793 Patent Act. In addition, Jefferson was himself an inventor of great note. His unpatented improvements on plows, to mention but one line of his inventions, won acclaim and recognition on both sides of the Atlantic. Because of his active interest and influence in the early development of the patent system, Jefferson's views on the general nature of the limited patent monopoly under the Constitution, as well as his conclusions as to conditions for patentability under the statutory scheme, are worthy of note.

Jefferson, like other Americans, had an instinctive aversion to monopolies. It was a monopoly on tea that sparked the Revolution and Jefferson certainly did not favor an equivalent form of monopoly under the new government. His abhorrence of monopoly extended initially to patents as well. From France, he wrote to Madison (July 1788) urging a Bill of Rights provision restricting monopoly, and as against the argument that limited monopoly might serve to incite "ingenuity," he argued forcefully that "the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression."

His views ripened, however, and in another letter to Madison (Aug. 1789) after the drafting of the Bill of Rights, Jefferson stated that he would have been pleased by an express provision in this form: "Monopolies may be allowed to persons for their own productions in literature, & their own inventions in the arts, for a term not exceeding ___ years, but for no longer term & no other purpose." And he later wrote: "Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. . . . Nobody wishes more than I do that ingenuity should receive a liberal encouragement."
Jefferson's philosophy on the nature and purpose of the patent monopoly is expressed in a letter to Isaac McPherson . . . ² He rejected a natural-rights theory in intellectual property rights and clearly recognized the social and economic rationale of the patent system. The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society — at odds with the inherent free nature of disclosed ideas — and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly. Jefferson did not believe in granting patents for small details, obvious improvements, or frivolous devices. His writings evidence his insistence upon a high level of patentability . . .

The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it, together with the underlying policy of the patent system that "the things which are worth to the public the embarrassment of an exclusive patent," as Jefferson put it, must outweigh the restrictive effect of the limited patent monopoly. The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent . . .

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(iii) What is invention? Graham's positivistic definition of intellectual nevertheless leaves a few questions. How do we delineate the specific contours of positive intellectual property law?

²"Stable ownership is the gift of social law, and is given late in the progress of society. It would be curious then, if an idea, the fugitive fermentation of an individual brain, could, of natural right, be claimed in exclusive and stable property. If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it. Its peculiar character, too, is that no one possesses the less, because every other possesses the whole of it. He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me. That ideas should freely spread from one to another over the globe, for the moral and mutual instruction of man, and improvement of his condition, seems to have been peculiarly and benevolently designed by nature, when she made them, like fire, expansible over all space, without lessening their density in any point, and like the air in which we breathe, move, and have our physical being, incapable of confinement or exclusive appropriation. Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody."
Most pointedly, what types of creativity deserve legal protection?

**Funk Bros. Seed Co. v. Kalo Inoculant Co.**
Supreme Court of the United States
333 U.S. 127 (1948)

Mr. Justice Douglas delivered the opinion of the Court.

This is a patent infringement suit brought by respondent. The charge of infringement is limited to certain product claims of Patent No. 2,200,532 issued to Bond on May 14, 1940. Petitioner filed a counterclaim asking for a declaratory judgment that the entire patent be adjudged invalid. The District Court held the product claims invalid for want of invention. The Circuit Court of Appeals reversed, holding that the product claims were valid. The question of validity is the only question presented by this petition for certiorari.

Through some mysterious process leguminous plants are able to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds. The ability of these plants to fix nitrogen from the air depends on the presence of bacteria of the genus *Rhizobium* which infect the roots of the plant and form nodules on them. These root-nodule bacteria of the genus *Rhizobium* fall into at least six species. No one species will infect the roots of all species of leguminous plants. But each will infect well-defined groups of those plants. Each species of root-nodule bacteria is

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1. Claim 4 is illustrative of the invention which is challenged. It reads as follows:

An inoculant for leguminous plants comprising a plurality of selected mutually non-inhibitive strains of different species of bacteria of the genus *Rhizobium*, said strains being unaffected by each other in respect to their ability to fix nitrogen in the leguminous plant for which they are specific.

2. The patent also contains process claims.

3. The six well-recognized species of bacteria and the corresponding groups (cross-inoculation groups) of leguminous plants are:

   - *Rhizobium trifolii*: Red clover, crimson clover, mammoth clover, alsike clover
   - *Rhizobium meliloti*: Alfalfa, white or yellow sweet clovers
   - *Rhizobium phaseoli*: Garden beans
   - *Rhizobium leguminosarum*: Garden peas and vetch
   - *Rhizobium lupini*: Lupines
   - *Rhizobium japonicum*: Soy beans
made up of distinct strains which vary in efficiency. Methods of selecting the strong strains and of producing a bacterial culture from them have long been known. The bacteria produced by the laboratory methods of culture are placed in a powder or liquid base and packaged for sale to and use by agriculturists in the inoculation of the seeds of leguminous plants. This also has long been well known.

It was the general practice, prior to the Bond patent, to manufacture and sell inoculants containing only one species of root-nodule bacteria. The inoculant could therefore be used successfully only in plants of the particular cross-inoculation group corresponding to this species. Thus if a farmer had crops of clover, alfalfa, and soy beans he would have to use three separate inoculants. There had been a few mixed cultures for field legumes. But they had proved generally unsatisfactory because the different species of the \textit{Rhizobia} bacteria produced an inhibitory effect on each other when mixed in a common base, with the result that their efficiency was reduced. Hence it had been assumed that the different species were mutually inhibitive. Bond discovered that there are strains of each species of root-nodule bacteria which do not exert a mutually inhibitive effect on each other. He also ascertained that those mutually non-inhibitive strains can, by certain methods of selection and testing, be isolated and used in mixed cultures. Thus he provided a mixed culture of \textit{Rhizobia} capable of inoculating the seeds of plants belonging to several cross-inoculation groups. It is the product claims which disclose that mixed culture that the Circuit Court of Appeals had held valid.

We do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. Bond does not create state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end. The Circuit Court of Appeals thought that Bond did much more than discover a law of nature, since he made an new and different composition of non-inhibitive strains which contributed utility and economy to the manufacture and distribution of commercial inoculants. But we think that that aggregation of species fell short of invention within the meaning of the patent statutes.

Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous
plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

There is, of course, an advantage in the combination. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops of leguminous plants. And, as respondent says, the packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like. But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. The application of this newly-discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature's secret of the non-inhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed. All that remains, therefore, are advantages of the mixed inoculants themselves. They are not enough. . . .

*Reversed.*

[Justice Frankfurter's concurrence and Justice Burton's dissent are omitted.]

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2. *How broadly should we protect agricultural inventions?*

As *Graham* illustrates, protecting intellectual property as an inducement for invention comes at a price: recognizing proprietary interests in human creativity necessarily suppresses its use by giving the creator a monopoly and possible market power over willing purchasers of new technology. On the other hand, as *Funk Brothers* shows, not every expression of creativity will satisfy positivistic limits on the breadth of intellectual property. Your attitude toward formal prerequisites to intellectual property protection may depend on the assumptions you adopt in answering *Graham*'s fundamental question. Generally speaking, what level of proprietary exclusivity will "induce" socially desirable inventions without unduly suppressing competition and innovations based on others' inventions?\(^{14}\) At the outset, we should acknowledge that *Graham*'s formulation tends to

\(^{14}\)See also *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984):

The monopoly privileges that Congress may authorize are neither unlimited nor
overstate the magnitude of the problem. Exclusivity, under the patent law or weaker forms of intellectual property protection, is not a true monopoly in either a legal or an economic sense.\textsuperscript{15} Regardless of the strength of protection, patented products must compete against substitutes. By the same token, consider carefully the social interest in competition and innovation. To be sure, "[t]he world goes ahead because each of us builds on the work of our predecessors. A dwarf standing on the shoulders of a giant can see farther than the giant himself."\textsuperscript{16} Nevertheless, when a subsequent user of agricultural technology developed by another simply applies it without paying the inventor and without enhancing the technology, we can easily perceive how this sort of expropriation could erode incentives to develop technology.

However we choose to frame the debate, we cannot escape it. Simply as a matter of first economic principles, agricultural technology may not warrant intellectual property protection. To state the case less stridently, one might argue that any proprietary protection that is extended should be minimized. Consider the following list of economically motivated reasons for eliminating or at least limiting the scope of agricultural intellectual property:\textsuperscript{17}

Incentives to create in the absence of intellectual property protection. Is it so clear that agricultural innovations, especially genetic ones, would cease in the absence of intellectual property protection? Farmers and agricultural scientists worked wonders with plant genetic resources before

primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved. It is intended to motivate the creative activity of authors and inventors by the provision of a special reward, and to allow the public access to the products of their genius after the limited period of exclusive control has expired.


\textsuperscript{15}\textit{See} Edmund W. Kitch, \textit{Patents: Monopolies or Property Rights?}, 8 Res. in Law & Econ. 31 (1986).

\textsuperscript{16}Zachariah Chafee, Jr., \textit{Reflections on the Law of Copyright}, 45 Colum. L. Rev. 503, 533 (1945).

the passage of the Plant Patent Act of 1930\textsuperscript{18} reversed the longstanding (and eventually abandoned) doctrine that plants could not be patented.\textsuperscript{19} Simply being the first among many suppliers to introduce a valuable innovation gives an agricultural inventor great prestige and superior knowledge of the invention's true commercial potential. A commercially savvy inventor can extend the economic leverage from this "headstart" by encouraging impressionable and lazy consumers to associate the product with the inventor's trademark. (Consider, for example, the amount of herbicide sold under the trade name "Roundup" versus the amount sold under a generic nameplate.)

Imperfect means of duplication. "Expropriation" of one inventor's product may fail in an unprotected market if the would-be duplicators cannot readily "steal" the product. Although a breeder of sexually reproduced plants may succumb to competition from farmers who reap seeds from their own mature plants, the technological difficulty of transferring discrete plant genes provides substantial nonlegal protection for inventors. To the extent that copying requires some investment, that cost further deters unauthorized copying. Specifically, the biological phenomenon of genetic drift makes it difficult, if not impossible, to transmit desired genetic traits beyond one or two generations.\textsuperscript{20} Finally, the irreducible biological process by which plants generate seeds gives the inventor at least a brief interval in which he or she faces no competition. (These factors, with appropriate modification, apply in the animal context as well.)

One factor to the contrary, perhaps a decisive factor, is the astonishing rate at which even one seed can reproduce itself into enough seed to plant all available acreage for a particular crop. Note, too, that "copying" — often a deviant and difficult deed for would-be patent infringers in many industries — through the cultivation of plants or through animal husbandry is the very essence of agriculture. Farmers specialize in plying reproductive techniques and technology. In the case of sexually reproduced plants, one seed purchase should be all that a skillful farmer needs, not only to plant his or her own acreage, but also to go into the business of selling seeds. Even if genetic drift limits effective seed production beyond one or two generations of plants, the sheer volume of viable seeds produced in the first harvest alone could devastate the breeder's market position.

In this regard, consider the analogous situation faced by computer software publishers. The disk operating system that enables a personal computer to load commercial software also enables the end user to copy the software, both for archival purposes (fair use) and for resale (infringement). As in agriculture, a weak form of genetic drift infects casual software copying, either through media defects (\textit{e.g.}, bad sectors, floppy disk failures) or human error (\textit{e.g.}, failure to copy an essential file). But software publishers have two crucial advantages that plant breeders do not. First, software serial


numbers facilitate relatively effective enforcement of software publishers' copyrights. Second, software publishers enjoy a substantial temporal edge. New, decisively superior versions of software appear within months of the release of any particular software package. By contrast, the successful breeding of a new plant variety sometimes takes years. In light of these factors, is it really any surprise that software publishing has remained a profitable business (sometimes very profitable), despite substantial confusion over the precise scope of software publishers' rights under copyright law, while private sector plant breeders have slowly retreated from the business of developing new plant varieties?

**Contractual remedies.** In a world without intellectual property, an inventor and a licensee could agree on contractual terms that reserve for the inventor the exclusive right to duplicate. The ultimate agribusiness integrator may already have established an extensive contractual relationship with individual farmers. There is little added cost in expanding any such contract to include terms and conditions governing the transfer of reproducible agricultural technology. And even if contracts cannot effectively patrol duplication—for instance, if a purchaser's ability to "cheat" outstrips the seller's ability to monitor a contractual provision against duplication—raising the contract price for the first copy of the technology can recapture some of that value for the seller. To be sure, an intellectual property system can reduce piecemeal contracting costs, especially as the number or the variety of contracts increases. On the other hand, creating and enforcing a formal system of intellectual property requires a very substantial and enduring social investment in administrative costs.

**Other hidden costs.** Proprietary protection—especially effective protection—has a perverse tendency to suppress invention. Virtually every invention borrows something from another invention. In the absence of intellectual property, inventors could borrow freely from all potential resources, focusing naturally on the most valuable and readily available. Stern intellectual property law will not necessarily foreclose borrowing; it will simply divert borrowers toward less valuable "primary materials" (whose owners will be less likely to protect) or increase the cost of borrowing. The number and quality of agricultural innovations could decrease.

**Treating agricultural inventions as public goods instead of intellectual property.** Why should an inventor receive legal recognition as the "owner" of his or her invention? Why not, instead, regard inventions as public goods from the moment of creation and innovative applications of inventions as imaginative uses whose benefit should flow to anyone who can envision those uses?

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The invention itself becomes the public good, and all subsequent applications should be pursued as long as returns exceed the marginal cost of any particular use. Far from being a crackpot idea, this notion resonates quite well with the modern concept of intellectual property:

Although intellectual property protection was at one time regarded primarily as an equitable means to guard inventors' rights inherent in their creations, it is today almost universally viewed as a utilitarian legal construct for the protection of ideal or intellectual goods. Knowledge or ideas associated with technological advances may be created as pure intellectual goods or embodied to some degree in a physical form, such as an invention. Like physical goods, intellectual goods may have great industrial value, and generating such knowledge may entail significant production costs of time and effort. Unlike physical goods, however, intellectual goods often do not encompass natural physical barriers that exclude potential consumers. Ideas, after all, may be held by more than one person at a time. In addition, the distribution costs for disseminating an intellectual good such as an idea are minimal or nonexistent. Once such intellectual goods are disclosed, there are no real barriers to free appropriation of the good.

In this way, intellectual goods appear to resemble public goods, such as national defense, that also may be held by more than one person at a time. Because it is difficult to exclude persons from deriving the benefit of the good, a significant number of persons may consume the good without recompensing the good's originator. This lack of recompense may create a disincentive to create the good and the market for the good may be undersupplied. The potential for an undersupply of intellectual goods is not precisely the same problem as the potential undersupply of public goods: the potential for "free riding" is likely much greater for intellectual goods. In the case of intellectual goods, unlike that of public goods, a consumer benefits only from the first unit consumed, and not from any additional units. Furthermore, although public goods can usually be obtained only from the initial source, each consumer of intellectual goods becomes a potential secondary source of supply. These additional complications in intellectual good supply amplify the difficulty of identifying potential consumers and estimating the good's value.\(^\text{22}\)

To compensate the inventor, private patrons, charitable organizations, land-grant universities, or the federal government could offer rewards for useful agricultural innovations. Again, this idea is not foreign to existing intellectual property law. In lieu of patent protection, Congress has

authorized prizes for civilian nuclear technology. James Madison and Alexander Hamilton favored a system of prizes and awards over the copyright and patent system that the Constitution eventually adopted. In light of the other economic implications of a rights-based intellectual property system, how appealing is the case for a prize-based public good system as an alternative to total deregulation?

The empirical evidence. The economic considerations outlined above are largely theoretical. What of the empirical evidence of how proprietary protection affects agricultural research and development? The following anecdotal observation finds strong empirical support:

Prior to 1930, plant breeding and research depended on federally funded agricultural experiment stations or the limited endeavors of private plant breeders to develop new varieties. Financial incentives for the private sector were inadequate to recover research and development costs. Indeed, the only opportunity for cost recovery was in the initial sales of the varieties, since purchasers could freely propagate the variety once it was released to the public.

At least one study suggests that the availability of intellectual property protection has increased both the amount invested in genetic research and the number of new organisms. Another suggests that the passage of the Plant Variety Protection Act in 1970 stimulated private development of new soybean and wheat varieties, but with a corresponding (albeit arguably justified) increase in seed prices. On the other hand, anecdotal evidence suggests that the presence of biotechnology patents

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may have slowed down some lines of research. On balance, however, most observers agree that intellectual property protection has stimulated private sector research and development in biotechnology.

Thanks to generous public support for agriculture-related education and research, the public sector plays a large, if not predominant, role in biotechnological research. How can we begin to assess interaction between public sector scientists at agricultural research stations and land-grant universities and private sector scientists employed by plant breeding firms? What are the incentives that motivate these dual engines of agricultural technology? Remember that the two predominant groups of research scientists – those who work for government or for universities and those who work at private biotechnology firms – often find themselves in direct competition with each other. What of the role farmers have played in discovering and (even more important) disseminating plant varieties? Does characterizing biotechnology as a "public good" help explain the support for research exemptions to systems of intellectual property?

Congress certainly seems to believe that biotechnology research and its fruits exhibit the classic characteristics of a public good. Consider the recently established National Genetic Resources Program, designed to "provide[e] for the collection, preservation, and dissemination of genetic

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31 See 7 U.S.C. § 2544 (exempting research uses from the definition of infringement under the Plant Variety Protection Act of 1970); H.R. REP. NO. 960, PT. I, 101ST Cong., 2d Sess. (1990) (describing the research exemption to proposed legislation establishing transgenic animal patents, H.R. 5598, § 402, Patent Competitiveness and Technological Innovation Act of 1990); Merges, supra note 20, at 1073-74; cf. 7 U.S.C. § 2404 (authorizing the Secretary of Agriculture to force distribution of a plant variety when necessary "to insure an adequate supply of fiber, food, or feed in this country [if] the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair").

material of importance to American food and agriculture production."\textsuperscript{33} The program follows the following mandate:

(1) provide for the collection, classification, preservation, and dissemination of genetic material of importance to the food and agriculture sectors of the United States;
(2) conduct research on the genetic materials collected and on methods for storage and preservation of those materials;
(3) coordinate the activities of the program with similar activities occurring domestically;
(4) make available upon request, without charge and without regard to the country from which such request originates, the genetic material which the program assembles;
(5) expand the types of genetic resources included in the program to develop a comprehensive genetic resources program which includes plants (including silvicultural species), animal, aquatic, insect, microbiological, and other types of genetic resources of importance to food and agriculture, as resources permit; and
(6) engage in such other activities as the Secretary [of Agriculture] determines appropriate and as the resources of the program permit.\textsuperscript{34}

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Current law, of course, has adopted several systems of agricultural intellectual property. The next excerpt should provide a fuller sense of the issues implicated by the new biotechnological developments:

Neil D. Hamilton

*Feeding Our Future: Six Philosophical Issues Shaping Agricultural Law*


VII. **Should Plant Genetic Resources Be Subject to Legal Ownership?**

President Thomas Jefferson, in many ways the architect of the American system of family farms once said, "The greatest service which can be rendered any country is to add a useful plant to its culture." An issue promising to irreversibly shape the development of agriculture production in the United States and abroad concerns the ownership and control of the plant and animal genetic resources Jefferson recognized as so important to the development of agriculture. The issue was a source of international conflict at the 1992 United Nations environmental conference in Rio de

\textsuperscript{33}7 U.S.C. § 5841(b).

\textsuperscript{34}Id. § 5841(d).
Janiero when United States' opposition to provisions on intellectual property rights in a proposed international treaty on biodiversity brought legal control of plant genetics to the world's attention. But even with this recent publicity, surprisingly few farmers know a controversy exists which may shape what they raise and how they farm. More surprisingly, farmers are not directly involved in the debate and will probably have little influence on the outcome.

A. The Importance of Plant Genetic Resources to Agriculture

Questions concerning commercial access to and control over the world's plant genetic resources (PGR) and the use of genetic engineering, may be some of the most important agricultural law issues facing society. The subject has assumed a heightened importance as increased expectations are focused on biotechnology to unlock the power of PGR and provide the keys to feed a growing world population, cure the diseases plaguing mankind, and protect our environment. Urgency has been added as the public recognizes how destruction of tropical rainforests and other activities are eroding the genetic diversity which holds the promise for genetic engineering, often before it can be evaluated by scientists. Concerns over genetic erosion, the loss of genetic diversity through extinction, have added new pressure to efforts to collect and conserve genetic materials. But with collection and conservation come questions of ownership and who will profit from any new improved varieties or products developed from these materials. As a result, access to plant genetic resources, the raw materials of genetic engineering, much of which exists in the developing countries, is an issue in the debate.

The ultimate issue for many is money and profit, but to others it is feeding humanity and seeking equity between the world's have's and have-nots. The question is who will benefit from unleashing the power of the world's plant genes. Will it be the scientists, companies and countries who develop and market improved seeds and the products they yield, as well as the farmers who raise them? Will the nations and traditional farmers who argue they have developed and preserved the genetic resources over the centuries receive a portion of the profits developed from what they see as their national wealth? Who will decide who controls the wealth of nature and the results of the laboratory — patent lawyers, courts, diplomats, scientists, lawmakers or the marketplace? Should farmers have a say in the debate?

The debate and struggle over control of PGR is being waged at many levels — in international forums such as: the U.N. Food and Agriculture Organization (FAO), which has adopted an "International Undertaking on Plant Genetic Resources" based on the concept that plant genetic resources are the common heritage of mankind and incorporating both farms rights and national sovereignty; the Union for the Protection of New Varieties of Plants (UPOV) located in Geneva, which administers the international convention signed by many developed countries to protect interests of plant breeders; and in the Uruguay round of the GATT negotiations, where the TRIP's agreement (trade related intellectual property) has become a major controversy. The issue is being debated in international scientific organizations and seed banks, at publicly funded international agricultural research centers (IARCs), universities, and most certainly, in the board rooms of...
companies involved in plant breeding, seed production, and genetic engineering. On the legal front, the issue is facing officials in the Patent Office, Congressional committees, the USDA, and even in state legislatures. The debate has pitted developing countries in the South against their Northern friends, private plant breeders against publicly funded researchers, and small farm advocates against large multi-national corporations. For the most part, at least until now, the issue has been the domain of a small group of interests – United States seed companies, many controlled by large international chemical and petroleum companies, plant breeders, patent attorneys, and diplomats. With only few exceptions, the voices of farmers and agricultural groups, either in the United States or the developing world, have not been heard.

B. Identifying the Legal Issues in Control Over Plant Genetic Resources

While the involvement of farmers in the debate over control and ownership of plant genetic resources has been limited, arguably the most direct impact of the resolution of these issues will be felt on the Nation's farms. The outcome will be seen in what is raised; in the price of the seeds, plants and animals used to grow food; and in how commodities are produced and marketed. Many developed countries recognize various forms of legal rights in plant materials developed through the work of plant breeders. In the United States a plant breeder may claim "breeders rights" to new varieties under the Plant Variety Protection Act (PVPA), a plant patent on asexually reproducing plants under the 1930 Plant Patent Act, and an actual patent on a newly engineered plant, under a 1985 patent office decision. In addition, seed breeders, such as hybrid seed corn producers, may use the law of trade secrets to protect the identity of their parent lines. The United States has signed the International Union for the Protection of New Varieties of Plants, or UPOV, created in 1961 to develop and refine an international system to recognize and protect the legal rights of plant breeders. The United States has also allowed the patenting of living organisms developed through genetic engineering.

There are two components to the legal issues concerning intellectual property rights and plant genetic resources. The first concerns the various forms of plant intellectual property rights which exist and the manner in which national and international legal regimes have developed to support legal claims. The second, which from the stand-point of farmers and their lawyers is probably more important, concerns the practical implementation questions which will accompany legal controls over the use of agricultural genetic resources. Identifying legal issues arising under each component, makes it possible to understand why plant intellectual property issues will have great impact on the future of agriculture. The issues include:

- Will developing nations require companies who collect plant genetic resources to sign "material transfer agreements," such as that recently entered between Merck Company and INBio, a Costa Rican organization, to share the profits of commercial products developed using the genes?
- Will the International Agricultural Research Centers (IARCs), such as the International Rice Research Institute (IRRI) in the Philippines, which helped lead the
Green Revolution by breeding improved varieties for farmers in developing countries, be forced to seek legal protections for their discoveries in order to work with plant breeders in the developed world? Will this move be compatible with the Centers' status as "trustees" for the genetic resources in their seed banks or will it interfere with their fiduciary obligation to poor farmers in the developing world?

- Will researchers at public universities be pressured (or required) to obtain legal protection for their discoveries, so the results can be licensed to private companies to generate funding for research programs? Will farmers pay higher costs for the seeds produced from research partially funded with their taxes? Will the seeds farmers buy be labeled "variety not stated" so the farmer lacks sufficient information to avoid planting genetically uniform and potentially vulnerable fields?

- Will farmers have to pay a royalty on some seeds to fund an international mechanism compensating "farmer rights" in developing countries where the parent material was discovered? How will the amount of the "contribution" be determined and how will the concept of "farmers rights" be implemented when deciding how funds are allocated?

- Will farmers have to pay a royalty on each generation of transgenic animals they produce, rather than owning the parent animals?

- Will farmers have the right to "plant back" seeds raised on their land from protected varieties, or sell such "saved seeds" to other farmers as they now can under the PVPA, or will the "saved seed sale exemption" be removed by Congress on the rationale it is necessary to comply with the 1991 amendments to UPOV?

- Will efforts to preserve the world's genetic resources from erosion be successful? Will the public adequately fund ex situ seed storage facilities such as the USDA's National Seed Storage Laboratory (NSSL) in Ft. Collins, Colorado? Can private groups and non-governmental organizations, such as the nationally recognized Seed Savers Exchange, in Decorah, Iowa, fill an important role by preserving heirloom varieties of vegetable seeds no longer considered economically important by the seed industry?

- Will new farming opportunities emerge for producing the "end use tailored varieties" seed companies are promoting as the future of agriculture? Will this mean most grain is produced under contract with seed breeders or the ultimate user? What effect will this have on traditional marketing and production relations? Will all farmers have access to contracts, or only the largest ones, helping fuel the "industrialization" of agriculture?

- Will consumers purchase foods produced with genetic engineering, such as the Flavr Savr tomato soon to be marketed? Will new agricultural opportunities be created to "pharm" patented transgenic animals to produce lower cost drugs and medicines and plants engineered to grow plastics? Or will social, environmental, or economic concerns limit how quickly the products of genetic engineering are commercialized?

- Will the genetically engineered seeds available to farmers be resistant to
increased pesticide use or to the pests themselves? How will the direction of the nation's research agenda on genetic engineering in agriculture be determined? At stake in the debate is whether the promise of genetic engineering to produce a new generation of "biopesticides" which harness the natural pest fighting forces found in nature will be realized or whether control over genetic engineering will be used to perpetuate agriculture's reliance on synthetic chemicals.

These examples illustrate the range and significance of the legal questions accompanying the debate over control and access to PGR. The legal dimensions of these issues are clear, as is the need for well informed lawyers. Granting patents to reflect property ownership in genetic resources, especially when the genes are naturally occurring, raises significant issues about society's concept of intellectual property. Jefferson, who also wrote the nation's first patent law, was no doubt correct about the importance of adding new plants to our agricultural heritage, but the question is whether he would also have expected the person who "discovered" the plant (or the scientist who "engineered" the gene) to be granted a legal right to own it. A sobering thought on the subject comes from Otto Frankel, a respected authority on the world's plant genetic resources, who warns, "[a] litigious world community insisting on sovereign rights to what evolved long before the beginnings of civilization is likely to lose in the long run what it tries to exploit in the short run."

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Historically, the federal government denied patent protection for genetically engineered plants and animals.\footnote{See Ex parte Latimer, 1889 Dec. Com. Pat. 123 (1889). In 1873, however, the United States Patent Office granted a patent to Louis Pasteur for "Yeast, free from organic germs of disease, as an article of manufacture." Diamond v. Chakrabarty, 447 U.S. 303, 314 n.9 (1980) (emphasis added).} No matter how great the degree of human intervention, any living organism could be classified as a product of nature rather than a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."\footnote{35 U.S.C. § 101.} if a biological inventor could clear this hurdle, he or she would be unable to describe the new plant or animal. The traditional patent law thus posed two massive obstacles to the patentability of biological inventions: a definition of patentable subject matter that excluded "products of nature" and the legal obligation to describe a patent claim. (These doctrines are represented in sections 101 and 112 of the

\footnote{Ed. note – Neil Hamilton has developed the ideas outlined in this excerpt more fully in another article, \textit{Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources}, 28 TULSA L.J. 587 (1993).}
contemporary Patent Act.)³ The Plant Patent Act of 1930⁴ represented Congress's first departure from these traditional doctrines. This statute had limited impact, however, because it extended patent protection only to certain asexually reproduced plants:

**Plant Patent Act of 1930**

35 U.S.C. §§ 161-164

§ 161. **PATENTS FOR PLANTS**

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

§ 162. **DESCRIPTION, CLAIM**

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible. The claim in the specification shall be in formal terms to the plant shown and described.

§ 163. **GRANT**

In the case of a plant patent, the grant shall be of the right to exclude others from asexually reproducing the plant, and from using, offering for sell, or selling or using the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States.

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**Yoder Brothers, Inc. v. California-Florida Plant Corp.**

United States Court of Appeals for the Fifth Circuit
537 F.2d 1347 (5th Cir. 1976), cert. denied, 429 U.S. 1094 (1977)

Before BROWN, Chief Judge, and JONES and GOLDBERG, Circuit Judges.


In this clash between two giants of the chrysanthemum business, we confront a myriad of antitrust and plant patent issues. Yoder Brothers (Yoder) . . . sued, alleging infringement of twenty-one chrysanthemum plant patents by California-Florida Plant Corp. (CFPC) and California-Florida Plant Corp. of Florida (CFPCF) (sometimes referred to collectively as Cal-Florida). CFPC and CFPCF denied the infringement and filed antitrust counterclaims under sections 1 and 2 of the Sherman Act. As to seven of the chrysanthemum plant patents, the lower court directed verdicts for Yoder that the patents were valid and infringed and awarded treble damages. The court also ruled for Yoder on Cal-Florida's section 2 claim. CFPC and CFPCF, however, prevailed in their antitrust counterclaim under section 1 and received treble damages for Yoder's derelictions.

Because many of the issues in this case turn on the particular nature of the ornamental plant industry and the specific characteristics of chrysanthemums, we shall describe the background facts in some detail before discussing the many complex legal issues presented on this appeal. Following our description of the facts, . . . we shall consider . . . the issues relating to the plant patent law.

I. General Background

A. The Chrysanthemum Industry

Chrysanthemums, in their natural state, blossom only during the fall. This is because they are photoperiodic in nature, meaning that their growth is affected by the relative lengths of lightness and darkness in the day. When the days are long, the chrysanthemum plant remains in a vegetative state. As the nights become longer, the initiation process of the chrysanthemum bud begins. Thus, in early August, when the nights achieve a duration of nine and one-half continuous dark hours, the chrysanthemum plant in its natural state will begin the process of developing a flower. During the fall and early winter months, the mature flower appears.

Yoder began doing business in the 1930's as a simple greenhouse operator, specializing in tomatoes. Soon thereafter, because the fall tomato crop was less profitable than the spring crop, it decided to replace the fall crop with chrysanthemums. In 1939 or 1940, Yoder employees began research into out-of-season flowering of chrysanthemums. By applying black cloth shades over the chrysanthemums when dark hours were needed and applying artificial light when light hours were needed, it became possible to flower chrysanthemums on a year-round basis. Yet this breakthrough was not without its problems. For example, the use of black cloth shades resulted in an abnormally high temperature build-up around the plants, which in turn retarded bud initiation. Similarly, when the finishing temperatures were too warm, the chrysanthemums would not hold their color. In an effort to adjust for these conditions and to improve the quality of the chrysanthemum generally, Yoder initiated a breeding program in the early 1940's. One of the most important goals of the breeding program was the development of new varieties for consumers.
Although the ornamental plant industry encompasses many different kinds of flowers, including azaleas, carnations, roses, african violets, geraniums, snapdragons, and others, chrysanthemums are one of the most popular of the genre. According to the United States Department of Agriculture, in 1971 approximately 2,134 growers in twenty-three states sold nearly 145 million blooms from about 129 million standard variety chrysanthemum plants, 34.5 million blooms from 136 million pompon chrysanthemum plants, and 17.5 million potted chrysanthemum plants. At the time of the trial there were over 475 different varieties of chrysanthemums available. The total wholesale value of growers' sales in the twenty-three states that year was approximately 83.5 million dollars.

Chrysanthemums have been subject to intensive breeding efforts over the past thirty years; each individual specimen is a genetically unique complex organism. Several definitions of the term "variety" of chrysanthemum were offered at trial. Mr. Duffett, Yoder's head breeder, defined a variety as a group of individual plants which, on the basis of observation by skilled floriculturists and according to reasonable commercial tolerances, display identical characteristics under similar environments. Cal-Florida defined variety in its complaint as "a subspecies or class of chrysanthemums distinguishable from other subspecies or classes of chrysanthemums by distinct characteristics, such as color hue, shape and size of petal or blossom or any of them."

New varieties of chrysanthemums are developed in two major ways: by sexual reproduction and by mutagenic techniques. Sexual reproduction, the result of self or cross pollination, produces a genetically unique seedling, the characteristics of which are impossible to predict. Mutagenic techniques simply accelerate the natural rate of mutation in the chrysanthemum plant itself. A mutation was defined by Mr. Duffett as "a change in the number of chromosomes or a change in the chromosome position or a specific change in the genes within those chromosomes." Technically, only those mutations that first express themselves as bud variations are properly called "sports"; however, the word is used loosely in the industry as a general synonym for mutation, and we will so use it. Two types of sports can appear: spontaneous sports and radiation sports. The cells of all living things occasionally mutate, and spontaneous sports are simply the result of that process. Radiation sports, on the other hand, are induced artificially, through exposure to such things as gamma radiation from radioactive cobalt and X-rays. These techniques do nothing that could not occur in nature apart from speeding up the natural mutation process. Although most of the mutations induced by radiation are not commercially usable plants, a skilled breeder will select for further development those that display such desirable characteristics as fast response time, temperature tolerance, durability, size, and vigor.

After a breeder has successfully isolated a new variety, the only way he can preserve his creation is by means of asexual reproduction. In the case of chrysanthemums, the most common technique of asexual reproduction is the taking of cuttings from a stock plant. Cuttings . . . are "sections or parts of chrysanthemum plants which may be grown into mature plants for sale as cut flowers and/or potted plants or from which additional cuttings may be harvested." . . . [C]uttin gs are simply immature chrysanthemum plants. Since a cutting is genetically identical to the parent plant, it will develop into a plant whose characteristics match the parent's exactly, so long as the same
environmental conditions obtain. A central fact of life in the chrysanthemum industry is the ease with which cuttings can be taken from parent plants: from one chrysanthemum, it is theoretically possible to develop an infinitely large stock, by taking cuttings, maturing some into flowered plants, taking more cuttings, and so on.

Over the years since Yoder first entered the chrysanthemum business, the industry has become internally specialized. At the first functional level are the breeders, who create new varieties of chrysanthemums. Breeding is an expensive, complex procedure. The breeder must possess the skill and discrimination to spot potential new varieties and recognize whether they possess desirable traits; facilities for elaborate testing and development must be available. Because chrysanthemums mutate rapidly, a breeder must always be on the lookout for new changes.

At the next level in the industry are the propagator-distributors. The propagator-distributors build up mother stock from sources such as breeders, retail florists, or their existing flowers, and reproduce cuttings from that mother stock. In a sense they are simply mass producers of cuttings. They do not develop cuttings to the mature flower stage (except for purposes of their own testing). Next are the growers, who develop cuttings purchased from propagator-distributors into mature plants either for cut flowers or potted plants. Combining the function of propagator-distributors and growers are the self-propagators. Cal-Florida defined a "self-propagator" as "a person who either buys or establishes stock and takes cuttings for the sole purpose of producing cut flowers and/or potted plants for resale or own use." In other words, the self-propagators are vertically integrated into one step. Finally, the growers (or self-propagators) sell their products to retail florists, who in turn sell to ultimate consumers.

B. The Parties

During the times relevant to this litigation, Yoder operated on two levels in the business: as a substantial (if not the largest) breeder of new varieties of chrysanthemums, and as a large propagator-distributor. In addition to chrysanthemums, Yoder dealt with carnation cuttings, azalea liners (baby azaleas), and snapdragon seeds. Yoder . . . sells its products nationwide.

CFPC, which . . . sells primarily in the western part of the United States, was a propagator-distributor. CFPCF, a wholly owned subsidiary of CFPC, was also a propagator-distributor. CFPCF is incorporated in Florida and it sells in the eastern United States. Both CFPC and CFPCF specialize in chrysanthemums. They entered the market in 1957, at a time when Yoder was clearly the largest of the propagator-distributors. During the period in question, Yoder and the two Cal-Florida companies competed horizontally as propagator-distributors they did not compete as breeders, although Cal-Florida did make a minor foray into breeding during the 1960's.

C. The Plant Protection Programs

The issues in this litigation arose out of Yoder's breeding operations and its desire to secure a
fair return from those efforts. Theoretically, once the first plant of a new variety is sold, it is impossible for a breeder ever again to be compensated for his efforts in developing it. As indicated above, anyone can take a cutting from that new plant, propagate a number of cuttings from the first cutting, and obtain an infinite supply of the plant. Even as a practical matter, the evidence at the trial suggested that it was relatively easy to obtain plant material of new varieties without the consent of the breeder.

Yoder's first effort to obtain compensation for its breeders took the form of a program entitled the Yoder Grower Agreement, or YGA, instituted around 1958. In return for access to new varieties developed by Yoder, growers were required to sign an agreement that prohibited purchasers of Yoder cuttings from selling, loaning, or otherwise disposing of purchased cuttings. Specifically, growers were prohibited from selling Yoder cuttings to self-propagators or to propagator-distributors. The agreement also contained a "sport return clause," which required purchasers of Yoder cuttings to return to Yoder any mutations which appeared either directly or indirectly on Yoder cuttings. Yoder enforced the YGA program by refusing to ship covered varieties to persons who did not sign a YGA agreement. The most significant aspect of the YGA program was the fact that a royalty was charged on all Yoder cuttings propagated or used.

In the early 1960's, the YGA program was replaced by a new system that took its name from the Breeder-Grower Agreement that was its central reason for being. A corporation called BGA, International (BGA) was created to administer the program. Any breeder could be a member of BGA. According to the members' regulations, voting strength was proportional to the amount of expenses the member bore. Expenses, in turn, were assessed in proportion to the amount of royalties collected on the breeder's new varieties. The practical effect of these provisions was to secure control of BGA in Yoder's hands. The bylaws and articles of incorporation of BGA indicated that its primary purpose was to insure a measure of remuneration to the breeders. A breeder would list his new variety of ornamental plant with BGA, and BGA would make plant material of that variety freely available to propagator-distributors. The breeder members of BGA agreed on the amount of royalty to be charged. Significantly, during most of the time that the BGA program was in existence, it was administered within Yoder's offices.

Three kinds of agreements were used in administering the BGA program. The first was the Propagator-Distributor Agreement, which permitted the signatory to make any desired commercial use of purchased cuttings or cuttings harvested from the stock plants. Participating propagator-distributors had an obligation to send a grower or grower license agreement to customers who wanted to purchase a BGA variety. For each cutting sold, the propagator-distributor had a contractual obligation to pay BGA a $.006 royalty. He also was required to report the number of cuttings sold quarterly, not to give cuttings to non-signatories, to exercise reasonable care to keep others from getting cuttings, and to allow the breeder to inspect and inventory his plantings at all reasonable times. The propagator-distributor agreement also contained a provision whereby the propagator-distributor was entitled to full credit from BGA if he was unable to collect the $.006 royalty from his customers. The agreement required the propagator-distributor to return all
mutations and sports to the breeder, who retained all rights to them.

Grower License Agreements were signed by self-propagators. These agreements conferred the right to grow and to propagate plants to sell as cut flowers or potted plants. The restrictions and conditions in the agreement were essentially the same as those in the Propagator-Distributor Agreement, except that the royalty payment was to go to the propagator-distributor who had furnished the cutting, instead of to BGA.

Finally, the growers signed a Grower Agreement. The Grower Agreement covered growers who purchased cuttings from propagator-distributors for the purpose of selling flowers or potted plants. All propagation rights were again reserved to BGA, and the grower agreed not to propagate without BGA's consent, not to give BGA varieties to others for the purpose of propagation, to allow reasonable inspections, and to return sports.

Typically, the BGA program operated as follows: A propagator-distributor would propagate a large number of cuttings of a BGA new variety. For each cutting he sold to a grower or a self-propagator, he would pay BGA $.006. On his invoices to his customers, a base price for the cutting would appear, and separately stated would be the amount of BGA royalty due. Evidence at the trial indicated that the industry was generally aware of the existence of the BGA royalties and understood that these royalties were in essence compensation to the breeders of the new variety. The customer would therefore pay the base price plus royalty to the propagator-distributor, and the latter would in turn remit the full royalty amount to BGA. Thus, the role of the propagator-distributor was that of a BGA administrator; his cooperation was essential in the process of collecting royalties from those who sold or used the protected varieties and channeling the monies to the appropriate breeder.

The degree of enforcement of the BGA program was the subject of some dispute at the trial. If Yoder knew that a grower or a self-propagator had not signed a BGA agreement, it would not ship the requested BGA variety. Instead, a substitute variety would be sent. On the other hand, the testimony indicated that a substantial number of complaints were voiced about the lack of enforcement of the BGA program against non-signatories. No lawsuits were ever filed. If a grower or self-propagator went out and purchased his mother stock from a retail florist, for example, there was nothing that Yoder could or would do about the fact that he had obtained a protected variety without signing a contract. Yoder explained its lack of enforcement by the need to maintain good will in the industry. If a grower member informed BGA that someone had access to BGA varieties who had not signed the contract, a BGA representative would check with the alleged pirate and try to persuade him to become a member. Yoder's representative testified that in almost every case, once the purpose of the BGA system was explained to a non-participant, the grower or self-propagator would usually agree to sign a contract and to pay the royalty to BGA. From Cal-Florida's perspective, Yoder's tactics were tantamount to strong-arm. Both parties agreed that new varieties were helpful to everyone in the industry. It was Yoder's position that BGA, by providing a means for breeder compensation, was helping in the development of new varieties of chrysanthemums.
The GRA program, (Grower Rights Agreement) developed by Yoder in 1968 to supplement BGA, was similar to the latter program in many ways. When a grower or propagator-distributor or self-propagator discovered a mutation on plant material that was not covered by a BGA agreement (in other words, any free plant), he could send the mutation to Yoder Brothers for evaluation of its commercial possibilities. After extensive testing, if Yoder decided that the new variety could profitably be introduced, the grower who discovered the variety would be entitled to 50% of the royalty return. The agreements used to administer GRA followed the BGA pattern a Propagator-Distributor Agreement, a Grower License Agreement, and a Grower Agreement. Unlike BGA, under GRA the royalties collected were returned directly to Yoder. The amount of the royalty under GRA was again $.006 per cutting.2

Cal-Florida participated in the BGA and GRA programs only as a propagator-distributor. Although it did conduct a breeding program of its own during the 1960's, it never registered any new varieties with BGA. Instead, it developed the CFPC program. The CFPC program used the same three kinds of agreements as the BGA program the propagator-distributor contract, the grower-propagator license, and the grower agreement. In one aspect, however, the CFPC program was more restrictive than the BGA program: sales to self-propagators and other propagator-distributors were prohibited. The royalty rate was the same $.006 per cutting. Like the BGA program from which it was copied, the CFPC program's basic purpose was to obtain remuneration for the company's breeding efforts. Sports discovered by participants in the CFPC program were required to be returned to Cal-Florida, the breeder.

As a propagator-distributor participant in the BGA program, Cal-Florida of course paid royalties to BGA. During the relevant period, CFPC and CFPCF combined paid $229,805.12 in BGA royalties and $27,941.18 in GRA royalties a total of $257,746.30. The evidence showed that over the years, more and more of Cal-Florida's sales were of varieties controlled by Yoder under either BGA or GRA. In 1963, 0.19% of their cutting sales were BGA or GRA varieties; by 1969, the number had grown to 17.59% of total sales, and by 1971, to 41.22%.

BGA and GRA royalties were always separately stated on Cal-Florida's invoices to its customers. In addition, the following explanation was to be found in its catalogs:

BGA (Breeder Grower Agreement) Varieties. The California-Florida Plant

2In some ways, the GRA program provided a service to growers. Normally, a grower would not have the facilities to test a mutation or sport that he found on a chrysanthemum plant to see if, indeed, a new variety that could be asexually reproduced had been discovered. By taking advantage of Yoder's extensive facilities for this work, both parties benefited Yoder had another new variety on which it was receiving royalties, and the grower had the benefit of half the royalties paid for his acuteness of observation in finding the new variety. Persons who wished to have access to the Yoder service, however, had to sign GRA agreements, which contained restrictions on use of varieties accepted by Yoder similar to those in the BGA agreement.
Corp. is licensed by BGA International to propagate and distribute BGA varieties. The terms of our Propagator-Distributor Contract call for the customer to sign a BGA Agreement prior to the shipment of any BGA variety. BGA varieties are subject to all discounts of Volume, Advance Order and Prompt Payment. The current BGA Royalty is $0.60 per 100 cuttings, rooted or unrooted, and is in addition to the listed base price. BGA Royalties are not subject to Discount or Adjustment of any kind and the total amount of BGA Royalty collected by us is returned to BGA International.

GRA (GROWER RIGHTS AGREEMENT) VARIETIES. The California-Florida Plant Corp. is licensed to grow, propagate and distribute GRA varieties. The terms of our Propagator-Distributor contract call for the customer to sign a GRA Agreement prior to us shipping any GRA varieties. GRA varieties are subject to all discounts of Volume, Advance Order and Prompt Payment. The current GRA Royalty is $0.60 per 100 cuttings, rooted or unrooted, and is in addition to the base price. GRA Royalties are not subject to Discount or Adjustment of any kind and the total amount of GRA Royalty collected by us is returned to the developer.

ROYALTY CHARGES. All Royalty Charges (CFPC, BGA, and GRA) will be billed separately and included in the monthly statement.

Thus, CFPC clearly segregated the BGA and GRA royalty charges from the prices charged for the cuttings it sold.

D. Government Intervention

On April 20, 1970, the United States brought an action against Yoder, alleging that the BGA and GRA programs violated sections 1 and 2 of the Sherman Act. The Government's suit ended in a consent judgment . . . . The consent decree abolished BGA and GRA and prohibited further collection of royalties and further enforcement of the sport return clauses; it also required Yoder to take certain affirmative actions to inform the former participants of the changed status quo. The judgment expressly stated that it did not apply to any rights that Yoder had obtained under the patent laws of the United States or of any foreign country. Cal-Florida had moved to intervene in the Government's case . . . . [T]he court denied its motion.

E. Post BGA: Plant Patents

After BGA ended, around the end of 1971, Yoder started patenting some of its new varieties under the Plant Patent Act. Several salient differences existed between the rights conferred by a plant patent and the rights secured under the old BGA and GRA agreements. For example, under a plant patent, sports of the patented plant are not covered by the original patent. Second, the royalty event for a patented plant is the asexual reproduction of the plant, instead of its use or sale. Even so, the Plant Patent Act and the BGA/GRA programs were quite similar. Under both, licenses for
propagation by others could be issued, and royalties could be charged for the use of the plant. These similarities have led Cal-Florida to allege that Yoder's new use of the plant patent laws is simply a continuation of its old and illegal BGA program. Since BGA and GRA ended, Yoder has secured plant patents on all new varieties it has introduced to the trade. Shortly after the Government suit was terminated, and after extensive unsuccessful negotiations with Cal-Florida, Yoder filed its complaint commencing this litigation.

II. SUMMARY OF PROCEEDINGS BELOW

[Yoder alleged infringement of twenty chrysanthemum plant patents by either CFPC or CFPCF or both. The Cal-Florida companies asserted the invalidity of twenty-two plant patents held by Yoder. Cal-Florida also lodged antitrust counterclaims against Yoder. The district court directed verdicts on several critical issues. It ruled for Yoder on the issues of patent validity and infringement of all twenty patents, subject to Cal-Florida's claims of contract rights and prior commercial exploitation. It also ruled in Yoder's favor on all issues of inventorship, newness and distinctness, asexual reproduction, and adequacy of description. The patent claims were submitted to the jury on special interrogatories. The jury found that CFPC and CFPCF had established a contractual right to use eight of the patented plants. For another seven patented plants, the court had instructed the jury that the patents were valid and infringed as a matter of law; as to these, the jury awarded compensatory damages. The jury also awarded damages on one patent, covering the "Deep Conquest" chrysanthemum, which it found valid and infringed. It was unable to reach a verdict on the rest of the patents.]

On this appeal, we are concerned only with the seven patents that the district court declared valid and infringed as a matter of law and with Deep Conquest.

[Part III of the court's opinion is omitted.]

IV. PLANT PATENTS

A. Introduction

[W]e return to . . . Yoder's allegation that Cal-Florida was infringing its plant patents and its consequent demand for damages. Cal-Florida responded with the predictable assertions of patent invalidity and noninfringement, among others. As discussed above, the only issues before this Court concern the seven patents that the district court ruled valid and infringed as a matter of law: Red Torch, Gold Marble, Morocco, Promenade, Southern Gold, Mountain Snow, and Mountain Sun. After considerable thought, we have decided that the district court correctly ruled that Cal-Florida failed to rebut the statutory presumption of validity with sufficient relevant evidence.
B. Constitutional and Statutory Background

Article I, section 8, clause 8 of the Constitution provided that

Congress shall have the power: To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . .

Although the first legislation implementing this provision for mechanical inventions was passed in 1790 by the first Congress, Congress did not include plants within the clause's protection until 1930. In its present form, the principal statute allowing patents on plants reads:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than an tuber-propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title. The provision of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

35 U.S.C. § 161. Since section 161 makes the general patent law applicable to plant patents except as otherwise provided, we take as our starting point the general requisites for patentability, and then apply them as well as we can to plants.

Normally, the three requirements for patentability are novelty, utility, and obviousness. For plant patents, the requirement of distinctness replaces that of utility, and the additional requirement of asexual reproduction is introduced.

The concept of novelty refers to novelty of conception, rather than novelty of use; no single prior art structure can exist in which all of the elements serve substantially the same function: "[S]ection 102, which pertains to novelty, requires that the patentee be the original inventor of the object claimed in his patent, and also that the invention not have been known or used by others before his discovery of it . . . ." Furthermore the prior art is to be considered as covering all uses to which it could have been put. As applied to plants, the Patent Office Board of Appeals held that a "new" plant had to be one that literally had not existed before, rather than one that had existed in nature but

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33These factors are taken from 35 U.S.C. § 101 ("any new and useful process, machine, manufacture, or composition of matter, or . . . improvement thereof") and 35 U.S.C. § 103 ("the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would [not] have been obvious").
was newly found, such as an exotic plant from a remote part of the earth.\(^{34}\) . . . [T]he Board believed that novelty was to be determined by a detailed comparison with other known varieties.

The legislative history of the Plant Patent Act is of considerable assistance in defining "distinctness." The Senate Report said:

[I]n order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties and it is immaterial whether in the judgment of the Patent Office the new characteristics are inferior or superior to those of existing varieties. Experience has shown the absurdity of many views held as to the value of new varieties at the time of their creation. The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; or soil conditions; color of flower, leaf, fruit or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.

A definition of "distinctness" as the aggregate of the plant's distinguishing characteristics seems to us a sensible and workable one.

The third requirement, nonobviousness, is the hardest to apply to plants, though we are bound to do so to the best of our ability. The traditional three part test for obviousness . . . inquires as to (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, and (3) the level of ordinary skill in the prior art. Secondary characteristics such as commercial success, long felt but unsolved needs, and failure of others can be used to illuminate the circumstances surrounding the subject matter sought to be patented.

The Supreme Court has viewed the obviousness requirement of section 103 as Congress' articulation of the constitutional standard of invention. "[A]s a judicial test, 'invention,' i.e., 'an exercise of the inventive faculty,' . . . has long been regarded as an absolute prerequisite to patentability." An "invention" is characterized by a degree of skill and ingenuity greater than that possessed by an ordinary mechanic acquainted with the business. The obviousness requirement appears to presume that if the gap between the prior art and the claimed improvement is small, then an ordinary mechanic skilled in the art would have been able to create the improvement, thus leading to the conclusion that the improvement was obvious and a patentable invention not present. Section 103 requires the determination of obviousness vel non to be made with reference to the time the invention was made. Obviousness, like the general question of patent validity, is ultimately a

\(^{34}\)In order for a plant to have "existed" before in nature, we think that it must have been capable of reproducing itself. Thus, we have concluded that the mere fact that a sport of a plant had appeared in the past would not be sufficient to preclude the patentability of the plant on novelty grounds, since each sport is a one-time phenomenon absent human intervention.
question of law, though factual inquiries are often necessary to its resolution.

Rephrasing the[se] tests for the plant world, we might ask about (1) the characteristics of prior plants of the same general type, both patented and nonpatented, and (2) the differences between the prior plants and the claims at issue. We see no meaningful way to apply the third criterion to plants, i.e., the level of ordinary skill in the prior art. Criteria one and two are reminiscent of the "distinctness" requirement already in the Plant Patent Act. Thus, if we are to give obviousness an independent meaning, it must refer to something other than observable characteristics.

We think that the most promising approach toward the obviousness requirement for plant patents is reference to the underlying constitutional standard that it codifies namely, invention.

The general thrust of the "invention" requirement is to ensure that minor improvements will not be granted the protection of a seventeen year monopoly by the state. In the case of plants, to develop or discover a new variety that retains the desirable qualities of the parent stock and adds significant improvements, and to preserve the new specimen by asexually reproducing it constitutes no small feat.

This Court's case dealing with the patent on the chemical compound commonly known as the drug "Darvon" provides some insight into the problem of how to apply the "invention" requirement to a new and esoteric subject matter. The court first noted that

[a]nalogue reasoning is necessarily restricted in many chemical patent cases because of the necessity for physiological experimentation before any use can be determined. In fact, such lack of predictability of useful result from the making of even the slightest variation in the atomic structure or spatial arrangement of a complex molecule . . . deprives the instant claims of obviousness and anticipation of most of their vitality . . . .

The court resolved the apparent dilemma by looking to the therapeutic value of the new drug instead of to its chemical composition:

[R]aison compels us to agree that novelty, usefulness and non-obviousness inhere in the true discovery that a chemical compound exhibits a new needed medicinal capability, even though it be closely related in structure to a known or patented drug.

The same kind of shift in focus would lead us to a more productive inquiry for plant patents. If the plant is a source of food, the ultimate question might be its nutritive content or its prolificacy. A medicinal plant might be judged by its increased or changed therapeutic value. Similarly, an ornamental plant would be judged by its increased beauty and desirability in relation to the other plants of its type, its usefulness in the industry, and how much of an improvement it represents over
prior ornamental plants, taking all of its characteristics together.  

Before reaching the issues on appeal, we make a final comment about the requirement of asexual reproduction. It has been described as the "very essence" of the patent. Asexual reproduction is literally the only way that a breeder can be sure he has reproduced a plant identical in every respect to the parent. It is quite possible that infringement of a plant patent would occur only if stock obtained from one of the patented plants is used, given the extreme unlikelihood that any other plant could actually infringe. If the alleged infringer could somehow prove that he had developed the plant in question independently, then he would not be liable in damages or subject to an injunction for infringement. This example illustrates the extreme extent to which asexual reproduction is the heart of the present plant patent system: the whole key to the "invention" of a new plant is the discovery of new traits plus the foresight and appreciation to take the step of asexual reproduction.

C. Yoder's Plant Patents' Validity

During the trial, Cal-Florida offered as evidence certain documents showing that growers had found mutations on the Mandalay variety that were the same as the patented variety Glowing Mandalay, i.e., evidence that the sport Glowing Mandalay had recurred. Although Glowing Mandalay is no longer in the case, Cal-Florida later proffered similar evidence with respect to Gold Marble, Promenade, and Red Torch, which are three of the patents whose validity is challenged on appeal. Gold Marble, Promenade, and Red Torch are all sport patents, meaning that they first appeared as a sport of another plant, in contrast to seedling patents, which develop from seeds. Of the remaining four challenged patents, two were sport patents and two were seedling patents. Cal-Florida never proffered any sport recurrence evidence as to the other two sport patents, Mountain Sun and Southern Gold, nor did it offer any specific evidence attacking the seedling patents, Morocco and Mountain Snow. Since we find that the district court's ruling on the sport recurrence evidence did not preclude Cal-Florida from introducing other types of evidence to attack the validity of the patents, and since no sport recurrence evidence was introduced as to Mountain Sun and

35We suspect that part of our problem in applying patent concepts to the facts before us lies in the fact that we are dealing with ornamental plants. Beauty for its own sake is not often a goal of inventors indeed, even ornamental plant breeders might be more aptly described as seekers of beauty for profit. Nevertheless, the statute does not exempt ornamental plants, and so we are bound to treat them on a par with more "useful" botanical creations.

36Lest the reader fear that Congress neglected to make adequate provision for reproduction of the sexual type, we hasten to note that the Plant Variety Protection statute, 7 U.S.C. §§ 2321-2583, applies only to sexually reproducing plants.

37Whether he might also be entitled to a patent on his plant is more problematic, although we would not want to rule out the possibility.
Southern Gold, we find no warrant on appeal to disturb the ruling that Mountain Sun, Southern Gold, Morocco, and Mountain Snow were valid and infringed. Plant patents, like others, enjoy a statutory presumption of validity that was not rebutted as to those four.

At the time the court rejected the sport return evidence for Glowing Mandalay, it made a ruling designed to apply to the rest of the trial with respect to that kind of evidence. That ruling is the focus of Cal-Florida's cross appeal on the plant patent validity point. Because of its importance, we set out the pertinent parts in some detail here:

[I]t seems clear that it was the Congressional intent that a person who discovered an asexually reproduced variety of a new and distinct plant was entitled to a patent. It was not contemplated, apparently, that he invent, in the term that is used, or in the significance of that term, as we understand it, traditional concept of inventing a machine . . . . In any event, the issue presented here is a rather narrow one and it has some practical overtones. I am frank to confess that I think [Yoder's counsel's] presentation here . . . is very persuasive. In all probability, this will be, or may be, the ultimate result of this trial. It may not be, after we have listened to the testimony, of course, of [Cal-Florida's counsel's] other witnesses who are coming in to testify on the genetics of this thing, but on this one narrow limited issue, it would seem that [Yoder was] entitled to prevail. Therefore, the objection to the introduction of the various letters and documents from . . . the growers and plant propagators around the country, which were forwarded to Yoder Brothers over the years, is sustained.

Cal-Florida construes the above-quoted ruling as an all-encompassing holding that the constitutional standard of invention does not apply to plant patents. It further claims that since the ruling was admittedly intended to apply to the entire trial, it was precluded from offering evidence on the issues of newness, distinctness, and obviousness by the court's action. In fact, it never even tried to introduce the expected expert genetics testimony, although it did make a formal offer of more sport return evidence at a later time in the trial.

Yoder disputes the breadth of the ruling and its effect on any other evidence Cal-Florida might have offered, and notes that the court's actual ruling on the issues of newness and distinctness did not come until some two weeks later. With regard to the ruling on the admissibility of the evidence, Yoder argues that the documents would not have shown lack of distinctness, since the fact that a sport with particular traits recurs says nothing about what those traits are and how they differ from other plants. Furthermore, Yoder argues that the documents would not have shown obviousness, because if sport recurrence were evidence of obviousness, then almost no mutations would be patentable, and that would be contrary to Congress' intent.

We do not construe the district court's evidentiary ruling as anything more than that; in our opinion, it simply held that the sport recurrence evidence was not relevant to any of the patent validity issues. We therefore confine our remarks accordingly.
The only possible probative value of the sport recurrence evidence would be to show that a sport of that particular size, shape, color, or other trait is predictable from a given variety of parent plant. Thus, we must first determine whether Congress intended predictability to negate the possibility of "invention." Next, if Congress considered that factor irrelevant, we must decide if the Constitution is offended by permitting patents on the kinds of sports that recur.39

Both the language of the statute and its legislative history persuade us that Congress did not intend to exclude the kind of mutation that might recur from the Act's protection. Instead, [various Senate Reports] speak generally about sports and mutations. The 1954 amendment was added to clarify Congress' intention that seedlings should be patentable, but in the process of describing the bill, the report states:

The enactment of this legislation will remove any doubt that the legislative intent of the Congress clearly means that sports, mutants, hybrids, and seedlings, discovered by persons engaged in agriculture or horticulture, should be patentable . . . .

Although we are willing to assume for purposes of this argument that some mutations may appear that would have been genetically impossible before, i.e., that a fundamental change in the biochemical structure of the chromosome may take place by far the majority of mutations and sports of chrysanthemums are predictable to some extent for those skilled in the field. For example, the testimony at trial indicated that a yellow sport could be expected from a white chrysanthemum. Indeed, part of the skill required of a chrysanthemum breeder is to know what to look for and to take steps immediately to preserve it by asexual reproduction if the desired trait appears. Given that fact, we think that the purpose of the Plant Patent Act would be frustrated by a requirement that only those rare, never-before-seen, if not genetically impossible sports or mutations would be patentable. That purpose was "to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry." To make it significantly more difficult to obtain a plant patent than another type of patent would frustrate that purpose.

We therefore find that Congress did not intend to exclude the kind of sport that recurs frequently from the Plant Patent Act. That being the case, the district court correctly ruled that the evidence proffered by Cal-Florida was irrelevant, as a matter of statutory law.

39In this discussion, we are concerned only with the "invention" or obviousness issue. As we have defined novelty, supra, the recurrence of a sport of a particular color would be irrelevant. Similarly, sport recurrence says nothing about the new plant's particular characteristics. The testimony at the trial amply established that Yoder's patented chrysanthemums were distinct to those skilled in the field, i.e., those in the breeding business. We note that there is a distinction between looking to the opinion of persons in the industry to prove a feature of patentability and relying on commercial success to prove nonobviousness. Yoder's arguments relied on the former kind of evidence.
The only way that the Constitution would be offended by permitting patents on recurring sports would be if such leniency indicated that no "invention" was present. We do not think that sport recurrence would negate invention, however. An infinite number of a certain sized sport could appear on a plant, but until someone recognized its uniqueness and difference and found that the traits could be preserved by asexual reproduction in commercial quantities, no patentable plant would exist. An objective judgment of the value of the sport's new and different characteristics, i.e., nutritive value, ornamental value, hardiness, longevity, etc. would not depend in any way on whether a similar sport had appeared in the past, or whether that particular sport was predictable. We therefore find no reason to disturb our approval of the district court's evidentiary ruling based on the constitutional standard of invention. As that standard applies to plant patents, the proffered evidence was irrelevant.

Viewing the evidence offered on the patent validity question as a whole, we find that Cal-Florida failed to rebut the statutory presumption of validity as to Gold Marble, Promenade, and Red Torch, as well as the other four discussed above. Thus, the lower court's finding of validity must be affirmed on this record.

D. Patent Infringement

On cross appeal, Cal-Florida asserts that the absence of flowering plants grown from the cuttings it had admittedly taken from Yoder's patented plants was fatal to Yoder's infringement counts. This is because the patent claim in each instance describes a mature flowering plant, and it is Cal-Florida's position that only another mature flowering plant could directly infringe. Yoder retorts that the Plant Patent Act provides that "[i]n the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced." 35 U.S.C. § 163. The district court ruled that the act of asexual reproduction was complete at the time the cutting was taken. Finally, the pretrial stipulations established that Cal-Florida had taken plant material, or cuttings, from Yoder's patented plants.

We agree with Yoder that it was not necessary to prove that the cuttings actually matured into flowered plants to show infringement. Under such a rule, it would be virtually impossible for a propagator-distributor directly to infringe a patent, despite the vital role he plays in dissemination of plant material. Furthermore, we think section 163 is plain in its statement that a patentee may exclude others from asexually reproducing, selling or using the plant. The negative inference to be drawn from this is that commission of one of those acts would constitute infringement. We therefore affirm the finding of infringement . . . .

[Chief Judge Brown's opinion dissenting in part and concurring in part is omitted.]

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4Ed. note – Accord, e.g., Armstrong Nurseries, Inc. v. Smith, 170 F. Supp. 519 (E.D. Tex. 1958) (holding that asexual reproduction through use of physically appropriated plant material is a necessary and sufficient condition to a finding of infringement).
A "breeder" of chrysanthemums is a person or firm which creates or invents new varieties of chrysanthemum plants through the process of hybridizing, i.e., crossing of male and female parents to derive new seedling varieties. The term also includes a person or firm who uses mutation inducing techniques such as radiation.

A "chrysanthemum cutting" is a reproductive part of a chrysanthemum plant. It can be part of a stem, part of the leaf or the tip of the plant. A cutting properly cared for and nurtured will produce another mature plant.

"Sport" is a general synonym for mutation, although it also has a more limited technical meaning as a mutation which first expresses itself as a bud variation.

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**Pan-American Plant Co. v. Matsui**
United States District Court for the Northern District of California 433 F. Supp. 693 (N.D. Cal. 1977)

RENFREW, District Judge.

This is an action brought by Pan-American Plant Company alleging plant patent infringement by defendant Andy Matsui . . . in violation of the Plant Patent Act of 1930. In his answer Matsui has denied infringement . . . and counterclaimed against Pan-American alleging patent invalidity . . . .

After examining the testimony and exhibits adduced at the hearing and reviewing the memoranda submitted by counsel, the Court finds that, even if plaintiff's plant patent is valid, defendant has not infringed it. As a result, the Court need not now reach the question of patent validity.

Plaintiff, an Illinois corporation, is engaged in a number of segments of the business of producing and selling ornamental plants including chrysanthemums. Plaintiff breeds and develops new varieties of chrysanthemum plants and produces and sells to greenhouses cuttings of a number of different varieties of chrysanthemum plants that have been bred by Pan-American or by others. A "variety" of chrysanthemum plant is a group of plants which exhibit similar essential characteristics and which are distinguishable from other groups of plants by the presence of significant differences with respect to one or more such characteristics.

In April, 1971, after subjecting plant material of the existing "May Shoesmith" chrysanthemum to radiation, Robert E. Danielson, a vice-president of Pan-American, discovered what he considered to be a new variety of chrysanthemum. The new sport appeared to have all the essential characteristics of the May Shoesmith, except that it had bright yellow blossoms when grown to

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3 A "breeder" of chrysanthemums is a person or firm which creates or invents new varieties of chrysanthemum plants through the process of hybridizing, i.e., crossing of male and female parents to derive new seedling varieties. The term also includes a person or firm who uses mutation inducing techniques such as radiation.

4 A "chrysanthemum cutting" is a reproductive part of a chrysanthemum plant. It can be part of a stem, part of the leaf or the tip of the plant. A cutting properly cared for and nurtured will produce another mature plant.

5 "Sport" is a general synonym for mutation, although it also has a more limited technical meaning as a mutation which first expresses itself as a bud variation.
finished flower. On August 16, 1972, Danielson filed an application with the United States Patent Office to obtain a plant patent on his discovery ("Danielson plant material"). The plant patent was issued on February 19, 1974. The patent claim reads as follows:

A new and distinct variety of chrysanthemum plant, substantially as herein shown and described, characterized by its very large, bright yellow blooms, its excellent production of well formed flowers, flowering with a very even eleven-week response and producing very few culls.

In March of 1972, another sport or mutation of May Shoesmith ("Nakano plant material") was found by Jim Nakano . . . . That sport was not an asexual reproduction of Danielson plant material. The sport or mutation found by Nakano also produced a bright yellow blossom when grown to finished flower. The Nakano greenhouse reproduced a number of plants from the Nakano plant material and in December, 1972, submitted cuttings of the Nakano plant material to Pan-American for its evaluation.

Pan American took a number of cuttings of the Nakano plant material and grew them together with cuttings of the Danielson plant material to make a comparative evaluation of the Nakano plant material and the Danielson plant material. Based on the observations of those trial flowerings by its employees in April and early May of 1973, Pan-American alleges that it concluded that the Danielson plant material and the Nakano plant material were the same variety.

In late May of 1973, deformities began to appear in the blossoms produced from the Danielson plant material. By the end of the growing season, the deformities appeared in 50 to 60% of the blossoms. The Nakano plant material, which was grown side by side with the Danielson plant material, on the other hand, did not develop similar defective blossoms. Pan-American experts believed that it might be possible to eliminate the defect in the Danielson plant material through application of selection or pathological techniques, but knew that doing so would have delayed offering the variety for sale for at least two years.

Because it did not desire to delay offering the variety for sale, Pan-American decided to build up stock of the Nakano plant material and supply cuttings of that material to the trade. It thus replaced the Danielson plant material with the Nakano plant material for commercial sale. In 1973, after the Nakano plant material was offered for sale and shipments had been made, all Danielson plant material existing in the United States was destroyed. All cuttings of the chrysanthemum Bright Yellow May Shoesmith sold commercially in the United States are derived from the original Nakano plant.

The plant which Pan-American alleges infringes the Danielson patent is also a yellow mutation of the variety May Shoesmith and is called "Sunshine." Andy Matsui discovered Sunshine on or about February 8, 1972, in a large bed of May Shoesmith white standard chrysanthemums located in a Matsui greenhouse in Salinas, California. Upon discovery, Andy Matsui tagged the plant and
allowed it to go to full bloom. Matsui then harvested the blooms and took the roots to a mother stock area in the Matsui Salinas greenhouse facility. The roots were replanted and Matsui took cuttings of the original plant to build up mother stock of Sunshine.

This process of taking and replanting cuttings to build up stock and grow flowers continued through to summer of 1972. By November 1972, Matsui was harvesting cut flowers from stock built up from the discovery of Sunshine. Matsui admits that it has asexually reproduced, used, and sold Sunshine since February 19, 1974.

Plaintiff alleges that defendant has infringed [the Danielson plant patent] by asexually reproducing and selling the same variety of chrysanthemum as is covered by the patent. The initial question in this action must therefore be whether Sunshine is the same variety as the Danielson plant material.

For the purposes of this action, plaintiff defines a variety of chrysanthemum plant as "a group of plants which exhibit similar essential characteristics and which are distinguishable from other groups of plants by the presence of significant differences with respect to one or more of such characteristics."

Both the President of Pan-American, William H. Hubbard, and the vice-president of Pan-American who discovered the Danielson plant material, Robert Danielson, have testified that resistance to disease and percentage of culls are very significant characteristics of a chrysanthemum variety. Indeed, Congress itself singled out immunity from disease and ease of asexual reproduction as characteristics which may distinguish a new variety:

The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; resistance to cold, drought, heat, wind, or soil conditions; color of flower, leaf, fruit, or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.

It is undisputed that before [the Danielson plant patent] ever granted, the Danielson plant material became diseased and produced blossoms that were 50 to 60% culls. It is also undisputed

To the extent that Danielson's patent claim describes his plant material as "producing very few culls," it is clearly inaccurate. This inaccuracy is especially troubling because before [the plant patent] was ever granted, Pan-American not only knew that the Danielson plant material produced 50 to 60% culls, but the company actually destroyed all the plant material. Such a knowing inaccuracy raises the spectre of fraud and serious questions about the validity of the patent. Failure to describe accurately in the patent claim the Danielson plant material's known propensity to produce culls also raises questions as to whether Pan-American's description of the
that the Sunshine chrysanthemum does not suffer the same problems. The Court finds that Sunshine's ability to be asexually reproduced with a far smaller percentage of culls than the Danielson plant material is a significantly different characteristic which makes it a different variety. Sunshine "is substantially different from plaintiff's patented [plant] and hence does not infringe."

The Court is not persuaded that the high percentage of culls was a temporary characteristic of the Danielson plant material. Pan-American is unable to say for certain that it could have eliminated the disease, because it destroyed all the Danielson plant material in the United States without even attempting to cure the defect.

Nor is the Nakano plant material covered by [the Danielson plant patent]. Although the Nakano plant material and Sunshine appear to be of the same variety, they both differ significantly from the patented plant material in their resistance to disease and the ease with which they may be asexually reproduced without deformities. The fact that Pan-American agreed with Nakano to distribute his plant material under the auspices of [the Danielson plant patent] does not make the Nakano plant material the same variety as the Danielson plant material.

Indeed, there is evidence in this case that, after deformities began to appear in the Danielson plant material, even Pan-American viewed the Nakano plant material as a different variety . . . .

Pan-American has presented evidence that it is not unusual for propagator-distributors to replace one of their diseased commercial varieties with outside plant material. This may be true, but it has no bearing on whether the outside plant material is covered by a specific plant patent. If two plants have significantly different characteristics, they are two different varieties within the meaning of the Plant Patent Act. Merely distributing one under the commercial name of the other does not make them the same variety . . . .

Accordingly, the Court hereby finds that there is a "sufficient difference" between Sunshine and the plant material covered by [the Danielson plant patent] to avoid infringement.

* * * * *

patented plant was "as complete as is reasonably possible" as required by 35 U.S.C. §§ 112 and 162.
RICH, Circuit Judge.

I. BACKGROUND

A. The Patent

Bruno Imazio, the owner of Imazio Nursery, Inc. (Imazio), is the inventor of the '336 patent which is entitled "Heather Named Erica Sunset." According to the '336 patent, Mr. Imazio discovered Erica Sunset heather in 1978 "as a seedling of unknown pollen parentage growing in a cultivated field of Erica persoluta, the variety believed to be the seed parent, where it was noticed because of its early blooming and particularly because of its reaching full bloom, from base to tip, more than a month before the parent plant begins to bloom." It was the early blooming of the Erica Sunset, during the Christmas and Valentine's Day seasons, that distinguished the Erica Sunset from other known varieties.

III. PLANT PATENTS

At least as early as 1892, legislation was proposed to grant patent rights for plant-related inventions. H.R.Rep. No. 5435, 52d Cong., 1st Sess. (1892). It was also supported by Luther Burbank, a leading plant breeder of the day, whose widow stated that her late husband "said repeatedly that until Government made some such provision [for plant patent protection] the incentive to create work with plants was slight and independent research and breeding would be discouraged to the great detriment of horticulture." H.R.Rep. No. 1129, 71st Cong., 2d Sess. 4 (1930) (House Report). It was the first legislation anywhere in the world to grant patent rights to plant breeders and was enacted to "afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given to industry, and thus assist in placing agriculture on a basis of economic equality with industry." Senate Report at 3.

Before enactment of the Plant Patent Act, two factors were thought to prevent plants from being patentable subject matter. The first was the belief that plants, even those bred by man, were products of nature and therefore not subject to patent protection. The second factor was that plants were not considered amenable to the "written description" requirement of the predecessor of 35 U.S.C. § 112, first paragraph.

With the promulgation of the 1952 Patent Act, the plant patent provisions were included as a separate chapter of the statute. Act of July 19, 1952, ch. 950, 66 Stat. 804 (current plant patent provisions at 35 U.S.C. §§ 161-164 (1988)). Additionally, as was done for utility patents
in 35 U.S.C. § 154(a)(1) (1988), the plant patent grant was changed from the "exclusive right" to the "right to exclude" following court decisions explaining the nature of the right conferred by a patent. 35 U.S.C. § 163 (1988); ... 
... Thus, section 161 "engrafts the Plant Patent Act onto the basic patent law, which requires us to apply thereto all the rules, regulations, and provisions of the basic patent law," except as otherwise provided. ... 
... Only a single claim is permitted in a plant patent. 37 C.F.R. § 1.164; Manual of Patent Examining Procedure (MPEP) § 1605 (Rev. 14, Nov. 1992) ("A plant patent is granted only on the entire plant. It therefore follows that only one claim is necessary and only one is permitted."); ... 

IV. STATUTORY CONSTRUCTION

....

B. Scope of a Plant Patent

....

1. The meaning of the term "variety"

   The parties dispute the meaning of the term "variety" in section 161. The meaning of that term may inform the scope of protection of plant patents inasmuch as such patents are granted to "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant." 35 U.S.C. § 161 (emphasis added). Imazio argues that in providing plant patent protection for "any distinct and new variety of plant," it was intended that a plant patent cover "all plants of that new and distinct variety, i.e., all plants having the same essential and distinctive characteristics." Thus, argues Imazio, "variety" should be construed in its technical, taxonomical sense and should be interpreted to encompass more than just clones of a single plant. Coastal, on the other hand, contends that "variety" should be construed in the vernacular sense as "something different from others of the same general kind." Coastal maintains that by use of the term "variety" Congress did not intend to afford plant patent protection to a range of plants but intended only to protect a single plant.

   Although the legislative history does not answer the question of what "variety" means in terms of whether a single plant or a range of plants is protected by a plant patent, in addition to being distinct and new, a patentable plant must also be asexually reproduced. 35 U.S.C. § 161; ... 

2. The significance of the asexual reproduction requirement

   ... It is clear from the legislative history that as a result of the asexual reproduction requirement, only a single plant, i.e., reproduction from one original specimen in the words of Congress, is protected by a plant patent. At the time of enactment, Congress recognized that the asexual reproduction prerequisite greatly narrowed the scope of protection of plant patents but found such a limitation necessary to ensure that the characteristics of the plant to be patented were maintained. Additionally, it has since been recognized that as intimated by Congress,
asexual reproduction confirms the existence of a new variety by separating variations resulting from fluctuations in environmental conditions from true plant variations. Kenneth J. Burchfiel, Biotechnology and the Federal Circuit 407 (1995); ...

Due to the asexual reproduction prerequisite, plant patents cover a single plant and its asexually reproduced progeny. Accordingly, "variety" in section 161 cannot be read as affording plant patent protection to a range of plants, as asserted by Imazio.

3. Comparison with the Plant Variety Protection Act

Both parties argue that the provisions of the Plant Variety Protection Act are relevant to a proper interpretation of the scope of protection afforded plant patents under the Plant Patent Act.

... It is true that both the Plant Patent Act and the PVPA use the term "variety" and grant some form of intellectual property protection. However, the two statutes differ significantly in their purposes. The Plant Patent Act grants a plant patent to one who "invents or discovers and asexually reproduces any distinct and new variety of plant." 35 U.S.C. § 161. Conversely, one is entitled to plant variety protection under the PVPA if he has sexually reproduced the variety and has otherwise met the requirements of 7 U.S.C. § 2402(a). The term "variety" in both statutes cannot be read divorced from the very different circumstances in which that term is used. Those circumstances, asexual reproduction in the case of plant patents, and sexual reproduction in the case of plant variety protection, mandate the protection afforded under these different statutory provisions. Asexual reproduction is the cornerstone of plant patent protection, while sexual reproduction is the distinguishing feature of plant variety protection. Indeed, this is why the PVPA was enacted, to afford protection for sexually reproduced plants. ...

It follows from this that the scope of protection afforded as a result of sexual versus asexual reproduction must be different; in the case of asexual reproduction, the same plant is produced, but in the case of sexual reproduction, a different plant, albeit like the parent plants, is produced. Given this, we reject Imazio's contention that the meaning of variety in the Plant Patent Act and the PVPA must be the same.

V. INFRINGEMENT

A. The Trial Court's Analysis

In issuing its December 1992 preliminary injunction order, the trial court adopted the standard set forth in Pan-American Plant Co. v. Matsui, 433 F.Supp. 693, 694 n. 2, 198 USPQ 462, 463 n. 2 (N.D.Cal.1977) that the Plant Patent Act "bars the asexual reproduction and sale of any plant which is the same variety (i.e., has the same essential characteristics) as the patented plant, whether or not the infringing plant was originally cloned from the patented plant." Imazio, 29 USPQ2d at 1219, 1992 WL 551670. The district court also addressed whether independent creation could be a defense to plant patent infringement as discussed in Yoder, 537 F.2d 1347, 193 USPQ 264. The district court stated that "independent creation is [not] a proper defense to patent infringement" and asserted that "the courts' recognition of an independent creation defense
would inadvertently entice deliberate infringement, with a fraudulent defense of independent creation asserted." Id.

On the merits of the infringement charge, the trial court reviewed the testimony of both parties' experts and found that the "undisputed evidence thus shows that the patented Erica Sunset heather and the Holiday Heather are the same plants both morphologically (internal and external characteristics) and phenologically (blooming cycle)." The trial court concluded that Imazio had "successfully demonstrated that the Holiday Heather is an asexual reproduction of the Erica Sunset."

C. Infringement of a Plant Patent

As to the first step, consistent with our analysis above, the scope of the claim of the '336 patent is the asexual progeny of the Heather persoluta shown and described in the '336 patent specification. To perform the second step of the infringement analysis, we first look to the language of the statute.

Section 163 grants to plant patentees the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced. 35 U.S.C. § 163. As stated above, the trial court held that asexual reproduction is shown if the patentee can prove that the alleged infringing plant has the same essential characteristics as the patented plant. We disagree.

We must construe the term "asexual reproduction" in section 163 in the same way as we did in section 161. Thus, for purposes of plant patent infringement, the patentee must prove that the alleged infringing plant is an asexual reproduction, that is, that it is the progeny of the patented plant. Yoder, 537 F.2d at 1380, 193 USPQ at 293 ("It is quite possible that infringement of a plant patent would occur only if stock obtained is used, given the extreme unlikelihood that any other plant could actually infringe.").

1. Independent creation as a defense to plant patent infringement

Below, the parties disputed whether independent creation is a proper defense to plant patent infringement. The trial court refused to recognize such a defense stating that the "patent holder would have great difficulties enforcing his patent rights if a defendant were allowed to raise independent creation as an affirmative defense." The trial court reasoned that it would be hard for the patentee to refute evidence of independent creation because all such evidence would be in the defendant's control.

We must reject the trial court's analysis of the independent creation defense because it is contrary to the plain meaning of the statute. See Wilner v. United States, 24 F.3d 1397, 1402 (Fed.Cir.1994) (in banc) (court's approach constituted legal error because it was contrary to the plain meaning of the statute). The statute requires asexual reproduction of the patented plant for there to be infringement. It is necessarily a defense to plant patent infringement that the alleged infringing plant is not an asexual reproduction of the patented plant. Part of this proof could be,
thus, that the defendant independently developed the allegedly infringing plant. However, the sine qua non is asexual reproduction. That is what the patentee must prove and what the defendant will seek to disprove.

....

The case is remanded for further proceedings consistent with this opinion.

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NOTE 1. For the decision on remand, read Imazio Nursery, Inc. v. Dania Greenhouses, 1997 WL 195434 (N. D. Calif.) On remand, the court focused its attention on the evidentiary issues relating to DNA tests and burdens of proof relating to the legal issues of infringement and independent creation. On remand, the district court ultimately ordered the appointment of an independent expert for the Court itself to assist the court in resolving the legal issues.

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C. THE PLANT VARIETY PROTECTION ACT OF 1970

1. Introduction

Although the Plant Patent Act of 1930 overcame the original doctrinal barriers to legal recognition of intellectual property in plant genetic resources, it excluded sexually reproduced plants. Because of doubts about whether sexually reproduced plants would breed true-to-type, Congress withheld proprietary protection. Research in these varieties remained the domain of public sector research institutions, which released new varieties without protection. Plant breeding technology evolved, however, and plant biologists came to accept the notion that sexually reproduced varieties would breed true-to-type.1 The United States' accession to the International Convention for the Protection of New Varieties of Plants (UPOV)2 finally forced Congress's hand. The Plant Variety Protection Act of 1970 (PVPA)3 authorizes the Department of Agriculture to extend patent-like protection for an 18-year period to a new, sexually reproduced plant variety. As you examine the following sections of the PVPA, try to anticipate the controversies that have arisen as new plant varieties protected under the PVPA entered the market.


2T.I.A.S. 10,199 (entered into force Nov. 8, 1971).

§ 2401. DEFINITIONS AND RULES OF CONSTRUCTION

The definitions and rules of construction set forth in this section apply for the purposes of this chapter.

(a) Definitions. As used in this chapter:

1. Basic seed. The term "basic seed" means the seed planted to produce certified or commercial seed.

2. Breeder. The term "breeder" means the person who directs the final breeding creating a variety or who discovers and develops a variety. If the actions are conducted by an agent on behalf of a principal, the principal, rather than the agent, shall be considered the breeder. The term does not include a person who redevelops or rediscovers a variety the existence of which is publicly known or a matter of common knowledge.

3. Essentially derived variety.

   A. In general. The term "essentially derived variety" means a variety that –

      (i) is predominantly derived from another variety (referred to in this paragraph as the "initial variety") or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety;

      (ii) is clearly distinguishable from the initial variety; and

      (iii) except for differences that result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

   B. Methods. An essentially derived variety may be obtained by the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, transformation by genetic engineering, or other method.

4. Kind. The term "kind" means one or more related species or subspecies singly or collectively known by one common name, such as soybean, flax, or radish.
(5) **Seed.** The term "seed," with respect to a tuber propagated variety, means the tuber or the part of the tuber used for propagation.

(6) **Sexually reproduced.** The term "sexually reproduced" includes any production of a variety by seed, but does not include the production of a variety by tuber propagation.

(7) **Tuber propagated.** The term "tuber propagated" means propagated by a tuber or a part of a tuber.

(8) **United States.** The terms "United States" and "this country" mean the United States, the territories and possessions of the United States, and the Commonwealth of Puerto Rico.

(9) **Variety.** The term "variety" means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter.

(b) **Rules of construction.** For the purposes of this chapter:

(1) **Sale or disposition for nonreproductive purposes.** The sale or disposition, for other than reproductive purposes, of harvested material produced as a result of experimentation or testing of a variety to ascertain the characteristics of the variety, or as a by-product of increasing a variety, shall not be considered to be a sale or disposition for purposes of exploitation of the variety.

(2) **Sale or disposition for reproductive purposes.** The sale or disposition of a variety for reproductive purposes shall not be considered to be a sale or disposition for the purposes of exploitation of the variety if the sale or disposition is done as an integral part of a program of experimentation or testing to ascertain the characteristics of the variety, or to increase the variety on behalf of the breeder or the successor in interest of the breeder.

(3) **Sale or disposition of hybrid seed.** The sale or disposition of hybrid seed shall be considered to be a sale or disposition of harvested material of the varieties from which the seed was produced.

(4) **Application for protection or entering into a register of varieties.** The filing of an application for the protection or for the entering of a variety in an official register of varieties, in any country, shall be considered to render the variety a matter of common knowledge from the date of the application, if the application leads to the granting of protection or to the entering of
the variety in the official register of varieties, as the case may be.

(5) Distinctness. The distinctness of one variety from another may be based on one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence.

(6) Publicly known varieties.

(A) In general. A variety that is adequately described by a publication reasonably considered to be a part of the public technical knowledge in the United States shall be considered to be publicly known and a matter of common knowledge.

(B) Description. A description that meets the requirements of subparagraph (A) shall include a disclosure of the principal characteristics by which a variety is distinguished.

(C) Other means. A variety may become publicly known and a matter of common knowledge by other means.

§ 2402. Right to plant variety protection; plant varieties protectable

(a) In general. The breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the successor in interest of the breeder, shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this chapter, if the variety is—

1. new, in the sense that, on the date of filing of the application for plant variety protection, propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons, by or with the consent of the breeder, or the successor in interest of the breeder, for purposes of exploitation of the variety—

(A) in the United States, more than 1 year prior to the date of filing; or

(B) in any area outside of the United States—

(i) more than 4 years prior to the date of filing; or

(ii) in the case of a tree or vine, more than 6 years prior to the date of filing;

2. distinct, in the sense that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the
filing of the application;

(3) uniform, in the sense that any variations are describable, predictable, and commercially acceptable; and

(4) stable, in the sense that the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.

(b) Multiple applicants.

(1) In general. If 2 or more applicants submit applications on the same effective filing date for varieties that cannot be clearly distinguished from one another, but that fulfill all other requirements of subsection (a) of this section, the applicant who first complies with all requirements of this chapter shall be entitled to a certificate of plant variety protection, to the exclusion of any other applicant.

(2) Requirements completed on same date

(A) In general. Except as provided in subparagraph (B), if 2 or more applicants comply with all requirements for protection on the same date, a certificate shall be issued for each variety.

(B) Varieties indistinguishable. If the varieties that are the subject of the applications cannot be distinguished in any manner, a single certificate shall be issued jointly to the applicants.
§ 2422. Content of application

An application for a certificate recognizing plant variety rights shall contain:

(1) The name of the variety except that a temporary designation will suffice until the certificate is to be issued. The variety shall be named in accordance with regulations issued by the Secretary.

(2) A description of the variety setting forth its distinctiveness, uniformity, and stability and a description of the genealogy and breeding procedure, when known. The Secretary may require amplification, including the submission of adequate photographs or drawings or plant specimens, if the description is not adequate or as complete as is reasonably possible, and submission of records or proof of ownership or of allegations made in the application. An applicant may add to or correct the description at any time, before the certificate is issued, upon a showing acceptable to the Secretary that the revised description is retroactively accurate. Courts shall protect others from any injustice which would result. The Secretary may accept records of the breeder and of any official seed certifying agency in this country as evidence of stability where applicable.

(3) A statement of the basis of the claim of the applicant that the variety is new.

(4) A declaration that a viable sample of basic seed (including any propagating material) necessary for propagation of the variety will be deposited and replenished periodically in a public repository in accordance with regulations to be established hereunder.4

(5) A statement of the basis of applicant's ownership.

§ 2483. Contents and term of plant variety protection

(a)(1) Every certificate of plant variety protection shall certify that the breeder (or the successor in interest of the breeder), has the right, during the term of the plant variety protection, to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom, to the extent provided by this chapter.

(2) If the owner so elects, the certificate shall

   (A) specify that seed of the variety shall be sold in the United States only as a class of certified seed; and

   (B) if so specified, conform to the number of generations designated by the owner.

4Ed. note – USDA regulations require the breeder to deposit 2,500 viable seeds in the National Seed Storage Laboratory in Fort Collins, Colorado. See 7 C.F.R. § 180.6(d).
(3) An owner may waive a right provided under this subsection, other than a right that is elected by the owner under paragraph (2)(A).

(4) The Secretary may at the discretion of the Secretary permit such election or waiver to be made after certificating and amend the certificate accordingly, without retroactive effect.

(b) The term of plant variety protection shall expire 20 years from the date of issue of the certificate in the United States. If the certificate is not issued within three years from the effective filing date, the Secretary may shorten the term by the amount of delay in the prosecution of the application attributed by the Secretary to the applicant, except that, in the case of a tree or vine, the term of the plant variety protection shall expire 25 years from the date of issue of the certificate.

(c) The term of plant variety protection shall also expire if the owner fails to comply with regulations, in force at the time of certificating, relating to replenishing seed in a public repository.

§ 2531. OWNERSHIP AND ASSIGNMENT

(a) Subject to the provisions of this title, plant variety protection shall have the attributes of personal property.

(b) Applications for certificates of plant variety protection, or any interest in a variety, shall be assignable by an instrument in writing. The owner may in like manner license or grant and convey an exclusive right to use of the variety in the whole or any specified part of the United States.

§ 2541. INFRINGEMENT OF PLANT VARIETY PROTECTION

(a) Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a protected variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a protected plant variety with the notice under section 2567 of this title:

(1) sell or market the protected variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

(2) import the variety into, or export it from, the United States;

(3) sexually multiply, or propagate by a tuber or a part of a tuber, the variety as a step in marketing (for growing purposes) the variety;
use the variety in producing (as distinguished from developing) a hybrid or different variety therefrom;
(5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the variety;
(6) dispense the variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or
(7) condition the variety for the purpose of propagation, except to the extent that the conditioning is related to the activities permitted under section 2543 of this title;
(8) stock the variety for any of the purposes referred to in paragraphs (1) through (7);
(9) perform any of the foregoing acts even in instances in which the variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or
(10) instigate or actively induce performance of any of the foregoing acts.

(b) Uses authorized by owner

(1) Subject to paragraph (2), the owner of a protected variety may authorize the use of the variety under this section subject to conditions and limitations specified by the owner.

(2) In the case of a contract between a seed producer and the owner of a protected variety of lawn, turf, or forage grass seed, or alfalfa or clover seed for the production of seed of the protected variety, the producer shall be deemed to be authorized by the owner to sell such seed and to use the variety if—

(A) the producer has fulfilled the terms of the contract;
(B) the owner refuses to take delivery of the seed or refuses to pay any amounts due under the contract within 30 days of the payment date specified in the contract; and
(C) after the expiration of the period specified in subparagraph (B), the producer notifies the owner of the producer's intent to sell the seed and unless the owner fails to pay the amounts due under the contract and take delivery of the seed within 30 days of such notification.
For the purposes of this paragraph, the term "owner" shall include any licensee of the owner.

(3) Paragraph (2) shall apply to contracts entered into with respect to plant varieties protected under this chapter as in effect on the day before the effective date of this provision as well as plant varieties protected under this chapter as amended by the Plant Variety Protection Act Amendments of 1994.

(4) Nothing in this subsection shall affect any other rights or remedies of producers or owners that may exist under other Federal or State laws.

(c) Applicability to certain plant varieties. This section shall apply equally to—

(1) any variety that is essentially derived from a protected variety, unless the
protected variety is an essentially derived variety;

(2) any variety that is not clearly distinguishable from a protected variety;

(3) any variety whose production requires the repeated use of a protected variety;

and

(4) harvested material (including entire plants and parts of plants) obtained through the unauthorized use of propagating material of a protected variety, unless the owner of the variety has had a reasonable opportunity to exercise the rights provided under this chapter with respect to the propagating material.

(d) Acts not considered infringing. It shall not be an infringement of the rights of the owner of a variety to perform any act concerning propagating material of any kind, or harvested material, including entire plants and parts of plants, of a protected variety that is sold or otherwise marketed with the consent of the owner in the United States, unless the act involves further propagation of the variety or involves an export of material of the variety, that enables the propagation of the variety, into a country that does not protect varieties of the plant genus or species to which the variety belongs, unless the exported material is for final consumption purposes.

(e) Private, noncommercial uses. It shall not be an infringement of the rights of the owner of a variety to perform any act done privately and for noncommercial purposes.

(f) As used in this section, the term "perform without authority" includes performance without authority by any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in the official capacity of the officer or employee. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this chapter in the same manner and to the same extent as any nongovernmental entity.

§ 2581. INTENT

It is the intent of Congress to provide the indicated protection for new varieties by exercise of any constitutional power needed for that end, so as to afford adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties. Constitutional clauses 3 and 8 of article I, section 8 are both relied upon.5

§ 2582. SEVERABILITY

If this chapter is held unconstitutional as to some provisions or circumstances, it shall remain in force as to the remaining provisions and other circumstances.

5Ed. note – Clause 8 is the copyright and patent clause reprinted above; clause 3 authorizes Congress to regulate interstate and international commerce.
Enforcement provisions

§ 2561. Remedy for infringement of plant variety protection

An owner shall have remedy by civil action for infringement of plant variety protection under section 2541 of this title. If a variety is sold under the name of a variety shown in a certificate, there is a prima facie presumption that it is the same variety.

§ 2562. Presumption of validity; defenses

(a) Certificates of plant variety protection shall be presumed valid. The burden of establishing invalidity of a plant variety protection shall rest on the party asserting invalidity.

(b) The following shall be defenses in any action charging infringement and shall be pleaded: (1) noninfringement, absence of liability for infringement, or unenforceability; (2) invalidity of the plant variety protection in suit on any ground specified in section 2402 of this title as a condition for protectability; (3) invalidity of the plant variety protection in suit for failure to comply with any requirement of section 2422 of this title; (4) that the asserted infringement was performed under an existing certificate adverse to that asserted and prior to notice of the infringement; and (5) any other fact or act made a defense by this chapter.

§ 2563. Injunction

The several courts having jurisdiction of cases under this subchapter may grant injunctions in accordance with the principles of equity to prevent the violation of any right hereunder on such terms as the court deems reasonable.

§ 2564. Damages

(a) Upon finding an infringement the court shall award damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the variety by the infringer, together with interest and costs as fixed by the court.

(b) When the damages are not determined by the jury, the court shall determine them. In either event the court may increase the damages up to three times the amount determined.

(c) The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

(d) As to infringement prior to, or resulting from a planting prior to, issuance of a certificate for the infringed variety, a court finding the infringer to have established innocent intentions, shall have discretion as to awarding damages.
§ 2567. LIMITATION OF DAMAGES; MARKING AND NOTICE

Owners may give notice to the public by physically associating with or affixing to the container of seed of a variety or by fixing to the variety, a label containing either the words "Unauthorized Propagation Prohibited" or the words "Unauthorized Seed Multiplication Prohibited" and after the certificate issues, such additional words as "U.S. Protected Variety." In the event the variety is distributed by authorization of the owner and is received by the infringer without such marking, no damages shall be recovered against such infringer by the owner in any action for infringement, unless the infringer has actual notice or knowledge that propagation is prohibited or that the variety is a protected variety, in which event damages may be recovered only for infringement occurring after such notice. As to both damages and injunction, a court shall have discretion to be lenient as to disposal of materials acquired in good faith by acts prior to such notice.

Exemptions

§ 2404. PUBLIC INTEREST IN WIDE USAGE

The Secretary may declare a protected variety open to use on a basis of equitable remuneration to the owner, not less than a reasonable royalty, when the Secretary determines that such declaration is necessary in order to insure an adequate supply of fiber, food, or feed in this country and that the owner is unwilling or unable to supply the public needs for the variety at a price which may reasonably be deemed fair. Such declaration may be, with or without limitation, with or without designation of what the remuneration is to be; and shall be subject to review . . . (any finding that the price is not reasonable being reviewable), and shall remain in effect not more than two years. In the event litigation is required to collect such remuneration, a higher rate may be allowed by the court.

§ 2543. RIGHT TO SAVE SEED; CROP EXEMPTION

Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 2567 of this title that the actions of the purchaser constitute an infringement.
§ 2544. RESEARCH EXEMPTION

The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter.

* * * *

Notes on the PVPA. Qualifying for a PVPA certificate requires less effort than obtaining a patent. To be protected under the PVPA, a sexually reproduced or tuber-propagated plant variety must be "new," "distinct," "uniform," and "stable." Each of these requirements represents a significant departure from the more stringent novelty, utility, and nonobviousness requirements of the general patent law. The uniformity and stability requirements relax the patent law's ordinary insistence on precise description and virtually perfect reproduction of any invention. The PVPA tolerates variations in a sexually reproduced or tuber-propagated plant to the extent that such variations do not obstruct trade in the plant variety. Furthermore, the PVPA's distinctiveness requirement quite substantially lowers the general patent law's hurdle of nonobviousness. It is enough that a protected plant variety contain at least one identifiable morphological, physiological, or other characteristic, including advantages that emerge in processing or in a final product.

Does the PVPA represent an unconstitutional extension of Congress's powers under the patent clause? Note that Congress took care to invoke both the patent clause and the commerce clause as constitutional authority for the PVPA. Cases such as *Graham* and *Funk Brothers* establish the principle that the patent clause does not authorize Congress to grant commercial monopolies willy-nilly. There must be an inventive step of some sort. If the "novelty" requirement codified in the Patent Act of 1952 is also the constitutional minimum, then the

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*See 35 U.S.C. § 101 ("any new and useful process, machine, manufacture, or composition of matter, or . . . improvement thereof"); id. § 103 ("the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would [not] have been obvious").

*U.S. Const. art. I, § 8, cl. 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . .").

*See id. cl. 3 ("The Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes . . .").

*See 7 U.S.C. § 2581; see also id. § 2582 (severability clause).

patent clause does not authorize Congress to grant plant variety protection certificates for levels of inventiveness that fall short of novelty required for utility patent patents. And if the commerce clause is interpreted as authorizing commercial monopolies not permitted under the patent clause, the patent clause becomes a piece of constitutional surplusage. These are the terms by which a constitutional challenge against the PVPA can be mounted.\textsuperscript{11}

Constitutional questions aside, Congress expressly intended the PVPA "to afford adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties."\textsuperscript{12} Whether the PVPA has actually achieved these objectives, however, was never entirely clear. As first enacted, section 113 of the PVPA contained a broad "crop exemption":

Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: Provided, That without regard to the provisions of section 2541(3) of this title it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable. A \textit{bona fide} sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 2567 of this title that his actions constitute an infringement.\textsuperscript{13}

More than any other aspect of the statute, this exemption triggered an enormous amount of debate over the PVPA:


\textsuperscript{12}7 U.S.C. § 2581.

[As of 1989] over 2,000 PVP [plant variety protection] certificates have been issued on new varieties. The total includes 458 soybean varieties, 176 wheat varieties, and 156 cotton varieties.

The wheat breeding experience demonstrates both the PVPA's potential and the PVPA's fundamental weakness. Wheat breeding programs at state agricultural experiment stations have been very successful. Since 1930, U.S. wheat yields have increased 115%, with genetic improvements accounting for forty percent to sixty percent of the increase. Not surprisingly, university-developed varieties are by far the most widely grown. In 1979, ninety percent of the total wheat acreage was planted to varieties developed by state agricultural experiment stations. By 1984, eighty percent of the acreage was still planted to public varieties.

In 1970, following passage of the PVPA, commercial breeders such as Pioneer Hi-Bred International Inc. joined the experiment station breeders and began to release private varieties. As a result, more varieties became available to farmers. However, plant breeding is a slow and expensive process, taking approximately ten years and one million dollars to breed a new, successful wheat variety.

Consequently, commercially developed wheat varieties did not appear until around 1980. Then, in the next decade, Pioneer varieties captured a sizable percentage of the market. For example, in 1989 Pioneer varieties accounted for 11.9% or 1.5 million acres of Kansas’ 12.4 million acres of hard red winter wheat. Pioneer 2157 alone was seeded on 1.2 million acres or 9.5% of the total.

However, Pioneer wheat breeding did not prosper, but lost six million dollars from 1984 to 1989. Therefore, in October 1989, after 20 years of development and sales with no profit, Pioneer announced that it was discontinuing its hard red spring wheat and hard red winter wheat breeding programs. In early 1990, Pioneer donated their spring wheat germplasm, research results, and commercial varieties to North Dakota State University. So, although commercial breeding can be successful, it is apparent that the PVPA does not adequately protect the breeders' intellectual property rights.

* * * * *

2. Enforcing the PVPA through infringement actions
Generally speaking, "plant variety protection [has] the attributes of personal property."\(^{14}\)

The following case illustrates the enforcement of that personal property right through infringement actions:

**Public Varieties of Mississippi, Inc. v. Valley Seed Co.**

United States District Court for the Northern District of Mississippi

734 F. Supp. 250 (N.D. Miss. 1990)

BIGGERS, District Judge.

The Mississippi Agricultural and Forestry Experiment Station ("MAFES") developed a novel variety of cotton, DES 119, for which it applied and was granted a certificate of plant variety protection pursuant to the Plant Variety Protection Act ("PVPA").

After MAFES received its certificate, it entered into an agreement with the plaintiff, Public Varieties of Mississippi, Inc. ("PVM"). The agreement required that MAFES produce foundation\(^2\) class seed and supply it exclusively to PVM, and that PVM "sublicense" the right to market and sell the seed for the purposes of lint production and seed propagation. Pursuant to the agreement, PVM sold substantial quantities of DES 119 and attached tags which notified prospective purchasers of the limitations regarding DES 119 use.

In 1987 and 1988, the owner and chief officer of both defendant corporations, Hal Jones, purchased significant tonnage of DES 119. Despite his awareness of the restrictions involving the resale of DES 119, Jones resold some of the seed he had purchased, and is continuing to sell DES 119 without permission of either MAFES or PVM.

PVM has filed suit for damages and injunctive relief and now moves for a preliminary injunction in order to protect its rights and the rights of MAFES. PVM claims that under the PVPA and its agreement with MAFES, it is entitled to enforce the certificate of plant variety protection issued for DES 119 if it brings alleged violations to the attention of MAFES and MAFES, in writing, notifies PVM that it does not wish to pursue a course of action on its own. The defendants, however, assert that PVM is a mere licensee of MAFES, and that as a licensee, the plaintiff has no authority under the PVPA to enjoin any violations of the DES 119 certificate.

\(^{14}\)Id. § 2531(a).

\(^{2}\)DES 119 is separated into four classes of seed, with each class name being determined by the number of reproduction generations from which it is distanced from the original seed. First generation seed is termed "breeder" class. In descending order of quality, the other classes are "foundation," "registered," and "certified."
Additionally, the defendants argue that PVM has not met the stringent requirements for a preliminary injunction, and that preliminary relief is therefore unwarranted. Because there is little case law construing the PVPA, the court will examine the underlying purpose and relevant legislative history of the Act before determining whether PVM is entitled to a preliminary injunction.

Congress enacted the Plant Patent Act of 1930 to provide patent protection to novel varieties of nonsexually reproduced plants. By 1970, it became apparent to Congress that true-to-type reproduction was possible for sexually reproduced plants; Congress accordingly passed the Plant Variety Protection Act to supplement the Plant Patent Act and granted patent-like protection for sexually reproduced plants. In effect, then, the PVPA awards the equivalent of patent protection to sexually reproduced plants which meet the Act's certification requirements.

Because of the similarity in purpose and construction between the PVPA and the patent laws, cases construing the patent statutes supply compelling analogies to aid the court in interpreting the PVPA. Under the patent laws, only an owner of the patent may bring a civil action to enforce the exclusionary right which the patent grants. In other words, a party must own some interest in the patent itself before he can invoke the patent laws and enforce the patent's exclusionary power.

This rule is merely an extension of the statutory property right granted under a patent – the right to exclude others from making, vending or using a particular item. The common law bestows upon every inventor the right to make, use and vend his invention, and the patent statute "clothes[s] him with the power to exclude everyone else from making, using or vending it." "The Government is not granting the common law right to make, use and vend, but it is granting the incident of exclusive ownership of that common law right, which can not be enjoyed save with the common law right." Hence, to effectively convey a patent's exclusionary power, which is the incident of owning all three common law rights in an invention, a patentee must sufficiently convey each of his common law rights to make, sell or vend his invention so as to also convey to the recipient the incidental statutory right of exclusivity.

"Agreements transferring patent rights must be either assignments or licenses." An assignment is defined as a conveyance which transfers the entire bundle of common law rights residing in a patent. Any agreement which transfers less than all of the rights in a patent is considered a license, and does not entitle the recipient to sue on the patent in his own name. A license merely grants a party permission to do something which would otherwise be unlawful; it grants immunity from suit rather than a proprietary interest in the patent.

To assign an interest in a patent, a patentee must assign, grant and convey either: (1) the whole patent, comprising the exclusive right to make, use and vend the invention throughout the United States; or (2) an undivided part or share of that exclusive right; or (3) the exclusive right under the patent throughout a specified part of the United States. . . . [O]nly three types of
assignments in interest are recognized: assignments of the entire interest, assignments of an undivided interest, and assignments of a territorial interest.

The PVPA appears to follow the same conceptual theory and statutory framework as the patent laws in defining who is entitled to sue on a certificate of plant variety protection. The Act declares that "it shall be an infringement of the rights of the owner of a novel variety" to sell, sexually multiply or otherwise propagate, produce, or dispense the novel variety without authority and that "[a]n owner shall have a remedy by civil action of his plant variety protection." By its plain meaning, the statute only permits a party with an ownership interest in a protected variety – through the common law rights to the variety and the certificate of plant variety protection which entitles a breeder to governmental protection – to bring a federal action and enforce the statutory rights granted by Congress. Just like the patent laws, the PVPA apparently does not permit transferral of the statutory right to a cause of action without an assignment of the common law rights to the variety itself. Although certificates of plant variety protection have the general attributes of personal property, the Supreme Court construed almost identical language under the patent laws as requiring assignment of the common law rights before any interest in the patent's incidental rights of exclusion could be transferred, and it must be presumed that Congress was aware of the Supreme Court's interpretation of the analogous patent statute when it worded PVPA section 2531 in near identical fashion.

The court . . . . holds that a party must be an assignee before he is entitled to bring suit in his own name under the PVPA, and that a mere licensee cannot bring suit, except with the owner or through the name of the owner.

PVM argues that the agreement between PVM and MAFES grants PVM authority to sue in its own name, should MAFES choose not to enforce its rights under the PVPA. Specifically, the license agreement states:

It is understood and agreed that licensor shall have the option to take such action as it considers necessary to protect its rights under the Federal Plant Variety Protection Act; but in the event that Licensor notifies Licensee in writing that it has declined to take such action, Licensee may take such action as it considers necessary to protect Licensor's and/or Licensee's rights under the Federal Plant Variety Protection Act or under any applicable state statute or under common law, or protect any other rights of Licensor as though Licensee owned those rights outright. In either event, each party shall cooperate fully with the other in this regard.

PVM's argument begs the question; the instrument cannot effectively convey to PVM the statutory right to exclude others because the statutory cause of action follows title in the certificate, and title in the certificate can only be assigned by transferring the entire bundle of common law rights . . . . The question the court must address, then, is whether PVM is an
assignee of the PVPA rights issued to MAFES.

The court finds that the agreement between MAFES and PVM is an exclusive license and not an assignment. Upon reading the document it becomes readily apparent that the agreement is essentially an exclusive release and that MAFES and PVM intended to leave all ownership rights to DES 119 in the hands of MAFES. Indeed, the agreement refers to itself as an "exclusive license" and PVM has proclaimed itself to be an exclusive licensee throughout the entire case. Even the clause which PVM seeks to enforce "grants" PVM the right to sue "as though" it actually owned the right. More importantly, MAFES solely retains its common law right to produce and supply to PVM all initial generations of DES 119, while PVM receives the right to "enjoy, commercialize, market and sell" DES 119 to sublicensees, who then in turn may produce future generations of seed. By exclusively retaining its right to produce the initial seed generation, and by conveying to PVM only the power to use and convey the foundation class seed provided, it is clear that the parties intended for MAFES to exclusively retain one of its common law rights in the variety and all of its ownership interest in DES 119 and the certificate of plant variety protection.

PVM's motion for a preliminary injunction must be denied because, as an exclusive licensee, PVM is unentitled to sue the defendants solely in its own name. . . .

* * * *

3. Section 113 of the PVPA – the crop exemption

Of the three major exemptions to the PVPA (public interest, crop, research), the crop exemption in section 113 has proved the most controversial. One commentator bluntly argues that "[s]ection 113 of the PVPA has placed commercial wheat and soybean breeding in jeopardy." The seed industry waged a legislative war against the provision, finally succeeding when Congress eliminated the most objectionable plank of the crop exemption.

Although 1994 amendments to the PVPA have rolled back the crop exemption

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significantly, the provision's rise and eventual decline vividly illustrate some of the prickliest problems in the legal regulation of agricultural biotechnology. The first of the next two cases, *Delta & Pine Land Co. v. Peoples Gin Co.*, describes the origins of the crop exemption and its tension with other provisions of the PVPA. The second case, *Asgrow Seed Co. v. Winterboer*, represents the culmination of numerous suits in which the Asgrow Seed Company aggressively enforced its PVPA rights against farmers who have sold saved seed under the crop exemption.

* * * *

**Delta & Pine Land Co. v. Peoples Gin Co.**
United States Court of Appeals for the Fifth Circuit
694 F.2d 1012 (5th Cir. 1983)

Before CLARK, Chief Judge, RUBIN and WILLIAMS, Circuit Judges.

CLARK, Chief Judge:

Delta & Pine Land Company brought this action against Peoples Gin Company and Hollandale Seed & Delinting Company alleging that they had infringed its rights under the Plant Variety Protection Act. The district court granted summary judgment in favor of Delta. The single issue on this appeal is a novel one. The question to be determined is whether Peoples and Hollandale are exempt from the operation of the Act pursuant to the "crop exemption," 7 U.S.C. § 2543. We hold that they are not, and affirm the judgment of the district court.

Delta holds a certificate of plant variety protection that gives it the exclusive right to market and reproduce a novel variety of cottonseed known as "Deltapine 41."¹ Peoples is a

¹A "novel variety" of seed exists if there is:

(1) Distinctness in the sense that the variety clearly differs by one or more identifiable morphological, physiological or other characteristics (which may include those evidenced by processing or product characteristics, for example, milling and baking characteristics in the case of wheat) as to which a difference in genealogy may contribute evidence, from all prior varieties of public knowledge at the date of determination . . .

(2) Uniformity in the sense that any variations are describable, predictable and commercially acceptable; and

(3) Stability in the sense that the variety, when sexually reproduced or reconstituted, will remain unchanged with regard to its essential and distinctive characteristics with a reasonable degree of reliability commensurate with that of
nonprofit agricultural cooperative with approximately fifty farmers as members. It gins the members' cotton, handles their cottonseed, and transacts other agricultural business on a cooperative basis. Hollandale operates a seed delinting\(^2\) and storage plant.

After a member's cotton is ginned, the separated cottonseed is normally sent to an oil mill. Prior to the bringing of this action, there were four situations in which that was not the case. A member who had a good crop would occasionally instruct Peoples to save his seed so that he could plant it the following spring. Or, he might direct Peoples to save the seed for a particular member other than himself. He might direct Peoples to hold the seed for anyone who expressed an interest in buying it. In the fourth situation, a prospective buyer would approach Peoples and request a certain variety of seed. Peoples would then contact potential sellers. No cash ever changed hands. Appropriate debits and credits were entered on the cooperative's books. Peoples itself did not buy or sell any seed.

Once it was determined that a batch of seed was to be saved from the oil mill, Peoples would transport it to Hollandale for delinting. After completing the delinting process, Hollandale placed the seed in labelled storage bags. The labels did not indicate that the seed was a protected variety. When it was time for spring planting, the farmers would either pick up their seed, or Hollandale would deliver it to them.

Peoples received cotton from its members for ginning in the fall of 1981. It followed the procedures outlined above, and saved a considerable amount of Deltapine 41. In the end, some of the members who obtained Deltapine 41 seed were not its original producers.

Delta found out about the practice the following fall. It filed suit against Peoples and Hollandale seeking injunctive relief and damages for unlicensed sales and transfers of Deltapine 41 seed. Delta based its claim on 7 U.S.C. § 2541 which provides in part:

> Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts . . . (1) sell the novel variety, or offer it or expose it for sale, deliver

varieties of the same category in which the same breeding method is employed.

7 U.S.C. § 2401. A "breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor . . . ." 7 U.S.C. § 2402. A certificate of plant variety protection gives the breeder the right "to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom . . . ." 7 U.S.C. § 2483.

\(^2\)Delinting is a treatment that must be applied to the seeds before they can be planted.
it, ship it, consign it, exchange it, or solicit any offer to buy it, or any other transfer of title or possession of it; . . .

(6) dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or . . .

(8) instigate or actively induce performance of any of the foregoing acts.

Peoples and Hollandale did not dispute that Delta was the owner of a novel variety protected under the Act. Rather, they argued that they were exempted from the operation of § 2541 by the "crop exemption," 7 U.S.C. § 2543 which provides in part:

It shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: Provided, That without regard to the provisions of section 2541(3) of this title it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable.

After an initial period of discovery, the district court granted summary judgment in favor of Delta. The district court held that § 2543 is limited to transactions in which farmers sell their seed directly to other producing farmers without the active assistance of a third party to arrange the sale. In applying this principle, the court concluded that Peoples violated the Act when it actually arranged sales between its members. This occurred when a member authorized Peoples to sell seed to any member who wanted to buy it. It also occurred when a member who wished to buy seed contacted Peoples and not the producing farmer, about the availability of seed. On the other hand, the court held that Peoples' practice of saving a producer's seed for a particular member at the producer's request did not violate the Act because Peoples did not arrange sales of that nature. The court also held that Hollandale was not protected by the crop exemption. Therefore, it violated § 2541(6) by dispensing the seed without notice to purchasers that it was a protected variety. . . .

Section 2543 exempts sales made by a person "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes." It is necessary in this case to determine whether, in order for a sale to fall within the crop exemption, it must be made by a farmer directly to another farmer without the intervention of a third party, as the district court held, or whether a third party such as Peoples may arrange such sales. . . .
In § 2581, Congress made clear its purpose for enacting the Act:

It is the intent of Congress to provide the indicated protection for new varieties by exercise of any constitutional power needed for that end, so as to afford adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties.

Congress expected the Act to stimulate private plant breeding, thus allowing government agricultural experiment stations to increase their efforts in needed basic research, and permit public expenditures for applied plant breeding to be diverted to important areas which industry would not pursue. Passage of the Act would give farmers and gardeners more choice, make American agricultural products more competitive in world markets, and ultimately result in superior products more resistant to disease and infestation and higher in overall yield and quality. "[M]ajor U.S. crops, like cotton . . . now largely ignored by the private researchers, would almost certainly benefit greatly from the impact of a competitive, private plant breeding effort."

During the course of its enactment some legislators expressed concern that the new law would impose higher costs on the farmer, and ultimately, on the consumer. Section 2543 was added in an attempt to allay these concerns. Although that section exempts sales between farmers, Congress recognized that higher seed prices might nevertheless result. In response to a question voicing concern for the farmers, Representative Poage, a congressman instrumental in the passage of the Act, stated:

I do not think there is any doubt that it will mean if somebody produces a seed that gives better results than anybody else's seed, and if he is the only one who can sell that seed, then he will get more for it . . . . This is the only way we know to get people to invest their time and money. It is expensive to develop such seeds. So in the long run we believe there will be beneficial results for the producers and farmers.

Thus, contrary to what Peoples and Hollandale argue, the crop exemption was not intended to provide farmers with unlimited insulation from the negative side effects of the Act.

In purpose and operation, the farmer exemption appears to be at odds with the primary purpose of the Act. While the main body of the Act assures developers of novel varieties the exclusive right to sell and reproduce that variety, the crop exemption dilutes that exclusivity by allowing individual farmers to sell the protected variety without liability. The broader the construction given the exemption, the smaller the incentive for breeders to invest the substantial time and effort necessary to develop new strains. The less time and effort that is invested, the smaller the chance of discovering superior agricultural products. If less time and effort is invested, long-term benefits to the farmer in the form of superior crops and higher yields will be lost. Although it may appear that the broadest reading of the exemption would benefit farmers
today, it could be detrimental to their interests tomorrow.

Thus, the narrower reading of the exemption is more in keeping with Congress' primary objective. Such a reading creates the greatest amount of internal harmony in the overall statutory scheme. We therefore conclude that Congress did not intend for the crop exemption to cover every sale from one farmer to another.

Because the solution adopted by the district court is a reasonable one, we affirm. It prevents the crop exemption from thwarting the purpose of the Act, while preserving the farmer's right to sell his seed directly to other farmers. The court's reasoning is persuasive: Absent active participation by a third party, a farmer's awareness of prospective farmer sellers and purchasers is necessarily limited by his own initiative and personal efforts, which serve to reduce the volume of sales that might qualify for exemption. Where a third party, such as a cooperative association, acts as agent, or broker, by bringing farmer buyers and sellers together, however, the volume of such sales is apt to increase according to the aggressiveness and size of the cooperative, often with no limitation upon its growth. To accord exempt status to extensive sales made on behalf of farmers by such entities would frustrate the basic purpose of providing protection to the breeder.

Under this construction, section 2543 only exempts sales of the protected variety from one farmer directly to another farmer accomplished without the active intervention of a third party. An agent or broker may not arrange the deal. There must be a one-on-one relationship between the farmers.

This is not to say that the seller farmer must physically deliver the seed to the buyer. A sale is exempt if the seller instructs his cooperative to forward his seed to a particular named buyer. In that situation, the cooperative has not arranged the sale. Nor has it played an active role in the transaction. It has merely served as the vehicle for the transfer of possession. A very different situation would develop if the cooperative is permitted to seek out potential buyers or sellers, or even to make it known that it holds seed for purchase by unidentified buyers. In those situations, the cooperative has actually arranged the sale. Therefore, the transaction falls outside the coverage of § 2543. The district court correctly ruled that Peoples' practice in arranging sales in this manner was not exempt under § 2543. Therefore, its conduct violated § 2541(1).

For the same reasons, Hollandale may not benefit from the farmer exemption. Because it dispensed the protected variety without notice that it was protected, it violated § 2541(6).

The crop exemption only contemplates direct sales between farmers without the active participation of a third party. Peoples and Hollandale violated the Act. The judgment appealed from is

Affirmed.

* * * * *
The seeds of discord – a note on "brown-bagging": This much is clear after Delta & Pine Land Co.: farmers cannot use section 2543 as a lever to enter the seed breeding business, in direct competition with commercial breeders who have invested years and millions of dollars in biotechnological research. But when does a farmer leave the business of farming and enter the business of breeding? Cattle ranchers and dairymen who use bull semen know that the distinction can be a tricky one. Consider section 2543's definition of "a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes." The Federal Circuit's initial interpretation of this provision took a binary approach. It assumed that a person's "primary farming occupation" can be determined by halves, so to speak:

[T]o determine application of the crop exemption, a court must determine the amount of crops a farmer grows for sale to consumers and the amount of crops a farmer grows for brown bag sales to other farmers. If a farmer grows more crop from a protected seed variety for sale to consumers than for sale to other farmers for planting, that farmer qualifies under this requirement to buy or sell saved seed. The farmer who qualifies under the entirety of section 2543’s requirements can then sell less than half of the crop grown from a specific novel variety as brown bag seed. A court must conduct this inquiry for each crop or variety of PVPA certified seed.19

Likewise, in Asgrow Seed Co. v. Kunkle Seed Co.,20 the farmer harvested 60,000 bushels of soybeans grown from seeds registered by Asgrow and set aside more than 20,000 bushels as seed. The district court nevertheless refused to grant a preliminary injunction against the farmer. The farmer had set aside less than 50 percent of his harvest, and his "primary" occupation was therefore growing crops for nonreproductive purposes. The parties eventually entered a consent decree that included a permanent injunction against brown-bagging by the farmer.21

Do you detect a potential problem with this interpretation of "primary farming occupation"? Just when does a farmer become a de facto plant breeder – and therefore a potent competitor against a commercial breeder – rather than a producer of food, fiber, or fuel commodities? Is there any agronomic or economic sense in fixing this definition at any particular percentage of a harvest? Even if a farmer diverts half of his or her crop toward nonreproductive purposes, the remainder of the crop retains substantial reproductive potential.

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Consider the following observation by a judge who objected to the Federal Circuit's original interpretation of the crop exemption:

[A] single bushel of soybean seed will produce between 25 and 45 bushels of soybeans. If only half of the crop is sold as seed in successive years, in three years this would allow the farmer to place on the market between 2,037 and 11,655 bushels of seed. . . . [A] single soybean seed, after three crops, would produce 27,000 seeds.\(^\text{22}\)

In other words, even a modest amount of putatively "saved" seed enables a farmer to siphon off a substantial portion of the seed market. A 50 percent limitation has little to no impact on the competitive threat that even one renegade farmer poses to a professional breeder.

In light of the potential for discord, one might ask why Congress included a crop exemption in the PVPA at all? With little or no controversy, the crop exemption covers two traditional farming practices. First, it exempts farmer-to-market sales of a crop grown from protected seeds as food or feed or for other nonreproductive purposes.\(^\text{23}\) Indeed, if the PVPA did not exempt "bona fide sales for other than reproductive purposes, made in channels usual for such other purposes," the statute would bar farmers from selling any crop in which the seed itself is sold for food or fiber.

The exemption also protects the traditional agricultural practice known as "bin run." This facet of the exemption effectively restricts a breeder to a one-time sale with each individual grower of a particular crop:

Bin run allows a farmer to save seed that he produced from a protected variety for use in producing subsequent crops. It is not an infringement for a farmer "to save seed produced by him" from a protected variety and "use such saved seed in the production of a crop." The practice is known as bin run because a farmer stores his crop in a grain bin and then retrieves the crop for use as seed the next planting season. Bin run lets a farmer make only a small initial purchase of seed. Thereafter, the farmer has the potential to multiply his supply of seed. . . . As a result, commercial seed companies can make only small sales, because after the initial purchase, a farmer can produce all the seed he requires.

Bin run is a valuable system for farmers . . . . for two reasons. First,
farmers can rely on bin run since wheat, like soybeans and cotton, is self pollinated, meaning it reproduces true-to-type. Wheat seed produces progeny that maintains the essential characteristics of the variety. In contrast, corn, sorghum and sunflowers are hybrid crops. Corn loses its hybrid vigor after one planting and so new seed must be purchased each year. Hybrids, therefore, need no intellectual property protection as they have biological protection. Second, properly maintained wheat can be kept in storage for years. A farmer need only segregate the varieties and clean the wheat prior to planting.\textsuperscript{24}

Bin run is not accessible to all farmers. It is the province of farmers who are (1) large enough to retain or borrow sufficient capital for building the additional silage and (2) liquid enough to withhold seed from one harvest for use in another crop year. Partial or complete crop failure defeats bin run. Whenever bin run fails or is not feasible, farmers must return to a plant breeder for each new round of seeds. At least in theory, however, bin run and the statutory exemption that makes it possible eliminate constant reliance on professional plant breeders. After one purchase, a farmer can replenish his or her own supply of proprietary seeds. In terms familiar to students and practitioners of intellectual property law, this is a robust version of the "first sale" doctrine under copyright law: the plant breeder gets one chance and one chance only to sell the information "encoded" in PVPA-certified seed to any individual farmer. In terms familiar throughout all of rural America, bin run is crop agriculture's equivalent of the Sears & Roebuck Company's traditional lifetime warranty on Craftsman tools: buy the hammer once, and you can be sure that it will be replaced if it ever wears out.

Imagine, though, how viable the Craftsman guarantee would be if the first purchaser of a Craftsman hammer could effortlessly transform that one hammer into 50 more and then attract potential customers directly away from Sears. That is the difference between bin run and brown-bagging.

Brown-bagging grows out of the crop exemption's protection of sales by a person "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes . . . to other persons so engaged, for reproductive purposes." Brown-bagging farmers can almost invariably underprice plant breeders offering PVPA-protected seed, with merely inconsequential loss in quality. To be sure, Delta bans third-party participation in farmer-to-farmer sales of brown-bagged seed. Even without the mass-marketing support that cooperatives offer, however, individual farmers have successfully advertised and sold brown-bagged seed coast to coast.\textsuperscript{26} (To

\textsuperscript{24}Id. at 4-5.

\textsuperscript{25}Cf. 17 U.S.C. § 109(a).

\textsuperscript{26}See Proposed Amendments to the Plant Variety Protection Act: Hearing Before the Subcommittee on Department Operations, Research, and Foreign Agriculture of the House
be sure, conduct of this sort is illegal even under the Federal Circuit's decision in *Winterboer.* This commercial reality sheds clarifying light on the commercial seed industry's vigorous efforts to defang the PVPA's crop exemption.

In the end, actions speak more loudly than laws. Commercial seed breeders are developing new varieties, but often not the sexually reproduced, open-pollinated varieties covered by the PVPA:

Firms do research on self-pollinated crops, but there is much less incentive to invest heavily because the companies cannot capture profits as they can with hybrids. Competition with saved seed also depresses the prices firms can charge for their seed.  

These economic factors eluded the federal judiciary's implicit assessment of "[t]he public interest" embedded in the crop exemption; social wealth, in the aggregate, was quite arguably not "furthered by providing [local] farmers an opportunity to purchase seed from [a brown-bagging farmer] at a price lower than that charged for legitimate [breeder-provided] seed." Indeed, the Federal Circuit's interpretation of the crop exemption in *Asgrow Seed Co. v. Winterboer* represented such a devastating setback to domestic plant breeders that the structure and direction of the entire industry seemed to hinge on the prospect of judicial relief or legislative reform:

[I]f [Asgrow Seed Co. v. Winterboer] is not reversed by Congress or the Supreme Court, it may encourage seed breeders to seek alternative forms of [intellectual property] protections for their new varieties either in the form of patents or by developing hybrid seed for crops now open pollinated. Developing hybrid seeds has so far proven commercially impractical for many crops, such as wheat, cotton, and soybeans, but may be nearer for canola. Developing hybrids allows the use of trade secrets as in the seed corn industry and reduces the threat of brown bagging. However, hybrids offer their own risks, notably, controlling the identification and use of the small number of self-pollinated seeds that may appear in the...
commercial product, known in the industry as "chasing selfs." . . .

At this juncture, it might help to remember that the PVPA did not spring, Aphrodite-like, from Congress's naked brain. American accession in UPOV, an international agreement on intellectual property rights in sexually reproduced plant varieties, prompted domestic legislation. But American participation in UPOV did not commit the United States to restrict breeders' rights for farmers' benefit. Consider Article 15 of UPOV ("Exceptions to the Breeder's Right"):  

(1) [Compulsory exceptions] The breeder's right shall not extend to  
   (i) acts done privately and for non-commercial purposes,  
   (ii) acts done for experimental purposes and  
   (iii) acts done for the purpose of breeding other varieties . . . .

(2) [Optional exception] . . . [E]ach Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety . . . .

In other words, to the extent that section 113 unraveled the PVPA, Congress inflicted that wound on itself by electing an optional exception to breeders' rights under UPOV. There are no foreigners to blame for this blunder. In fact, might a breeder have plausibly argued that American law actually offended UPOV to the extent that the PVPA's crop exemption entitled farmers to sell protected seeds "for propagating purposes" outside "their own holdings"? The farmer-to-market exemption can be considered an inherent limit on plant variety protection as intellectual property, since its absence would utterly eliminate the market for crops grown from commercially developed, legally protected seeds. Besides, farmer-to-market sales of seeds for nonreproductive uses can hardly be characterized as an encroachment on plant variety developers' right to breed. Bin run falls squarely within the "optional exception" under article 15(2) of UPOV. And, for what it is worth, article 15(1) covers – yea, compels – the PVPA's research

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**Asgrow Seed Co. v. Winterboer**  
Supreme Court of the United States  
115 S. Ct. 780 (1995)

Justice Scalia delivered the opinion of the Court.

The Plant Variety Protection Act of 1970 protects owners of novel seed varieties against unauthorized sales of their seed for replanting purposes. An exemption, however, allows farmers to make some sales of protected variety seed to other farmers. This case raises the question of whether there is a limit to the quantity of protected seed that a farmer can sell under this exemption.

I

In 1970, Congress passed the Plant Variety Protection Act (PVPA) in order to provide developers of novel plant varieties with "adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties." The PVPA extends patent-like protection to novel varieties of sexually reproduced plants (that is, plants grown from seed) which parallels the protection afforded asexually reproduced plant varieties (that is, varieties reproduced by propagation or grafting) under Chapter 15 of the Patent Act.

The developer of a novel variety obtains PVPA coverage by acquiring a certificate of protection from the Plant Variety Protection Office. This confers on the owner the exclusive right for 18 years to "exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom."

Petitioner, Asgrow Seed Company is the holder of PVPA certificates protecting two novel varieties of soybean seed, which it calls A1937 and A2234. Respondents, Dennis and Becky Winterboer, are Iowa farmers whose farm spans 800 acres of Clay County, in the northwest corner of the state. The Winterboers have incorporated under the name "D-Double-U

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34 In addition, new articles 14(2) and 14(3) of UPOV, as amended in 1991, requires ratifying countries (not, at this moment, including the United States) to allow breeders to take legal action against end products made from crops harvested after unauthorized use of protected seed. See generally Hamilton, supra note 17, at 641-43.
Corporation" and do business under the name "DeeBee's Feed and Seed." In addition to growing crops for sale as food and livestock feed, since 1987 the Winterboers have derived a sizable portion of their income from "brown-bag" sales of their crops to other farmers to use as seed. A brown-bag sale occurs when a farmer purchases seed from a seed company, such as Asgrow, plants the seed in his own fields, harvests the crop, cleans it, and then sells the reproduced seed to other farmers (usually in nondescript brown bags) for them to plant as crop-seed on their own farms. During 1990, the Winterboers planted 265 acres of A1937 and A2234, and sold the entire saleable crop, 10,529 bushels, to others for use as seed – enough to plant 10,000 acres. The average sale price was $8.70 per bushel, compared with a then-current price of $16.20 to $16.80 per bushel to obtain varieties A1937 and A2234 directly from Asgrow.

Concerned that the Winterboers were making a business out of selling its protected seed, Asgrow sent a local farmer, Robert Ness, to the Winterboer farm to make a purchase. Mr. Winterboer informed Ness that he could sell him soybean seed that was "just like" Asgrow varieties A1937 and A2234. Ness purchased 20 bags of each; a plant biologist for Asgrow tested the seeds and determined that they were indeed A1937 and A2234.

Asgrow brought suit against the Winterboers in Federal District Court for the Northern District of Iowa, seeking damages and a permanent injunction against sale of seed harvested from crops grown from A1937 and A2234. The complaint alleged infringement under 7 U.S.C. § 2541(1), for selling or offering to sell Asgrow's protected soybean varieties; under § 2541(3), for sexually multiplying Asgrow's novel varieties as a step in marketing those varieties for growing purposes; and under § 2541(6), for dispensing the novel varieties to others in a form that could be propagated without providing notice that the seeds were of a protected variety.

The Winterboers did not deny that Asgrow held valid certificates of protection covering A1937 and A2243, and that they had sold seed produced from those varieties for others to use as seed. Their defense, at least to the §§ 2541(1) and (3) charges, rested upon the contention that their sales fell within the statutory exemption from infringement liability found in 7 U.S.C. § 2543. That section, entitled "Right to save seed; crop exemption," reads in relevant part as follows: "Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: Provided, That without regard to the provisions of section 2541(3) of this title it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained
by authority of the owner for seeding purposes shall not constitute an infringement . . . "

The Winterboers argued that this language gave them the right to sell an unlimited amount of seed produced from a protected variety, subject only to the conditions that both buyer and seller be farmers "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes," and that all sales comply with state law. Asgrow maintained that the exemption allows a farmer to save and resell to other farmers only the amount of seed the seller would need to replant his own fields -- a limitation that the Winterboers' sales greatly exceeded. The District Court agreed with Asgrow and granted summary judgment in its favor.

The United States Court of Appeals for the Federal Circuit reversed. Although "recogniz[ing] that, without meaningful limitations, the crop exemption . . . could undercut much of the PVPA's incentives," the Court of Appeals saw nothing in § 2543 that would limit the sale of protected seed (for reproductive purposes) to the amount necessary to plant the seller's own acreage. Rather, as the Court of Appeals read the statute, § 2543 permits a farmer to sell up to half of every crop he produces from PVPA-protected seed to another farmer for use as seed, so long as he sells the other 50 percent of the crop grown from that specific variety for nonreproductive purposes, e.g., for food or feed. The Federal Circuit denied Asgrow's petition for rehearing and suggestion for rehearing en banc by a vote of six judges to five. We granted certiorari.

II

It may be well to acknowledge at the outset that it is quite impossible to make complete sense of the provision at issue here. One need go no further than the very first words of its title to establish that. Section 2543 does not, as that title claims and the ensuing text says, reserve any "[r]ight to save seed" -- since nothing elsewhere in the Act remotely prohibits the saving of seed. Nor, under any possible analysis, is the proviso in the first sentence of § 2543 ("Provided, That") really a proviso.

With this advance warning that not all mysteries will be solved, we enter the verbal maze of § 2543. The entrance, we discover, is actually an exit, since the provision begins by excepting certain activities from its operation: "Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him . . . and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section . . . ." Thus, a

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2Congress has recently amended this section by striking from the first sentence the words "section: Provided, That' and all that follows through the period and inserting 'section.'" That amendment has the effect of eliminating the exemption from infringement liability for farmers who sell PVPA-protected seed to other farmers for reproductive purposes. That action, however, has no bearing on the resolution of the present case, since the amendments affect only those certificates issued after April 4, 1995, that were not pending on or before that date.
The dissent asserts that the Federal Circuit's more demanding interpretation of "marketing" is supported by the ancient doctrine disfavoring restraints on alienation of property. The wellspring of that doctrine, of course, is concern for property rights, and in the context of the PVPA it is the dissent's interpretation, rather than ours, which belittles that concern. The whole purpose of the statute is to create a valuable property in the product of botanical research by giving the developer the right to "exclude others

farmer does not qualify for the exemption from infringement liability if he has "(3) sexually multiplied the novel variety as a step in marketing (for growing purposes) the variety; or (4) used the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom."

In 1990, the Winterboers planted 265 bushels of Asgrow protected variety seed and collected a harvest of 12,037 bushels of soybeans. The parties do not dispute that this act of planting and harvesting constituted "sexual multiplication" of the novel varieties. The Winterboers sold almost all of these beans for use as seed (i.e., "for growing purposes"), without Asgrow's consent. The central question in this case, then, is whether the Winterboers' planting and harvesting were conducted "as a step in marketing" Asgrow's protected seed varieties for growing purposes. If they were, the Winterboers were not eligible for the § 2543 exemption, and the District Court was right to grant summary judgment to Asgrow.

The PVPA does not define "marketing." When terms used in a statute are undefined, we give them their ordinary meaning. The Federal Circuit believed that the word "marketing" requires "extensive or coordinated selling activities, such as advertising, using an intervening sales representative, or similar extended merchandising or retail activities." We disagree. Marketing ordinarily refers to the act of holding forth property for sale, together with the activities preparatory thereto (in the present case, cleaning, drying, bagging and pricing the seeds). The word does not require that the promotional or merchandising activities connected with the selling be extensive. One can market apples by simply displaying them on a cart with a price tag; or market a stock by simply listing it on a stock exchange; or market a house (we would normally say "place it on the market") by simply setting a "for sale" sign on the front lawn. Indeed, some dictionaries give as one meaning of "market" simply "to sell." Of course effective selling often involves extensive promotional activities, and when they occur they are all part of the "marketing." But even when the holding forth for sale relies upon no more than word-of-mouth advertising, a marketing of goods is in process. Moreover, even if the word "marketing" could, in one of its meanings, demand extensive promotion, we see no reason why the law at issue here would intend that meaning. That would have the effect of preserving PVPA protection for less valuable plant varieties, but eliminating it for varieties so desirable that they can be marketed by word of mouth; as well as the effect of requiring courts to ponder the difficult question of how much promotion is necessary to constitute marketing. We think that when the statute refers to sexually multiplying a variety "as a step in marketing," it means growing seed of the variety for the purpose of putting the crop up for sale. Under the exception set out in the

3The dissent asserts that the Federal Circuit's more demanding interpretation of "marketing" is supported by the ancient doctrine disfavoring restraints on alienation of property. The wellspring of that doctrine, of course, is concern for property rights, and in the context of the PVPA it is the dissent's interpretation, rather than ours, which belittles that concern. The whole purpose of the statute is to create a valuable property in the product of botanical research by giving the developer the right to "exclude others
first clause of § 2543, then, a farmer is not eligible for the § 2543 exemption if he plants and saves seeds for the purpose of selling the seeds that they produce for replanting.

Section 2543 next provides that, so long as a person is not violating either §§ 2541(3) or (4), "it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section . . . ." Farmers generally grow crops to sell. A harvested soybean crop is typically removed from the farmer's premises in short order and taken to a grain elevator or processor. Sometimes, however, in the case of a plant such as the soybean, in which the crop is the seed, the farmer will have a portion of his crop cleaned and stored as seed for replanting his fields next season. We think it clear that this seed saved for replanting is what the provision under discussion means by "saved seed" -- not merely regular uncleaned crop that is stored for later market sale or use as fodder.

There are two ways to read the provision, depending upon which words the phrase "for sale as provided in this section" is taken to modify. It can be read "production of a crop . . . for sale as provided in this section"; or alternatively "use such saved seed . . . for sale as provided in this section." The parallelism created by the phrase "for use on his farm" followed immediately by "or for sale as provided in this section," suggests the former reading. But the placement of the comma, separating "use [of] such saved seed in the production of a crop for use on his farm," from "or for sale" favors the latter reading. So does the fact that the alternative reading requires the reader to skip the lengthy "Provided, That" clause in order to find out what sales are "provided [for] in this section" -- despite the parallelism between "provided" and "Provided," and despite the presence of a colon, which ordinarily indicates specification of what has preceded. It is surely easier to think that at least some of the sales "provided for" are those that are "Provided" after the colon. (It is of course not unusual, however deplorable it may be, for "Provided, That" to be used as prologue to an addition rather than an exception.)

We think the latter reading is also to be preferred because it lends greater meaning to all the provisions. Under the former reading, ("production of a crop . . . for sale as provided in this section") the only later text that could be referred to is the provision for "bona fide sale[s] for other than reproductive purposes" set out in the second sentence of § 2543 -- the so-called "crop exemption." (The proviso could not be referred to, since it does not provide for sale of crops grown from saved seed, but only for sale of saved seed itself.) But if the "or for sale" provision has such a limited referent, the opening clause's ("Except to the extent that . . . .") reservation of § 2541(3) infringement liability (i.e., liability for growing as a step in marketing for reproductive

from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it," etc. Applying the rule disfavoring restraints on alienation to interpretation of the PVPA is rather like applying the rule disfavoring restraints upon freedom of contract to interpretation of the Sherman Act.
purposes) would be devoid of content, since the provision to which it is attached would permit no sales for reproductive purposes. Under the latter reading, by contrast, the farmer may not "use [his] saved seed . . . for sale" as the proviso allows if the seed was intentionally grown for the purpose of such sale — i.e., "sexually multiplied . . . as a step in marketing (for growing purposes) the variety." A second respect in which our favored reading gives greater meaning to the provision is this: The other reading ("crop . . . for sale as provided in this section") causes the "permission" given in the opening sentence to extend only to sales for nonreproductive purposes of the crops grown from saved seed, as opposed to sales of the saved seed itself. But no separate permission would have been required for this, since it is already contained within the crop exemption itself; it serves only as a reminder that crop from saved seed can be sold under that exemption — a peculiarly incomplete reminder, since the saved seed itself can also be sold under that exemption.

To summarize: By reason of its proviso the first sentence of § 2543 allows seed that has been preserved for reproductive purposes ("saved seed") to be sold for such purposes. The structure of the sentence is such, however, that this authorization does not extend to saved seed that was grown for the very purpose of sale ("marketing") for replanting — because in that case, § 2541(3) would be violated, and the above-discussed exception to the exemption would apply. As a practical matter, since § 2541(1) prohibits all unauthorized transfer of title to or possession of the protected variety, this means that the only seed that can be sold under the proviso is seed that has been saved by the farmer to replant his own acreage. (We think that limitation is also apparent from the text of the crop exemption, which permits a farm crop from saved seeds to be

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*This reading also gives meaning to the proviso's statement that "without regard to the provisions of section 2541(3) . . . it shall not infringe any right hereunder" for a person to engage in certain sales of saved seed for reproductive purposes. This serves to eliminate the technical argument that a production of seed which was originally in compliance with § 2541(3) (because it was not done as a step in marketing for reproductive purposes) could retroactively be rendered unlawful by the later sale permitted in the proviso, because such sale causes the earlier production to have been "a step in the marketing" for reproductive purposes.

For crops such as soybeans, in which the seed and the harvest are one and the same, this will mean enough seeds for one year's crop on that acreage. Since the germination rate of a batch of seed declines over time, the soybean farmer will get the year-after-next's seeds from next year's harvest. That is not so for some vegetable crops, in which the seed is not the harvest, and a portion of the crop must be permitted to ripen ("go to seed") in order to obtain seeds. One of the amici in the Court of Appeals asserted (and the parties before us did not dispute) that it is the practice of vegetable farmers to "grow" seeds only every four or five years, and to "brown bag" enough seed for four or five future crops. A vegetable farmer who sets aside protected seed with subsequent replantings in mind, but who later abandons his plan (because he has sold his farm, for example), would under our analysis be able to sell all his saved seed, even though it would plant (in a single year) four or five times his current acreage.
sold— for nonreproductive purposes— only if those saved seeds were "produced by descent on such farm." It is in our view the proviso in § 2543, and not the crop exemption, which authorizes the permitted buyers of saved seeds to sell the crops they produce.) Thus, if a farmer saves seeds to replant his acreage, but for some reason changes his plans, he may instead sell those seeds for replanting under the terms set forth in the proviso (or of course sell them for nonreproductive purposes under the crop exemption).

It remains to discuss one final feature of the proviso authorizing limited sales for reproductive purposes. The proviso allows sales of saved seed for replanting purposes only between persons "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes." The Federal Circuit, which rejected the proposition that the only seed sellable under the exemption is seed saved for the farmer's own replanting, sought to achieve some limitation upon the quantity of seed that can be sold for reproductive purposes by adopting a "crop-by-crop" approach to the "primary farming occupation" requirement of the proviso. "[B]uyers or sellers of brown bag seed qualify for the crop exemption," it concluded, "only if they produce a larger crop from a protected seed for consumption (or other nonreproductive purposes) than for sale as seed." That is to say, the brown-bag seller can sell no more than half of his protected crop for seed. The words of the statute, however, stand in the way of this creative (if somewhat insubstantial) limitation. To ask what is a farmer's "primary farming occupation" is to ask what constitutes the bulk of his total farming business. Selling crops for other than reproductive purposes must constitute the preponderance of the farmer's business, not just the preponderance of his business in the protected seed. There is simply no way to derive from this text the narrower focus that the Federal Circuit applied. Thus, if the quantity of seed that can be sold is not limited as we have described— by reference to the original purpose for which the seed is saved— then it is barely limited at all (i.e., limited only by the volume or worth of the selling farmer's total crop sales for other than reproductive purposes). This seems to us a most unlikely result.

***

We hold that a farmer who meets the requirements set forth in the proviso to § 2543 may sell for reproductive purposes only such seed as he has saved for the purpose of replanting his own acreage. While the meaning of the text is by no means clear, this is in our view the only reading that comports with the statutory purpose of affording "adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties." 7 U.S.C. § 2581. . . .

Reversed.

Justice Stevens, dissenting.

The key to this statutory puzzle is the meaning of the phrase, "as a step in marketing," as used in 7 U.S.C. § 2541(a)(3). If it is synonymous with "for the purpose of selling," as the Court
holds, then the majority's comprehensive exposition of the statute is correct. I record my dissent only because that phrase conveys a different message to me.

There must be a reason why Congress used the word "marketing" rather than the more common term "selling." Indeed, in § 2541(a)(1), contained in the same subsection of the statute as the crucial language, Congress made it an act of infringement to "sell the novel variety." Yet, in § 2541(a)(3), a mere two clauses later, Congress eschewed the word "sell" in favor of "marketing." Because Congress obviously could have prohibited sexual multiplication "as a step in selling," I presume that when it elected to prohibit sexual multiplication only "as a step in marketing (for growing purposes) the variety," Congress meant something different.

Moreover, as used in this statute, "marketing" must be narrower, not broader, than selling. The majority is correct that one dictionary meaning of "marketing" is the act of selling and all acts preparatory thereto. But Congress has prohibited only one preparatory act — that of sexual multiplication — and only when it is a step in marketing. Under the majority's broad definition of "marketing," prohibiting sexual multiplication "as a step in marketing" can be no broader than prohibiting sexual multiplication "as a step in selling," because all steps in marketing are, ultimately, steps in selling. If "marketing" can be no broader than "selling," and if Congress did not intend the two terms to be coextensive, then "marketing" must encompass something less than all "selling."

The statute as a whole — and as interpreted by the Court of Appeals — indicates that Congress intended to preserve the farmer's right to engage in so-called "brown-bag sales" of seed to neighboring farmers. Congress limited that right by the express requirement that such sales may not constitute the "primary farming occupation" of either the buyer or the seller. Moreover, § 2541(a)(3) makes it abundantly clear that the unauthorized participation in "marketing" of protected varieties is taboo. If one interprets "marketing" to refer to a subcategory of selling activities, namely merchandising through farm cooperatives, wholesalers, retailers, or other commercial distributors, the entire statute seems to make sense. I think Congress wanted to allow any ordinary brown-bag sale from one farmer to another; but, as the Court of Appeals concluded, it did not want to permit farmers to compete with seed manufacturers on their own ground, through "extensive or coordinated selling activities, such as advertising, using an intervening sales representative, or similar extended merchandising or retail activities."

This reading of the statute is consistent with our time-honored practice of viewing restraints on the alienation of property with disfavor. The seed at issue is part of a crop planted and harvested by a farmer on his own property. Generally the owner of personal property — even a patented or copyrighted article — is free to dispose of that property as he sees fit. A statutory restraint on this basic freedom should be expressed clearly and unambiguously. As the majority recognizes, the meaning of this statute is "by no means clear." Accordingly, both because I am persuaded that the Court of Appeals correctly interpreted the intent of Congress, and because doubts should be resolved against purported restraints on freedom, I would affirm the judgment.
DELTA AND PINE LAND COMPANY v. The SINKERS CORPORATION
177 F.3d 1343 (Fed. Cir. 1999)

MICHEL, Circuit Judge.

Plaintiffs-Appellants Delta and Pine Land Company ("DPL") and Mississippi Agriculture and Forestry Experiment Station (a unit of the Mississippi State University) ("Mississippi") (collectively, "Delta") appeal from the judgment of the United States District Court for the Eastern District of Missouri dismissing all of Delta's claims against The Sinkers Corporation ("Sinkers"). See Delta and Pine Land Co. v. The Sinkers Corp., No. 93CV77- DJS (E.D.Mo. Mar. 5, 1998). Delta is the owner of numerous Certificates of Plant Variety Protection ("PVP Certificates") issued by the Plant Variety Protection Office of the United States Department of Agriculture, including PVP Certificates for many varieties of cotton, several of which are at issue here. Delta brought the instant action in the district court, claiming infringement of Delta's intellectual property rights under the Plant Variety Protection Act ("PVPA"), 7 U.S.C. §§ 2321-2581 (1994). Specifically, Delta presented three claims that Sinkers infringed their rights by: (1) transferring possession of protected seed without Delta's authority; (2) failing to mark bags of protected seed with a notice that they contained protected seed; and (3) funneling large quantities of protected seed through its facilities with knowing indifference to the lack of authority from Delta and the absence of an exemption, thereby actively inducing infringing acts by others. Following a bench trial, the district court found no infringement and dismissed all three of Delta's claims on March 5, 1998. The appeal was submitted for our decision following oral argument on February 2, 1999. We affirm the district court's dismissal of Delta's active inducement claim; we vacate the district court's dismissal of Delta's unauthorized transfer of possession and failure of notice claims as based on the application of incorrect legal tests concerning implied exemptions under the PVPA; and we remand Delta's transfer of possession and notice claims to the district court for superseding fact-finding under the correct construction of the disputed terms of the relevant subsections of the statute as set forth herein, or such further proceedings as it deems necessary, consistent with our opinion.

BACKGROUND

DPL is a developer and breeder of cotton planting seed. It holds numerous PVP Certificates protecting its novel seed varieties. DPL sells these protected cottonseed varieties through approved distributors. The authorized distributors sell seed to growers who plant the seed, harvest the cotton, and then dispose of all excess protected cottonseed.

Mississippi is engaged in developing, breeding and processing cotton planting seed for the production of commercial crops. Mississippi owns a PVP Certificate for a cotton variety known as DES-119, and has granted DPL an exclusive license for the sale and distribution of this seed. Pursuant to this agreement, DPL distributes DES-119 cottonseed to farmers through its
approved distributors.

Sinkers is headquartered in Kennett, Missouri. Its principal business activity consists of delinting and conditioning cottonseed for use as planting seed. Cotton growers bring undelinted cottonseed to Sinkers, Sinkers delints the cottonseed per their request, and then turns the cottonseed over to whomever the grower specifies. The delinting process is an essential step in preparing cottonseed for planting. Virtually all cotton farmers in the United States utilize delinted cottonseed in planting their crops.

To process cottonseed, such as a farmer might purchase from Delta, the seed is first taken to a gin where most of the fiber or lint is separated from the seed. The seed can then be taken to a delinter, such as Sinkers. The delinting process removes the remaining lint. Undelinted, but ginned, cottonseed arrives at Sinkers's Kennett facility in a truck. In some cases, individual farmers bring cottonseed to the facility in pickup trucks. In other cases, however, large quantities of cottonseed, from many different distributors, farmers and farming cooperatives, arrive in tractor-trailer rigs. Upon its arrival at Sinkers's facility, undelinted cottonseed is placed in a "run bin". The seed is then fed into an auger, where it is wetted with a sulfuric acid solution. From there, the seed passes through a centrifuge where the solution is spun off. The seed emerges in a damp-dry condition and is passed through two dryers and two buffers. In the drying and buffing process, all remaining lint is separated from the seed. After culls, sticks and debris are removed from the bulk seed, the seed is treated with chemicals (if the client so requests--this is the "conditioning" stage of the process, the seed having by now been delinted), and then placed in fifty-pound bags. [FN2] After the seed has been bagged, it is loaded onto trucks and transported to its next destination, which may or may not be the place from which the seed was sent, depending on the instructions given to the delinter.

FN2. This seed is typically referred to as "brown bag seed".

Delta develops new varieties of seed by pollinating one unique variety with another. A new variety sought to be reproduced for sale by DPL is turned over to DPL's foundation seed department, which increases the volume through repeated replanting while protecting the genetic purity of the variety, to reach saleable quantities of seed. Thereafter, to increase the amount of seed they have to sell, DPL hires farmers as contract growers who will return to DPL the progeny of their crop. These seed varieties are protected by the PVPA, which "protects owners of novel seed varieties against unauthorized sales of their seed for replanting purposes." Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 181, 115 S.Ct. 788, 130 L.Ed.2d 682 (1995).

In 1992, Delta obtained information which led them to believe that cottonseed of their PVPA-protected varieties was being delinted at Sinkers's delinting facility in Kennett, Missouri, and was being sold in violation of Delta's rights under the PVPA. In essence, Delta believed that suspected sales by Sinkers, which were certainly unauthorized by Delta, did not fall within any of the statutory exemptions to the PVPA. ... The district court found, at the conclusion of a bench trial, that Delta had failed to prove by a preponderance of the evidence that Sinkers committed any violations of Delta's PVPA rights. In essence, the court found that as a passive conduit of seed which it transferred according to the instructions of its customer, Sinkers had no liability
under the PVPA, as construed by the district court. All injunctive relief and damages were, therefore, denied.

... 

DISCUSSION

The relevant subsections of the PVPA provide as follows:

[I]t shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a novel plant variety with the notice under section 2567 of this title:

(1) sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

(6) dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or ...

(8) instigate or actively induce performance of any of the foregoing acts.

7 U.S.C. § 2541 (emphasis added). As can be seen from the above language, the PVPA gives the holder of a PVP Certificate rather broad exclusive rights. However, at the time this case was brought in the district court, there was one express, broad exemption to these exclusive rights.

[FN3] The PVPA allowed a farmer to save seed and to use such "saved seed" to produce crops on his own farm, and furthermore allowed certain "farmer-to-farmer" sales of excess saved seed. This exemption was contained in 7 U.S.C. § 2543, which provided as follows:

FN3. This exemption is no longer part of the PVPA. The pertinent language was deleted from the statute in 1994 greatly narrowing this sole express exemption. The amendments deleting certain language, however, apply only to PVP Certificates issued after April 4, 1995, that were not pending on or before that date. See Pub.L. No. 103-349, §§ 14(a), 15, 108 Stat. 3144, 3145 (1994). Thus, the original exemption applies to this case, for all asserted certificates were issued before April 4, 1995.

Except to the extent that such action may constitute an infringement under §§ 2541(3) and (4), it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained ... by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: Provided, that without regard to [§ 2541(3) ] it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes.

The Supreme Court later interpreted this exemption to mean that, for a farmer to meet the requirements of the above proviso, the farmer may sell for reproductive purposes only so much
seed as he has saved for the purpose of replanting his own acreage. See Asgrow Seed Co. v. Winterboer, 513 U.S. 179, 192, 115 S.Ct. 788, 130 L.Ed.2d 682 (1995). Presumably, such sales occur only when the farmer reduces or eliminates his cotton acreage, and, thus, has "saved seed" for which he or she has no farming use. Otherwise, there has been little case law interpreting the PVPA. But the language of the statute is clear: the only express exemption to a PVP Certificate holder's rights is that included in section 2543 for farmer-to-farmer transfers of protected seed. In the instant case, however, the district court implied an additional exemption to the rights of a PVP Certificate holder. We must decide if the court was correct in its discernment and its definition of this exemption.

I. Transfer of Possession Without Authority: 7 U.S.C. § 2541(1)

Delta alleges that Sinkers infringed their rights under 7 U.S.C. § 2541(1) "merely by virtue of its transfer of possession of seed without the benefit of an exemption from PVPA liability." Pl.-Appellant's Br. at 4. Sinkers's defense rested on an extension of the express exemption for the farmer-to-farmer sales that it viewed as implied in the PVPA, as previously interpreted. Sinkers argued that it was a mere passive third-party to the lawful transfers of possession incident to sales arranged between farmers under the express exemption and therefore could not itself be liable. Until Asgrow, the leading case on the farmer-to-farmer exemption was Delta and Pine Land Co. v. Peoples Gin Co., 694 F.2d 1012 (5th Cir.1983) ("Peoples"). It remains the only other significant precedent on implied exemptions under the PVPA.

... In the instant case, however, the district court made a fact-finding that Sinkers did not broker or actively intervene to arrange the sales that led to the transfers of possession challenged by Delta. See Delta and Pine Land Co., slip op. at 19. We must agree with that fact-finding because on this record it cannot be seen as clearly erroneous. Indeed, it is essentially undisputed. Therefore, we see this case as entirely distinguishable on its facts from Peoples. See Peoples, 694 F.2d at 1012. The issue raised in this case, then, is one of first impression. It is whether a passive third-party to a sales transaction, such as a ginner or a delinter, can be held liable for infringement under 7 U.S.C. § 2541(1), as a participant in unauthorized possession transfers, if they fall outside the farmer-to-farmer exemption.

... [T]he district court applied an active/passive (or broker/non-broker) distinction to the subsection (1) transfer of possession claim in the instant case, even though Sinkers was obviously not a broker, holding that:

the passive conduct of [Sinkers] on the facts here [does] not ... constitute a delivery, shipment or transfer of possession of seed by [Sinkers] within the meaning of § 2541(1), regardless of whether the seed involved is protected or the underlying sale or transfer involving [Sinkers's] customer is within the § 2543 exemption.

Delta and Pine Land Co., slip op. at 20 (emphasis added).

Today we hold that the district court's interpretation of 7 U.S.C. § 2541(1) is erroneous as it neither comports with the plain meaning of subsection (1) ("any other [unauthorized] transfer
of ... possession" of seed varieties for which someone holds certificates (emphasis added)), nor the evident intent of Congress as seen in the statute as a whole.

Significantly, although the word "active" appears in 7 U.S.C. § 2541(8), it does not appear in 7 U.S.C. § 2541(1). Because the plain language of subsection (1) itself does not require the transfer act to be an "active" one, i.e., by a broker, the subsection necessarily appears to comprehend a situation where infringement by transfer of possession could occur without the delinter or a third party brokering a sale, or deciding to whom to transfer possession, but rather was nonetheless transferring possession without authorization from the PVP Certificate holder. Applying the exemption more broadly to grant blanket immunity to a delinter conflicts with the provision providing for liability for any transfer of possession of protected seed.

More importantly, we do not believe the adaptation of Peoples to this case by the district court was consistent with the structure and purpose of the prohibition on unauthorized and non-exempt transfers of possession in subsection (1). The district court is, in effect, adding limiting language ("actively") to subsection (1) that was left out by Congress in subsection (1) and used by Congress only in subsection (8). The purpose of the PVPA was to "afford adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties." 7 U.S.C. § 2581 (1988). Congress laid out many ways to infringe the rights of an owner of a certificate for a novel variety in 7 U.S.C. § 2541, including to "deliver", or "ship", or make "any ... transfer of title or possession of it," and to "instigate or actively induce performance of ... the foregoing acts." The district court found that Sinkers did not induce anyone to take possession of or sell the seed. The district court also found that Sinkers did not transfer title to the seed. However, Sinkers undeniably transferred possession of the seed, when it delivered the seed to whomever its customer requested delivery be made. Sinkers was given control over the undelinted seed by the farmer or cooperative that delivered the seed to Sinkers, and then Sinkers transferred control of the delinted seed to the farmer or cooperative identified as the recipient by Sinkers's customer. For these reasons, we hold there is no requirement associated with subsection (1) of active intervention or brokering, as there is with subsection (8). The district court therefore applied the wrong legal test and accordingly its dismissal of Delta's claims under 7 U.S.C. § 2541(1) was error. The dismissal is therefore vacated.

On the other hand, the broadest possible reading of subsection (1) does not make much sense to us, either. As a matter of common sense, there must be some limitation inherent in its applicability, despite the scant legislative history which says only:


We cannot imagine that Congress would have meant to make a completely innocent third-party liable for infringement because it transferred possession of seed to a farmer at the request of another farmer, its customer. An example of when Congress could not have meant to impose liability might be where a single farmer, Joan, brings in one truckload of seed to be delinted, and Farmer Bob picks the seed up in a transfer of possession that is illegal, because, unbeknownst to the delinter, Joan does not actually farm cotton. Thus, while the transaction
appears to fall within the exemption for farmer-to-farmer transfer, actually it does not. The delinter, we think, should be liable for all illegal transfers of possession, when not brokered by them, only if it has scienter. That is, when transferring possession of protected seed under instructions from its customer, the delinter is liable only if it knows the transfer is not within the exemption for farmer-to-farmer transfers. Absent scienter, however, involvement in farmer-to-farmer transfers outside the express exemption, should not subject delinters and ginners to liability for infringement.

The dissent disagrees with this test, arguing, in effect, that delinters and ginners should not be liable for infringement, even with scienter, as long as they did not broker the transfer of possession of the seed. We do not believe that Congress meant for delinters and ginners to be exempt from infringement of the PVPA, even when they are following the instructions of their customers, if they know they are participating in an illegal activity. An example of a scenario highlighting this difference between the dissent's view and our own might be one in which Farmer Joan brings in her seed to be delinted, and signs a contract for two points of delivery. Farmer Joan has had a bumper harvest of protected cottonseed this year, in our example, and Farmer Bob has had a terrible year. Farmer Joan agrees to sell her excess protected seed to Farmer Bob, so that he doesn't have to pay the higher prices charged by the PVP Certificate holder for the protected seed. Farmer Joan tells the delinter that she would like half of her seed delinted and returned to her so that she can replant the same acreage that she had the year before (e.g., the "saved seed" allowed under Asgrow ). Farmer Joan then tells the delinter that she would like the other half of her protected seed delinted and delivered to Farmer Bob to use for reproductive purposes on his farm. The delinter at this point clearly has scienter, and knows that Farmer Joan, at least, is participating in an unlawful activity. We cannot believe that Congress did not mean for the delinter to be found liable for infringing the PVPA in this scenario, but that is the result the dissent's test would cause. ...

We therefore hold that the correct reading of subsection (1) requires that a delinter, ginner, or other third-party transferor facilitating a farmer-to-farmer sale know (knowledge is presumed in a scenario where the third party brokers the transaction) or should reasonably know that its unauthorized transfer of possession is an infringing transaction, i.e., that the sale is not exempt under section 2543. Liability for infringement under subsection (1) thus turns on knowledge. If Sinkers knew, or should have known, that the transfer of possession was not within the farmer-to-farmer exemption, then it can be held liable for infringing subsection (1), but only then.

We note that the district court also erred in stating that "the passive conduct of [Sinkers] on the facts here [does] not ... constitute [infringement] ... regardless of whether the seed involved is within the § 2543 exemption." Delta and Pine Land Co., slip op. at 20 (emphasis added). Under Asgrow a farmer is allowed to save seed to replant his or her own acreage the next year. In order to plant the seed it must be delinted. Therefore, Asgrow must also carve an exemption out for the transfer of possession of protected seed to a delinter if it is only the seed the farmer is saving for his or her own acreage. Whether the seed involved is within the section 2543 exemption thus becomes a crucial and important question.

We vacate the district court's decision and remand for a reconsideration of the claim of
infringement by the unauthorized transfer of possession under the correct legal test as described above. It may make a difference in result as illustrated by at least one sale of record, as discussed below. Therefore, it cannot be deemed harmless error.

The district court found that Nodena, a family cooperative of several corporations and individuals that conducted farming operations in Mississippi County, Arkansas, was a large customer of Sinkers and had its cottonseed delinted by Sinkers. The district court furthermore found that in calendar year 1993, Nodena sold to other farmers over 122 tons of cottonseed for planting ("reproductive") purposes that Sinkers had delinted. A further fact-finding was that at least some of this seed was referenced in Sinkers's germination logs as "Lot 5" seed, reflecting Nodena's practice of designating seed in that manner to indicate that the seed was DPL-50 seed, a variety of seed protected under Delta's PVP Certificates. The district court's only finding regarding Sinkers's exact role in these transactions was that "the considerable evidence involving sales by Nodena Planting Company to other farmers does not suggest that defendant played any role in arranging those sales." Delta, slip op. at 18 (emphasis added). The district court did not address what Sinkers's knowledge was of the legality of its transfer of possession according to Nodena's directions. It seems clear, for instance, when Nodena brought in 122 tons of undelinted seed in 1993, although only three years earlier Nodena had brought in just fifty-seven tons, that it would be highly unusual for all of that seed to be seed saved by Nodena to replant its own members' fields. On the other hand, if Sinkers knew that Nodena, a farming cooperative, had greatly increased its total cotton acreage, for example, as a result of signing up additional farmers, then the opposite inference might be warranted. In this scenario, if the district court were to find that Sinkers knew or should have known it was involved in non-exempt farmer-to-farmer transactions, it must be held liable for infringing 7 U.S.C. § 2541(1). This would be so, even if Sinkers was not expressly informed by Nodena that the 122 tons of seed was more than the amount of seed Nodena was allowed to save from year to year, because it would be reasonable and necessary to infer such knowledge. This is true, even if the seed were returned to Nodena by Sinkers, because the amount, if Nodena had not greatly increased its total acreage, greatly exceeds the amount of seed that Nodena is allowed to save under the exemption as construed in Asgrow.

We note that the scenario where the seed is returned to the farmer or cooperative from which the seed was received potentially complicates application of the "should have known" standard, as a farmer is entitled to save seed for reproductive use on his own farm, and may in fact save seed for several years of future plantings. However, there are still "red flags" which a delinter such as Sinkers can spot. If a farmer returns year after year with more seed than he or she could possibly use, based either on Sinkers's knowledge of the actual size of the farmer's acreage or, as in the Nodena example, simply an absurdly large amount of seed, then clearly this seed is not being saved for reproductive purposes just for the farmer's own acreage, and Sinkers would have scienter. Under the correct test, the outcome at least as to the Nodena seed could well be different, although we, of course, do not so decide here.

... Presumably the ginners and delinters process seed full-time. This would suggest that they work with the same farmers from year to year, and have some idea of how much seed is a
reasonable amount of saved seed for a particular farmer, or farming cooperative lawfully to bring in for processing. It should be obvious, for example, that enough seed to replant forty square miles of cotton fields is not a reasonable amount for a cooperative to bring in as saved seed for processing. In such a case, but only then, the ginner or delinter may indeed want to ask for written reassurance that it will not be breaking the law by processing this huge quantity of seed, because processing inevitably requires transferring possession of the seed, once delinted or ginned, to someone. However, this written assurance does not impart immunity. If the certificate holder can prove actual knowledge, or show that the delinter or ginner should have known it was handling hot seed, the delinter or ginner is still liable for infringement of the PVPA. We note, furthermore, that while, of course, on this record we could not describe the contents of a standard contract between a farmer or cooperative and a delinter or ginner, it is reasonable to assume that it would address: the price per pound for the processing; the delivery terms; and the condition the farmer can expect the seed to be in when it is returned or re-delivered by the ginner and/or delinter. This contract may also specify the chemical conditioning treatments the farmer or cooperative wants the seed exposed to ("So ... they tell you ... whether they want [the seed] double treated or triple treated" J.A. at 306); the amount of cleaning the seed should be given ("we have ... some farmers that like to have the seed ... cleaned a little heavy [,t]ake a little more waste out to give you a better seed" J.A. at 307); it may give the farmer a warranty that his seed will not be mixed with colored cottonseed, that his seed will not be mixed with non-USDA approved seed, and that he will receive the same variety of seed back that he dropped off to be processed. We do not believe, with this many other specifications which may be present in a contract for cottonseed processing, that it is placing a significant burden on the delinters or ginners to place one more paragraph in the contract, thus providing some limited protection against liability. Accordingly, our test hardly "creates" a complex record-keeping regime. One apparently already exists.

II. Active Inducement by Brokerage: 7 U.S.C. § 2541(8)

Delta next alleged that by willfully ignoring the large quantities of apparently protected seed that Sinkers was processing without its authority, Sinkers actively induced unlawful transfers of possession by others, and thus infringed Delta's rights under 7 U.S.C. § 2541(8). The district court found, as stated above, that Sinkers did not intervene as a third-party in the transfers of possession of the protected seed. We agree, for it was not clear error for the district court to find that Sinkers did not broker protected seed transfers and did not actively induce anyone to transfer possession of the seed to other parties in any way violative of the statute. Sinkers merely turned delinted seed over to whomever its customers, such as Nodena, identified. In subsection (8) of section 2541, the critical words "instigate or actively induce", clearly evince congressional intent to limit liability under this subsection to those such as brokers, who perform such functions when they arrange transfers of seed, in the instant case via the delinter, between independent sellers and buyers. The district court correctly found, however, that Sinkers did not perform either of these functions. Certainly, its findings are not clearly erroneous. ...Indeed, the facts seem undisputed. Delta argues here only that Sinkers recklessly or with willful indifference
transferred possession of large quantities of protected seed in violation of the PVPA. This might be true, but we make no decision on that issue here, because, even if the allegation is true, it is insufficient to trigger 7 U.S.C. § 2541(8). Sinkers did not broker the sale or transfer of possession of any protected seed, or otherwise instigate or actively induce others to infringe. We therefore affirm the district court's dismissal of Delta's claim against Sinkers for actively inducing infringement of Delta's PVPA rights under 7 U.S.C. § 2541(8).


Finally, we address the issue of the notice required under subsection (6) of 7 U.S.C. § 2541. The district court only summarily addressed this issue, holding that "the Court would read the 'under which it was received' clause of § 2541(6) to limit the notice requirement to instances in which the seed was received with a label stating that it was a protected variety." Delta, slip op. at 23 (emphasis added). We vacate the judgment based on this holding by the district court. The proper test is not whether a physical label is somehow attached to the seed when the seed is received, but rather whether through that or other means the one in receipt, here Sinkers, knew, or should have known that the seed is a protected variety. Subsection (6) provides that it is infringement to "dispense the novel variety to another ... without notice as to being a protected variety under which it was received." The notice that must be received is not restricted to actual notice, or to notice in the form of labels on the seed, as the district court concluded, or else Congress would surely have included language indicating such restrictions.

Once again, if we look at the Nodena example discussed above, we can see why this case must be remanded for application of the correct legal test to the facts, which might result in a potentially different outcome. In the Nodena example, the district court found that references in Sinkers's own germination logs to this seed as "Lot 5" seed reflected Nodena's own designation of the seed in that manner to indicate that the seed was DPL-50 seed. See Delta and Pine Land Co., slip op. at 11. Under the test applied by the district court, because this seed arrived with no physical tag on it to indicate that it was protected DPL-50 seed, Sinkers had no responsibility to notify its transferee that the transferred seed was protected seed. However, Sinkers was informed by Nodena that it was Lot 5 seed, according to the notations in its own logs. If on remand the district court finds that Sinkers had notice, i.e., that it knew the term "Lot 5" was Nodena's way of designating protected DPL-50 seed, then Sinkers infringed Delta's way of designating protected DPL-50 seed when it did not label the bags containing Nodena's delinted seed as protected seed. We further understand that in order to protect the vigor and germination ability of the cottonseed, the delinter and ginner need to know the type of seed they are processing so that they know how to process it, e.g., the proper storage method, the amount of moisture to expose it to, and the temperature least likely to cause it to germinate early. Early maturation seed that has undergone no chemical treatments by the manufacturer, is processed differently from late maturation seed that may have been genetically altered to not be affected by herbicides. It is, therefore, likely that they are accurately informed by the cooperative and farmers of the varieties of seed being delivered for processing and that they may want to take affirmative steps, e.g., germination tests, to assure themselves of the exact varieties accepted for processing, lest they become liable for harming the seed. Once a
ginner or delinter has determined the variety of cottonseed undergoing processing, it has an affirmative duty to label the cottonseed with the variety upon returning or re-delivering the cottonseed.

...
4. Abby Hoffman, a famous radical in the 1960s and 1970s, wrote a book titled *STEAL THIS BOOK*. Edward Abby, a famous environmentalist, wrote a novel titled, *THE MONKEY-WRENCH GANG*. Both books are in the genre of anti-establishment, anti-authority, and anti-capitalist literature. Do you think that the attitudes expressed in those books shape or affect how people respond to the *Sinkers Corporation* case?

* * * * *

4. **Revisiting and revitalizing the PVPA**

*Revision of the PVPA's crop exemption.* A desire to conform to UPOV finally provided the putative impetus for the long-awaited reform of the PVPA's crop exemption. Congress described the Plant Variety Protection Act Amendments of 1994\(^{35}\) as an effort to make the PVPA "consistent with the International Convention for the Protection of New Varieties of Plants of March 19, 1991, to which the United States is a signatory."\(^{36}\) Throughout the debates over the PVPA amendments, "it [was] apparent that the farmer's exemption [was] the most contentious issue."\(^{37}\)

* * * * *

**Plant Variety Protection Act Amendments of 1994**

House of Representatives, Committee on Agriculture  

[The amendments are] intended to conform the Plant Variety Protection Act to the articles of the International Convention for the Protection of New Varieties of Plants of March 1991, otherwise referred to as the UPOV Convention.

In the United States, one effective form of protecting new plant varieties that are reproduced by seed is by means of the Plant Variety Protection Act (PVPA). The PVPA . . . provides for the issuance of "certificates of plant variety protection" assuring the developers of novel varieties of sexually reproduced plants exclusive rights to sell, reproduce, import or export


such varieties, or use them in the reproduction of hybrids or different varieties.

To afford our plant breeders protection in other countries as well, the United States became a member of the 1978 Act of the UPOV Convention, in 1981 by Executive Agreement. The UPOV currently has 25 member countries and provides for uniform practices in the construction and administration of plant variety protection laws in the various member states. After several years of extended negotiations, the UPOV Convention was significantly revised in 1991 to provide plant breeders with improved protection for innovative plant varieties. The United States is a signatory to the 1991 Act of the UPOV Convention and this legislation will conform the Plant Variety Protection Act of the United States to the 1991 revision of the UPOV agreement.

Development of new plant varieties is important for reasons beyond increasing the production of food and fiber. The ever-changing picture of plant pests and diseases is a frightening one. New pests, like the Russian wheat aphid, are sometimes introduced into this country despite our best efforts at quarantine. New strains of fungus, like the newest forms of barley stem rust and leaf rust, evolve and threaten cereal production. The most environmentally-sound method of coping with these threats is to develop new resistant varieties of crop plants.

Increasing pressure on the environment also necessitates the development of new plant varieties that are more efficient consumers of resources and producers of food and fiber. Drought-tolerant varieties of buffalo grass, for example, may hold out promise of turf that needs less watering than more conventional grass. Increased production per acre remains a goal of the plant breeder these days when more and more agricultural land is being converted from agricultural use to housing and industry.

The development of new plant varieties is arduous, time-consuming, and costly. Many years must be spent in the development of a single new variety, with no guarantee of its success or profit. By granting to the owner of a variety the right to prevent unauthorized sale of seed of that variety, the PVPA provides the owner with the opportunity to recover the costs of development. This encourages investment in new varieties that respond to the changing needs of American agriculture.

Major provisions of [these amendments] include: (1) Prohibiting the unauthorized sale of seed by farmers to others; (2) establishing a category of "essentially derived varieties"; (3) using date of filing for protection as the basis for determining eligibility for protection; (4) requiring that protected varieties be sold by variety name only (with a narrow exemption provided for lawn, turf, or forage grass seed, alfalfa, or clover seed); (5) extending protection to first generation hybrids; (6) extending the period of protection from 18 to 20 years for most crops and from 18 to 25 years for trees and vines; and (7) expanding the scope of protection. Each of these changes are needed to conform the PVPA to the 1991 Act of the UPOV Convention. In addition, and at the request of the potato industry, a provision is made for including tuber-propagated
varieties within the scope of the PVPA. This legislation will, therefore, enable the United States to ratify the 1991 UPOV Convention.

Section 10 of the bill amends section 113 of the PVPA by deleting the provision of current law that allows a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell "saved seed" to other such persons, for reproductive purposes. The amendment does not diminish the right of a farmer to save seed for replanting and to use the resulting crop or to sell the seed for other than reproductive purposes.

It is not the intent of the Committee that deletion of the provision allowing the sale of saved seed to be viewed as a step toward the eventual end to the traditional right of farmers to save seed for use on their own holdings. During the UPOV negotiations, many representatives to the UPOV conference asserted that farmers in their countries had a traditional right to save seed for their own use and that removal of this right would likely preclude some non-member countries, currently considering joining, from doing so. Retention of the farmers' exemption is an attempt to balance the varying interest of U.S. companies and producers, as well as to strengthen acceptance of plant breeders' rights internationally. The PVPA exemption concerning a farmer's use of saved seed should be interpreted in a practical manner. The exemption should not be limited, for example, to the replanting of saved seed on the same acre from which it [is] harvested. Instead, the exemption should be interpreted broadly to allow the farmer, for example, to plant the saved seed on any acreage involved in the farmer's partnership, or corporate farming operation, whether the land is rented or owned by the farming operation. In another example, in the normal course of the ginning of cotton, seed can become commingled, one farm's with another's. This is a result of the manner in which seed is removed from cotton and stored at the gin. The saved seed exemption is not to be interpreted so restrictively as to place cotton farmers (or other farmers in similar situations) in jeopardy of violating the PVPA because seed may become commingled due to established agricultural practices.

This modification to section 113 is to prevent farmers from selling seed of protected varieties, for the purpose of propagation, without permission of the certificate owner. The committee realizes that in some cases farmers may have incidental amounts of treated seed or saved seed for use pursuant to section 113 and, due to prevented planting or other unforeseen causes (such as a change in government farm programs), may have excess seed. Under these circumstances, the Committee encourages farmers to seek, and certificate owners or their agents to grant, on a case-by-case basis, permission for sale of such incidental amounts of seed. Certificate owners are encouraged to establish and have in place clear policies that allow such requests to be handled at the farmer/dealer level.

Although for purposes of sections 111 and 113 it shall remain within the sole prerogative of the owner of a protected variety to give consent for the sale of such variety, consent to sell saved seed should ordinarily not be withheld from a farmer in circumstances irreparably affecting the farmer's economic viability. For example, where the farmer is unable to plant seed saved
with the intent of planting a particular crop because of serious illness or disability, financial distress, or other unanticipated events that unavoidably disrupt farming operations, or upon disposition of all farm assets and inventory, consent to sell such seed should generally be granted. Even under such dire circumstances, however, consent may still be limited to the sale of seed only to another farmer whose primary occupation is the growing of crops for other than reproductive purposes, and in an amount not to exceed that which was saved by the first farmer for planting that year's crop on the first farmer's holdings.

* * * *

After the 1994 amendments, section 113 of the PVPA reads as follows:

§ 2543. Right to save seed; crop exemption

Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm the farm of the person, or for sale as provided in this section. Provided, That without regard to the provisions of section 2541(3) of this title it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable. section. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. A purchaser who diverts seed from such channels to seeding purposes shall be deemed to have notice under section 2567 of this title that his actions constitute an infringement.

* * * *

(i) PVPA protection reborn and reinvigorated? The 1994 amendment of the PVPA's crop exemption represents a virtually complete victory for plant breeders over advocates of brown-bagging. As framed by Winterboer, the debate over the old crop exemption was whether a brown-bagging farmer could sell up to half of a crop or merely an "incidental" amount limited by the scale of ordinary (and
The new crop exemption disallows brown-bagging altogether, and the "incidental" sales exception once regarded as a reasonable compromise has been relegated to the realm of wishful thinking. Even if we take the House Agriculture Committee at its word, sales of protected seeds by farmers for reproductive purposes will occur only at the grace of certified plant breeders, and then only in "distress" situations.

The 1994 amendments also expand the scope of PVPA protection in three other significant ways. First, breeders of tuber-propagated plants such as potatoes have finally acquired a sub-patent form of intellectual property protection under American law, more than sixty years after the drafters of the Plant Patent Act of 1930 excluded these plants from a statute otherwise designed to cover asexually reproduced plants. The potato industry successfully lobbied Congress to expand the PVPA to include tuber-propagated plants during this legislative round.

Second, by adopting a rule of construction that regards the sale or disposition of hybrid seed as a sale of harvested material of the varieties from which the hybrid was produced, the newly amended PVPA effectively protects first-generation hybrids.

Finally and perhaps most significantly, the 1994 amendments allow certificate holders to protect not only their "initial" varieties but also all "essentially derived" varieties. Slight innovations on a successful variety will no longer qualify for PVPA protection. As an acknowledgement of "those who discovered and developed [a] variety in the first place," the essentially derived varieties concept is intended to "redistribute the right to profit among the owners of varieties" without "extend[ing] the rights of owners to the detriment of farmers and others." The impetus for extending plant variety protection to essentially derived varieties


generation hybrids came directly from UPOV, which embodies the essentially derived variety concept in Article 14(5) of the 1991 revision of its Convention.\textsuperscript{42}

* * * * *

D. Patent Protection for Artificially Induced New Life Forms

1. Introduction

The Plant Patent Act and the Plant Variety Protection Act represented legislative responses to longstanding legal doctrine precluding protection of new life forms under the general patent laws. Both statutes have withered away as biotechnological advances and economic maneuvers have outstripped the law. The PVPA's crop exemption, in particular, has effectively eliminated any impetus that the rest of the PVPA provided to the commercial plant breeding industry. Despite the emotions and the lawsuits, these conflicts may already be moot. Recent interpretations and applications of the Patent Act of 1952 have laid the foundation for the ultimate form of intellectual property protection for plant and animal genetics: a utility patent, indistinguishable from the patents that motivate and protect invention in nonagricultural sectors of the economy. From the biotechnology industry's perspective, the most important aspects of the Patent Act are the things it lacks: limitations as to life form and the crop and research exemptions. In other words, microorganisms, plants, and animals can all qualify for patent protection, and — at least for the time being — any protection conferred cannot be evaded under a statutory exemption favoring farmers.

* * * * *

Patent Act of 1952

§ 101. Inventions patentable.

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor,

subject to the conditions and requirements of this title.

§ 102. CONDITIONS FOR PATENTABILITY; NOVELTY AND LOSS OF RIGHT TO PATENT

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

§ 103. CONDITIONS FOR PATENTABILITY; NON-OBSVIOUS SUBJECT MATTER

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.
Patentability shall not be negatived by the manner in which the invention was made.

§ 112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

§ 154. Contents and Term of Patent

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of twenty years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States, and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

§ 271. Infringement of Patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed
without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act\(^1\) and the Act of March 4, 1913)\(^2\) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products. . . .

* * * * *

The materials in the remainder of this subchapter implicate three types of prerequisites to patent protection. First, does an invention fall within § 101's definition of *patentable subject matter*? Second, does the invention satisfy the substantive requirements of *novelty*, *utility*, and *nonobviousness* under sections 101, 102, and 103? Finally, does the *specification* accompanying a patent claim satisfy the requirements of section 112?

* * * * *

2. *Crawling up from primordial muck: precursors to utility patent protection for plants and animals*

Even as Congress enacted the PVPA, the United States Court of Customs and Patent Appeals (the predecessor of today's Court of Appeals for the Federal Circuit) began hinting at the possibility of patenting new life forms. In the following two decisions, the patent court denied patent applications but effectively invited a full debate on the ultimate question of plants' and animals' patentability.

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As will appear from the discussion, this title is misleading. Except for one product-by-process claim, the claimed invention is a process of producing "normal" chickens for eating purposes at less expense by reducing the amount of chicken feed consumed at one stage of production. The application does not show that strains of chickens are "improved" in any way, but only that a breeding stock of a dwarf strain may be maintained and used for appellants' process.

Sex determination in chickens is different from that in humans. A male (♂) chicken carries two X chromosomes in each cell; a female (♀) carries one X and one Y chromosome in each cell.
There is . . . another dwarfism gene in chickens which is known to be a sex-linked recessive, denoted "dw." The dominant normal gene is denoted "Dw." [The court then charted the possible phenotypes, or appearances, of chickens with respect to these genes.]

**THE CLAIMED INVENTION**

Appellants' invention lies in breeding a strain of dwarf hens and thereafter breeding them with "normal" cocks of heavy meat strains, producing offspring claimed to be of normal heavy meat size. The claims read:

1. A process for production of normal chickens from dwarf hens and normal cocks which includes passing through a dwarf breed and a heavy breed into which an nr sex-linked recessive dwarfism gene has been introduced, comprising crossing females of a cooking breed of poultry having good growth and fattening characteristics with cocks of small size which carry the nr gene, causing the animals obtained by this first crossing to reproduce with one another retaining all the subjects of small size which carry the nr gene so as to constitute a basic breed, and coupling the dwarf hens of this breed with any desired breed of normal heavy meat cocks, thereby obtaining, as an industrial product, a chick to be raised as a cooking chicken of normal heavy meat size.

2. The product obtained by the controlled process of claim 1.

3. A process of producing cooking chickens of normal size comprising controllably introducing an nr sex-linked recessive dwarfism gene into a dwarf

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4Appellants' specification, after discussing the "dw" gene . . . , says of the gene they discovered and denoted "nr":

However, since it was not possible to carry out the necessary genetics work to demonstrate that the newly observed gene and the dw gene were, in fact, identical, the latter (former?) is being called the nr gene with the normal allele gene being called Nr, the dominant.

5According to one of the prior art references cited by the board:

We may define recessive genes then, as ones which will produce their effects only when an individual has two of them which are identical (or when, in the case of sex-linked recessive genes, the individual having the recessive gene also is of the sex determined by the carrying of a Y chromosome), and dominant genes as those which will produce their effects even when only one of them is present in an individual.
hen and coupling said dwarf hen with a normal heavy meat rooster to provide siblings of normal heavy meat size.

4. The process of producing cooking chickens comprising the steps of (1) controllably introducing a sex-linked recessive dwarfism gene into a heavy breed of chicken; (2) causing said heavy breed of chicken having said dwarfism gene to reproduce; (3) selecting dwarf hens from the siblings of step (2); and (4) coupling said dwarfism [sic] hens with a normal heavy meat rooster thereby obtaining as offspring of said coupling normal size heavy meat cooking chickens.

**THE REJECTIONS**

All the claims were rejected by the examiner under 35 U.S.C. § 101 as directed to non-statutory subject matter, on the theory that a method of breeding animals is not a "process" within the meaning of § 101 and that a "thing occurring in nature (presumably the chicken of claim 2) under controlled propagation is not a manufacture." The board agreed with this position and stated further:

> Our views on the propriety of the rejection under 35 USC § 101 are further strengthened by the provisions of § 161 of Title 35 relating to plant patents. If § 101 of Title 35 were interpreted as broadly as appellants would have us interpret it; i.e., to include processes for the breeding of things occurring in nature to improve their qualities; it would be broad enough to include breeding plants also. Thus obviating the need for 35 USC 161. This we do not feel the Congress intended us to do.

The board entered new rejections . . . under 35 U.S.C. §§ 103 and 112, second paragraph. The prior art references cited by the board were portions of two general biology textbooks dealing with heredity and genetics. The board reasoned that appellants' process, and the product thereof, would have been obvious to a person of ordinary skill in the art familiar with the Mendelian laws of inheritance as described in the references. With respect to the § 112 rejection, the board said:

> Claims 1, 2, 3 and 4 are further rejected under 35 USC § 112, second paragraph, as not distinctly claiming that which appellants regard as their invention. . . . We also point out that the normal cocks claimed (i.e., those recited in the claims) are ones with NR dominant genes. If their genes are not NR dominant, the end product could, even under appellants' process, be a hybrid without the qualities he

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6"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."
is seeking (i.e., they would not be "normal"). This is also a new ground of rejection.

**OPINION**

We conclude that the rejection entered by the board under § 112, second paragraph, must be affirmed. This renders it unnecessary to discuss the other grounds of rejection.

Under the second paragraph of § 112, our inquiry . . . "is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity." It is here where the definiteness of the language employed must be analyzed not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.² [In a prior case, the court explained § 112 in the following way:]

No claim may be read apart from and independent of the supporting disclosure on which it is based. We are thus required to read the claims in light of the disclosure and in that light the term "opaque finish" as it appears in the preamble of each claim must take on the meaning ascribed to it in that disclosure. The result is an inexplicable inconsistency within each claim requiring that the rejection under 35 U.S.C. § 112 on grounds of indefiniteness be sustained.

The problem with the claims here lies in the word "normal." At oral argument appellants contended that the term "normal," as used in the claims, means "normal in size." We shall take them at their word, for if such is the case, the claims, construed in light of the meanings given to words in appellants' disclosure, are inexplicably inconsistent. This is what the board meant, we believe, when it said, "If their genes are not NR (which must be the same as "Nr") dominant, the end product could, even under appellants' process, be a hybrid without the qualities he is seeking."

²It is important here to understand that under this analysis claims which on first reading in a vacuum, if you will appear indefinite may upon a reading of the specification disclosure or prior art teachings become quite definite. It may be less obvious that this rule also applies in the reverse, making an otherwise definite claim take on an unreasonable degree of uncertainty.
and 3 speaks of a process for producing "normal" chickens, and the conclusions of process claims 1, 3, and 4 state "thereby obtaining . . . normal heavy meat size . . . chickens," or equivalent words. Under [one of the claimants'] definition[s] of "normal," only 50% normal chickens are produced by the process; under the [other] definition the characteristics of the offspring cannot be predicted.

The language of each claim requires that "normal" chickens, i.e., those of normal heavy meat size, be produced by appellants' process. The question under § 112, second paragraph, is whether the claim language, when read by a person of ordinary skill in the art in light of the specification, describes the subject matter with sufficient precision that the bounds of the claimed subject matter are distinct. In this case, if the [first] definition of "normal" is chosen, the manipulative steps of the process to be followed are clear, since a "normal" . . . cock must have the Nr Nr genotype; but an irreconcilable conflict is created because the product, under the Echelon A definition of "normal," will be "normal" only 50% of the time, not substantially all of the time as the claims contemplate. Under the [second] definition of "normal," it is not possible to determine what kind of "normal" cock the claimed process contemplates to be mated with the dwarf hen in the final step. Nr Nr and Nr nr cocks are both "normal," and hence physically indistinguishable, under the [second] definition. . . . [T]he offspring of the Nr Nr cock will all be "normal," while the offspring of the Nr nr cock will be 50% "normal" and 50% dwarf. Since the claim language is not precise enough to indicate which kind of cock to use to produce the result required by the claims, it fails to comply with § 112, second paragraph. Similarly, depending on which definition of "normal" is chosen, the chicken claimed in claim 2 may be either "normal," "sub-normal," or dwarf. This spectrum of possible products cannot be reconciled with the statement in claim 1, from which claim 2 depends, that from the process is obtained "a chick to be raised as a cooking chicken of normal heavy meat size."9

We conclude that claims 1-4 do not particularly point out or distinctly claim the subject matter of appellants' invention. The decision of the board is

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9It appears from our examination of the specification that appellants' invention cannot be practiced unless chickens with the nr gene are available. The specification contains no disclosure of where chickens having the nr gene may be obtained, nor does it indicate that breeding stocks of nr-bearing chickens are presently being maintained. Furthermore, the language of claim 3 appears unintelligible to us in the phrase "controllably introducing an nr sex-linked recessive dwarfism gene into a dwarf hen." Presumably, a dwarf hen is a dwarf because it already possesses an nr gene. Compare claim 3 with claims 1 and 4.
In re Bergy
United States Court of Customs and Patent Appeals
563 F.2d 1031 (C.C.P.A. 1977),

Before MARKEY, Chief Judge, RICH, BALDWIN and MILLER, Judges, and SHIRO KASHIWA, Judge, United States Court of Claims.

RICH, Judge.

This appeal is from the majority decision of the divided Board of Appeals (board) of the United States Patent and Trademark Office (PTO) affirming the rejection of claim 5 of application serial No. 477,766, filed June 10, 1974. We reverse.

THE INVENTION

The subject of the application, which, when filed, had the noncommittal title "Process," is made clear from the Abstract of the Disclosure, which reads:

Microbiological process for preparing the antibiotic lincomycin at temperatures ranging from 18°C to 45°C using the newly discovered microorganism *Streptomyces vellosus*.

The subject process advantageously results in the preparation of lincomycin without the concomitant production of lincomycin B (4'-depropyl-4'-ethyllincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency.

THE REJECTION

No references have been cited against claim 5 because the novelty and unobviousness of the biologically pure culture claimed are not questioned. Neither has utility been questioned.

The examiner's sole ground of rejection of claim 5, as stated in his final rejection, was: "Claim 5 is rejected under 35 USC § 101 as non-statutory subject matter. Claim 5 claims a product of nature (*Streptomyces vellosus* NRRL 8037)." Appellants responded with a request to reconsider this rejection supported by affidavits... pointing out that the microorganism did not exist as a biologically pure culture in nature and asserting that such a culture is a "manufacture" under § 101... In so arguing, appellants made the point that the pure culture is "a product of a microbiologist." The examiner adhered to his position and appeal was taken to the board.

Since the only ground given by the examiner in support of his nonstatutory-subject-matter rejection was that the culture was a product of nature, that was the only point argued by
appellants in their brief before the board, in which they cited a number of precedents for holding that a pure product could be patentable over a known impure product of similar kind.

The Examiner's Answer . . . merely summarized his product-of-nature position and cited two cases . . . . With reference to the cases cited by appellants as precedents for patenting pure materials, the examiner noted that they were all pure chemical compounds "as contrasted with the instant microorganism." He noted that the cases cited by him all "involve isolated or biologically pure microorganisms." Appellants replied briefly, taking exception to the last-quoted statement of the examiner . . . since (1) none of the decisions cited, nor any known decision, has held that a "biologically pure culture" is unpatentable, and (2) there is no evidence that a "biologically pure culture" was in issue in any of the cited decisions. On the issue thus framed, the case went to the board.

THE BOARD OPINIONS

The opinion of the majority of the board is quite out of the ordinary. While it affirms the "decision" of the examiner, that is to say his rejection of claim 5, it wholly disregards his reason for rejecting it to the point of expressly declining to consider it. Instead, the board majority decided that claim 5 is not directed to statutory subject matter within the meaning of § 101 because it is for "a living organism," an issue entirely new to the application at bar, so far as the record shows. The dissenting board member's opinion confirms in its first paragraph that that is, strictly, the basis of the majority's decision. Without stating a new ground of rejection was being made . . . , the majority opinion commences its explanation of its reasoning as follows:

We have extensively researched prior court decisions for guidance to the question of whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter, but, other than possibly non-controlling dicta, have not found any case directly in point. It is our view that 35 U.S.C. § 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism. We reach this conclusion on the basis that only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of those categories listed. An analogous result has been reached by the courts with respect to non-patentability of mental processes, printed matter or methods of doing business none of which are also expressly excluded by the indicated section of the statute, but neither can they be said or have been held to be included thereby.

The board majority opinion then makes two points in support of its conclusion that § 101 precludes patenting anything living. The first is based on this court's [1940] decision . . . that bacteria are not included in the plant patent provision of former Title 35 . . . , notwithstanding that they may be scientifically classified as plants, because Congress plainly did not intend them to be when, in 1930, it enacted the Plant Patent Act. The case was concerned only with the plant
patent statute and this court did not have before it any other issue, such as inclusion of bacteria in any other statutory category, appellant having applied for a "plant patent" on a bacterium. The second aspect of the board majority's supporting reasoning is fully stated in the following paragraph:

If we were to adopt a liberal interpretation of 35 U.S.C. § 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. § 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. § 101. We do not believe that Congress intended 35 U.S.C. § 101 to encompass any living organism, whether they be plants or microorganisms.

The dissenting board member, stating that he had reviewed all of the precedents cited by either side and others as well, many of which he discussed in detail, expressed these views:

I do not believe that the fact that plants and bacteria have some properties in common is sufficient basis for holding that bacteria are to be excluded from patent coverage. . . . I do not find it improper to claim living organisms . . . . In view of the discussed cases, and since 35 U.S.C. § 101 does not expressly exclude patents to living organisms, it is my opinion that living organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute.

He also expressed disagreement with the examiner's view that claim 5 defined a "product of nature," or that being a product of nature was sufficient reason, alone, for holding an invention nonstatutory. He made these observations:

Rather, I view a "product of nature" as being something that "exists" in nature and therefore evidence that it may not be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art. Certainly vitamin B-12, as it exists in liver, and adrenalin, as it appears in adrenal glands, are products of nature, yet the courts have held . . . that when such materials are extracted and concentrated in a purified form they are patentable. Accordingly, it is not sufficient to determine whether the pure culture claimed is a product of nature.

OPINION

Under the peculiar circumstances of this case, in which the board switched the supporting reasoning for the rejection of claim 5 as for nonstatutory subject matter without expressly making a new rejection, we deem it prudent to clarify the issue we have to decide. The brief of the PTO
Solicitor sees but a single issue: "whether living organisms are the kind of `manufacture' or 'composition of matter' intended by Congress to be included within 35 U.S.C. § 101."

Appellants argue that issue, making no objection to the board having raised it sua sponte, and also perhaps out of an abundance of caution argue the product-of-nature question sidetracked by the board. Appellants forcefully presented the latter issue before the board and submitted affidavits of three experts in the field to the effect that the "biologically pure culture" of claim 5 is not found in nature. The evidence appears to us to be incontrovertible. The dissenting member of the board accepted it. The board did not refute it, and the solicitor has not challenged it. The circumstances persuade us that the board went in search of another reason to support the rejection because it realized the examiner's position was untenable. We consider the product-of-nature issue to have been abandoned and no longer in the case. [Moreover], we find it wholly lacking in merit. The biologically pure culture of claim 5 clearly does not exist in, is not found in, and is not a product of, "nature." It is man-made and can be produced only under carefully controlled laboratory conditions. . . .

Since their appearance before the board, appellants have added another statutory category string to their bow. Before the board, they argued that the claim 5 pure culture is a "manufacture" under § 101. Before us they also argue that it is a "composition of matter," which is another § 101 category. This is not a matter of great moment since there is considerable overlap between these two broad categories, notwithstanding what some textwriters have said. The arguments have not made a distinction between the two. If it is either, it is statutory subject matter, and it is not intellectually profitable to attempt a distinction in this regard.

We therefore proceed to a decision solely on the basis of . . . the single question of whether the uncontroverted fact that the biologically pure culture, as claimed, is alive removes it from the categories of inventions enumerated in § 101. Our conclusion is that it does not.

As to what the issue is, however, we make one further clarifying observation. We do so in part because of the solicitor's statement that a similar issue was present but not decided in In re Merat, a case involving chicken breeding, and in part because of the board's reasoning herein. The solicitor's statement about Merat is correct, but we emphasize that we are not here deciding the issue left open in Merat or anything other than the issue before us in this case, whether the subject matter of claim 5 is within either of the terms "manufacture" or "composition of matter" in § 101. In other words, we are not deciding whether living things in general, or, at most, whether any living things other than microorganisms, are within § 101. These questions must be decided on a case-by-case basis and anything said herein is to be taken as said in the context of a discussion of the subject matter of claim 5 and § 101.

As presented to us, the question is clearly one of first impression. . . .

[This court's prior] decisions illustrate what we believe to have been the state of the law ever since, namely, that processes, one of the categories of patentable subject matter specified in
§ 101, are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living organisms and their life processes. Witness the action of the PTO in the present case in allowing the process claims. Other examples of such patentable process claims involving living bacteria are to be seen in the [1934] bacterial sewage treatment cases . . . . A still earlier one is [a 1908 case], wherein . . . bacterial-action process claims were held valid and infringed. (The original "septic tank.") It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101. Of course it is clear . . . that there is nothing in the words of § 101 which excludes patents for living organisms.

We cannot agree with the board majority's view that § 101 "must be strictly construed." But even a "strict construction," whatever that may entail, fails to lead inexorably to the exclusion of a manufacture or composition of matter because it is alive. The statute makes no distinction between manufactures and compositions on the one hand and processes on the other. If the board is right in excluding products because there is life in them, then logic dictates that it should take the same position with regard to processes. But it does not do so. Indeed, in light of what the courts have done over the past seventy years in holding such process claims valid, it could not properly do so. We have never heard of a case holding that the categories of patentable subject matter, as enumerated in § 101 or any of its predecessor statutes, should be strictly construed and the board has cited none.

In 1932, when the Board of Appeals was faced with an examiner's contention that a biological process for producing butyl and isopropyl alcohols by bacterial action was unpatentable because the bacteria were doing only what by nature they are capable of doing, its response was that if such a view were accepted, it would hardly be possible to grant a patent on any chemical process, indicating an early appreciation of the essential similarity of what we normally think of as "chemical reactions" and the complex chemical procedures wrought by the life processes of microorganisms. As a result of that decision, . . . [a] patent . . . was issued . . . for "Production of Butyl and Isopropyl Alcohols" with process claims. The board said: "We are unable to agree with the Examiner that processes involving bacterial action do not involve patentable subject matter . . . ."

What we have before us is an industrial product used in an industrial process, a useful or technological art if there ever was one. The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses. . . . [M]icrobiological processes have long been used "to make beer, wine, cheese, bread, pickles and sauerkraut, rett flax, age tobacco, bate leather, produce silage and digest sewage." But more to the point here, in recent years, . . . they have come to be used to "produce a vast variety of chemicals and drugs such as alcohols, ketones, fatty
acids, amino acids, vitamins, antibiotics, steroids, and enzymes." . . . [A] "far from complete list" of chemical reactions carried out by microorganisms . . . include[s] oxidation, reduction, condensation, esterification, amination, deamination, phosphorylation, hydrolysis, decarboxylation, methylation, dismutation, acylation, and dehydration. In short, microorganisms have come to be important tools in the chemical industry, especially the pharmaceutical branch thereof, and when a new and useful tangible industrial tool is invented which is unobvious, so that it complies with the prerequisites to patentability other than the enumerated statutory categories, we do not see any reason to deprive it or its creator or owner of the protection and advantages of the patent system by excluding it from the § 101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. The law unhesitatingly grants patent protection to new, useful, and unobvious chemical compounds and compositions, in which category are to be found the products of microbiological processes, for example, vitamin B-12 and adrenalin . . . and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves a kind of tool used by chemists and chemical manufacturers in much the same way as they use chemical elements, compounds, and compositions which are not considered to be alive, notwithstanding their capacities to react and to promote reaction to produce new compounds and compositions by chemical processes in much the same way as do microorganisms. We think it is in the public interest to include microorganisms within the terms "manufacture" and "composition of matter" in § 101. In short, we think the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance and that disposes of the board's ground of rejection and the sole reason for refusal of a patent argued by the solicitor.

As for the board's fears that our holding will of necessity, or "logically," make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far-fetched. In any case, that question is not before us, as we have indicated above. Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms, so far as we know. The collective mind of Congress was not turned in that direction . . . Reversed.

KASHIWA, Judge, concurring.

I agree with the result and the reasoning of the opinion by Judge Rich joined by Chief Judge Markey. Nevertheless, I wish to emphasize, out of a super-abundance of caution, that I read the majority opinion as setting forth an extremely limited holding. While the PTO and the dissenting opinion raise the specter of patenting higher forms of living organisms, quite clearly the majority opinion does not support such a broad proposition. Each case must necessarily be considered on its own facts. On the facts of this case, I join the narrow confines of the majority opinion.
MILLER, Judge, dissenting, with whom BALDWIN, Judge, joins.

I do not agree that a biologically pure culture of microorganisms is within the scope of 35 U.S.C. § 101 intended by Congress.

The board majority concluded:

[35 U.S.C. § 101] does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturalists and agriculturalists. If 35 U.S.C. § 101 were to be broadly construed there would clearly not have been any necessity for [the Plant Patent Act]. We are especially impressed by the legislative history of [the Plant Patent Act's predecessor statute]. We believe that the legislative history reveals a clear Congressional intent that plants were not covered by the predecessor of 35 U.S.C. § 101 . . . . Based upon the legislative history . . . we do not believe that the terms "manufacture" or "composition of matter," as employed in 35 U.S.C. § 101, were intended to encompass any living organism, whether plants or the microorganism appellants are claiming here.

The response of the majority opinion here is simply: "Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms . . . ." It then attempts to distinguish between microorganisms and more-complex living things, such as those included within the common meaning of "plants," saying: "The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses." Such a distinction is purely gratuitous and clearly erroneous. The nature of organisms, whether microorganisms, plants, or other living things, is fundamentally different from that of inanimate chemical compositions. For example, both the microorganisms claimed herein and honeybees are alive, reproduce, and act upon other materials to form technologically useful products (lincomycin and honey, respectively). This cannot be said of chemical compositions. The weakness of the majority's position is further apparent from its failure to advance any rationale for distinguishing between different types of living things particularly between a biologically pure culture of a microorganism and plants for purposes of 35 U.S.C. § 101.

I agree with the board majority that . . . the Plant Protection Act of 1930 and the legislative history of the 1930 Act support the conclusion that living organisms (e.g., plants and biologically pure cultures of microorganisms) were not intended by Congress to be within the scope of 35 U.S.C. § 101.

That Congress believed it necessary to enact a statute extending patent protection to
certain plants . . . demonstrates that Congress never intended that plants or other organisms be within the scope of the terms "manufacture" and "composition of matter." If, indeed, organisms were within the scope of such terms, the 1930 Act would have been superfluous. Presumably the 1930 Act was not superfluous, and the majority opinion here contains nothing to rebut that presumption.

Moreover, the Senate committee report accompanying the bill which became the Plant Patent Act of 1930 stated:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry . . . . The bill will remove the existing discrimination between plant developers and industrial inventors.

This underscores Congressional understanding that plants were not patentable subject matter under the law then in effect, since, if they were, agriculture would already have been afforded "the same opportunity to participate in the benefits of the patent system."

If, prior to the 1930 Act, plants had been within the scope of the patent statutes, as the majority opinion apparently assumes, a plant patent would have had to comply fully with what is now 35 U.S.C. § 112; but after the 1930 Act, a plant patent for certain plants need not do so (since a plant patent could not be declared invalid if its description "is made as complete as is reasonably possible" [under] section 2 of the Plant Patent Act of 1930). This would have constituted a repeal of the full-compliance requirement in the case of such plants without any Congressional discussion thereof. Repeal by implication is not favored statutory construction. The conclusion follows that, prior to the 1930 Act, plants were not within the scope of the patent statutes.

The Plant Variety Protection Act, although enacted long after the original use of the terms "manufacture" and "composition of matter" appearing in 35 U.S.C. § 101, further supports the conclusion that Congress did not intend organisms to be included within the scope of such terms. Both the Senate Judiciary Committee report and the House Committee on Agriculture report accompanying the bill which became the Plant Variety Protection Act stated:

Under patent law, protection is presently limited to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

Thus, the Patent Act of 1952 was considered to be limited to plants falling under 35 U.S.C.
§ 161, and 35 U.S.C. § 101 was not considered to cover any plants whatsoever.

The majority, in holding that the biologically pure culture of a microorganism defined by claim 5 constitutes patentable subject matter, relies heavily on the fact that processes of using the microorganism constitute patentable subject matter . . . . However, this court has pointed out that claims directed to processes of using an algorithm to operate a system constitute patentable subject matter while claims directed to the algorithm per se (or to methods of calculating using the algorithm) do not. Similarly here, the fact that claims directed to a process of using microorganisms constitute patentable subject matter does not logically compel the conclusion that claims to biologically pure cultures of microorganisms are patentable. . . .

The majority opinion says "it is in the public interest to include microorganisms within the terms `manufacture' and `composition of matter' in § 101." Although such a statement might be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent. . . .

[T]he patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances.

The majority opinion, after stating that "[w]e consider the product-of-nature issue . . . no longer in the case," then finds the issue "wholly lacking in merit." Since the culture defined in claim 5 is not a "manufacture" or a "composition of matter" and since we do not have the view of the board majority on the product-of-nature issue, I would not reach that issue on this appeal.

In view of the foregoing, the decision of the board should be affirmed.

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Diamond v. Chakrabarty
Supreme Court of the United States
447 U.S. 303 (1980)

MR. CHIEF JUSTICE BURGER delivered the opinion of the Court.

We granted certiorari to determine whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.

I

In 1972, respondent Chakrabarty, a microbiologist, filed a patent application, assigned to the General Electric Co. The application asserted 36 claims related to Chakrabarty's invention of "a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway." This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills.

Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The

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1Plasmids are hereditary units physically separate from the chromosomes of the cell. In prior research, Chakrabarty and an associate discovered that plasmids control the oil degradation abilities of certain bacteria. In particular, the two researchers discovered plasmids capable of degrading camphor and octane, two components of crude oil. In the work represented by the patent application at issue here, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single Pseudomonas bacterium, which itself has no capacity for degrading oil.

2At present, biological control of oil spills requires the use of a mixture of naturally occurring bacteria, each capable of degrading one component of the oil complex. In this way, oil is decomposed into simpler substances which can serve as food for aquatic life. However, for various reasons, only a portion of any such mixed culture survives to attack the oil spill. By breaking down multiple components of oil, Chakrabarty's micro-organism promises more efficient and rapid oil-spill control.
The Board concluded that the new bacteria were not "products of nature," because *Pseudomonas* bacteria containing two or more different energy-generating plasmids are not naturally occurring.

Chakrabarty appealed the rejection of these claims to the Patent Office Board of Appeals, and the Board affirmed the Examiner on the second ground. Relying on the legislative history of the 1930 Plant Patent Act, in which Congress extended patent protection to certain asexually reproduced plants, the Board concluded that § 101 was not intended to cover living things such as these laboratory created micro-organisms.

The Court of Customs and Patent Appeals, by a divided vote, reversed on the authority of its prior decision in *In re Bergy*, which held that "the fact that microorganisms . . . are alive . . . [is] without legal significance" for purposes of the patent law. Subsequently, we granted the Acting Commissioner of Patents and Trademarks' petition for certiorari in *Bergy*, vacated the judgment, and remanded the case "for further consideration in light of Parker v. Flook, 437 U.S. 584 (1978)." The Court of Customs and Patent Appeals then vacated its judgment in *Chakrabarty* and consolidated the case with *Bergy* for reconsideration. After re-examining both cases in the light of our holding in *Flook*, that court, with one dissent, reaffirmed its earlier judgments.

The Commissioner of Patents and Trademarks again sought certiorari, and we granted the writ as to both Bergy and Chakrabarty. Since then, *Bergy* has been dismissed as moot, leaving only Chakrabarty for decision.

II

The Constitution grants Congress broad power to legislate to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. The authority of Congress is exercised in the hope that "[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101, which provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

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3The Board concluded that the new bacteria were not "products of nature," because *Pseudomonas* bacteria containing two or more different energy-generating plasmids are not naturally occurring.
Specifically, we must determine whether respondent's micro-organism constitutes a "manufacture" or "composition of matter" within the meaning of the statute.5

III

In cases of statutory construction we begin, of course, with the language of the statute. And "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." We have also cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed."

Guided by these canons of construction, this Court has read the term "manufacture" in § 101 in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." Similarly, "composition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.

The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." See Graham v. John Deere Co. Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man."

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc²; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity "having a

5This case does not involve the other "conditions and requirements" of the patent laws, such as novelty and nonobviousness. 35 U.S.C. §§ 102, 103.
distinctive name, character [and] use." The point is underscored dramatically by comparison of the invention here with that [of a] patentee [who] had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. Concluding that the patentee had discovered "only some of the handiwork of nature," the Court ruled the product nonpatentable:

Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

[Citing Funk Bros.] Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

IV

Two contrary arguments are advanced, neither of which we find persuasive.

A

The petitioner's first argument rests on the enactment of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection. In the petitioner's view, the passage of these Acts evidences congressional understanding that the terms "manufacture" or "composition of matter" do not include living things; if they did, the petitioner argues, neither Act would have been necessary.

We reject this argument. Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. This position appears to have derived from the decision of the patent office in Ex parte Latimer, in which a patent claim for fiber found in the needle of the Pinus australis was rejected. The Commissioner reasoned that a contrary result would permit "patents [to] be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible." The Latimer case, it seems, came to "set forth the general stand taken in these matters" that plants were natural products not subject to patent
Writing three years after the passage of the 1930 Act, [the] Editor of the Journal of Heredity, commented: "It is a little hard for plant men to understand why [Art. I, § 8] of the Constitution should not have been earlier construed to include the promotion of the art of plant breeding. The reason for this is probably to be found in the principle that natural products are not patentable."

In enacting the Plant Patent Act, Congress addressed both of these concerns. It explained at length its belief that the work of the plant breeder "in aid of nature" was patentable invention. And it relaxed the written description requirement in favor of "a description . . . as complete as is reasonably possible." 35 U.S.C. § 162. No Committee or Member of Congress, however, expressed the broader view, now urged by the petitioner, that the terms "manufacture" or "composition of matter" exclude living things. The sole support for that position in the legislative history of the 1930 Act is found in the conclusory statement of Secretary of Agriculture Hyde, in a letter to the Chairmen of the House and Senate Committees considering the 1930 Act, that "the patent laws . . . at the present time are understood to cover only inventions or discoveries in the field of inanimate nature." Secretary Hyde's opinion, however, is not entitled to controlling weight. His views were solicited on the administration of the new law and not on the scope of patentable subject matter — an area beyond his competence. Moreover, there is language in the House and Senate Committee Reports suggesting that to the extent Congress considered the matter it found the Secretary's dichotomy unpersuasive. The Reports observe:

There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man. . . . On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man . . . .

Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's micro-organism is the result of human ingenuity and research. Hence, the passage of the Plant Patent Act affords the Government no support.

Nor does the passage of the 1970 Plant Variety Protection Act support the Government's position. As the Government acknowledges, sexually reproduced plants were not included under the 1930 Act because new varieties could not be reproduced true-to-type through seedlings. By

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3Writing three years after the passage of the 1930 Act, [the] Editor of the Journal of Heredity, commented: "It is a little hard for plant men to understand why [Art. I, § 8] of the Constitution should not have been earlier construed to include the promotion of the art of plant breeding. The reason for this is probably to be found in the principle that natural products are not patentable."

3*Ed. note* – Compare *In re Merat*, excerpted above in part II.D.2, beginning at page 152.
1970, however, it was generally recognized that true-to-type reproduction was possible and that plant patent protection was therefore appropriate. The 1970 Act extended that protection. There is nothing in its language or history to suggest that it was enacted because § 101 did not include living things.

In particular, we find nothing in the exclusion of bacteria from plant variety protection to support the petitioner's position. The legislative history gives no reason for this exclusion. As the Court of Customs and Patent Appeals suggested, it may simply reflect congressional agreement with the result reached by that court [when it] held that bacteria were not plants for the purposes of the 1930 Act. Or it may reflect the fact that prior to 1970 the Patent Office had issued patents for bacteria under § 101. In any event, absent some clear indication that Congress "focused on [the] issues . . . directly related to the one presently before the Court," there is no basis for reading into its actions an intent to modify the plain meaning of the words found in § 101.

B

The petitioner's second argument is that micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. His position rests on the fact that genetic technology was unforeseen when Congress enacted § 101. From this it is argued that resolution of the patentability of inventions such as respondent's should be left to Congress. The legislative process, the petitioner argues, is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection. In support of this position, the petitioner relies on our recent holding in *Parker v. Flook* and the statement that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress."

It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is "the province and duty of the judicial department to say what the law is." Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity. The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad

"In 1873, the Patent Office granted Louis Pasteur a patent on "yeast, free from organic germs of disease, as an article of manufacture." And in 1967 and 1968, immediately prior to the passage of the Plant Variety Protection Act, that Office granted two patents which, as the petitioner concedes, state claims for living micro-organisms."
terms.

Nothing in *Flook* is to the contrary. That case applied our prior precedents to determine that a "claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101." The Court carefully scrutinized the claim at issue to determine whether it was precluded from patent protection under "the principles underlying the prohibition against patents for `ideas' or phenomena of nature." We have done that here. *Flook* did not annouce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable *per se*.

To read that concept into *Flook* would frustrate the purposes of the patent law. This Court frequently has observed that a statute is not to be confined to the "particular application[s] . . . contemplated by the legislators." This is especially true in the field of patent law. A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. *See Graham v. John Deere Co.* [T]he inventions most benefiting mankind are those that "push back the frontiers of chemistry, physics, and the like." Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.\(^\text{10}\)

To buttress his argument, the petitioner . . . points to grave risks that may be generated by research endeavors such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates – that with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."

It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under § 101. We disagree. The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may

\(^{10}\)Even an abbreviated list of patented inventions underscores the point: telegraph (Morse, No. 1,647); telephone (Bell, No. 174,465); electric lamp (Edison, No. 223,898); airplane (the Wrights, No. 821,393); transistor (Bardeen & Brattain, No. 2,524,035); neutronic reactor (Fermi & Szilard, No. 2,708,656); laser (Schawlow & Townes, No. 2,929,922).
determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.

What is more important is that we are without competence to entertain these arguments – either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.11

We have emphasized in the recent past that "[o]ur individual appraisal of the wisdom or unwisdom of a particular [legislative] course . . . is to be put aside in the process of interpreting a statute." Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Cf. 42 U.S.C. § 2181(a), exempting from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent's invention.

Affirmed.

MR. JUSTICE BRENNAN, with whom MR. JUSTICE WHITE, MR. JUSTICE MARSHALL, and MR. JUSTICE POWELL join, dissenting.

I agree with the Court that the question before us is a narrow one. Neither the future of scientific research, nor even, the ability of respondent Chakrabarty to reap some monopoly profits from his pioneering work, is at stake. Patents on the processes by which he has produced and employed the new living organism are not contested. The only question we need decide is whether Congress . . . intended that he be able to secure a monopoly on the living organism itself, no matter how produced or how used. Because I believe the Court has misread the applicable legislation, I dissent.

11We are not to be understood as suggesting that the political branches have been laggard in the consideration of the problems related to genetic research and technology. They have already taken action. In 1976, for example, the National Institutes of Health released guidelines for NIH-sponsored genetic research which established conditions under which such research could be performed. In 1978 those guidelines were revised and relaxed. And Committees of the Congress have held extensive hearings on these matters.
The patent laws attempt to reconcile this Nation's deep seated antipathy to monopolies with the need to encourage progress. Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.1

In this case, however, we do not confront a complete legislative vacuum. The sweeping language of the Patent Act of 1793, as re-enacted in 1952, is not the last pronouncement Congress has made in this area. In 1930 Congress enacted the Plant Patent Act affording patent protection to developers of certain asexually reproduced plants. In 1970 Congress enacted the Plant Variety Protection Act to extend protection to certain new plant varieties capable of sexual reproduction. Thus, we are not dealing — as the Court would have it — with the routine problem of "unanticipated inventions." In these two Acts Congress has addressed the general problem of patenting animate inventions and has chosen carefully limited language granting protection to some kinds of discoveries, but specifically excluding others. These Acts strongly evidence a congressional limitation that excludes bacteria from patentability.2

First, the Acts evidence Congress' understanding, at least since 1930, that § 101 does not include living organisms. If newly developed living organisms not naturally occurring had been patentable under § 101, the plants included in the scope of the 1930 and 1970 Acts could have been patented without new legislation. Those plants, like the bacteria involved in this case, were new varieties not naturally occurring.3 Although the Court rejects this line of argument, it does

1I read the Court to admit that the popular conception, even among advocates of agricultural patents, was that living organisms were unpatentable.

2But even if I agreed with the Court that the 1930 and 1970 Acts were not dispositive, I would dissent. This case presents even more cogent reasons . . . not to extend the patent monopoly in the face of uncertainty. At the very least, these Acts are signs of legislative attention to the problems of patenting living organisms, but they give no affirmative indication of congressional intent that bacteria be patentable. The caveat of Parker v. Flook, an admonition to "proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress," therefore becomes pertinent. I should think the necessity for caution is that much greater when we are asked to extend patent rights into areas Congress has foreseen and considered but has not resolved.

3The Court refers to the logic employed by Congress in choosing not to perpetuate the "dichotomy" suggested by Secretary Hyde. But by this logic the bacteria at issue here are distinguishable from a "mineral . . . created wholly by nature" in exactly the same way as were the new varieties of plants. If a new Act was needed to provide patent protection for the plants, it was equally necessary for bacteria. Yet Congress provided for patents on plants.
not explain why the Acts were necessary unless to correct a pre-existing situation. \(^4\) I cannot share the Court's implicit assumption that Congress was engaged in either idle exercises or mere correction of the public record when it enacted the 1930 and 1970 Acts. And Congress certainly thought it was doing something significant. The Committee Reports contain expansive prose about the previously unavailable benefits to be derived from extending patent protection to plants. Because Congress thought it had to legislate in order to make agricultural "human-made inventions" patentable and because the legislation Congress enacted is limited, it follows that Congress never meant to make items outside the scope of the legislation patentable.

Second, the 1970 Act clearly indicates that Congress has included bacteria within the focus of its legislative concern, but not within the scope of patent protection. Congress specifically excluded bacteria from the coverage of the 1970 Act. 7 U.S.C. § 2402(a). The Court's attempts to supply explanations for this explicit exclusion ring hollow. It is true that there is no mention in the legislative history of the exclusion, but that does not give us license to invent reasons. The fact is that Congress, assuming that animate objects as to which it had not specifically legislated could not be patented, excluded bacteria from the set of patentable organisms.

The Court protests that its holding today is dictated by the broad language of § 101, which cannot "be confined to the 'particular application[s] . . . contemplated by the legislators.'" But as I have shown, the Court's decision does not follow the unavoidable implications of the statute. Rather, it extends the patent system to cover living material even though Congress plainly has legislated in the belief that § 101 does not encompass living organisms. It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

* * * * *

4. New species of biotechnology patents after Chakrabarty

In Bergy, the Court of Customs and Patent Appeals rejected as "far-fetched" the fear that allowing the patent laws to cover life forms would necessarily confer intellectual property

\(^4\)If the 1930 Act's only purpose were to solve the technical problem of description referred to by the Court, most of the Act, and in particular its limitation to asexually reproduced plants, would have been totally unnecessary.
protection on inventors of all new, useful, and unobvious species.\textsuperscript{4} The Supreme Court in \textit{Chakrabarty} took pains to disclaim judicial responsibility for the breadth of its holding, emphasizing instead the intrinsically legislative nature of the patent laws. As a practical matter, however, the Patent and Trademark Office and its Board of Appeals have dominated the development of the post-\textit{Chakrabarty} law on biotechnology patents. Is there any realistic limit to the scope of intellectual property in biotechnology under the patent laws?

* * * * *

(i) \textit{Plants}

\textit{Ex parte Hibberd}

Patent & Trademark Office Board of Patent Appeals & Interferences

[The patent examiner below rejected various claims as unpatentable under 35 U.S.C. § 101.] The subject matter on appeal relates to maize plant technologies, including seeds, plants and tissue cultures which have increased free tryptophan levels, or which are capable of producing plants or seeds having increased free tryptophan levels, or which are capable of producing plants or seeds having increased tryptophan content. Claims [that] are representative of the three groups of rejected claims . . . are reproduced as follows:

239. A maize seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight and capable of germinating into a plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight.

249. A maize plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed is capable of germinating into a plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight.

260. A maize tissue culture capable of generating a plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed is capable of germinating into a plant capable of producing seed having endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight.

There are no rejections based on prior art; rather, [the claims at issue] are rejected solely under 35 USC § 101. It is the examiner's position that the claims drawn to seeds and plants . . . comprise subject matter which is inappropriate for protection under 35 USC § 101 because the subject matter of plants and seeds is within the purview of the Plant Variety Protection Act of 1970 . . . . The examiner's position with respect to [the] claims . . . drawn to tissue cultures is that such subject matter is inappropriate for protection under 35 USC § 101 because it is within the purview of the Plant Patent Act of 1930. The examiner asserts that, to the extent that the claimed subject matter can be protected under the Plant Variety Protection Act (PVPA) or the Plant Patent Act (PPA), protection under 35 USC 101 is not available.¹

We shall not sustain this rejection. . . . The examiner acknowledges in his answer that, in view of the decision in Chakrabarty, it appears clear that § 101 includes man-made life forms, including plant life. Moreover, the examiner's allowance of claims drawn to hybrid seeds and hybrid plants is a further indication that the examiner considers the scope of § 101 to include man-made plant life. The examiner asserts in his answer, however, that by enacting the PPA in 1930 and the PVPA in 1970 "Congress has specifically set forth how and under what conditions plant life covered by these Acts should be protected." The examiner contends that the only reasonable statutory interpretation is that the PPA and the PVPA, which were later in time and more specific than § 101, each carved out from § 101, for specific treatment, the subject matter covered by each. Thus, it is the position of the examiner that the plant-specific Acts (PPA and PVPA) are the exclusive forms of protection for plant life covered by those acts.

We disagree with these contentions that the scope of patentable subject matter under § 101 has been narrowed or restricted by the passage of the PPA and the PVPA and that these plant-specific Acts represent the exclusive forms of protection for plant life covered by those acts. The position taken by the examiner presents a question of statutory construction concerning the scope of patentable subject matter under 35 USC § 101, i.e., has the scope of § 101 been narrowed or restricted by reason of the enactment of the plant-specific Acts.

. . . . The examiner does not point to any specific language in the plant-specific Acts to support his position that the plant-specific Acts restrict the scope of patentable subject matter under § 101 . . . . [N]either the PPA nor the PVPA expressly excludes any plant subject matter from protection under § 101. Accordingly, we look next to the legislative histories of the plant-specific Acts to determine whether there is any clear indication of congressional intent that protection under the plant-specific Acts be exclusive.

The examiner does not refer to the legislative histories of the plant-specific Acts to support his position as to the intent of Congress. Rather, he merely asserts . . . that "it is clear that Congress intended a 'distinct and new variety of plant' covered by the Plant Patent Act to be

¹Claims directed to hybrid seeds, claims 244 through 248, and to hybrid plants, claims 256 through 259, have been allowed because the PVPA and the PPA exclude such subject matter. . . .
something apart from the statutory categories of invention embraced by § 101" and . . . "the only reasonable statutory interpretation is that each [PPA and PVPA] carved out from § 101, for specific treatment, the subject matter covered by each." However, . . . , there is nothing in the legislative histories of the plant-specific Acts from which one could conclude that Congress intended to remove from protection under § 101 any subject matter already within the scope of that section. Rather, the Senate Committee on the Judiciary concluded . . . in its Report . . . in which it recommended passage of the Plant Variety Protection Act that "it does not alter protection currently available within the patent system."

The Supreme Court in *Chakrabarty* addressed the legislative history and purpose of the plant-specific Acts and noted that prior to 1930 there were two obstacles to obtaining patent protection on plants. The first was the belief that plants, even those artificially bred, were products of nature not subject to patent protection; the second was the fact that plants were thought not amenable to the "written description" requirement of the patent law. The Supreme Court noted that Congress addressed both of these obstacles in enacting the PPA. Congress explained at length its belief that the work of the plant breeder "in aid of nature" was patentable invention, and it relaxed the written description requirement in favor of a description "as complete as is reasonably possible." In our view, the Supreme Court's analysis of the legislative history of the plant-specific Acts makes it clear that the legislative intent of these acts was to extend patent protection to plant breeders who were stymied by the two noted obstacles.

We find no explicit support in the legislative history for the notion . . . of an intent to restrict or limit the scope of patentable subject matter available pursuant to 35 USC § 101. The examiner tacitly admits such lack of explicit support for his notion of legislative intent by his failure to refer to the legislative history and by the following statement . . . : "When Congress carved out and established distinct forms of protection for certain plants, they implicitly excluded protection of these plants under § 101." Thus, the examiner's rejection in the final analysis is based on . . . an implied partial repeal of § 101 based on the passage of the plant-specific Acts.

The examiner's contention that § 101 has been "implicitly" narrowed or partially repealed by implication is not persuasive. The overwhelming weight of authority is to the effect that repeals by implication are not favored and that when there are two acts on the same subject the rule is to give effect to both unless there is such a "positive repugnancy" or "irreconcilable conflict" that the statutes cannot co-exist. . . . In the absence of such "positive repugnancy" or "irreconcilable conflict" that the statutes cannot co-exist, and we find none, . . . § 101 and the plant-specific Acts must be given full effect. . . .

Simply because a later enacted statute affects in some way an earlier enacted statute is poor reason to ask us to rewrite the earlier statute. Repeals by implication are not favored. . . . The examiner [invoked] the proposition that a specific statute controls over a general statute where there is a conflict. We find no application of this principle to the facts involved here because before a specific statute can be found to control over a general statute, there must first be
an irreconcilable conflict between them . . . .  [W]e find no such irreconcilable conflict . . . .

In an attempt to show a conflict, the examiner points in his answer to provisions of the plant-specific Acts which differ from § 101. He notes, for example, that (1) the PVPA contains both research (experimental use) and farmer's crop exemptions, while § 101 does not explicitly contain such exemptions; (2) the PVPA spells out infringement in great detail and includes a compulsory licensing provision, while no such congressional guidance exists under § 101 protection; (3) the PVPA limits protection to a single variety, whereas the opportunity for greater and broader exclusionary rights exists under § 101 protection; (4) under 35 USC § 162 (PPA), the applicant is limited to one claim in formal terms to the plant described, whereas there is no such limitation on coverage under § 101; and (5) under 35 USC § 163 (PPA), the plant patent conveys the right to exclude others from asexually reproducing the plant, or selling or using the plant so produced. However, this analysis . . . merely serves to indicate that there are differences in the scope of protection offered by § 101 and the plant-specific Acts. In our view, such differences fall far short of what could be required to find an irreconcilable conflict or positive repugnancy that would mandate a partial repeal of § 101 by implication.

Nor does the fact that subject matter patentable under § 101 overlaps with subject matter protectable under the plant-specific Acts provide a basis for concluding that there is irreconcilable conflict between the statutes. There is ample precedent that the availability of one form of statutory protection does not preclude (or irreconcilably conflict with) the availability of protection under another form. For example, . . . an overlap between statutory subject matter under the copyright statute and statutory subject matter under the design patent statute [is] not . . . an irreconcilable conflict . . . ; rather, the overlap was viewed as an indication that Congress intended the availability of both modes of protection . . . .

The Congress, through its legislation under the authority of the Constitution, has interpreted the Constitution as authorizing an area of overlap where a certain type of creation may be the subject matter of a copyright and the subject matter of a design patent. We see nothing in that legislation which is contradictory and repugnant to the intent of the framers of the Constitution. Congress has not required an author-inventor to elect between the two modes which it has provided for securing exclusive rights on the type of subject matter here involved. If anything, the concurrent availability of both modes of securing exclusive rights aids in achieving the stated purpose of the constitutional provision.

The examiner urges that protection under 35 USC § 101 under the circumstances of this case would be a violation of Article 2 of the International Union for the Protection of New Plant Varieties (UPOV). As pointed out by appellants, however, UPOV is an Executive Agreement that has not been ratified by the Senate. Such agreements are not treaties within the Constitution, and are not the Supreme Law of the Land. Valid enactments of Congress, such as § 101, override conflicting provisions of international executive agreements, irrespective of which came
Ed. note

Polyploidy refers to a condition of having chromosomes numbering some multiple greater than two of the number found in the species' gametic cells. In other words, if a particular species' sperm or egg cell ordinarily contains 23 chromosomes, a polyploid member of that species would have nongametic tissue (i.e., everything except sperm or egg cells) comprising cells that contained 69 chromosomes.

Why did scientists bother? Money, of course:

first in point of time.

The examiner acknowledges that an executive agreement cannot modify a federal statute, but urges, nevertheless, that the agreement can and should be considered "in interpreting a statute on which it bears." This argument overlooks the fact that the Supreme Court in Chakrabarty has already interpreted the scope of Section 101 to cover everything under the sun made by man. In our view, the examiner is asking for an implied partial repeal of § 101 on the basis of an executive agreement. To do so would . . . elevate the agreement to a status superior to an Act of Congress . . . , and we decline to do so.

In his rejection of claims 260 through 265 drawn to tissue cultures, the examiner contends that the claims to tissue cultures are drawn to "asexual propagating material" and may, therefore, be protected under the PPA under § 161. We disagree, and the rejection of claims 260 through 265 is, therefore, reversed for the additional reason that tissue cultures are not "plants" within the purview of 35 USC § 161. The Court of Customs and Patent Appeals [has] interpreted the meaning and scope of the term "plant" in the PPA as having its common, ordinary meaning which is limited to those things having roots, stems, leaves and flowers or fruits. In our view, tissue cultures manifestly do not come within the noted "common, ordinary meaning" of the term "plants" and are, therefore, not within the scope of the PPA. . . .

Reversed.

* * * * *

(ii) Animals

Ex parte Allen
Patent & Trademark Office Board of Patent Appeals & Interferences
2 U.S.P.Q.2d 1425 (1987), 
aff'd without opinion, 846 F.2d 77 (Fed. Cir. 1988)

The subject matter on appeal relates to polyploid oysters.\(^5\) The four rejected claims are

\(^5\)Ed. note – Polyploidy refers to a condition of having chromosomes numbering some multiple greater than two of the number found in the species' gametic cells. In other words, if a particular species' sperm or egg cell ordinarily contains 23 chromosomes, a polyploid member of that species would have nongametic tissue (i.e., everything except sperm or egg cells) comprising cells that contained 69 chromosomes.
The invention at issue in the *Allen* decision is an example of enhanced food source research. That case involved a patent on a method for making Pacific oysters unable to reproduce. Scientists found that exposing newly fertilized oyster eggs to extreme water pressure disrupts the normal allocation of chromosomes during cell division, leaving the oysters with three copies of each chromosome, instead of the normal two (called polyploidy). This makes the oysters sterile and also eliminates their normal two-month reproductive cycle, during which they are inedible. Thus oysters treated with the new method can be harvested year-round.

fertilizing said eggs with sperm to form zygotes;
applying hydrostatic pressure of approximately 6000 to 10,000 psi for a
predetermined duration approximately 15 minutes after fertilization
to said zygotes to induce polyploidy; and
cultivating said polyploid zygotes.

Claims 8 and 12 through 14 are rejected for obviousness under 35 USC § 103 in view of
(existing studies of polyploid oysters) and are also rejected under 35 USC § 101 on the ground
that the claimed invention is directed to nonstatutory subject matter.

In support of his rejection under 35 USC § 101, the examiner states that polyploid oysters
are held to be living entities and do not fall within the statutory subject matter of 35 USC § 101.
The examiner adds that the animal produced by the method claimed is "controlled by laws of
nature and not a manufacture by man that is patentable." The examiner also relies on In re Merat
and In re Bergy in support of his position. In . . . Merat the Court affirmed a rejection under 35
USC § 112 and did not reach the 35 USC § 101 rejection made by the examiner . . . . Although
the Court reversed a 35 USC § 101 rejection in Bergy and held that living microorganisms were
within the terms "manufacture" and "composition of matter" in § 101, the examiner notes that the
Court in its opinion categorized the claimed microorganisms as "more akin to inanimate
chemical compositions such as reactants, reagents, and catalysts than they are to horses and
honeybees or raspberries and roses."

We shall not sustain this rejection. As we have previously noted in our decision in Ex
parte Hibberd, the Supreme Court has interpreted the scope of 35 USC § 101 in the recent case
of Diamond v. Chakrabarty . . . . The examiner's position that the claimed polyploid oysters are
"held to be living entities" is not controlling on the question of whether the claims are drawn to
patentable subject matter under 35 USC § 101 because the Supreme Court made it clear in its
decision in Chakrabarty that § 101 includes man-made life forms. The issue, in our view, in
determining whether the claimed subject matter is patentable under § 101 is simply whether that
subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable
subject matter under § 101. The fact, as urged by the examiner, that the oysters produced by the
claimed method are "controlled by the laws of nature" does not address the issue of whether the
subject matter is a non-naturally occurring manufacture or composition of matter. The examiner
has presented no evidence that the claimed polyploid oysters occur naturally without the
intervention of man, nor has the examiner urged that polyploid oysters occur naturally. The
record before us leads to no conclusion other than that the claimed polyploid oysters are non-
naturally occurring manufactures or compositions of matter within the confines of patentable
subject matter under 35 USC § 101. Accordingly, the rejection under Section 101 must be
reversed.

The examiner's reliance on . . . Merat is misplaced because Merat was decided before the
decision by the Supreme Court in Chakrabarty. The Board in Merat did not have the benefit of
the Supreme Court's analysis of the scope of § 101 . . . . The Board of Patent Appeals and Interferences is now obliged to interpret § 101 in accordance with *Chakrabarty*.

Nor does the examiner's position find any support in the *Bergy* decision. The holding in *Bergy* that the fact that the claimed culture was alive did not remove it from the categories of invention enumerated in § 101 is consistent with *Chakrabarty*. The Court in *Bergy* made clear that it was only deciding the case before it and was not "deciding whether living things in general, or, at most, whether any living things other than microorganisms, are within § 101." Moreover, . . . *Chakrabarty* is controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man."

[The appeals board affirmed the examiner on the § 103 issue, reasoning that "it would have been obvious to one of ordinary skill in the art to induce polyploidy in Pacific *Crassostrea gigas* oysters." As a result, the board affirmed the examiner's rejection of the disputed patent claims despite its holding that oysters qualified as patentable subject matter under § 101.]

*Affirmed.*

*Policy on Patenting of Animals*
United States Patent and Trademark Office

A decision by the Board of Appeals and Patent Interferences in *Allen* held that claimed polyploid oysters are nonnaturally occurring manufacture or compositions of matter within the meaning of 35 U.S.C. § 101. The Board relied on the opinion of the Supreme Court in *Diamond v. Chakrabarty*, as it had done in *Hibberd*, as controlling authority that the Congress intended statutory subject matter to '"include anything under the sun that is made by man."' The Patent and Trademark Office now considers nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter under 35 U.S.C. § 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. §§ 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties, or combination not present in the original article existing in nature . . . .

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. § 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a nonplant multicellular organism which would include a human being within its scope include the limitation "nonhuman" to avoid this ground of rejection. . . .
Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a nonhuman "nonnaturally occurring manufacture or composition of matter – a product of human ingenuity, Chakrabarty, such claims will not be rejected under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.

* * * * *

Although Allen established the patentability of animals under 35 U.S.C. § 101 and the Patent Office announced its policy on animal patents almost immediately, no animal patent issued until April 12, 1988. That day the Patent Office issued the following patent for an invention that came to known as the "Harvard mouse":

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Notice that the text does not include any images, tables, or diagrams. It is a continuous block of text discussing the patentability of animals.
Ed. note — A eukaryote's cells house genetic material in a nucleus and contain other specialized structures to coordinate cell functions. Unlike simpler prokaryotes (such as bacteria), eukaryotic organisms are usually multicellular. Germ cells are sperm and egg cells; somatic cells are all else. The text of the patent defines "transgenic" and "oncogene" better than I can.

7Ed. note — See also U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE 12-13 (1989) ("Transgenic animals are those whose DNA, or hereditary material, has been augmented by adding DNA from a source other than parental germplasm, usually from different animals or from humans.").
neoplasms (particularly malignant tumors) in the animal.

Introduction of the oncogene sequence at the fertilized oocyte stage ensures that the oncogene sequence will be present in all of the germ cells and somatic cells of the transgenic animal. The presence of the oncogene sequence in the germ cells of the transgenic "founder" animal in turn means that all of the founder animal's descendants will carry the activated oncogene sequence in all of their germ cells and somatic cells. Introduction of the oncogene sequence at a later embryonic stage might result in the oncogene's absence from some somatic cells of the founder animal, but the descendants of such an animal that inherit the gene will carry the activated oncogene in all of their germ cells and somatic cells.

Any oncogene or effective sequence thereof can be used to produce the transgenic mice of the invention. The animals of the invention can be used to test a material suspected of being a carcinogen, by exposing the animal to the material and determining neoplastic growth as an indicator of carcinogenicity. This test can be extremely sensitive because of the propensity of the transgenic animals to develop tumors. This sensitivity will permit suspect materials to be tested in much smaller amounts than the amounts used in current animal carcinogenicity studies, and thus will minimize one source of criticism of current methods, that their validity is questionable because the amounts of the tested material used is greatly in excess of amounts to which humans are likely to be exposed. Furthermore, the animals will be expected to develop tumors much sooner because they already contain an activated oncogene. The animals are also preferable, as a test system, to bacteria because they, like humans, are vertebrates, and because carcinogenicity, rather than mutagenicity, is measured.

The animals of the invention can also be used as tester animals for materials, e.g., antioxidants such as beta-carotene or Vitamin E, thought to confer protection against the development of neoplasms. An animal is treated with the material, and a reduced incidence of neoplasm development, compared to untreated animals, is detected as an indication of protection. The method can further include exposing treated and untreated animals to a carcinogen prior to, after, or simultaneously with treatment with the protective material.

The animals of the invention can also be used as a source of cells for cell culture. Cells from the animals may advantageously exhibit desirable properties of both normal and transformed cultured cells; i.e., they will be normal or nearly normal morphologically and physiologically, but can be cultured for long, and perhaps indefinite, periods of time. Further, where the promoter sequence controlling transcription of the oncogene sequence is inducible, cell growth rate and other culture characteristics can be controlled by adding or eliminating the inducing factor.

**Testing for Cancer Protection**

The animals of the invention can be used to test materials for the ability to confer
protection against the development of neoplasms. An animal is treated with the material, in parallel with an untreated control transgenic animal. A comparatively lower incidence of neoplasm development in the treated animal is detected as an indication of protection.

**Tissue Culture**

The transgenic animals of the invention can be used as a source of cells for cell culture. Tissues of transgenic mice are analyzed for the presence of the activated oncogene, either by directly analyzing DNA or RNA, or by assaying the tissue for the protein expressed by the gene. Cells of tissues carrying the gene can be cultured, using standard tissue culture techniques, and used, e.g., to study the functioning of cells from normally difficult to culture tissues such as heart tissue.

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Seven months after the Patent Office issued Patent No. 4,736,866, E.I. DuPont de Nemours & Co., as licensee of the President and Fellows of Harvard College, announced it would sell "Oncomice" containing activated human cancer genes at $50-$100, five to ten times the price of an ordinary laboratory mouse.

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_The patentability of human genetic information_. The Harvard mouse patent suggests that "[m]ost potentially patentable animals are likely to be transgenic animals produced via recombinant DNA techniques or genetic engineering." Is there any biological limit on legal recognition of property rights in life forms? Recall that the Patent Office's policy on animal patents declared that "[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." What could the Patent Office have meant? That granting a patent on a transgenic human would violate the constitutional ban on "slavery [and] involuntary servitude"? "Despite [the Patent Office's] proclamation, the patentability of [an invention involving a human genotype that meets the statutory patent requirements and expresses a distinct phenotype] remains an unsettled question, both because the PTO did not detail the grounds for its position and because the PTO policy appears to rest on constitutional issues it lacks the authority to resolve." Congress has attempted a preemptive strike at the still unrealized prospect of

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8_**Id.**_ at 12.

9_See (perhaps) U.S. **CONST.** amend. XIII._

Patenting Biotechnology

Patent law, however, may not deliver the final answer on the recognition of property rights in human tissue and the human genome. In Moore v. Regents of the University of California, the California Supreme Court rejected the argument that an individual enjoys a right of ownership or possession in cells excised from his or her body.

The Human Genome Project, an ambitious $3 billion, 15-year project dedicated to the monumental mission of locating all human genes, raised the possibility of patents on human DNA sequences. On June 20, 1991, the National Institutes of Health (NIH), applied for patents on 315 distinct human DNA sequences. Most observers gave these applications little chance of success because no one had identified the useful function, if any, of these sequences and because the DNA sequences were more readily characterized as products of nature rather than as invented compositions of matter. In February 1992 and again in August 1993, the NIH filed additional patent applications; these filings embraced 2,106 and 4,448 DNA sequences respectively. Together, these claims, if successful, would have given the NIH exclusive control over roughly five percent of the human genome. On February 10, 1994, the NIH abandoned its patent bid, and the British Medical Research Council withdrew its parallel patent application on the next day.

Suffice it to say that the furious debate over this issue will surely continue. How this

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branch of the law will affect agriculture is largely a matter of speculation.

5. Challenges to Patents on Living Matter

United States: In recent years, holders of seed/crop utility patents have used the judicial system against farmers and farm supply companies to enforce their patent rights. In response, some farmers and supply companies defended by alleging that patents on higher living matter are unconstitutional and statutorily unauthorized. The Supreme Court rejected these arguments in \textit{v. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l Inc.}, 534 U.S. 124 (2001). The Supreme Court reaffirmed \textit{Diamond v. Chakrabarty} that living matter is patentable subject matter under the patent statutes of the United States. The \textit{J.E.M. Ag Supply} case is the first case specifically to uphold utility patents for plants because the \textit{Chakrabarty} case involved microorganisms. The \textit{J.E.M. Ag. Supply} case did not involved genetically modified plants. Pioneer Hi-Bred had obtained a patent on conventionally bred corn. Patents depend upon proving the elements for obtaining a patent and are not contingent upon the technique used. As of January 2003, two patent infringement cases do involve genetically modified plants: \textit{Monsanto Co. v. McFarling}, 302 F.3d 1291 (Fed. Cir. 2002) and \textit{Monsanto Co. v. Trantham}, 156 F. Supp.2d 855 (W.D. Tenn. 2001).

Canada: Patents on living matter have also been a contentious issue in Canada. In 1985, Harvard University filed a patent application with the Canadian Intellectual Property Office (CIPO) for the “oncomouse.” As you know from a reading a few pages earlier in this book, the United States Patent and Trademark Office (USPTO) issued a patent to Harvard for this oncomouse in 1988.

After several hearings and significant debate, the CIPO rejected a patent on the oncomouse for Harvard in 1995 on the basis that living animals were not within the subject matter for which patents were allowed under Canadian law. In December, 2002, the Supreme Court of Canada agreed with the CIPO. The Supreme Court of Canada focused on statutory interpretation of the Canadian patent laws and expressly disclaimed any decision on ethics, morality, or constitutional interpretation. \textit{Commissioner of Patents v. President and Fellows of Harvard College}, 2002 SCC 76. While declining to allow a patent on the “oncomouse,” the Supreme Court of Canada did uphold Harvard’s process patents for creating the mouse.

With the decision of the Supreme Court of Canada denying a patent for the oncomouse, it is unclear what impact this decision will have upon \textit{Monsanto Co. v. Schmeiser}, 2001 FCT 256 (Sask.) \textit{aff’d on appeal}, 2002 FCA 309. In the \textit{Schmeiser} case the federal Canadian trial court and the federal Canadian appellate court have found that Mr. Schmeiser infringed Monsanto’s patent in Round-up Ready canola by saving seed that he knew or should have known contained Monsanto’s patented gene and cell that makes canola a herbicide-tolerant to glyphosate. Schmeiser has asked the Supreme Court of Canada to take his case.

The \textit{Schmeiser} case raises the issue as to whether plants and animals will both be considered higher life forms or whether the Supreme Court will draw the line between animals and plants. In addition, unlike Harvard, Monsanto Company has never claimed a patent in the
corn plant, but only the created gene and the transformed cell. The Commissioner of Patents of Canada has issued hundreds of patents on plants during the same time the Commissioner has continuously refused to issue a patent for the oncomouse to Harvard. As is obvious, the Commissioner draws a line of some kind between plants and animals based on statutory interpretation of the Canadian patent laws.

European Union: The situation in the European Union and under the World International Property Organization (WIPO) is described later in this book in materials dealing with international law and biotechnology.

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E. PROPOSED REFORMS OF PATENT LAW

It is no understatement to say that Chakrabarty has shaken and reshaped the law affecting farm production. With his usual flair for hyperbole, Jim Hightower has asserted that "animal patents represent the greatest change in agriculture since the invention of the plow." Although genetically altered plants and animals have yet to redefine agriculture, some believe that scientific and economic progress portend an inevitable agricultural revolution. Legislative activity, present and future, is directly proportional to the likelihood that such a revolution will occur. Two factors will drive any legislative reform of the general patent law after the extension of Chakrabarty to agriculture. First, the patentability of new plants and animals promises to restructure individual producers' financial and contractual arrangements and, concomitantly, agricultural markets in general. Second, as our experience with the PVP Act suggests, these patented inventions are uniquely capable of reproducing themselves. So far, proposed reforms of patent law have focused on two distinct class-based interests. Biotechnology firms are keenly interested in removing or lowering "obviousness" as a hurdle to obtaining patents on new plants and animals. By contrast, farmers have sought an exemption to relieve them of some of the burdens of paying royalties on patented animals.

1. The economic impact of biotechnology patents on agriculture

Although the patent laws govern "anything under the sun that is made by man," virtually every patent case excerpted in this chapter has a direct bearing on some aspect of agriculture as food or fiber production. Even the cases chosen as illustrations of general concepts – Graham (plow shanks) and Funk Brothers (organic fertilizer) – involved farming inputs. If successful in promoting additional research and invention, intellectual property protection for plants, animals, and nonliving farming inputs affects the structure of agricultural markets in the following four

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In other words, successfully creating agricultural intellectual property portends the same sort of structural impact on farming as any other industrial advance, at least in the short run. The longer-run benefits that biotechnology patents promise — for example, enhanced export capacity and markets for previously nonexistent products made from novel plant varieties and transgenic animals — may never accrue to the individual producers who will have been forced out of farming by then. Not surprisingly, some agricultural fundamentalists have condemned animal and plant patents. Consider the following excerpt:

**Rebecca Dresser**

*Ethical and Legal Issues in Patenting New Animal Life*

28 Jurimetrics J. 399 (1988)

[A] major target of the anti-patenting efforts is the policy's projected economic effect, particularly on U.S. agriculture. Some say patenting threatens the very survival of the family farm. Many farmers are deeply disturbed at the idea of paying licensing fees and royalties to the biotechnology companies that obtain patents on genetically-engineered animals. They fear that higher costs and increased productivity will force more family farmers out of business, depriving them of their livelihood and destroying the cultural and community values traditionally so important in American agriculture.

Farmers are also worried that patenting will allow a relatively small number of large corporations to gain control of the market for genetically-engineered animals. The current trend toward large firms controlling the livestock business will be exacerbated, they charge, with negative effects on both farmers and consumers. According to Representative Charles Rose, who introduced the bill calling for a moratorium on animal patenting, the PTO [animal patent] policy
"places major chemical, biotechnological and pharmaceutical companies in the position to virtually take over animal husbandry in America." Already, fewer than twenty companies control the poultry industry and have created a system in which individual farmers raise chickens on contract for the companies. To many farmers, this "tenant farming" constitutes an unacceptable loss of independence and autonomy for the individual farmer.

Farmers also cite the seed industry as a disturbing precedent in this regard. Corporate acquisitions of seed companies rose dramatically after the Plant Variety Protection Act was passed in 1970. Seed prices have also risen sharply since that time, and some economists attribute this to the availability of patents. Patenting critics are afraid the same process will occur in the food animal industry, with farmers and consumers bearing the resultant burdens.

Farm groups are also dubious about the true need for animal patenting as a means of increasing agricultural production. Before the patenting policy was issued, over 100 livestock biotechnology companies already existed, and numerous advancements have occurred in the absence of animal patenting. In addition, many believe the major problem in U.S. agriculture is overproduction, not underproduction. Efforts to increase milk production in cows, for example, seem unjustified in light of the existing surplus in the dairy industry. In 1986, the federal government spent $1.8 billion on a dairy buy-out program in which it purchased dairy cows for slaughter in an effort to cut production by 8.7 percent. Farm groups fear innovations such as patented animals will simply worsen the situation, at a high cost to farmers and taxpayers.

But even farmers are not completely unified in their opposition to the patenting policy. In contrast to organizations advocating on behalf of family farmers, the American Farm Bureau Federation generally favors animal patenting. Its representatives predict that patenting will yield healthier and cheaper animals and create new agricultural markets in areas such as molecular farming. They believe the changes will help U.S. agriculture maintain its economic strength and competitive position in world markets.

Other patenting supporters claim that the move toward large corporate control over agriculture will persist whether or not patenting is available. Thus, those dissatisfied with this development are again seeking change in the wrong forum. Others have asserted that patenting could actually help family farmers by reducing the food and drug costs of raising their animals or increasing the value of their commodities (such as might occur with low-calorie beef). This group claims that the market will keep the fees patent holders charge below the advantage the farmer gains in productivity. In this vein, they also note that economists disagree on the genuine effects of patenting on the seed industry, with some analysts attributing the current situation to factors other than patenting.

Finally, patenting advocates argue that any government decision to limit corporate control over the food animal industry should be implemented through the antitrust, tax, or agricultural policy laws, not the patent law. They contend that prohibiting animal patenting would be an
ineffective method to limit corporate control, because corporations could still find ways of controlling access to genetically-engineered animals through trade secret protection or patents on the processes or genes used in creating the novel animals. If the government wants to avoid any negative impact of animal patents on the family farm, the appropriate approach is to create mechanisms to enable all farmers to gain access to this new technological development through agricultural extension services and special subsidies.

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**Biotechnological patents and agricultural market structure.** Predicting the actual impact of any particular animal patent is a daunting task indeed. Complex market structures and the diverse uses of new technology confound any effort to calculate the effect of patenting on inventors, producers, and consumers. The major livestock market sectors present a study in contrasts: surging consumption has boosted broiler chicken production, which happens to be the most thoroughly integrated and most concentrated livestock industry in the United States. Three breeding firms control 90 percent of the market in female chicks; four firms command the same market share in male chicks. Similar trends characterize pork production, though biological factors – a slower reproduction cycle and live birth – will retard the rise of a hog breeding oligopoly comparable to the one in the chick business. (Remember: virtually no form of mammalian reproduction could ever permit the kind of industrialized reproduction that egg-laying by birds enables.) Declining markets provide no shield against concentration; egg production is becoming more concentrated (but remaining competitive). The diminishing sheep market is divided among numerous farms, but only fourteen packers. The complex beef and dairy cattle industries defy quick description, but two distinctions bear noting. First, dairy production is dispersed nationwide (thanks largely to federal milk pricing policies), whereas the beef industry conducts its calf production and cattle feeding operations in a geographically and economically concentrated fashion. Second, dairy farmers rely much more readily than beef producers on artificial insemination.

The potential uses of biotechnology fall into two broad categories: (1) high-value pharmaceutical production and (2) low-value food production. Markets for pharmaceutical products depend initially on the use of patented animals such as Oncomice in biomedical research. Once these animals as disease models establish the viability of pharmaceutical products, larger, milk-producing animals (i.e., cattle) will then become biological factories, generating commercially lucrative quantities of drugs for human consumption. The food markets will shape themselves largely according to various animals' reproductive rate: rapid (as in the case of poultry) or slow (as in the case of cattle, hogs, and sheep). In all cases, industrial structure and methods of reproduction will dictate the economic outcome of animal patents in any particular livestock industry.\(^{18}\)

\(^{18}\)For a fuller discussion of potential economic impacts from animal patents, see U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY:
Patented plants fall into three categories. First, genetically altered plants may enjoy bioengineered resistance to insect, fungal, and viral infestation. Second, plants may be altered to tolerate chemical herbicides. The first improvement directly enhances productivity by reducing crop losses to pests; the second does so indirectly by improving the effectiveness of a chemical pesticide. Finally, as illustrated by a recent process patent on a "Method of inducing lysine overproduction in plants,"\(^{19}\) genetic engineering may improve the nutritional quality of food and feed crops:

Lysine, an amino acid essential in the diet of humans and monogastric animals, is among the three most limiting nutrients in most of the cereal crops. Consequently, grain-based diets, such as those based on corn, barley, wheat, rice, maize, millet, sorghum, and the like, must be supplemented with more expensive synthetic lysine or with lysine-containing oilseed protein meals. Increasing the lysine content of these grains or of any of the feed component crops would result in significant added value. To date, attempts to elevate lysine levels in plants have relied on conventional breeding methods and, more recently, mutagenesis and cell culture technology.

Naturally-occurring high lysine mutants of maize, barley, and grain sorghum have been identified. In each case, the improved lysine content results not from increased free lysine production, but from shifts in the overall protein profile of the grain: the reduced levels of lysine-deficient endosperm proteins (prolamines) are complemented by elevated levels of more lysine-rich proteins (albumins, globulins and glutelins). While nutritionally superior, these mutants are associated with reduced yields and poor grain quality, limiting their agronomic usefulness.\(^{20}\)

By introducing a bacterial dihydrodipicolinic acid synthase gene, the process described in this patent would induce transformed plants to produce at least 50 times more free L-lysine than nontransgenic plants of the same species. In one blow, the patent owner, DeKalb Genetic Corporation, has rendered obsolete any traditional breeding techniques that deliver a less nutrition-laden plant or a less readily cultivated crop.

Note also that the "usefulness" that makes a biotechnological improvement both

\(^{19}\)U.S. Patent No. 5,258,300 (Nov. 2, 1993).

\(^{20}\)Id.
biotechnology

patentable and marketable is often contingent upon changing consumer demand. Iowa State University researchers recently introduced two varieties of "healthier" soybeans: one that remains more shelf-stable without hydrogenation and one that produces an oil low in saturated fats. By the researchers' own admission, had these varieties been discovered twenty years ago, their market prospects would have looked quite dim. Thanks to growing consumer awareness of the links between saturated fat consumption and heart disease, however, these soybean varieties have virtually unlimited market potential.21

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2. Obviating "technical" impediments to biotechnology patents

Now that Chakrabarty and its progeny have firmly established new plant varieties and transgenic animals as patentable subject matter, legal attention has turned to certain "technical" impediments to patenting plants and animals. As the rejection in Merat suggests, section 103's requirement that "the subject matter sought to be patented" not "be[] obvious . . . to a person having ordinary skill in the [prior] art" can prove daunting in the biotechnological context.22 To similar effect are the requirement that an invention not be "known or used by others in this country, or patented or described in a printed publication in this or a foreign country"23 or "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country."24 What is true of pest control is equally true of agriculture: "He who seeks to build a better mousetrap today has a long path to tread before reaching the Patent Office."25 To be sure, the novelty and nonobviousness requirements help prevent needless patents from cluttering the world of invention and discovery. At the same time, the procompetitive impulse "to require that those persons granted the benefit of a patent monopoly be charged with an awareness of . . . changed conditions" in the relevant "fields of science" must nevertheless adhere to the principle of "evenhanded application" across all classes of inventors.26 The next two cases illustrates the peculiar difficulties of overcoming these hurdle in the agricultural context. After reading them and reviewing Merat, consider whether you would favor the legislative proposal

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21See Thomas R. O'Donnell, Developing More Healthful Soybeans, Des Moines Register, Sept. 19, 1994, at 4-B.


23Id. § 102(a)

24Id. § 102(b).


26Id.
that Congress weighed in 1992.

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Ex parte Thomson
Patent and Trademark Office Board of Patent Appeals and Interferences

This is an appeal from the final rejection of claims 1-3, 5 and 6. . . . Claims 1 and 2 are illustrative:

1. A cotton cultivar having the designation Siokra (ATCC 40405).
2. Seeds of the cotton cultivar according to Claim 1

In the rejection of the appealed claims, the examiner relies upon the following references:

Luckett et al., New Zealand Agronomy Society Special Publication No. 5, Quality Requirements and Cotton Breeding in Australia (1986).

Appellant's claimed invention is directed to a cotton cultivar having the designation Siokra. According to appellant, Siokra "possesses the okra leaf character in combination with a high yield, high ginning out turn, good quality fiber and with resistance to 18 common races of the wide spread disease, bacterial blight." In addition, it is said that Siokra provides a good yield under a range of environmental conditions. . . .

Appealed claims 1-3, 5 and 6 stand rejected under 35 USC § 102(b) as being clearly anticipated by either Luckett or Duff in light of Thomson.

We have thoroughly reviewed the entire record before us, which includes the well-articulated positions presented by both appellant and the examiner. In so doing, we concur with the examiner that the claimed subject matter was described in a printed publication under circumstances whereby it was in the possession of the public more than one year prior to the filing date of the present application. Accordingly, we will sustain the examiner's rejection for essentially those reasons expressed in the Answer, and add the following.

There is certainly no dispute that the claimed cotton cultivar, seeds of the cultivar, etc. are disclosed in each of the applied references . . . . Each discloses the commercial growth of the claimed Siokra. There is also agreement [over] the applicable law governing the propriety of rejections under 35 USC § 102(b) . . . :
It is well settled that prior art under 35 USC § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it . . . . Such possession is effected if one of ordinary skill in the art could have combined the publication’s description of the invention with his own knowledge to make the claimed invention . . . . Accordingly, even if the claimed invention is disclosed in the printed publication, that disclosure will not suffice as prior art if it was not enabling.

It is appellant's position that inasmuch as at least 12 breeding steps are necessary to arrive at the claimed Siokra cultivar, and not one of the applied references provides sufficient disclosure of such breeding steps, the references are non-enabling for the skilled artisan and, therefore, cannot anticipate the claimed invention within the meaning of 35 USC § 102. On the other hand, while the examiner acknowledges that the cited references do not disclose appellant's breeding steps, the examiner maintains that the references do disclose that the claimed Siokra, at least in Australia, was commercially available to the skilled artisan for more than one year prior to the present filing date. Therefore, the examiner concludes that both Duff and Luckett are enabling disclosures since "in the absence of evidence to the contrary, it is self-evident that the public was already in possession of the invention such that a person of skill in the art could obtain and reproduce the invention by seed germination without experimentation."

In upholding the examiner's rejection, we think it important to focus upon both the subject matter being claimed and the knowledge that can be reasonably attributed to one skilled in the relevant art at the time of filing the present application. In the present case, the claims on appeal are not directed to the process of breeding a specific cotton cultivar. Rather, the appealed claims define particular agricultural products, such as the cotton cultivar Siokra, as well as the seed, plants and pollen thereof. Thus, keeping in perspective the nature of the claimed subject matter, the question becomes would the skilled artisan, armed with the disclosures of the cited articles, have had the requisite knowledge to make the claimed invention, viz., the Siokra cultivar and its seeds, plants and pollen.

Stated as such, we are convinced that the skilled cotton grower would have had the wherewithal, upon reading the publicly disseminated reference articles, to purchase the commercially available Siokra seeds, and employ conventional techniques to plant and nurture the seeds to maturity in order to obtain the claimed invention, i.e., Siokra plants, seeds and pollen. . . . Appellant has proffered no objective evidence on this record that the claimed Siokra seeds were unavailable to the skilled artisan, or that undue experimentation would have been required to reproduce Siokra by germination of the commercially available seeds.

In the absence of such evidence, the examiner's position is reasonable and in accordance with current patent jurisprudence.

Appellant contends that the examiner's position amounts to an improper and
impermissible combination of the two separate and distinct bars to patentability recited in section 102(b), namely that 1) the invention was patented or described in a printed publication in this or a foreign country or 2) in public use or on sale in this country. Appellant urges that the printed publication bar is not available because the publication is not enabling, and that the "on sale" bar is not available because the on sale activities occurred in a foreign country. However, we concur with the examiner that the applied rejection does not rely upon or incorporate the public use or on sale bar of the statute. As explained above, we are satisfied that the material disclosed in each of Luckett, Duff and Thomson, when considered in conjunction with the knowledge of the skilled cotton grower, would have enabled such a skilled artisan to make the claimed Siokra cultivar, along with its seeds, plants, pollen, etc., by purchase and planting of the requisite seeds . . . .

Manifestly, it is reasonable to conclude that, at the time the cited articles were published, skilled artisans throughout the world would have found Siokra seeds readily available on the open market. Again, there is no evidence of record to the contrary. . . .

In the present case there is ample evidence, indeed, not any dispute, that seeds of the claimed cotton cultivar described in the cited publications were commercially available more than one year prior to appellant's filing date. . . . [T]he sexually reproduce seeds of the Siokra cultivar do reproduce the claimed Siokra cultivar. Hence, the commercially available seeds themselves enable reproduction of the claimed cotton cultivar. We find it significant that for enablement purposes the descriptive words of the specification herein do not differ substantially from the disclosures of the cited publications. Appellant's specification is rendered enabling by virtue of the availability of the claimed seeds deposited in the American Type Culture Collection while the enabling quality of the cited publications is assured by the public availability of the same cotton seeds. Such public accessibility to the claimed seeds would have enabled the skilled artisan to make and use the claimed cotton cultivar, its seeds, etc. . . .

Affirmed.

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Ex parte Allen
Patent & Trademark Office Board of Patent Appeals & Interferences
2 U.S.P.Q.2d 1425 (1987),
aff’d without opinion, 846 F.2d 77 (Fed. Cir. 1988)

[In the portion of this opinion excerpted above, the board reversed the patent examiner's conclusion that animals fell outside 35 U.S.C. § 101's definition of patentable subject matter. In the portion excerpted below, the board turned to the § 103 problem of "obviousness":]

With respect to the rejection under 35 USC § 103 . . . [w]e have decided that we will affirm . . . .
[Existing scholarship by Stanley et al.] disclose[s] a method of inducing polyploidy in oysters involving the use of cytochalasin B. [The authors] report that they successfully induced polyploidy in the American oyster, *Crassostrea virginica*, by treating the fertilized eggs with cytochalasin B. The treatment resulted in polyploidy of over half the individuals. [The authors] recommend the induction of polyploidy in oysters as a way to increase growth as follows:

We have shown a clear growth advantage in triploid American oysters produced by blocking the first meiosis division. We recommend induction of polyploidy as a way to increase growth in cultured oysters.

We agree with the examiner that in view of the express recommendation [by] experts in the art who have successfully induced polyploidy in one species of oysters, it would have been obvious to one of ordinary skill in the art to induce polyploidy in Pacific *Crassostrea gigas* oysters. Moreover, one of ordinary skill in the art would have a reasonable expectation that the [Stanley] method would be successful in inducing polyploidy in *Crassostrea gigas* oysters based on the success . . . *Crassostrea virginica* oysters and the recommendation . . . to utilize the method with cultured oysters. Although appellants utilize a different process . . . to induce polyploidy in oysters, involving the use of hydrostatic pressure rather than chemical treatment, the patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Thus, the examiner has correctly adduced a prima facie case of obviousness for the claimed polyploid oysters, and the burden shifted to appellants to rebut the prima facie obviousness. In our view appellants have not done so.

In an attempt to rebut the examiner's prima facie case of obviousness, appellants rely on the declaration of co-inventor Allen . . . that there are distinctive phenotypic differences between *c. gigas* and *c. virginica*, and that it would not have been obvious to apply the prior art techniques to *c. gigas*, because the [Stanley] techniques . . . do not work on *c. gigas*. Appellants argue that, based on the Allen declaration, the claimed Pacific *c. gigas* oysters would not have been obvious . . . because the [Stanley] techniques do not work on *c. gigas* oysters. Allen urges further that a modification of a prior art process which renders the process inoperable cannot serve as a basis for a § 103 rejection.

We agree with the Examiner that the Allen declaration is not persuasive of nonobviousness . . . [T]he examiner challenged the noted conclusion of inoperability, as do we, and pointed out that the declaration as a whole supports the examiner's position of obviousness. . . . [T]he declaration indicates . . . that low yields are obtained and near total mortality is experienced when treating *c. gigas* oysters at the precise temperature and duration of chemical treatment [as Stanley recommended]. Such facts do not establish inoperability of the reference. Quite clearly, inoperativeness is not established merely by showing that the particular disclosed embodiment for carrying out the principles of the invention is lacking in perfection.
We agree with the examiner that it is well within the skill of the art to optimize the parameters such as temperature and time of chemical treatment when applying the [existing] process to a different species of oyster in order to obtain the optimum yield of polyploid oysters. The fact that such optimization may be required when utilizing the . . . recommended method to induce polyploidy in *c. gigas* oysters does not in our view render polyploid *c. gigas* oysters unobvious. . . .

We attach no significance to the fact that appellants may have experimented for three years to develop an "acceptable" treatment in the absence of any indication of what experimentation was undertaken and what constitutes an "acceptable" treatment. The fact remains that [Stanley] recommended the cytochalasin B treatment for the induction of polyploidy in cultured oysters generally, and that appellants followed that recommendation by using the cytochalasin B treatment to induce polyploidy in *c. gigas* oysters. After some modifications in process parameters, such as temperature and time of treatment, the process was "acceptable." . . .

We disagree with appellants' characterization of the examiner's rejection as "obvious to try." In the circumstances here where experts in the art have successfully utilized the process with one species of oyster and have specifically recommended that the process be utilized with cultured oysters generally, we agree with the examiner that it would have been obvious to one skilled in the art to apply the process to Pacific *c. gigas* oysters, and that he would have had a reasonable expectation, indeed a strong expectation, of success in producing a polyploid oyster. In our view the successful utilization of the [Stanley] process to produce an "acceptable" cytochalasin B treatment for induction of polyploidy in *c. gigas* oysters, albeit with some optimization of process parameters, substantiates the reasonableness of the expectation of success.

Appellants' argument that the claimed polyploid *c. gigas* oysters are unobvious because they are sterile and do not devote significant portions of their body weight to reproduction, thereby remaining edible year around, is not persuasive. It was known in the area that polyploids exhibit sterility. Thus, it is not unexpected that sterile, polyploid *c. gigas* oysters do not devote significant portions of their body weight to reproductive gamete formation.

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**Biotechnology Patent Protection Act (proposed)**
S. 654, 102d Cong., 2d Sess.
138 Cong. Rec. S14,313-01 to S14,314 (Sept. 21, 1992)

S. 654

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
TITLE I – BIOTECHNOLOGICAL PROCESS PATENTS

§ 101. CONDITIONS FOR PATENTABILITY; NONOBSVIOUS SUBJECT MATTER.

Section 103 of title 35, United States Code, is amended—

(1) in the first unnumbered paragraph by inserting "(a)" before "A patent";

(2) in the second unnumbered paragraph by inserting "(b)" before "Subject matter"; and

(3) by adding at the end thereof the following new subsections:

"(c) Notwithstanding any other provision of this section, a claimed process of making or using a machine, manufacture, or composition of matter is not obvious under this section if—

"(1) the machine, manufacture, or composition of matter is novel under section 102 of this title and nonobvious under this section;

"(2) the claimed process is a biotechnological process as defined in subsection (d); and

"(3)(A) the machine, manufacture, or composition of matter, and the claimed process invention at the time it was made, were owned by the same person or subject to an obligation of assignment to the same person; and

"(B) claims to the process and to the machine, manufacture, or composition of matter, are entitled to the same effective filing date, and appear in the same patent application, different patent applications, or patent application and patent which are owned by the same person and which expire or are set to expire on the same date.

"(d) For purposes of this section, the term `biotechnological process' means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material." . . . .

* * * *

In Chakrabarty, Hibberd, and other cases, you may have noticed the very important distinction between product claims and process claims. Even when a product claim for a patent on a bioengineered plant or animal fails, the inventor may be able to retain substantial proprietary protection by preserving his or her claim to a biotechnological process based on the unpatented or unpatentable organism. Both the proposed Biotechnology Patent Protection Act of 1992 and
its 1993 successor, S. 298, sought to enhance the patentability of biotechnological research by establishing a presumption of validity with respect to the process claim even when the related product claim is invalidated.

* * * * *

Grinding farmers into oblivion inside the treadmill of the gods. The disputes that the new generation of plant and animal patents has spawned are as varied as the intricacies of the patent laws. Neil D. Hamilton has documented several of the more contentious battles, each pitting biotechnological giants against each other over control of potentially huge markets.\(^{27}\) Pioneer Hi-Bred International has challenged Librizol's patent claims to "high oleic acid sunflowers" on grounds similar to those in Thomson.\(^{28}\) Calgene's work in antisense technology, which enables a plant to block protein production and slow its ripening process, may hinge on its efforts to invalidate a 1983 patent held by Enzo Biochem and to defend its own 1989 patent against a challenge by ICI Seeds.\(^{29}\)

Perhaps the most remarkable of the recent wave of biotechnology patents involved a claim that has threatened to give one biotechnology firm effective command of the world cotton market. Agracetus, Inc., a biotech subsidiary of W.R. Grace & Co., originally announced in 1987 that it had used the plant pathogen Agrobacterium tumefaciens to effect the genetic transformation of upland cotton (Gossypium hirsutum).\(^{30}\) By 1992, Agracetus secured a patent on not only the Agrobacterium-mediated method of genetic engineering, but also any plant varieties developed with this method:

Cotton seed capable of germination into a cotton plant comprising in its genome a chimeric recombinant gene construction including a foreign gene and promoter and control sequences operable in cotton cells, the chimeric gene construction being effective in the cells of the cotton plant to express a cellular product coded by the foreign gene, the cellular product imbuing the plant with a detectable trait, the cellular product selected from the group consisting of a foreign protein and a


\(^{28}\)Id. at 648-49.

\(^{29}\)Id. at 649, 651-52.

negative strand of RNA.\textsuperscript{31}

Agracetus scientists have also developed a technique for blasting DNA-coated metallic particles into cotton germ cells.\textsuperscript{32} The firm will not license rights to this so-called Accell® technology.\textsuperscript{33}

The Agracetus patent casts an immense over the world cotton trade because upland cotton, the species at issue, represents nine-tenths of the world's cotton output and because cotton engineered through Agracetus technology is seizing an ever larger share of the upland cotton market. As owner of a marvelous new technology, Agracetus can reap massive rents at all levels of production — not only the growing of genetically engineered cotton, but also the manufacturing and marketing of new fabrics made possible by the improved cotton crop. Agracetus's commercial ambitions are as grand as its legal claims; the firm expects that it will be in a position to license all transgenic cotton in the United States and any other country that recognizes its proprietary interest in this cotton technology.\textsuperscript{34} As Hamilton describes the implications of Agracetus's patent:

If the patent is determined to be as broad-based as claimed and if future developments lead to the prevalence of genetically engineered cotton in the U.S., then the company will have literally patented cotton, much like how Polaroid has patented instant processing cameras. . . . A claim to a whole crop species is perhaps the ultimate trump card in a serial stacking of competing patent claims. If such a broad-based patent is in fact possible, the ability of other researchers, both public and private,\textsuperscript{35} to continue efforts to improve cotton would be directly affected. Cotton producers would also be directly affected because patents do not contain an express farmer crops exemption, as do breeders' rights under the PVPA. As a result, farmers could not save seed from one crop to plant the next

\textsuperscript{31}U.S. Patent No. 5,159,135, cl. 1.


\textsuperscript{35}Ed. note – Recall that the Patent Act of 1952, unlike the PVPA, does not include a research exemption.
year without being subject to allegations of infringing the patent. In addition the ability of a company . . . to claim the patented crop would create a mechanism for them to capture most or all of the higher value engineered into the product. Farmers would pay more for the improved genetics with perhaps the only "improvement" being the higher profits of the companies marketing the seed.36

On November 25, 1994, a patent examiner in the United States Patent Office reexamined and rejected Patent Nos. 5,159,135 and 5,004,863 – the legal heart of Agracetus's cotton juggernaut – on the grounds that some claims had been described in scientific publications for more than one year prior to Agracetus's patent application and that other claims were obvious from the prior art in plant genetics.37 As of this printing, the patent remains in legal limbo.

The battle over "super-patents" is spreading, in legal terms and in biological terms. The Rural Advancement Foundation International (RAFI), one of the most vocal opponents of biotechnological patents,38 has challenged Agracetus's European patent on genetically engineered soybeans on the grounds that plant or animal patents violate the *ordre publique* provision of the European Patent Convention. The soybean patent, RAFI argues, threatens the "public morality" by "granting a single corporation monopoly control over genetic research on one of the world's most important food crops."39 Closer to home, Mycogen Plant Science, Inc., has recently received a patent on "[s]ynthetic *Bacillus thuringiensis* toxin genes to be expressed in plants at a level higher than naturally-occurring *Bt* genes are provided."40 (*Bt* toxin is an insect-killing protein.) Because this patent governs biotechnology at such a basic level – Mycogen's method modifies *Bt* gene sequences so that they resemble plant genes and are therefore readily activated by a target plant – Mycogen's coup casts a long legal shadow "over efforts at several other companies to develop *Bt* plants."41

The Agracetus patent and the legal developments related to it raise the specter of plant


38See *supra* note 33.


breeders and animal genetics companies seizing complete control of farm production through forced licensing of critical agricultural intellectual property. In the cotton fields that swaddle the world, agribusiness marketing and biotechnological wizardry have combined to transform the mythical power to create life into a coarse but very tangible power to corner basic commodity markets. In such a world, farmers have reduced value as skilled laborers and almost no value at all as traditional plant breeders. Like no other technological advance before it, an agribusiness-driven "treadmill of the gods" promises to obliterate the economic, political, and social market for farming skills and agrarian values. Hence the recurring call for patent law reform in the image of the PVPA as that statute existed before 1994.

* * * * *

3. A farmer's exemption under the general patent law?

Recall that biotechnology firms pressed to protect their inventions under the general patent law partly because the crop exemption to the PVPA reduced the profitability of new openly pollinated plant varieties. Plant breeders and farm advocates are reasonably close in agreeing that abuse of the crop exemption helps neither inventors nor producers. Animals, however, may present a distinguishable situation. Furthermore, as we have just seen, broad patent protection for plants could expose farmers to potential liability and additional administrative burden. The following excerpt describes the farmer's perspective in the animal context and states the case for a farmer's exemption:

Robert P. Merges

*Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*

47 Md. L. Rev. 1051, 1068-73 (1988)

V. PRACTICAL IMPACT OF ANIMAL PATENTS

At least in the short term, [most of] the problems engendered by animal patents . . . . will stem from the fact that animals are self-reproducing. Unlike other patented technologies, humans will not have to intervene for a patented animal to be "copied."

The self-reproducing feature of animals will have one of two effects, depending on the normal function of the animal and the goal of the people involved in its reproduction. Under current law, if the purchaser or licensee of a patented animal intentionally breeds it, or tries to copy its patented features in the laboratory, with the goal of attempting to maintain and reproduce the patented trait, the purchaser probably will be liable for patent infringement. But if the animal is simply permitted to mate with other, nonpatented animals under normal pen or cage conditions, the law is unclear as to whether liability will attach. This gap in current law – and the uncertainty it creates – provides the rationale for [a] farmer's exemption . . . .
To understand the law as it relates to intentional reproduction of the patented feature, consider the example of a research laboratory which buys or licenses a patented rat. Suppose the rat has been engineered so that it contains a defective human gene which causes a common disease in humans. The patentee sells the rat to laboratories who want to test the effectiveness of drugs against the disease. To avoid paying more royalties, the owners of the research laboratory could mate the rat with one of their own and hope that half of the offspring exhibit the patented feature. The patentee would argue that the laboratory was infringing its patent.

A line of Supreme Court cases provides the authority for this argument. Under these cases the Court has held that while the purchaser or licensee of a patented product may use or resell the product, or even replace worn-out components, the entire product may not be reconstructed when its useful life is over. Thus so long as the patentee could prove that the infringer intentionally mated the patented animal, with the goal of reproducing the patented trait, infringement probably would be established.

As a practical matter, it would not be difficult for the patentee to prove infringement. Molecular biologists have devised a number of techniques for determining the presence of a specific gene or sequence. Patentees no doubt would find it worth their while to apply these techniques to the development of simple tests that would indicate the presence of the patented gene or sequence in offspring of the animal.

In addition, license agreements can be expected to resolve many potentially troublesome issues. Such issues as the right of the patentee to test for infringing offspring, and the right to prohibit the resale of patented animals for breeding purposes, can be expected to be solved in this manner. In other areas where intellectual property right involve difficult problems of infringement and enforcement, such as in the licensing of computer software, the parties involved have demonstrated a high degree of creativity in drafting contractual solutions to these problems.

In sum where a customer tries to perpetuate a patented trait, infringement is clear. Moreover, the existence of sound law in this area will provide a solid framework within which parties to license agreements may bargain over the details of enforcement and the like. But what about incidental or unintentional reproduction as a result of normal breeding activities? The rules here are far less clear, making a farmer's exemption a logical solution.

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80 Unintentional mating outside the breeder's control, however, might be a different story. The intent to reproduce the trait would best reveal itself if, for example, the purchaser of the patented animal began to sell the offspring of the animal containing the trait. Such an obvious attempt to set up a business competing with the patentee's would clearly establish infringement.
A. Necessity for a Limited Livestock Farmer's Exemption

As mentioned above, unintentional copying of the patented trait via routine reproduction presents an ambiguous situation under existing law. In reality, this copying will probably not be of much concern to companies in the business of supplying research animals, because those animals are easy to keep separate. It is likely to be a real problem, however, with farmers.

Farmers will want to use patented animals (and their descendants) for normal breeding with the other animals on their own farms. For reasons outlined below, this is a problem area where private, contractual solutions are unlikely to be effective. Thus there exists a need for a limited livestock farmer's exemption from infringement liability.

The exemption would closely parallel the provisions of the farmer's crop exemption of the Plant Variety Protection Act of 1970, which reads as follows:

[I]t shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale [to another farmer without use of a middleman].

The Plant Variety Protection Act (PVPA) protects sexually reproduced varieties of plants; it is only intellectual property statute in American law that has ever dealt with the question of self-reproducing subject matter. Equally important, it was drafted with a sensitivity to the practical problems of farmers who have to cope with intellectual property rights over their primary source of livelihood. The PVPA therefore provides an excellent starting place to look for solutions to the practical problems farmers will be faced with in the area of animal patents.

Such an exemption would not destroy the market for a patentee's invention, because of a phenomenon known as "genetic drift." Even in the first generation of offspring from a patented animal (assuming it was not mated with another that possessed the patented trait), only a maximum of sixty percent of the offspring, and quite likely a much smaller percentage, would possess the patented trait. As a consequence, farmers who wanted the advantages of a patented animal would soon have to buy or license a new one, even with an exemption for on-farm breeding. Thus the exemption would not undercut in any serious way the financial incentives for patentees to engage in research and development of new animals.

A similar situation prevails with respect to seeds protected by the PVPA. The farmer's crop exemption has not severely undermined the efficacy of the PVPA, because farmers typically have to buy new seeds after two or three years. Again, genetic drift is the reason. In addition, there is some evidence that seed companies have taken the exemption into account, and have adjusted the prices of the protected seed to reflect a two- or three-year useful life.
In any event, the farmer's exemption in the PVPA has not reduced the effectiveness of that statute, which is generally credited with inspiring a very substantial increase in the number of productive new plant varieties developed in the United States. And it has helped to ensure that farmers will reap the benefits of new varieties without excessive and burdensome involvement in the enforcement of seed companies' proprietary rights.

Thus there is little danger that a farmer's exemption would severely reduce the incentive effect of patent protection for animals. This would be especially true if the exemption were explicitly limited to true farmers, i.e., as in the PVPA exemption those "whose primary farming occupation is the [raising] of [animals] for sale for other than reproductive purposes."

While only minimally reducing the incentive effect of patent protection, such an exemption would help farmers in a number of ways. First, it would ensure that they will not be saddled with burdensome recordkeeping and patent enforcement duties. Although the burden of establishing infringement is normally upon the patentee, patent licensing agreements might require farmers to keep records to avoid infringement liability. An exemption would remove this burden. This would be especially important to the United States beef cattle industry, because beef cattle reproduce freely on the open plain, making recordkeeping of specific matings virtually impossible. Even outside the beef cattle industry, recordkeeping by small farmers raising dairy cows and hogs would be onerous.

Second, a farmer's exemption would reduce uncertainty. Under present law, it is simply not clear whether a farmer who allowed a patented animal to breed would be infringing the patent. A farmer's exemption would make clear that a farmer would have no liability for infringement in these circumstances — so long as the farmer was not breeding a patented animal just to reproduce the patented trait or to sell offspring for breeding purposes.

Third, a statutory farmer's exemption would prevent patentees from using the threat of patent infringement to extract major concessions from farmers negotiating license agreements. In the absence of an exemption, for example, the parties might bargain for a license containing two clauses: (1) a provision stating that royalties are to be paid for the first and second generation of the patented animal but not for the third generation and beyond — i.e., a contractual version of the exemption; and (2) a provision restricting the farmer's right to resell the animal, or requiring the farmer to purchase unpatented ancillary products (e.g., special feeds or hormones) which the patentee claims are necessary to make the animal's patented trait more effective. In such a situation, the farmer would not be able to challenge the restrictive clause (number two above) as a violation of the antitrust laws, for fear that if the license agreement were declared invalid, the farmer would no longer be protected by the first clause. Farmers might easily fear that if a court invalidates the entire agreement, third generation (and beyond) animals that would have been exempt from royalty payments under the licensing agreement might be found to infringe the patent; as a result, they would be unlikely to challenge restrictive clauses in the agreement.
During the 100th Congress, the House of Representatives passed the Transgenic Animal Patent Reform Act, H.R. 4970, which said in relevant part:

It shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.

On the other hand, the bill defined as an infringing act the sale of "the germ cells, semen, or embryos of a patented transgenic farm animal."

The following excerpt details a later (and equally unsuccessful) effort to enact a farmer's exemption to the patent law. After reading it, consider the following two questions: (1) Would you enact a farmer's exemption of any sort? (2) If you would enact a farmer's exemption, which of the two proposals that Congress has considered do you prefer? Why?

* * * * *

Transgenic Animal Patent Improvements Act (proposed)

Title II of H.R. 5598,
Patent Competitiveness and Technological Innovation Act of 1990

4. Farmers exemption. The fourth and most important area of reform in our patent law is to clarify the rules of the road with respect to downstream liability for reproduction of an animal from patented transgenic animals. The patenting of animals will have a significant effect on agriculture. As observed by one witness during Subcommittee hearings, "animal patents represent the greatest change in agriculture since the invention of the plow." Another respected commentator wrote . . . that "family farmers, in particular, have feared the economic impact of animal patenting on their operations and the structure of their industry." Before addressing the question from a patent law perspective, it should be kept in mind that the vast majority of the transactions involving transgenic animals will probably be dealt with through the use of contracts. Marketplace solutions are likely to be the most efficient method of allocating the costs of enforcement. Thus, it is likely that the patent owner will allocate the costs of enforcement into the initial costs of the product. For example, a genetically altered cow that cost one million dollars to develop could be sold for ten thousand dollars if the patent owner claims no residual rights to fees based on the reproduction of the animal. On the other hand, the developer of the cow may choose to sell the animals for one hundred dollars if the purchaser agrees to make small payments for the offspring produced by the cow. This type of pricing policy and enforcement mechanism is already prevalent in some segments of the livestock market and is likely to be repeated for patented animals.
Under current patent law, there is a well-established exhaustion-of-patent-rights doctrine. "Once someone purchases something covered by a patent, that person has a right to use the patented item for all of its intended purposes." Given that doctrine and the ability of parties to contract freely for the sale or licensing of a patented item under existing patent law, there would be sufficient flexibility for parties to reach appropriate commercial results, given the individual circumstances of each case. Unfortunately, the exhaustion of rights doctrine only addresses the right to slaughter or milk an animal and not the right to reproduce it. In short, there are serious lingering questions about the appropriate role the patent law should play in the enforcement of rights in the area of reproduction. The only time that Congress has faced this question with respect to life forms was in the context of the Plant Variety Protection Act. In the PVPA a policy decision was made to exempt farmers from liability for reproduction when the farmer used the seeds for his/her own domestic purposes. A similar exemption makes eminent good sense in the area of animals. Higher life forms like plants and animals differ from other patented technologies insofar as they are "self reproducing."

As the American Farm Bureau Federation put it, "farmers hate paperwork." It is unrealistic to expect farmers to become involved in patent enforcement unless it is in their own self interest. For the foreseeable future most of the transgenic animals produced will be useful in the context of a laboratory, thus, the creation of a limited farm-based exemption will not immediately serve to encumber the financial rewards available to transgenic animal innovators. On the other hand, it is not exactly certain how the marketplace will respond to the existence of transgenic livestock. The type of exemption anticipated is limited to the ability of a farmer to reproduce without liability a genetically altered animal for his/her own purposes. This approach is the least socially disruptive for farmers. A "farmers exemption" would free farmers from paperwork and other concerns about patent royalties while neatly avoiding problems regarding reproduction of transgenic animals. More importantly, adoption of this approach enables Congress to subsequently expand the coverage of a patent on the transgenic animal if the marketplace response to the farmers exemption is not conducive to the stimulation of innovation. Finally, as with plants in the PVPA farmer's exemption, genetic drift could serve to reduce the likelihood that a "copy" of the patented transgenic animals contains the desired trait. After a generation or two, even the farmer who had purchased a transgenic animal will be back in the market to obtain a pure "breed." The financial impact of a farmers exemption may be slight, but the potential social benefits large. The presence of a "farmers exemption" will remove farmers as involuntary patent enforcers. Finally, it will help balance the negotiations on patent licensing, thereby leaving enforcement questions to the marketplace.

Title II of H.R. 5598 differed from previous versions of the proposed legislation in three important regards. First, the exemption from patent liability is not limited to individuals whose occupation is farming but rather is expanded to those engaged in a farming operation. It stands to reason that if anyone is engaged in farming activities — be they children of farmers enrolled in 4H clubs or hobby farmers — they may be producing farm animals that ultimately end up in the
country's food chain. The bill should not differentiate between these various operations.

Second, the original bill defined a "transgenic farm animal" as a farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal, specifying that it would not be an act of patent infringement to sell such animal or the offspring of such animal. This provision was ambiguous in several respects. First, a transgenic animal may not necessarily have its germ line cells infected by a "foreign" gene, resulting in production of a "mosaic" transgenic animal which cannot pass the introduced gene to its progeny, and yet has non-naturally occurring DNA in its somatic cells. Moreover, the "parent/offspring" terminology caused confusion as to whether the progeny past the second generation were included in the definition. Further, the protection of transgenic animals and not their offspring implies that the offspring were not transgenic animals when, in fact, they were transgenic if they carry non-naturally occurring genes. Finally, the original definition of "farm animal" included only those animals used or intended for use as food or fiber, such as cattle, and was ambiguous as to whether it included animal members of the same species used primarily for reproduction, such as a bull. Title II was clarified to define "farm animal" as a member of any animal species used or intended to be used as food or fiber, therefore covering bulls.

Third, the farmer's right to sell reproductive materials was broadened to include germ cell, sperm, eggs, or embryos of transgenic animals used in farming operation. The inclusion of the right to sell reproductive material in Title II is an important issue to the farming community. Artificial insemination has become a common agricultural practice. Many farmers actively sell semen as part of their normal daily farming operation. At times, reproductive material may be the only easily liquidated, saleable commodity on the farm. Farmers wish to retain the traditional right to sell reproductive materials of their animals in order to use the animals to their maximum benefit and dispose of them as they wish. If the right to sell reproductive materials was not in the bill, farmers using patented transgenic animals would have to track the genes of their animals for the term of the patent to ensure against inadvertently selling transgenic materials. Tracking would require enormous paperwork and laboratory genetic testing expenses which would be exceedingly difficult for the family farm to bear. Also, farm animals many generations removed from the founder transgenic animals will most likely have been bred with non-transgenic animals and could lose their value due to the introduction of undesirable traits and diseases. As a consequence, it would be unfair to track and inhibit the sale of those animals which have a diminished value. The inclusion of the right of farmers to sell reproductive materials of the transgenic animal will allow farmers to continue to practice traditional farming by utilizing their animals to the fullest possible extent.

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TITLE II – TRANSGENIC ANIMAL PATENT IMPROVEMENTS

SECTION 201. – SHORT TITLE
Section 201 of the bill provides that Title II may be cited as the "Transgenic Animal Patent Improvements Act."

SECTION 202. – INFRINGEMENT OF PATENT

Section 202 amends section 271 of title 35, United States Code, by adding at the end thereof a new subsection (h). The basic thrust of subsection (h) is to provide an exemption from patent liability for persons engaged in farming operations. New section 271(h) is divided into two paragraphs: (1) the first creates the farmers' exemption; and (2) the second provides definitions.

Paragraph (1) provides that it shall not be an act of infringement for a person to reproduce a patented transgenic farm animal through conventional breeding in a farming operation, use or sell such animal in the farming operation, or use or sell the reproductive material (including germ cells, sperm, eggs, or embryos) of such animal in the farming operation. The exemption for the use of a farm animal that is covered by a patent is a codification of current law to the extent that the purchaser of a patent is expected to use the patented invention for the purpose intended. The other portions of the farmers' exemption chart new ground. The exemption for farmers who intentionally reproduce patented farm animals is necessary, because it is likely that without this amendment, courts would find such activity an act of patent infringement. By the very nature of farming operations, farmers will use patented animals on their own farms for reproductive purposes. Because this is an area in which contractual solutions are unlikely to be effective, a statutory exemption is necessary. A similar exemption exists for patented plants in the Plant Variety Protection Act, the only other American intellectual property law that regulates rights in self-reproducing subject matter. The third element of the farmers exemption authorizes the sale of the animal in the farming operation, or the reproductive material of such animal by persons engaged in farming operations without patent infringement liability. The approach taken in the bill is somewhat similar to the "first sale" doctrine in the copyright law, wherein the rights of the property holder over activity after the first sale are limited. The ability of a farmer to compete with the patent holder in the commercial context is limited by the provision of proposed section 271(h)(2)(C), regarding conventional breeding, thus prohibiting a farmer from practicing biotechnical gene manipulation and nuclear transfer, which are preserved to the patent holder. In short, the farmers' sale right does not require farmers to differentiate between transgenic animals and other animals. New section 271(h) does not create a compulsory or mandatory license. Its terms are permissive in nature, as patent holders are not required to sell transgenic animals to those engaged in farming operations. The patent holder could contractually set the terms and conditions for most, if not all, sales. The provisions of the farmers' exemption, however, do come into play after an initial sale, without a contractual agreement, is made. The existence of a farmers exemption will have a number of beneficial results: (1) reduce burdensome recordkeeping; (2) avoid placing farmers in the role of patent enforcers; (3) eliminate uncertainly about the law; and (4) promote the market for patented transgenic farm animals. The market for
patented farm animals will continue because of genetic drift. In addition, it is likely that farmers and patent owners will reach contractual understandings with respect to liability rather than relying on the patent law. These contractual solutions will let the marketplace determine the fair value of the patented animal and the nature of payments, if any, for the sale of such animals or their offsprings. The existence of a farmers exemption will prevent patent holders from using the threat of patent infringement litigation to extract concessions from farmers when the parties are negotiating licensing agreements.

Paragraph (2) sets forth three definitions that narrow the scope and focus of paragraph (1). Subparagraph (A) defines the term "transgenic farm animal" as a farm animal whose germ cells or somatic cells contain genetic material that does not naturally occur for such animal. The definition includes all farm animals from any generation that carry a non-naturally occurring gene in any cell. This eliminates the germ cell, interspecies, and parent/offspring issues, and mirrors the language used by the U.S. Patent and Trademark Office to define patentable transgenic animals. Subparagraph (B) defines "farm animal" as being a member of any animal species used or intended for use as food or fiber. In other words, a bull — although not ordinarily used as food or fiber — is covered by the definition by virtue of its inclusion in the cow species. Subparagraph (C) provides a definition for the term "conventional breeding," which means breeding using only conventional selection and breeding practices, including use of reproductive material during artificial insemination and embryo transfer but not including techniques involving gene manipulation or nuclear transfer. As a consequence, any on-farm reproduction that involves the use of non-traditional breeding techniques (such as gene manipulation) is not immunized by this provision and could constitute a patent infringement.

* * * *

§ 271. INFRINGEMENT OF PATENT. (a) . . .

(h)(1) It shall not be an act of infringement for a person to reproduce a patented transgenic farm animal through conventional breeding in the farming operation, use such animal in the farming operation, sell such animal in the farming operation, or use or sell the reproductive material, including germ cells, sperm, eggs, or embryos, of such animal in the farming operation.

(2) For purposes of paragraph (1) –

(A) the term "transgenic farm animal" means a farm animal whose germ cells or somatic cells contain genetic material which do not naturally occur for such animal;

(B) the term "farm animal" means a member of any animal species used or intended for use as food or fiber; and

(C) the term "conventional breeding" means breeding using only conventional selection
and breeding practices, including use of reproductive material during artificial insemination and embryo transfer but not including techniques involving gene manipulation or nuclear transfer.  

* * * * *

There are, of course, other legislative alternatives. At one extreme, one could eliminate problems of royalty payments, bookkeeping, and infringement altogether by suspending or banning animal patents. The 100th Congress pondered a bill, H.R. 3247, to impose a 2-year moratorium on the granting of patents on genetically altered animals except for animals whose commercialization is subject to federal regulatory review and approval. A similar proposal, the Life Patenting Moratorium Act of 1993, surfaced during the 103d Congress. This proposal aimed to halt an anticipated flow of patents on "certain human tissues and organs, on human gene cells and on animal organisms, in order to provide time for Congress to fully assess, consider and respond to the economic, environmental, and ethical issues raised by the patenting of such entities."

At the other extreme, congressional inaction leaves the development of the law on animal patents to gradual evolution through contractual negotiation and judicial interpretation. This is Congress's course so far. Nor must a farmer's exemption conform to the versions contemplated in the 100th and 101st Congresses. It might be limited to farms displaying typical characteristics of traditional family farms: family-based ownership structures, limited gross receipts, acreage limitations, and limited numbers of animals. Finally, Congress could establish an animal patent royalty tribunal, akin to the existing Copyright Royalty Tribunal, to set rates and disburse payments from farmers to inventors.  

Somewhere in between these polar extremes lies an alternative that combines private contractual arrangements and creative statutory interpretation by the federal courts. As the Merges excerpt and the various patent reform proposals suggest, one of the gravest problems with plant and animal patents lies in an excessively stringent interpretation of 35 U.S.C. § 271. This leads us to our next major topic in subpart G on claims of infringement by holders of utility patents in plants.

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4. 2001 USPTO Guidelines for patent inspectors

The USPTO issued two Guidelines for patent inspectors on Jan. 5, 2001. These Guidelines provide instructions to patent inspectors about evaluating patent applications. While the Guidelines apply to all patent applications, the USPTO amended its previous Guidelines to address concerns primarily about biotechnological patents. As you read the excerpts from these two Guidelines (Utility Examination Guidelines and Written Description Guidelines), attempt to discern how these guidelines address the utility and written description requirements for biotechnological patent applications. What were the issues? What are the resolutions offered by the USPTO Guidelines?

**United States Patent and Trademark Office**
**Utility Examination Guidelines**

I. Discussion of Public Comments

(1) Comment: Several comments state that while inventions are patentable, discoveries are not patentable. According to the comments, genes are discoveries rather than inventions. These comments urge the USPTO not to issue patents for genes on the ground that genes are not inventions. Response: The suggestion is not adopted. An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S. Constitution uses the word "discoveries" where it authorizes Congress to promote progress made by inventors.

When Congress enacted the patent statutes, it specifically authorized issuing a patent to a person who "invents or discovers" a new and useful composition of matter, among other things. The pertinent statute is 35 U.S.C. 101, ... Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.

If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.

(2) Comment: Several comments state that a gene is not a new composition of matter because it exists in nature, and/or that an inventor who isolates a gene does not actually invent or discover a patentable composition because the gene exists in nature. These comments urge the USPTO not to issue patents for genes on the ground that genes are products of nature. Others state that naturally occurring DNAs are part of our heritage and are not inventions. Response: The comments are not adopted. A patent claim directed to an isolated and purified DNA
An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

Patenting compositions or compounds isolated from nature follows well-established principles, and is not a new practice. For example, Louis Pasteur received U.S. Patent 141,072 in 1873, claiming "[y]east, free from organic germs of disease, as an article of manufacture." Another example is an early patent for adrenaline. In a decision finding the patent valid, the court explained that compounds isolated from nature are patentable: "even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it [adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent." Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 103 (S.D.N.Y. 1911) (J. Learned Hand).

In a more recent case dealing with the prostaglandins PGE\textsubscript{2} and PGE\textsubscript{3}, extracted from human or animal prostate glands, a patent examiner had rejected the claims, reasoning that "inasmuch as the 'claimed compounds are naturally occurring' * * * they therefore 'are not 'new' within the connotation of the patent statute.'" In re Bergstrom, 427 F.2d 1394, 1397, 166 USPQ 256, 259 (CCPA 1970). The Court reversed the Patent Office and explained the error: "what appellants claim--pure PGE\textsubscript{2} and PGE\textsubscript{3} --is not 'naturally occurring.' Those compounds, as far as the record establishes, do not exist in nature in pure form, and appellants have neither merely discovered, nor claimed sufficiently broadly to encompass, what has previously existed in fact in nature's storehouse, albeit unknown, or what has previously been known to exist." Id. at 1401, 166 USPQ at 261-62. Like other chemical compounds, DNA molecules are eligible for patents when isolated from their natural state and purified or when synthesized in a laboratory from chemical starting materials.

A patent on a gene covers the isolated and purified gene but does not cover the gene as it occurs in nature. Thus, the concern that a person whose body "includes" a patented gene could infringe the patent is misfounded. The body does not contain the patented, isolated and purified gene because genes in the body are not in the patented, isolated and purified form. When the patent issued for purified adrenaline about one hundred years ago, people did not infringe the patent merely because their bodies naturally included unpurified adrenaline.

(4) Comment: Several comments state that patents should not issue for genes because the sequence of the human genome is at the core of what it means to be human and no person should be able to own/control something so basic. ... Response: The comments are not adopted. Patents do not confer ownership of genes, genetic information, or sequences. The patent system promotes progress by securing a complete disclosure of an invention to the public, in exchange for the inventor's legal right to exclude other people from making, using, offering for sale, selling, or importing the composition for a limited time. That is, a patent owner can stop
infringing activity by others for a limited time.

Discoveries from nature have led to marketable inventions in the past, but assessing the marketability of an invention is not pertinent to determining if an invention has a specific, substantial, and credible use. "[D]evelopment of a product to the extent that it is presently commercially salable in the marketplace is not required to establish 'usefulness' within the meaning of § 101." In re Langer, 503 F.2d 1380, 1393, 183 USPQ 288, 298 (CCPA 1974). Inventors are entitled to patents when they have met the statutory requirements for novelty, nonobviousness and usefulness, and their patent disclosure adequately describes the invention and clearly teaches others how to make and use the invention. The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility. As noted in a response to other comments, it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents.

(5) Comment: Several comments state that the Guidelines mean that anyone who discovers a gene will be allowed a broad patent covering any number of possible applications even though those uses may be unattainable and unproven. Therefore, according to these comments, gene patents should not be issued. Response: The comment is not adopted. When a patent claiming a new chemical compound issues, the patentee has the right to exclude others from making, using, offering for sale, selling, or importing the compound for a limited time. The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

(6) Comment: One comment suggests that the USPTO should not allow the patenting of ESTs because it is contrary to indigenous law, because the Supreme Court's Diamond v. Chakrabarty decision was a bare 5-to-4 decision, because it would violate the Thirteenth Amendment of the U.S. Constitution, because it violates the novelty requirement of the patent laws, because it will exacerbate tensions between indigenous peoples and western academic/research communities and because it will undermine indigenous peoples' own research and academic institutions. The comment urges the USPTO to institute a moratorium on patenting of life forms and natural processes. Response: The comments are not adopted. Patents on chemical compounds such as ESTs do not implicate the Thirteenth Amendment. ... ESTs which meet the criteria for utility, novelty, and non-obviousness are eligible for patenting when the application teaches those of skill in the art how to make and use the invention.

(8) Comment: Several comments stated that DNA should be considered unpatentable because a DNA sequence by itself has little utility. Response: A DNA sequence--i.e., the sequence of base pairs making up a DNA molecule--is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable. A purified
DNA molecule isolated from its natural environment, on the other hand, is a chemical compound and is patentable if all the statutory requirements are met. An isolated and purified DNA molecule may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not per se unpatentable for lack of utility, and each application claim must be examined on its own facts.

Comment: One comment states that the disclosure of a DNA sequence has inherent value and that possible uses for the DNA appear endless, even if no single use has been worked out. According to the comment, the "basic social contract of the patent deal" requires that such a discovery should be patentable, and that patenting should be "value-blind." Response: The comment is not adopted. The Supreme Court did not find a similar argument persuasive in Brenner v. Manson, 383 U.S. 519 (1966). The courts interpret the statutory term "useful" to require disclosure of at least one available practical benefit to the public. The Guidelines reflect this determination by requiring the disclosure of at least one specific, substantial, and credible utility. If no such utility is disclosed or readily apparent from an application, the Office should reject the claim. The applicant may rebut the Office position by showing that the invention does have a specific, substantial, and credible utility that would have been recognized by one of skill in the art at the time the application was filed.

Comment: Several comments stated that DNA should be freely available for research. Some of these comments suggested that patents are not necessary to encourage additional discovery and sequencing of genes. Some comments suggested that patenting of DNA inhibits biomedical research by allowing a single person or company to control use of the claimed DNA. Another comment expressed concern that patenting ESTs will impede complete characterization of genes and delay or restrict exploration of genetic materials for the public good. Response: The scope of subject matter that is eligible for a patent, the requirements that must be met in order to be granted a patent, and the legal rights that are conveyed by an issued patent, are all controlled by statutes which the USPTO must administer. ... Congress creates the law and the Federal judiciary interprets the law. The USPTO must administer the laws as Congress has enacted them and as the Federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications claiming DNA compositions, or to limit a patent's scope in order to allow free access to the use of the invention during the patent term.

Comment: Several comments suggested that DNA sequences should be considered unpatentable because sequencing DNA has become so routine that determining the sequence of a DNA molecule is not inventive. Response: The comments are not adopted. A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule. An isolated and purified DNA molecule may be patentable because a molecule is a "composition of matter," one of the four classes of invention authorized by 35 U.S.C. 101. A DNA molecule must be nonobvious in order to be patentable. Obviousness does not depend on the amount of work required to characterize the DNA molecule. ... As the nonobviousness requirement has been interpreted by the U.S. Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular
structure of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made. See, e.g., In re Deuel, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995) ("[T]he existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious."); see also, In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993).

(15) Comment: One comment stated that the specification should "disclose the invention," including why the invention works and how it was developed. Response: The comment is not adopted. The comment is directed more to the requirements imposed by 35 U.S.C. 112 than to those of 35 U.S.C. 101. To satisfy the enablement requirement of 35 U.S.C. 112, 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. If all the requirements under 35 U.S.C. 112, 1, are met, there is no statutory basis to require disclosure of why an invention works or how it was developed. "[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989).

(16) Comment: One comment suggested that patents should "allow for others to learn from and improve the invention." The comment suggested that claims to patented plant varieties should not prohibit others from using the patented plants to develop improved varieties. The comment also stated that uses of plants in speculative manners should not be permitted.

Response: By statute, a patent provides the patentee with the right to exclude others from, inter alia, making and using the claimed invention, although a limited research exemption exists. See 35 U.S.C. 163, 271(a), (e). These statutory provisions are not subject to revision by the USPTO and are not affected by these Guidelines. ... It is somewhat rare for academic researchers to be sued by commercial patent owners for patent infringement. Most inventions are made available to academic researchers on very favorable licensing terms, which enable them to continue their research.

(17) Comment: Two comments suggested that although the USPTO has made a step in the right direction in raising the bar in the Utility Guidelines, there is still a need to apply stricter standards for utility. Response: The USPTO is bound by 35 U.S.C. 101 and the case law interpreting § 101. The Guidelines reflect the USPTO's understanding of § 101.

(21) Comment: Several comments stated that the Guidelines erroneously burden the examiner with proving that a person of skill in the art would not be aware of a well-established utility. One comment states that this requires the examiner to prove a negative. Another comment states that the Guidelines should direct examiners that if a specific utility has not been disclosed, the applicant should be required to identify a specific utility. Response: The comments have been adopted in part. The Guidelines have been revised to indicate that where the applicant has not asserted a specific, substantial, and credible utility, and the examiner does not perceive a well-established utility, a rejection under § 101 should be entered. That is, if a well-established utility is not readily apparent and an invention is not otherwise supported by an
asserted specific, substantial, and credible utility, the burden will be shifted to applicant to show either that the specification discloses an adequate utility, or to show that a well-established utility exists for the claimed invention. Again, most often the search of the closest prior art will reveal whether there is a well-established utility for the claimed invention.

II. Guidelines for Examination of Applications for Compliance With the Utility Requirement

A. Introduction

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 112. These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

B. Examination Guidelines for the Utility Requirement

Office personnel are to adhere to the following procedures when reviewing patent applications for compliance with the "useful invention" ("utility") requirement of 35 U.S.C. 101 and 112, first paragraph.

1. Read the claims and the supporting written description.
   (a) Determine what the applicant has claimed, noting any specific embodiments of the invention.
   (b) Ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof).
   (c) If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

2. Review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible:
   (a) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.
   (1) A claimed invention must have a specific and substantial utility. This requirement excludes "throw-away," "insubstantial," or "nonspecific" utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility

(2) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

(b) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well-established utility, reject the claim(s) under § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection.

(c) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under § 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The §§ 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

1. Explicitly identify a specific and substantial utility for the claimed invention;
   and
2. Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

3. Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the prima facie showing of no specific and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.

(a) Where the asserted utility is not specific or substantial, a prima facie showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The prima facie showing must contain the following elements:
(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;
(2) Support for factual findings relied upon in reaching this conclusion; and
(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(b) Where the asserted specific and substantial utility is not credible, a prima facie showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention.

The prima facie showing must contain the following elements:
(1) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;
(2) Support for factual findings relied upon in reaching this conclusion; and
(3) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.

(c) Where no specific and substantial utility is disclosed or is well-established, a prima facie showing of no specific and substantial utility need only establish that applicant has not asserted a utility and that, on the record before the examiner, there is no known well-established utility.

4. A rejection based on lack of utility should not be maintained if an asserted utility for the claimed invention would be considered specific, substantial, and credible by a person of ordinary skill in the art in view of all evidence of record.

Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a prima facie showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the prima facie showing. If the applicant responds to the prima facie rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on
lack of utility be maintained.

If the applicant satisfactorily rebuts a prima facie rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

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Responses to Specific Comments

(1) Comment: ... Response: The suggestions have been adopted in part. The purpose of the written description analysis is to confirm that applicant had possession of what is claimed. The Guidelines have been modified to instruct the examiners to compare the scope of the invention claimed with the scope of what applicant has defined in the description of the invention. That is, the Guidelines instruct the examiner to look for consistency between a claim and what provides adequate factual support for the claim as judged by one of ordinary skill in the art from reading the corresponding written description.

(4) Comment: One comment stated that the Guidelines change the substance of the written description requirement to require some level of enablement. The comment stated that the Eli Lilly case should not be followed because its change in the quality of the description required is in conflict with precedent. Another comment suggested that to comply with the written description requirement, the description must both (i) demonstrate possession of the claimed invention by the applicant; and (ii) put the public in possession of the claimed invention.
Response: As noted in the comment above, the USPTO is bound by the Federal Circuit's decision in Eli Lilly. The Guidelines have been revised to clarify that an applicant must provide a description of the claimed invention which shows that applicant was in possession of the claimed invention. The suggestion to emphasize that the written description requirement must put the public in possession of the invention has not been adopted because it removes much of the distinction between the written description requirement and the enablement requirement. Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.

(7) Comment: Several comments urge that actual reduction to practice, as a method of satisfying the written description requirement by demonstrating possession, has been over-emphasized. Response: The Guidelines have been clarified to state that describing an actual reduction to practice is one of a number of ways to show possession of the invention. Description of an actual reduction to practice offers an important "safe haven" that applies to all applications and is just one of several ways by which an applicant may demonstrate possession of the claimed invention. Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming
components and combining steps, in such a way as to distinguish the composition with particularity from all others. Thus, the emphasis on actual reduction to practice is appropriate in those cases where the inventor cannot provide an adequate description of what the composition is, and a definition by function is insufficient to define a composition "because it is only an indication of what the [composition] does, rather than what it is." Eli Lilly, 119 F.3d at 1568, 43 USPQ at 1406. See also Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

(9) Comment: One comment stated that the written description of a claimed DNA should be required to include the complete sequence of the DNA and claims should be limited to the DNA sequence disclosed. Response: Describing the complete chemical structure, i.e., the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. See Eli Lilly, 119 F.3d at 1566, 43 USPQ2d at 1404 ("An adequate written description of a DNA * * * requires a precise definition, such as by structure, formula, chemical name, or physical properties." (emphasis added, internal quote omitted)). Therefore, there is no basis for a per se rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.

(14) Comment: Two comments indicated that if the amino acid sequence for a polypeptide whose utility has been identified is described, then the question of possession of a class of nucleotides encoding that polypeptide can be addressed as a relatively routine matter using the understanding of the genetic code, and that the endnote addressing this issue should be revised. Response: The suggestion of these comments has been incorporated in the Guidelines and will be reflected in the training materials. However, based upon In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), this does not mean that applicant was in possession of any particular species of the broad genus.

(15) Comment: One comment disagreed with an endnote which stated that a laundry list disclosure of moieties does not constitute a written description of every species in a genus. Specifically, the comment indicates that if the existence of a functional genus is adequately described in the specification, a laundry list of the species within that genus must satisfy the written description requirement. Response: The suggestion to revise the endnote will not be adopted. A lack of adequate written description problem arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosure. This was aptly demonstrated in In re Bell and In re Baird where possession of a large genus did not put a person of ordinary skill in the art in possession of any particular species. See also Purdue Pharma, 230 F.3d at 1328, 56 USPQ2d at 1487 (because the original specification did not disclose the later claimed concentration ratio was a part of the invention, the inventors cannot argue that they are merely narrowing a broad invention).

(16) Comment: One comment suggested that in the majority of cases, a single species will support a generic claim, and that the Guidelines should emphasize this point. Response: The suggestion has been adopted to a limited degree. The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when
the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus. Note, however, Tronzo v. Biomet, Inc., 156 F.3d 1154, 47USPQ2d 1829 (Fed. Cir. 1998), where the species in the parent application was held not to provide written description support for the genus in the child application.

(22) Comment: One comment stated that the written description should "disclose the invention," including why the invention works and how it was developed. Response: This suggestion has not been adopted. An inventor does not need to know how or why the invention works in order to obtain a patent. Newman v. Quigg, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345 (Fed. Cir. 1989). To satisfy the enablement requirement of 35 U.S.C. 112, 1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, 1, the description must show that the applicant was in possession of the claimed invention at the time of filing. There is no statutory basis to require disclosure of why an invention works or how it was developed. "Patentability shall not be negatived by the manner in which the invention was made." 35 U.S.C. 103(a).

(25) Comment: One comment recommended that the Guidelines be amended to state that the appropriate skill level for determining possession of the claimed invention is that of a person of ordinary skill in the art. Response: The comment has not been adopted. The statutory language itself indicates that compliance with the requirements of 35 U.S.C. 112, 1, is judged from the standard of "any person skilled in the art." It is noted, however, that the phrases "one of skill in the art" and "one of ordinary skill in the art" appear to be synonymous. See, e.g., Union Oil Co. v. Atlantic Richfield Co., 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' Thus, § 112, 1, ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims." ...
to this comment, states that Members "shall require" patent applicants to disclose their invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." If the written description is not clear and complete, the applicant may not have been in possession of the invention. This may support both written description and enablement standards. In addition, Article 29 expressly authorizes Members to require patent applicants to disclose the best method the inventor knows at the time of filing an application for carrying out the invention.

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1, "Written Description" Requirement

I. General Principles Governing Compliance With the "Written Description" Requirement for Applications

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement. The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." Another objective is to put the public in possession of what the applicant claims as the invention. The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis.
II. Methodology for Determining Adequacy of Written Description

A. Read and Analyze the Specification for Compliance With 35 U.S.C. 112, 1

Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. 112, 1. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. Consequently, rejection of an original claim for lack of written description should be rare. The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis.

1. For Each Claim, Determine What the Claim as a Whole Covers

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. The entire claim must be considered, including the preamble language and the transitional phrase. The claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement.

The examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble. The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, 1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

2. Review the Entire Application to Understand How Applicant Provides Support for the Claimed Invention Including Each Element and/or Step

Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention. The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.
3. Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention as a Whole at the Time the Application Was Filed

a. Original claims. Possession may be shown in many ways. For example, possession may be shown, inter alia, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 et seq.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.

(1) For each claim drawn to a single embodiment or species:
(a) Determine whether the application describes an actual reduction to practice of the claimed invention.
(b) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.
(c) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.
Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. 112, 1.

(2) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above).

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, 1.

III. Complete Patentability Determination Under All Statutory Requirements and Clearly Communicate Findings, Conclusions, and Their Bases

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112, 1, is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of title 35 of the U.S. Code.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.
F. PATENT INFRINGEMENT RELATED TO PLANTS

Nicholas J. Seay

*Intellectual Property Rights in Plants*

Suppose that a utility patent is obtained by a plant breeder on an inbred plant of variety X. The breeder of X then goes into commerce selling seed of the inbred variety X as a product of commerce to farmers. Unlike the PVPA, there is no farmer or other exemption for saved seed.

When a farmer buys the seed from the breeder, by law he receives an implied license to use the seed for its normal purpose. Presumably the normal purpose is growing plants from the seed under cultivation. However, if the plant breeds true to seed, the result of that cultivation, after the harvest, will be a greatly multiplied crop of the same seed. What is the farmer permitted to do with that seed? Clearly he must be able to sell this product as food or a commodity, since that is the purpose for which the farmer bought his seed, and presumably the breeder would have no quarrel with that. However, suppose the farmer sells the saved seed as seed. Presumably the breeder will have a significant quarrel with that. However, the method of determination of infringement of utility patents, as codified in [35 U.S.C. § 271] and the case law, does not envision a determination as to the intention of the accused infringer when he sells the product, \textit{i.e.}, whether he is selling it for seed or selling it for food. If the product seed may be sold as food, is a buyer who buys the seed from the farmer as food and then resells it as seed an infringer?

One way to solve this problem would be to impose a post-sale restriction on the use of the seed. Such a restriction might permit the product of the cultivation to be sold as a commodity, but forbid the purchaser from selling the saved seed from cultivation. Traditionally such post-sale restrictions on patented material are viewed with great suspicion, but at least one writer has argued that such restrictions may be permissible in certain circumstances.\textsuperscript{88} Even if one seeks to impose such post-sale restrictions, there are practical difficulties in doing so. One court has recently held that post-sale restrictions as are commonly applied in commerce today to computer software are invalid both as adhesion contracts and due to federal preemption.\textsuperscript{89} In a case not involving plants, a patent holder was permitted to require that the patented product he sold be limited to a single use.\textsuperscript{90} If this restriction were used to limit the use of patented plant seed, it

\textsuperscript{88}Jeffers, *Restiction of Propagation of Patented Bacteria Sold by the Patente -- Can It Be Done?,* 70 J. PAT. OFF. SOC'y 137 (1988).

\textsuperscript{89}Vault Corp. v. Quaid Software Ltd., 847 F.2d 255 (5th Cir. 1988).

might effectively control post-sale use of the seed. Attempts to impose post-sale restrictions are likely to continue and need to be carefully considered if they are to be enforceable.

1. The Canadian Experience

Monsanto Canada Inc. v. Schmeiser
[2003] 2 F.C. 165 (Court of Appeal)
aff'd 2004 SCC 34

SHARLOW J.A.


[2] At trial, Monsanto Canada Inc. and Monsanto Company (collectively, "Monsanto") alleged that Schmeiser Enterprises Ltd. and Percy Schmeiser had infringed Monsanto's Canadian patent number 1,313,830 in 1998 by planting for harvest a crop of glyphosate resistant canola having a gene or cell that is the subject of the patent. The Trial Judge found that certain claims of the patent had been infringed and granted Monsanto an injunction, an order for delivery up, an award of damages (only against Schmeiser Enterprises Ltd.) in the amount of $19,832, pre-judgment interest, post-judgment interest, and costs.

[3] Schmeiser Enterprises Ltd. and Mr. Schmeiser appealed the finding of infringement, the award of damages and the granting of the injunction. Monsanto cross-appealed on a number of grounds, but at the hearing relied only on the argument that the award of damages was too low.

Facts

....

[7] Monsanto Company and Monsanto Canada Inc. are the owner and licensee respectively of Canadian patent number 1,313,830, entitled "Glyphosate-Resistant Plants". The patent was issued on February 23, 1993 and will expire on February 23, 2010.

[8] The Monsanto patent discloses the invention of a genetic insert which, when introduced into the DNA of canola cells by a transformation vector, produces a variety of canola with a high level of resistance to glyphosate. Glyphosate inhibits an enzyme required to produce a particular amino acid essential for the growth and survival of a broad range of plants. Most plants sprayed with a glyphosate based herbicide do not survive. However, a canola plant grown from seed containing the modified gene will be comprised of cells with the modified gene, and for that reason will survive if sprayed with a glyphosate based herbicide. The modified gene, which I will refer to as the "Monsanto gene", is the subject of the Monsanto patent.

[9] Since 1996, canola seed containing the Monsanto gene has been produced in Canada under license from Monsanto and marketed to farmers under the trade name "Roundup Ready Canola". The trade name reflects its resistance to a herbicide sold under the trade name "Roundup", a glyphosate based herbicide manufactured by Monsanto.

....
[11] In 1996, approximately 600 farmers in Canada planted Roundup Ready Canola on some 50,000 acres. In 2000, approximately 20,000 farmers in Canada planted it on approximately 4.5 to 5 million acres, producing nearly 40% of the canola grown in Canada.

[12] A farmer who wishes to grow Roundup Ready Canola must enter into a licensing agreement called a Technology Use Agreement (TUA), and must attend a Grower Enrollment Meeting conducted by Monsanto representatives, who describe the technology and its licensing terms. By signing the TUA, the farmer becomes entitled to purchase Roundup Ready Canola from an authorized seed agent but must promise to use the seed for planting only one crop, to sell the crop for consumption to a commercial purchaser authorized by Monsanto, and not to sell or give seed to any third party or save seed for replanting or inventory. The TUA gives Monsanto the right to inspect the fields of the contracting farmer and to take samples to verify compliance with the TUA. The farmer must also pay a licensing fee for each acre planted with Roundup Ready Canola. In 1998 the licensing fee was $15 per acre.

[13] A Roundup Ready Canola plant cannot be distinguished from other canola plants except by a chemical test that detects the presence of the Monsanto gene, or by spraying the plant with Roundup. A canola plant that survives being sprayed with Roundup is Roundup Ready Canola.

[18] The uncontradicted evidence of Mr. Schmeiser was that he has never purchased Roundup Ready Canola and has never signed a TUA relating to Roundup Ready Canola. Monsanto had initially alleged that Mr. Schmeiser had somehow acquired Roundup Ready Canola in 1997 but that allegation was withdrawn along with all claims of infringement with respect to Mr. Schmeiser's 1997 canola crop.

[22] In late June or early July of 1997, Mr. Schmeiser and his employee Carlyle Moritz hand sprayed Roundup around power poles and in the ditches along the Bruno road where it bordered fields 1, 2, 3 and 4. This was part of his normal weed control practice. Several days after the spraying, he noticed that a large number of canola plants had survived the spraying. To determine why the canola plants had survived the Roundup spraying, Mr. Schmeiser conducted a test in field 2. Using a machine sprayer set to spray 40 feet, he sprayed Roundup on a section of field 2 in a strip along the road. He made two passes, the first weaving between and around the power poles and the second adjacent to the first pass, parallel to the power poles. He testified that by this means he sprayed a good three acres of field 2. According to Mr. Schmeiser's evidence, after some days, approximately 60% of the canola plants sprayed were still alive, growing in clumps that were thickest near the road and thinner as one moved into the field.

[23] At harvest time in 1997 Mr. Schmeiser, who was then recovering from a leg injury, instructed Mr. Moritz to swath and combine field 2. Mr. Moritz did so, harvesting the canola in the field as well as the surviving canola along the roadside. The harvested seed was put into the box of a 1962 Ford pickup truck. The box was covered with a tarp and the truck with its tarped load of canola seed was stored in one of Mr. Schmeiser's buildings over the winter.

[24] Mr. Schmeiser testified that in the spring of 1998 the seed from the Ford truck was transferred to another truck and taken to the Humboldt Flour Mill for treatment, a normal process
to rid the seeds of disease before planting. The treated seed, mixed with untreated seed from his
granary ("bin-run seed"), was planted in all or part of each of his nine fields, for a total of 1,030
acres.

[26] Experts for the parties conducted a number of tests on the canola plants growing beside field
2 in 1997, some seeds from those plants, and the canola plants growing in all the Schmeiser
fields in 1998. These included "grow-out tests" in which canola seeds from the subject fields
were planted and the resulting plants were sprayed with Roundup. The result of the tests was that
the presence of the Monsanto patented gene was found in the plants that survived the spraying.
The opinion of Dr. Downey, an expert called by Monsanto, was that the high rate of survival of
plants that had germinated from the 1997 samples was consistent only with the presence in field
2 of canola grown from commercial Roundup resistant seed. The evidence of the various tests, as
explained by the expert witnesses, led the Trial Judge to this conclusion (at paragraph 114 of his
reasons):

... Despite questions raised about particular aspects of the sampling and the
handling of samples of the defendants' 1998 canola crop, subject to consideration
of any defence raised, the balance of probabilities supports a conclusion that the
growing and sale of Roundup tolerant canola by the defendants infringed the
exclusive rights of the plaintiffs to use the patented gene and cell. I reach that
tentative conclusion having also concluded on a balance of probabilities that the
samples taken from the borders of nine fields in July 1998 and three samples
taken at random from within each field in August 1998 are representative of the
entire crop, bearing in mind that all of the nine fields were planted with seed that
was saved in 1997 in field number 2, which seed was known to be Roundup
tolerant.

Points in issue

....

(1) Is the patent infringed if Mr. Schmeiser did not use Roundup in the 1998 crop?

[29] The uncontradicted evidence of Mr. Schmeiser is that he did not spray Roundup on his 1998
canola crop. The Trial Judge did not say whether he believed Mr. Schmeiser on that point or not,
because he concluded that spraying with Roundup was not an essential element of the alleged
infringement. Counsel for Mr. Schmeiser argued that this conclusion was based on an incorrect
construction of the Monsanto patent. He argued that Mr. Schmeiser cannot be held to have
infringed Monsanto's patent rights by growing a canola crop that is resistant to glyphosate unless
he also took advantage of its glyphosate resistant quality by spraying Roundup to control weeds
within the crop.

[30] To assess this argument, it is necessary to determine what Monsanto's patent rights are. The
starting point is section 42 of the Patent Act, which gives the holder of a patent the right to
exclude others, for the term of the patent, from making, constructing or using the invention, or
saying it to others to be used: (citations omitted)

[32] Infringement is not defined in the Patent Act, but it has been said that infringement is any act that "interferes with the full enjoyment of the monopoly granted": Lishman v. Eron Roche Inc. (1996), 68 C.P.R. (3d) 72 (F.C.T.D.), affirmed 71 C.P.R. (3d) 146 (F.C.A.). Counsel for Mr. Schmeiser argued that this definition of infringement is too broad because the words "full enjoyment" may imply that mere possession of a patented invention can be infringement. In my view, the definition of infringement stated in Lishman is intended to reflect the idea that what constitutes infringement in a particular case is a function of the scope of the statutory monopoly, so that any act that impairs the statutory monopoly is by definition "infringement". I do not read the Lishman definition as saying anything more than that.

[33] Thus, to determine whether a certain act amounts to infringement, the scope of the statutory monopoly must be determined by construing the claims of the patent. The construction of a patent claim is a question of law: Whirlpool, at paragraph 76.

[40] The Trial Judge construed the claims as follows (at paragraph 26 of his reasons):

... Claims 1, 2, 5, 6 and 7 each claim a chimeric plant gene with characteristics as specified in the claim. Claims 22, 23, 26, 27, and 28, each concern a glyphosate-resistant plant cell comprising a chimeric plant gene of claim 1, with other specified characteristics of the cell specified for claims other than claim 22. Finally, claim 45 claims simply a glyphosate-resistant oil seed rape cell of claim 22. The presence of the chimeric plant gene described in claim 1 is essential for all of the claims. The claims relate to genes and cells which are glyphosate-resistant. Obviously the invention has utility in resistance to glyphosate, but none of the claims specifies this utility nor does it require the use of glyphosate, such as Roundup herbicide, for the invention claimed.

[41] Counsel for Mr. Schmeiser argued that if merely planting a crop of Roundup Ready Canola is infringement, then the patent claims have been too broadly construed because the patented invention, the Monsanto gene, has no function if it is present in a plant that has not actually survived an application of Roundup. Echoing Mr. Justice Dickson in Consolboard, it is argued that the construction propounded by Monsanto and accepted by the Trial Judge is unfair to the public, as represented by Mr. Schmeiser, because if it stands Mr. Schmeiser could find himself liable for infringement simply by following his normal farming practices.

[42] It is true that the only characteristic added to a plant by the presence of the Monsanto gene is resistance to glyphosate, and that the desire for glyphosate resistance was what motivated the work that led to the invention. The latter point is clear from the following statements in the disclosure in the patent (Appeal Book, page 238):
The object of this invention is to provide a method of genetically transforming plant cells which causes the cells and plants regenerated therefrom to become resistant to glyphosate and the herbicidal salts thereof.

This invention involves a cloning or expression vector comprising a gene which encodes 5-enolpyruvylylsikimate-3-phosphate synthase (EPSPS) polypeptide which, when expressed in a plant cell contains a chloroplast transit peptide which allows the polypeptide, or an enzymatically active portion thereof, to be transported from the cytoplasm of the plant cell into a chloroplast in the plant cell, and confers a substantial degree of glyphosate resistance upon the plant cell and plants regenerated therefrom.

[43] However, it does not follow that the use of Roundup is essential to a finding of infringement. It seems to me that the argument made for Mr. Schmeiser on this point is flawed in two respects. First, it incorrectly relies on the disclosure in the patent to import a limitation that is not found in the words of the claims themselves (see Dableh). Second, it proposes a construction of the patent claim that is defined or limited by the alleged infringement. Mr. Justice Binnie said in Whirlpool, at paragraph 49(a), that such a result oriented approach to patent construction is incorrect.

[46] In my view, the Trial Judge correctly applied the principles applicable to the construction of patent claims. He was presented with expert evidence to assist in understanding the claims through the eyes of persons skilled in the art. Having heard that evidence, he found no ambiguity in the claims that would justify recourse to the disclosure, and concluded that the essence of each claim was the presence of the Monsanto gene. In my view, his construction is correct. It is also a complete answer to the argument of counsel for Mr. Schmeiser that the claims of the patent cannot be infringed by someone who cultivates plants containing the Monsanto gene but does not spray them with Roundup.

(2) Does it matter how the Monsanto gene came to be in the 1998 Schmeiser crop?

[47] Only the Schmeiser canola crop for 1998 was found to infringe the Monsanto patent. That crop came mainly from seed saved from the glyphosate resistant canola found on and adjacent to the Schmeiser property in 1997. However, the Trial Judge did not reach any conclusion as to how glyphosate resistant canola came to be there in 1997, because in his view it did not matter. He explains why it did not matter at paragraphs 119 and 120 of his reasons:

[119] Yet the source of the Roundup resistant canola in the defendants' 1997 crop is really not significant for the resolution of the issue of infringement which relates to the 1998 crop. It is clear from Mr. Schmeiser himself that he retained
seed grown in 1996 in field number 1 to be his seed for the 1997 crop. In 1997 he was aware that the crop in field number 2 showed a very high level of tolerance to Roundup herbicide and seed from that field was harvested, and retained for seed for 1998.

[120] I find that in 1998 Mr. Schmeiser planted canola seed saved from his 1997 crop in his field number 2 which seed he knew or ought to have known was Roundup tolerant, and that seed was the primary source for seeding and for the defendants' crops in all nine fields of canola in 1998.

[48] It was submitted for Mr. Schmeiser that the Trial Judge was wrong to say that the source of the 1997 glyphosate resistant canola is irrelevant, because infringement could not have been found if Mr. Schmeiser took no steps to cause glyphosate resistant canola plants to grow on or adjacent to his property in 1997.

....

[50] I will deal with these arguments under three headings, (a) conflict of rights, (b) the innocent infringer, and (c) the effect of unconfined release.

(a) Conflict of rights

[51] I am prepared to assume, without deciding, that the owner of real property has legal title to any volunteer plant found on his land, and generally has a right to save the seed from such a plant, and to plant and harvest the seed for profit in subsequent years. However, there is no authority for the proposition that ownership of a plant must necessarily supercede the rights of the holder of a patent for a gene found in the plant. On the contrary, the jurisprudence presents a number of examples in which the rights of ownership of property are compromised to the extent required to protect the patent holder's statutory monopoly. Generally, the existence of such a conflict of rights is not relevant to the determination of infringement, but only when fashioning the remedy if infringement is found.

[52] The closest analogy is found in the cases where there is a conflict between the rights of an owner of a machine and the rights of the holder of a patent for a component of the machine. Absent the consent of the patent holder to that particular use of the invention, the owner of the machine may be ordered to remove the infringing component or, if that cannot be done, to deliver the machine to the patent holder: (citations omitted):

....

(b) The innocent infringer

[55] Counsel for Mr. Schmeiser submitted that a finding for Monsanto in this case would be highly prejudicial to any farmer who does not wish to grow Roundup Ready Canola. That is because glyphosate resistant canola can appear in a field without having been planted there, but a
farmer cannot detect it without spraying Roundup, thereby killing any conventional canola in the field.

[56] There is considerable force to the argument that it would be unfair to grant Monsanto a remedy for infringement where volunteer Roundup Ready Canola grows in a farmer's field but its resistance to glyphosate remains unknown, or if that characteristic becomes apparent but the seeds of the volunteer plants are not retained for cultivation. It is often said that intention is not material to a finding of infringement: H. Fox, *The Canadian Law and Practice relating to Letters Patent for Inventions*, 4th ed. (1969), at page 381; *Computalog Ltd. v. Comtech Logging Ltd.* (1992), 44 C.P.R. (3d) 77 (F.C.A.). That principle was developed in the context of patents for conventional inventions: see, for example, *Stead v. Anderson* (1847), 2 W.P.C. 156, *Wright v. Hitchcock* (1870), L.R. 5 Ex. 37, *Young v. Rosenthal* (1884), 1 R.P.C. 29 (Q.B.), *Skelding v. Daly et al.* (1941), 1 C.P.R. 266 (B.C.C.A.). Clearly, in most cases of patent infringement, to allow a defence of ignorance or lack of intention to infringe would destroy the efficacy of the patent, because the actual content of any particular patent is known to very few people.

[57] However, it seems to me arguable that the patented Monsanto gene falls into a novel category. It is a patented invention found within a living plant that may, without human intervention, produce progeny containing the same invention. It is undisputed that a plant containing the Monsanto gene may come fortuitously onto the property of a person who has no reason to be aware of the presence of the characteristic created by the patented gene. It is also reasonable to suppose that the person could become aware that the plant has that characteristic but may tolerate the continued presence of the plant without doing anything to cause or promote the propagation of the plant or its progeny (by saving and planting the seeds, for example). In my view, it is an open question whether Monsanto could, in such circumstances, obtain a remedy for infringement on the basis that the intention of the alleged infringer is irrelevant. However, that question does not need to be resolved in this case.

[58] In this case, Mr. Schmeiser cultivated glyphosate resistant canola plants. His 1998 canola crop was mostly glyphosate resistant, and it came from seed that Mr. Schmeiser had saved from his own fields and the adjacent road allowances in 1997. Although the Trial Judge did not find that Mr. Schmeiser played any part initially in causing those glyphosate resistant canola plants to grow in 1997, the Trial Judge found as a fact, on the basis of ample evidence, that Mr. Schmeiser knew or should have known that those plants were glyphosate resistant when he saved their seeds in 1997 and planted those seeds the following year. It was the cultivation, harvest and sale of the 1998 crop in those circumstances that made Mr. Schmeiser vulnerable to Monsanto's infringement claim.

(c) The effect of unconfined release

[59] Counsel for Mr. Schmeiser argued that Monsanto, by permitting farmers to plant Roundup Ready Canola without undertaking steps to limit its spread by means of the movement of pollen and through accidental spillage, has waived any exclusive rights it may have had. This argument, if accepted, would have the effect of nullifying Monsanto's patent. The Trial Judge rejected this
argument. I agree with his analysis and conclusions on this issue as stated at paragraphs 95 to 98 of his reasons for judgment:

....

[96] That assessment places much weight on photographs of stray plants in Bruno, said to have survived spraying with Roundup, in addition to photographs of canola in fields which is said to be of canola, some with the potential gene incorporated. With respect, the conclusion the defendants urge would ignore the evidence of the licensing arrangements developed by Monsanto in a thorough and determined manner to limit the spread of the gene. Those arrangements require agreement of growers not to sell the product derived from seed provided under a TUA [Technology Use Agreement] except to authorized dealers, not to give it away and not to keep it for their own use even for reseeding. It ignores evidence of the plaintiffs' efforts to monitor the authorized growers, and any who might be considered to be growing the product without authorization. It ignores the determined efforts to sample and test the crops of the defendants who were believed to be growing Roundup Ready canola without authorization. It ignores also the evidence of Monsanto's efforts to remove plants from fields of other farmers who complained of undesired spread of Roundup Ready canola to their fields.

[97] Indeed the weight of evidence in this case supports the conclusion that the plaintiffs undertook a variety of measures designed to control the unwanted spread of canola containing their patented gene and cell.

[98] I am not persuaded that the plaintiffs have lost the right to claim exclusive use of their invention, or that they have waived any such claim. There clearly is no expressed waiver, and none can be implied from the conduct of the plaintiffs so far as that is a matter of record before the Court.

....

******************

NEWMAN, Circuit Judge.

Mr. Homan McFarling appeals the grant of a preliminary injunction by the United States District Court for the Eastern District of Missouri, prohibiting Mr. McFarling, pendente lite, from using the plant genes and seed obtained from crops grown from Monsanto Company's patented soybean seed having the brand name Roundup Ready. We conclude that the district court acted within its discretion in granting the preliminary injunction.

BACKGROUND

Monsanto developed genetically modified plants that are resistant to glyphosate herbicides such as Roundup® brand herbicide. The herbicide can then be sprayed broadly in planted fields, killing the weeds but not harming the resistant crops. This results in substantial savings in labor costs for weed control. Monsanto's United States Patents Nos. 5,633,435 and 5,352,605 claim the glyphosate-tolerant plants, the genetically modified seeds for such plants, the specific modified genes, and the method of producing the genetically modified plants.

Monsanto authorizes various companies to manufacture the patented seeds, which are then sold to farmers. Monsanto requires that sellers of the patented seeds obtain from the farmers/purchasers a "Technology Agreement," and the farmers pay a license fee to Monsanto of $6.50 per 50-pound bag of soybean seed. Mr. McFarling, a farmer in Mississippi, purchased Roundup Ready® soybean seed in 1997 and again in 1998; he signed the Technology Agreement and paid the license fee for each purchase. The signature line is immediately below the following statement: "I acknowledge that I have read and understand the terms and conditions of this Agreement and that I agree to them."

The agreements include the requirement that the seeds are to be used "for planting a commercial crop only in a single season" and direct the licensee not to "save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting." Mr. McFarling does not dispute that he violated the terms of the Technology Agreement. He saved 1,500 bushels of the patented soybeans from his harvest during one season, and instead of selling these soybeans as crop he planted them as seed in the next season. He repeated this activity in the following growing season, and stated that unless enjoined he intended to plant soybeans saved from the 2000 harvest in 2001. McFarling paid no license fee for this saved soybean seed, which retained the genetic modifications of the Roundup Ready® seed.

Monsanto filed suit in the Eastern District of Missouri, charging patent infringement and
breach of contract, and seeking a preliminary injunction. Mr. McFarling challenged the Missouri court’s jurisdiction, and raised various counterclaims and defenses including charges of antitrust violation, patent misuse, and violation of the Plant Variety Protection Act, 7 U.S.C. § 2321 et seq. (PVPA). The district court interpreted the argument concerning violation of the PVPA as a request for declaration that the patents are invalid or unenforceable, granted McFarling’s motion to stay the proceeding pending review by the Supreme Court of this court’s ruling that plant seeds and seed-grown plants are within the subject matter of § 101 of the Patent Act. The Court affirmed that ruling in J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124, 122 S.Ct. 593, 60 USPQ2d 1865 (2001).

The district court denied Mr. McFarling’s motion to dismiss for lack of personal jurisdiction and granted Monsanto's motion for a preliminary injunction. This appeal followed.

DISCUSSION

....

The Injunction Pendente Lite

....

1.

First, Mr. McFarling argues that the Technology Agreements create an illegal tying arrangement by requiring farmers to buy new Roundup Ready® seed each year instead of allowing them to produce their own Roundup Ready® seed from the prior year's crop. McFarling cites Jefferson Parish Hospital District No. 2 v. Hyde, 466 U.S. 2 (1984), for the proposition that a tying arrangement violates the Sherman Act when the seller exploits “its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms.” Id. at 12. According to McFarling, the tied product is a fresh supply of Monsanto's Roundup Ready® seed in future years, while the tying product is the original purchase of Roundup Ready® seed. McFarling states that he does not want to buy future Roundup Ready® seed, because he can produce his own genetically modified Roundup Ready® seed. McFarling also states that even if these restrictions do not constitute antitrust violations, the requirement that farmers buy new seed each year impermissibly broadens the patent grant, with anti-competitive effect.

Mr. McFarling further argues that the Technology Agreements constitute illegal agreements among competitors, referring to the agreements between Monsanto and its local distributors whereby the local sellers must require farmers to enter into the Technology Agreements as a condition of buying the Roundup Ready® seed. McFarling cites Citizen Publishing Co. v. United States, 394 U.S. 131 (1969), for the proposition that agreements among competitors to fix the material terms of a sale are illegal. As a result of such alleged collusion, McFarling states that farmers in the United States pay higher prices for Roundup Ready® seed than do farmers in Argentina. Monsanto states that as the patent holder it decides unilaterally the terms on which its patents are licensed and its product sold under the Technology Agreements.
Monsanto explains that the seed companies that are licensed by Monsanto to produce and sell the modified soybean seed have no control over the terms of the Technology Agreements that Monsanto requires of farmers who choose to purchase the Monsanto seed.

The district court found that Mr. McFarling was not likely to succeed on his Sherman Act or patent misuse claims, that he had not presented any evidence raising a substantial question as to whether the Technology Agreements constitute a form of unreasonable or illegal restraint of trade. The district court's finding is not challenged, that there was no obligation upon Mr. McFarling to buy future seed as a condition of buying seed in the present. The court found that there were no impediments preventing Mr. McFarling from switching to other soybean seeds, the court recognizing that there are over two hundred commercial sources of soybean seed, including several herbicide-resistant soybeans.

A purchaser's desire to buy a superior product does not require benevolent behavior by the purveyor of the superior product. Nor does an inventor of new technology violate the antitrust laws merely because its patented product is favored by consumers. See Abbott Labs. v. Brennan, 952 F.2d 1346, 1354, 21 USPQ2d 1192, 1199 (Fed.Cir.1991) ("The commercial advantage gained by new technology and its statutory protection by patent do not convert the possessor thereof into a prohibited monopolist.")

In accordance with the Technology Agreement, the purchaser agrees to use the purchased seed for the purpose of growing crops and not for the purpose of producing new seed. In Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 24 USPQ2d 1173 (Fed.Cir.1992) this court held that use of a patented product "in violation of a valid restriction may be remedied under the patent law, provided that no other law prevents enforcement of the patent." Id. at 701, 24 USPQ2d at 1174. A restriction on use to make additional patented product, to constitute an antitrust violation, must meet the requirements of such violation and be outside the scope of the patent grant. See General Talking Pictures Corp. v. Western Elec. Co., 305 U.S. 124, 127, 39 USPQ 329, 330 (1938). The district court correctly held that Mr. McFarling has not shown a reasonable likelihood of success on antitrust/misuse grounds; the record does not support Mr. McFarling's theory that he is required to buy future patented seeds from Monsanto in order to buy present patented seeds.

2.

As a second ground for challenging the agreements, Mr. McFarling states that the contractual prohibition against using the patented soybeans to produce additional seeds for planting by the farmer violates the doctrines of patent exhaustion and first sale, and that the parties could not enter into an enforceable contract that has this effect. In support, McFarling cites the statement in United States v. Univis Lens Co., 316 U.S. 241, 249, 53 USPQ 404, 407 (1942), that when a patented product has been sold the purchaser acquires "the right to use and sell it, and ... the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold." It follows, McFarling argues, that once Monsanto sold the patented seeds to McFarling, its patent rights on the seeds and their products were exhausted and could not be restricted by agreement. Monsanto responds that it is within the scope of Monsanto's patent rights to prevent others from making, for the
purpose of planting, a new batch of patented seeds from the purchased seeds.

The restrictions in the Technology Agreement are within the scope of the patent grant, for the patents cover the seeds as well as the plants. The "first sale" doctrine of exhaustion of the patent right is not implicated, as the new seeds grown from the original batch had never been sold. The price paid by the purchaser "reflects only the value of the 'use' rights conferred by the patentee." B. Braun Medical Inc. v. Abbott Labs., 124 F.3d 1419, 1426, 43 USPQ2d 1896, 1901 (Fed.Cir.1997). The original sale of the seeds did not confer a license to construct new seeds, and since the new seeds were not sold by the patentee they entailed no principle of patent exhaustion.

3.

McFarling argues that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following season, violates section 2543 of the PVPA, which permits farmers to save seeds of plants registered under the PVPA.

The PVPA and the Patent Act are complementary forms of statutory protection of plant "breeders' rights." Utility patents under Title 35 provide rights and privileges that differ from those provided by Plant Variety Protection certificates. In J.E.M. Ag Supply, 534 U.S. at ----, 122 S.Ct. at 604-05, 60 USPQ2d at 1873-74, the Court held that utility patents are available to plants and seeds that meet the requirements of patentability, independent of and in addition to rights under the PVPA. The Court observed that one of the differences between the two statutes is that "there are no exemptions for research or saving seed under a utility patent." Id. at ----, 122 S.Ct. at 604, 60 USPQ2d at 1873. It is thus established that the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patent Act.

4.

Mr. McFarling complains that the price charged for Roundup Ready® seeds is higher than for other soybean seeds, and that it is cheaper for him to produce his own Roundup Ready® seeds. He also states that Monsanto sells Roundup Ready® seeds at a lower price in Argentina.

We need not repeat that in a market economy a purveyor may charge the price that the product can sustain; there is no requirement that a patentee must lower his price to that of the less desired products he replaces. See, e.g., E. Bement & Sons v. National Harrow Co., 186 U.S. 70, 93 (1902) ("The owner of a patented article can, of course, charge such price as he may choose...."); Carter-Wallace, Inc. v. United States, 449 F.2d 1374, 1383, 171 USPQ 359, 365 (Ct.Cl.1971) ("[A]s a general rule and absent any overriding unlawful conduct, patentees can charge for their patented products and licenses whatever the market will bear.") This aspect does not add weight to the antitrust arguments pressed by Mr. McFarling.

CONCLUSION

Mr. McFarling conceded that he violated the terms of the Technology Agreements. The district court found that Monsanto had a reasonable likelihood of success on the issues of infringement and breach of contract, and that it was unlikely that an antitrust violation would be found. We do
not discern error in these findings, and the other factors relevant to grant of an injunction pendente lite are not contested. We conclude that the district court did not abuse its discretion in granting the injunction.

AFFIRMED.

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For additional reading about intellectual property rights in living matter (bacteria, plants, and animals), please consult the website of the Oklahoma Journal of Law & Technology at [http://www.okjolt.org](http://www.okjolt.org). The *Oklahoma Journal of Law & Technology* (OkJoLT) has a project on intellectual property rights in living matter that is exploring this issue country-by-country around the world. By the fall 2005, OkJoLT hopes to have an explanation for intellectual property rights in living matter in twelve countries published.

G. **Alternative Forms of Agricultural Intellectual Property**

The Patent Act and patent-like laws by no means exhaust the store of available methods for recognizing and protecting intellectual property in crop plants and farm animals. Most of these alternatives rest on state law rather than on federal statutes. Animal patents have yet to render livestock registration entirely obsolete as a privately ordered method for regulating animal breeding. In the plant context, the breeders' tendency to favor hybrid seed lines — exacerbated by Winterboer and the PVPA's crop exemption — has breathed new life into trade secret law as a source for legal protection. Under federal patent law or state trade secret law, biotechnology firms and farmers can reconfigure their relationships through contract. Finally, just as federal trademark law protects all firms' interest in consumers' ability to associate a name or a mark with the source of a product, various states have created "virtual trademarks" for local specialty crops.

1. **Livestock registration**

As a private group, a breeders' association can generally set the terms by which it will accept livestock registrations. To be effective, an association must maintain a reputation for effectively patrolling its members' breeding practices. Functionally, livestock registration resembles a collectively operated, private trademark system; a breeders' association's good name enables its members to communicate a certain cachet of quality to potential customers. Until
patented genetic manipulation techniques supplant traditional breeding practices, livestock registration will remain important to farmers. Patent reform, if and when it occurs, will probably protect traditional breeding. Proposed farmer's exemptions have shielded artificial insemination and embryo transfer, but not gene manipulation or nuclear transfer.

For a case discussing breed registry laws, read Hatley v. American Quarter Horse Association, 552a F.2d 646 (5th Cir. 1977). The case explores the power of breed registry associations to define what is or is not the “breed animal" that is subject to registration. This power to define the breed is discussed in terms of antitrust and procedural due process.

* * * * *

2. Trade secret protection of hybrid seed lines

Disappointed by Winterboer and other expansive interpretations of the PVPA's crop exemption, commercial seed companies have begun marketing hybrid seed lines. Unlike openly pollinated lines, hybrids offer breeders a form of built-in biological protection in that they cannot reproduce true-to-form. The breeders can then rely on state law to protect the parent lines' identities as trade secrets. Patent law generally does not preempt state-law protection of trade secrets, especially where the subject matter falls outside the scope of federal patent protection.¹ Accordingly, a breeder may enforce a contract for royalties on a hybrid seed line in the absence of federal patent or patent-like protection for trade secrets subsiding in the line.² Resort to trade secret protection as an alternative form of agricultural intellectual property has nevertheless sparked litigation. One dispute involving the giant breeder, Pioneer Hi-Bred International, Inc., is particularly instructive:


**Pioneer Hi-Bred International, Inc. v. Holden's Foundation Seeds, Inc.**

United States Court of Appeals for the Eighth Circuit

35 F.3d 1226 (8th Cir. 1994)

Before MAGILL, Circuit Judge, JOHN R. GIBSON, Senior Circuit Judge, and MORRIS SHEPPARD ARNOLD, Circuit Judge.

JOHN R. GIBSON, Senior Circuit Judge.

This case involves a dispute between competing breeders of corn seed. The district court awarded $46,703,230.00 to Pioneer Hi-Bred International based on Holden Foundation Seeds, Inc.'s misappropriation of the genetic make-up of certain seed corn. Holden contests the district court's liability determination and damage award on numerous grounds. Pioneer cross-appeals from the district court's denial of prejudgment interest. We affirm. . . .

The sale of hybrid seed corn is a multi-billion dollar industry. Pioneer is a vertically integrated seed corn company. It conducts a breeding program, develops parent seed, and produces hybrid\(^2\) seed corn for the retail market. The superior performance of its products, obtained in part through millions of dollars spent annually on corn research and development, has enabled it to gain a sizeable portion of the retail seed corn market. Its marketed seed corns include Pioneer hybrids 3780 (Pioneer's leader in sales for several years) and 3541 – which share a common parent, designated H3H.

Holden indirectly competes with Pioneer. Holden is a foundation seed company that develops inbred parent seed lines and sells these lines to its customers, also seed corn companies, which use them to produce hybrid seed in competition with Pioneer. During the 1980s, Holden's LH38, LH39, and LH40 ("LH38-39-40") were among its most popular parent lines.

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\(^2\)"Hybrid" corn seed is produced by planting two inbred parents together and allowing pollen from one inbred (used as the male parent) to fertilize silks on the other inbred (used as the female parent). In corn, inbred lines are lines developed by self-pollination and selection until the line is relatively homozygous. Inbred lines may be "public" if developed and released by a public university, or "private" if developed by a private entity.
Pioneer sued Holden on a number of legal theories, claiming that Holden developed LH38-39-40 from misappropriated Pioneer H3H or H43SZ7 – protected trade secrets of Pioneer ("H3H/H43SZ7"). During discovery, the district court decided, at Pioneer's request, that the nature of this dispute required that Holden "freeze in" a particular story regarding the development of LH38-39-40. The court did so to prevent Holden from altering its story to conform to the scientific evidence eventually introduced. Holden claimed that although LH38-39-40 demonstrated some similarity to Pioneer's seed lines, Holden developed LH38-39-40 from an internal line, designated L120. The district court held that the genetic make-up of H3H/H43SZ7 is a protected trade secret of Pioneer. The court determined that although LH38-39-40 differed in some respects from Pioneer's seed, the lines had nonetheless been derived from misappropriated Pioneer material. The district court based its decision on expert testimony that LH38-39-40 derived from H3H/H43SZ7 and Holden's inability to offer adequate evidence of its "L120 story." The court also ruled in Pioneer's favor on its Lanham Act, interference with business advantage, unjust enrichment, and conversion claims. The district court awarded over 46 million dollars in damages to Pioneer. Holden appeals.

I.

Much of Holden's argument before this court attacks Pioneer's scientific evidence as inadequate to support the district court's judgment. A threshold issue, however, is Holden's assertion that the district court erred in admitting the scientific evidence relating to electrophoresis, liquid chromatography, and growout testing.

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6Pioneer claimed that Holden violated § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and also brought pendent state law claims based on trade secret misappropriation, unjust enrichment, interference with business advantage, conversion, and unfair competition. The parties focused their efforts before this court on the district court's trade secret holding.

7Pioneer initially asserted that Holden misappropriated Pioneer's seed known as H3H. Trial testimony showed, however, that H3H and H43SZ7, derived from H43SZ7, could have been used interchangeably to create LH38-39-40. Thus, the court permitted Pioneer to bring H43SZ7 into the litigation. For our purposes, they can be considered as a single line, "H3H/H43SZ7."

8Stating that "the law of trade secrets provides a better fit for the facts of this case," the court expressed concern over pushing the frontiers of common law conversion. Thus, the court made its ruling in favor of Pioneer on its conversion claim conditional on the ultimate failure of its trade secret claim.

9The court held in favor of Holden on Pioneer's state unfair competition claim. Pioneer does not appeal from this decision.
According to Lewis, "backcrossing" refers to the process in which when a breeder crosses two genetically different parental lines of corn to produce hybrids, and then backcrosses, often repeatedly, those hybrid plants demonstrating a desired trait to one of the parents. Backcrossing serves as a means of incorporating a favorable genetic trait found in one line into an existing line.

According to Holden, W64A served as the particular disease resistant seed.

After briefing in this case, the Supreme Court decided Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786 (1993), which held the "austere" Frye standard "should not be applied in federal trials." Rule 702 of the Federal Rules of Evidence, the Court stated, displaced Frye and the "general acceptance" standard. Thus, the focal point of Holden's admissibility argument before this court has been removed. Moreover, we are convinced that the district court considered the factors discussed in Daubert, and committed no error in admitting the evidence.

The three tests played a significant role in evaluating Holden's claims as to how it developed the contested lines. Holden asserts that each of these lines developed from a common parent, L120. Because Holden discarded L120 two years before Pioneer filed suit when it began putting its inventory on computer and discarded a number of "old lines," the parties could not directly test L120. Instead, the parties attempted to reconstruct the genetic make-up of L120 from its pedigree supplied by Holden. Much of the scientific testimony in this case sought to prove the genetic makeup of L120. This, in turn, would indicate whether L120 could have been the parent of LH38-39-40, and whether it derived from protected Pioneer material.

Holden claims it developed L120 during repeated backcrossings between a disease resistant (Ht) seed and a public line, Oh43, which is freely available to breeders such as Holden. Holden stated that plant breeder Arlyn Eggerling selected certain plants (later labeled

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13 According to Lewis, "backcrossing" refers to the process in which when a breeder crosses two genetically different parental lines of corn to produce hybrids, and then backcrosses, often repeatedly, those hybrid plants demonstrating a desired trait to one of the parents. Backcrossing serves as a means of incorporating a favorable genetic trait found in one line into an existing line.

14 The symbol Ht, according to Lewis, represents the gene that controls resistance to helminthosporium turcium, commonly referred to as northern leaf blight in corn.

15 According to Holden, W64A served as the particular disease resistant seed.
L120) from this backcross program. These plants were "tagged and bagged" but never entered into the nursery records. Holden explained that it could not provide a more accurate pedigree because inadequate nursery records\(^{16}\) existed as to L120's early development. Holden's L120 pedigree provided to the court placed its selection at approximately the fifth to eighth backcrossing. Other testimony suggested that the selection may have occurred even later in the backcross program, perhaps as late as the thirteenth generation. Holden's statement that it initially selected L120 from the fifth backcross generation or later proved increasingly significant as the trial progressed. The experts agreed that a plant randomly selected so late in a backcrossing program would theoretically consist almost entirely of Oh43 genetic material.\(^{17}\)

In an attempt to evaluate the parties' competing claims, the court oversaw three series of tests — electrophoresis, reverse phase high-performance liquid chromatography and growouts. Each test was supervised by the court, performed by independent experts, and monitored by the parties.

By consent and court order, isozyme electrophoresis tests were conducted. These tests

\(^{16}\)Nursery records are precise books commonly kept by corn breeders. These records identify the line of corn growing in a particular row of a field and enable breeders to trace a seed's genealogy.

\(^{17}\)The following table . . . illustrates the predicted genetic composition of a plant randomly selected from a particular backcross generation.

<table>
<thead>
<tr>
<th>Generation</th>
<th>Ht-source percentage</th>
<th>Oh43 percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Cross</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>BC1 (First Backcross)</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BC2</td>
<td>12.500</td>
<td>87.50</td>
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<tr>
<td></td>
<td>6.250</td>
<td>93.75</td>
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<td></td>
<td>3.125</td>
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<td>.781</td>
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<td></td>
<td>.006</td>
<td>99.99</td>
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</tbody>
</table>
According to Stuber, electrophoresis tests are conducted by first placing solutions from a plant in a medium (here, a starch gel). An electric current is then applied to the medium, causing the various enzymes to migrate across the medium at different rates. The tester may then identify groups of enzymes by using a staining mixture which reacts with the enzymes. Stuber testified that the term "isozyme" refers to the fact that several enzymes may catalyze or facilitate the same reaction.

The argument appears to be that the #2 allele contained in this disease resistant (Hooker or Ht) strain continued in at least some plants until a Holden employee selected the L120 plant from the backcross program. As Holden states: "At the fifth backcross generation there is nearly an even chance of there being at least one corn plant in a 40-plant row with the #2 allele when a plant carrying the allele is being backcrossed to a line carrying the 3.8 allele (Oh43), as here." This roughly equates to Pioneer's claim that a given plant at the fifth backcross level would be more than 98% Oh43. The court reached similar figures and explicitly stated that it rely upon the general principle that an allele found in a line of corn (e.g., LH38-39-40) must have been provided by one of the two parents. Alleles are the two individual genes in a particular gene pair. Thus, the presence of alleles in the child which are not in either of its purported parents discounts the possibility of parentage. According to Dr. Charles Stuber, the court-appointed expert who conducted the tests, electrophoresis indirectly examines these alleles by separating and then analyzing the various enzymes found in plants. This analysis of the enzymes, stated Stuber, informs the tester of a plant's genetic structure because of "one of the central dogmas of genetics" – the one-to-one correlation between genes and enzymes – which, he testified, is "essentially . . . true."

According to Stuber, LH38 contained isozyme allele 2.0 ("#2 allele") at a particular locus, Pgd 1. At this same locus, one of its alleged parents, A619, contained a different allele. Thus, the #2 allele found in LH38 presumably came from LH38's other alleged parent – L120. Since Holden lost or discarded L120 two years before Pioneer filed its complaint, no L120 seed could be directly tested. However, Holden's theory of parentage indicates that L120 resulted from repeated backcrossings with Oh43. As referenced earlier, Drs. Stuber and Stephen Smith agreed that if L120 were randomly selected from the Ht backcross program, over 98% of its genetic material should be identical to Oh43. Relying on the fact that the 3.8 allele (found on Oh43) should have been found in L120, and hence at locus Pgd 1 of LH38, Stuber concluded that Holden's L120 story was "possible but . . . highly unlikely." Smith reached a similar result, testifying that the "isozyme data and the [L120] pedigree don't match" while Pioneer's stated pedigree was "absolutely consistent." Stuber reached a similar conclusion with respect to LH40.

Holden contends the #2 allele resulted from W64A, the disease resistant seed in its L120 pedigree, and that Pioneer failed to show otherwise. Holden attacks the foundation for

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Pioneer's assertion that L120 would necessarily be 98% Oh43. Among the possibilities Holden cited were a much greater degree of contamination and relic heterozygosity in inbred corn lines than commonly assumed, or non-Mendelian events such as mutation. Holden also challenges the validity of the general principle underlying electrophoresis testing (i.e., a given allele must come from one of two parents). After considering these attacks, the district court accepted Stuber's testimony which showed that "Holden's two lines – LH38 and LH40 – might well be fathered by Pioneer's H3H, but would not be fathered in the way Holden claims they were, as the probability is so low that it is not logical." The duty of weighing the strength of the testimony supporting the parties' respective views lies with the district court. Thus, we cannot say that the district court clearly erred in finding that L120 would consist primarily, although not entirely, of genetic material found in Oh43.

The electrophoresis evidence does not eliminate the possibility that L120 is a parent of LH38-39-40. As with such tests as typical DNA testing, the electrophoresis testing (even under Pioneer's interpretation) did not and could not conclusively prove that a given child (i.e., LH38-39-40) derived from particular parents. Nonetheless, the court did find, based on Stuber's testimony, that electrophoresis testing "is very precise" and "a very important technique now being utilized by the seed corn industry on a day-to-day basis." "All parties," the court concluded, "agreed that electrophoresis cannot recognize all differences, but that it can establish differences and that it cannot establish sameness."

The details of reverse phase high-performance liquid chromatography testing are also complex, but basically similar to electrophoresis. Like electrophoresis, liquid chromatography testing identifies certain gene proteins within the genetic structure of a plant. According to

"recognize[d] that even after five backcrosses, the [genetic] material is 'not all the same' as stated by Dr. Stuber."

23In particular, Holden directs the court to testimony . . . that the Oh43 backcrossing program (from which L120 was allegedly selected) was "segregating" after several backcrosses. Segregating corn populations are genetically diverse, that is, not homozygous. Several witnesses testified that some genetic variability remains after five or even ten to twelve backcrosses. Indeed, Pioneer conducts 10-15 backcrosses in its own programs to obtain the desired homozygosity. Nonetheless, as discussed earlier, Pioneer's experts testified that after only five backcrosses, the offspring would be virtually (over 98%) genetically identical to the recurrent parent. . . . Holden's present policy is to consider a line "finished" after six generations. Stuber conceded the possibility of contamination or mutation, but stated that accidental fertilization by a contaminant strain probably would have resulted in additional genetic variances not found in the tested seeds. He estimated the probability of mutation as one in one million. After reviewing the record, we are convinced that the district court weighed these various considerations. . . .
Stuber and Bietz, this process examines different genes from those measured by the electrophoresis tests. This is significant. Since the two tests measure different gene structures and are independent, their combined accuracy is higher than if either was conducted alone. Liquid chromatography testing creates a graph consisting of a series of peaks and valleys for a given seed corn. These peaks and valleys represent collections of genetic material, which theoretically must have come from one of the parents. The testimony showed that although its application to corn is relatively new, this methodology is "well established in testing other cereal grains."

Pioneer relies on the presence of two peaks in LH39 which are not present in Oh43. Holden claims that LH39 is the result of a cross between L120 and Oh43. Pioneer responds that since L120 is "essentially Oh43 itself . . . LH39 should . . . have a chromatogram identical to Oh43." Thus, according to Pioneer, the peaks indicate that L120 could not be a parent, while supporting the theory that LH39 derived from H3H/H43SZ7. LH38 also displayed a peak inconsistent with Holden's asserted pedigree. Pioneer's position hinges on the finding that L120 would necessarily have an identical chromatogram to Oh43. If L120 differed significantly from Oh43, the existence of a couple of differing chromatogram peaks in the contested seed might very well be expected. Based on the evidence before it, the court concluded that L120 should exhibit a chromatogram identical to Oh43.

As with electrophoresis, liquid chromatography testing could not determine the precise parentage of LH38-39-40. Rather, it could only exclude certain possibilities. As with the electrophoresis testing, the liquid chromatography testing failed to rule out H3H/H43SZ7 as a possible parent, while raising doubts as to the viability of Holden's L120 story. The court found it significant that Pioneer wanted the tests conducted, since the tests could "torpedo" Pioneer's story but not conclusively confirm it.

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24 As the court stated, scientists do not know how many genes are being measured by each peak.

26 The parties agree that the mere presence of the disease resistant (Ht) gene (allegedly present in L120 but not Oh43) would not affect the liquid chromatography results. The critical inquiry is whether other genetic differences could reasonably remain after five or more backcrosses.

27 . . . [L]iquid chromatography tests on several seeds with a known 87.5% relationship (obtained after two backcrosses) . . . typically showed "a very great number of similarities" and "very small" or "no qualitative differences between the two chromatograms." As stated by the court, "[t]hese specific examples illustrate and document the sound basis [for expert] opinions that after five backcrosses one would predict and expect [that] the chromatogram of the original line, and the line after five backcrosses would be indistinguishable."
At Holden's request, the court also directed three seasons of growing, cross-pollinating, and comparing the various disputed lines. The results, particularly with respect to LH39, demonstrated similar physical characteristics and comparable degrees of hybrid vigor\(^{31}\) (heterosis) among several of the plants.\(^{32}\) Pioneer's witnesses . . . concluded that this evidence cast doubt on Holden's asserted L120 pedigree, and that the seeds more likely derived from H3H/H43SZ7. [One witness] testified that Holden's LH38 and LH39 are too similar to Pioneer's H3H to have been developed independently.

Holden interprets the growout evidence quite differently. Holden correctly states that the growout evidence reflected differences as well as similarities between the Holden and Pioneer lines. Holden points out that Pioneer's own witness . . . stated that the growouts showed only the "possibility" of derivation from H3H. . . . [W]itnesses for Holden[ ] looked at different traits . . . and found substantial differences between LH38 and H3H. Based on this investigation, [Holden's witness] expressed his serious doubts about whether LH38-39 derived from Pioneer's line. Finally, any perceived similarities in the growouts, Holden suggests, merely reflect the large percentage of Oh43 in each of the tested lines -- Holden's and Pioneer's alike.

The court rejected Holden's attempt to attack the concept or purpose of the growouts, which Holden initially requested. Moreover, the court acknowledged the growouts' limitations, but concluded they were "imperfect but reliable." The results, however, were "sweet and sour pork" insofar as there were "pluses and minuses for each litigant."

Each of the three tests certainly had its own set of limitations and inadequacies. Electrophoresis and chromatography could not, even under the court's view, conclusively prove the parentage of LH38-39-40. The growouts were, as we just discussed, indecisive. Nonetheless, all of the tests contributed to the court's finding that Holden's L120 story was highly unlikely, while Pioneer's theory of parentage was more likely.

II.

Much of Holden's argument before this court focused on the district court's ruling that

\(^{31}\)As stated by the court, when a plant breeder crosses two distantly-related inbreds, the offspring are often much more vigorous than either parent. When, however, two closely related inbreds are crossed, the offspring produced have very little "vigor."

\(^{32}\)The court found that LH39, for example, displayed similar size, shape, angle, number of branches, susceptibility to aphids, husk type, ear type, silk color, and disease resistance to Pioneer's H3H. The similar degree of hybrid vigor is quite relevant because hybrid vigor serves as one measurement of the similarity of two lines.
Holden misappropriated Pioneer's protected trade secret. According to Iowa law, a plaintiff must generally show three elements to prevail in a trade secret action: "(1) existence of a trade secret, (2) acquisition of the secret as a result of a confidential relationship, and (3) unauthorized use of a secret." . . .

Holden does not argue on appeal that genetic messages cannot qualify as trade secrets. Ronald Holden, Holden's chief operating officer, testified that he does not "have any problem" with the idea that there is a claimed proprietary interest in inbreds and parent lines. Thus, we assume without deciding that genetic messages can qualify for trade secret status. See RESTATEMENT OF TORTS § 757 cmt. b (1939). Holden instead argues that it should not be liable for misappropriating H3H/H43SZ7 because Pioneer failed: (1) to keep the genetic messages secret; (2) to prove that Holden actually possessed the protected genetic messages; and (3) to prove that Holden obtained the material by improper means. The district court rejected each of Holden's arguments. . . .

A.

Holden argues that H3H/H43SZ7 are not trade secrets because Pioneer failed to maintain their secrecy. Fundamental to the existence of a trade secret is that the matter be, in fact, secret. By definition, trade secret law does not protect information in the public domain or otherwise readily ascertainable. The secrecy, however, need not be absolute. Reasonable precautions to protect the secrecy of a trade secret will suffice. Companies need not "guard against the unanticipated, the undetectable, or the unpreventable methods of espionage now available" or create "an impenetrable fortress."

The district court found that the genetic messages of H3H and H43SZ7 were trade secrets. The district court found that the "formula" did not exist outside Pioneer's and its contractors' fields, and that Pioneer took reasonable precautions to protect the secrecy of the genetic message.

Pioneer takes several measures to preserve the secrecy of its inbreds.37 Growers operate under contracts which prohibit disclosure of the seed. Fields have no labels indicating what seed is being grown, and all seed bags are coded to avoid identification. Pioneer removes male inbred lines and commingles them with other corn, thereby frustrating those seeking to obtain the inbred seed.

37By restricting the availability of its inbred lines, Pioneer prevents competitors from obtaining access to the genetic message contained therein. It is this message that we assume is protected by trade secret law.
Despite these steps, Holden argues that Pioneer failed to maintain adequate security in several ways. First, during the 1970s Pioneer harvested the male rows of its production fields and sold the seed to grain elevators. This grain was readily available to any purchaser. Holden also states that H3H could be present in Hybrid Pioneer 3780 or 3541 seed sold to farmers, and thus H3H plants may be found in farmers' fields. Holden further argues that Pioneer lost the requisite secrecy by selling H3H/H43SZ7 in the Soviet Union without restriction. Holden cites testimony indicating that some of this seed was "leaked out," and that Pioneer taught experts in Hungary how to produce H3H and H3H-derived hybrids.

Although there is conflicting evidence on whether Pioneer had maintained the secrecy of the genetic messages, there is sufficient evidence to support the district court's finding that Pioneer took reasonable precautions to protect the secrecy of the genetic message of H3H/H43SZ7. First, Holden's claim that the message was "widely disseminated" because it could be obtained from seed elevators and farmers' seed bags is overstated. Although a Pioneer employee, Thomas Urban, acknowledged that the male corn could get into a seed bag as a contaminant, he also stated "it's almost impossible." Urban explained that Pioneer had "many, many employees who stood looking at corn ears... [and] [t]he chances of that happening are not very great." Urban knew of no instances of the male corn being found in bags of hybrid seed. Moreover, the seed in the bags and elevators is mixed, and a grower would have no way of easily identifying the desired male seed from the many other seeds in the overall mix. "The more difficult, time consuming and costly it would be to develop the information, the less likely it is 'readily' ascertainable."

It is also relevant that the possible means identified by Holden of obtaining H3H/H43SZ7 were not the means by which Holden claimed it developed LH38-39-40. Many courts have held that the fact that one "could" have obtained a trade secret lawfully is not a defense if one does not actually use proper means to acquire the information. This evidence does not lead us to conclude that the district court clearly erred in finding that Pioneer maintained the requisite secrecy for trade secret protection of H3H/H43SZ7.

Holden's argument that Pioneer abandoned its trade secret by selling H43SZ7 to the Soviet Union is similarly unpersuasive. Pioneer did sell H43SZ7 to the Soviet Union during the 1970s. This sale, however, was pursuant to an agreement which restricted use of the seed and contained a confidentiality provision. Holden's evidence that the material was "leaked out" of the Soviet Union to other Eastern bloc countries is based only on rumor, and does not convince us

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38 As stated by the court, the male parent, if planted alongside a detasseled (female) inbred line, will fertilize the other inbred and produce a hybrid.

39 Pioneer uses H3H to produce 3780 and 3541 hybrid seed.
that the district court clearly erred in finding that Pioneer maintained the requisite secrecy for trade secret protection of H3H/H43SZ7.

B.

Holden also argues that Pioneer's trade secret claim is invalid because insufficient evidence supports the district court's finding that Holden possessed H3H or H43SZ7. Holden contends that since none of the tests can conclusively prove parentage, the district court clearly erred in finding possession. Holden points out particular shortcomings with each of the tests. First, tables provided by Stuber suggest that electrophoresis is less accurate than Pioneer's experts claimed. More importantly, Pioneer's experts' conclusions, drawn from both the electrophoresis and liquid chromatography testimony, rested on the assumption that L120 was essentially Oh43 – an assumption which Holden brought into question. Finally, Holden emphasizes that the court found the growout testimony to be indecisive.

Holden's argument rests on its claim that the scientific evidence was based on methodology not generally accepted in the scientific community. Holden's argument . . . is no longer tenable in light of Daubert. Further, relying on Chaney v. Smithkline Beckman Corp., 764 F.2d 527 (8th Cir.1985), Holden argues that the evidence was insufficient to warrant a finding that Holden derived LH38-39-40 from H3H/H43SZ7. Holden argues that the evidence showed only that it is possible that Holden's lines were derived from Pioneer's, and that to establish possession as a scientific fact, Pioneer must show more than a mere possibility of derivation.

In Chaney, we affirmed the district court's entry of summary judgment for four drug manufacturers because the plaintiff failed to present a submissible issue of causation. Because plaintiff's "most favorable characterization showed only that there was a 20-80% probability" of causation, we held that such speculative testimony was insufficient to take the case to the jury. Thus, the question in Chaney was the degree of certainty required by scientific evidence before a jury can consider it. Holden makes the same argument with respect to the evidence before us, essentially arguing that there was insufficient evidence to support the district court's finding that Holden derived LH38-39-40 from H3H/H43SZ7.

We believe that there is sufficient evidence to warrant a finding that Holden derived LH38-39-40 from H3H/H43SZ7. Holden does not attack the qualifications of the various

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40 More particularly, Dr. Jon L. Geadelmann testified that several seeds on Stuber's tables contained alleles not detected in either of their designated parents. "Based on [Stuber's tables], it is therefore incorrect to assume that an inbred line cannot have an isozyme allele not found in its parents," concluded Geadelmann.
We do not mean to suggest that the owner of a trade secret enjoys an absolute property right in the trade secret which may be used to exclude the world from using the secret. We have found no case so holding, and believe that any attempt by state law to do so might well be preempted by the federal patent laws. Trade secret law and patent law — both aspects of the elusive concept of intellectual property — serve quite different functions. Patent protection, which is often difficult and costly to obtain, gives the patent holder the right to exclude others from using the patented device, process, etc., for a limited time period. Trade secret law, on the other hand, protects a person's right to keep certain information "secret," by providing a cause of action against anyone who misappropriates a reasonably-protected secret. Moreover, by labeling certain wrongful, if not actually otherwise illegal, acts "improper," trade secret law plays an important role in
Pioneer failed to prove improper means. In support of its position, Holden suggests there is absolutely no evidence of misappropriation or improper means. Thus, Holden argues we must reverse because mere possession of a trade secret cannot support a trade secret award.

After considering Holden's arguments, the district court found "that Pioneer has met its burden regarding misappropriation." . . . Certainly, the issue is close. Pioneer presented no direct evidence regarding how Holden obtained H3H/H43SZ7. However, "direct evidence of industrial espionage is rarely available" and not required. "Wrongful taking of a trade secret can be found based on circumstantial evidence." Moreover, the fact that Holden may have altered Pioneer's secret does not insulate it from liability. Slight alteration of a competitor's protected secret implicates the same concerns as cases of outright misappropriation.

The record displays a long history of Holden attempts to obtain Pioneer's genetic material. Roland Holden, the now-retired founder of Holden's Foundation Seeds, Inc., testified about his repeated searches for Pioneer's seed. As the court stated, "it is very clear that for a number of years, Roland Holden was doing anything he could to try to find out more about and grow Pioneer lines." These efforts included searching "friendly farms" for stray inbred plants (e.g., H3H) – a process by which he admitted obtaining possession of several Pioneer lines. Although the court concluded that "Pioneer has not specifically shown" that these efforts were the "exact source" of L120, the testimony supports such an inference. Holden's inadequate explanation of its faulty record-keeping and the untimely disposal of all L120 seed also give rise to an inference of misappropriation.

An inference of misappropriation from limited facts is especially warranted in situations such as this where the secret itself is so unique that any form of duplication would probably be improper. Unlike the situation where a competitor is found to have possession of a process, product or fact which is similar to plaintiff's "secret," this case involves possession of a product derived from the protected secret. Proof of derivation removes the possibility of independent regulating commercial behavior. If the law forces businesses to take extreme measures to protect themselves against all forms of commercial espionage not otherwise unlawful, "the incentive to invest resources in discovering more efficient methods of production will be reduced and with it the amount of invention." Our analysis is consistent with the stated purposes of trade secret protection: (1) maintaining commercial morality, and (2) encouraging innovation.

"The district court found that although Holden maintained "meticulous records during the late 1960s," the records of the development of L120 were woefully deficient. "This glaring, poorly explained and consistent failure to record source designations for every L line used by Holden is hard to accept as continuing oversight." On appeal, Holden renews its explanation for the inadequate records, but concedes that no detailed records of the development of L120 exist.
development, further supporting the court's finding that Holden misappropriated genetic material from Pioneer.

The court did not end its analysis after determining that Pioneer met its burden as to misappropriation or improper means. Rather, the court concluded that since Pioneer "met this burden, Holden has the burden of showing that H3H and/or H43SZ7 were lawfully acquired" — a burden which the court concluded Holden did not meet. Holden construes this language as expressing the court's decision to place upon it, and not Pioneer, the burden of proof on the issue of improper means.

There is authority supporting a shift in the burden of proof once a plaintiff proves that the defendant obtained and used the trade secret. However, the cases employing a burden-shifting analysis typically involve breaches of confidential relationships. Nonetheless, a burden-shifting analysis may be appropriate in those instances, such as this case, where the defendant actively pursued plaintiff's secrets, discarded highly relevant information, consistently denied obtaining the protected material through any means, and possessed secrets shown to have probably been derived from (not merely exhibiting similarities to) plaintiff's secret.

It was only after finding sufficient evidence of "misappropriation" by Holden that the court first discussed shifting the burden of proving lawful acquisition to Holden. The court's later discussion of "burden shifting" merely expresses its appreciation of the fact that once Pioneer produced convincing evidence of misappropriation, Holden was obligated to provide persuasive evidence of lawful derivation. We reject Holden's argument that the court improperly placed the burden on it to show that it lawfully acquired H3H/H43SZ7. The court's procedure can simply be read as an allocation of the burdens of going forward with the evidence. After weighing and balancing the parties' competing evidence, the district court found Holden's L120 story less persuasive than Pioneer's misappropriation claim, hence the district court held in favor of Pioneer. In light of the evidence discussed above, and after reviewing the entire record, we cannot say the district court's finding of misappropriation was clearly erroneous.

III.

Holden makes several additional arguments on appeal. We briefly consider Holden's argument that Pioneer's claim of reverse passing off in violation of section 43(a) of the Lanham Act is "completely without merit." 15 U.S.C. § 1125(a).

The district court concluded that Holden's misappropriation of H3H/H43SZ7 and subsequent marketing of LH38-39-40 violated § 43(a) of the Lanham Act. Section 43(a) prohibits the use of false descriptions or false designations of origin in the advertising or selling of goods or services in commerce. Holden does not dispute that it sells and advertises LH38-39-
The district court found that Holden held out during all relevant times, "and still does now, that LH38 and LH39 were developed solely by Holden by the use of L120." The court cited testimony indicating that Holden marketed LH38 x B73, for example, by displaying it alongside Pioneer's 3541. According to the court, "the obvious intended message" was that Holden possessed its "own corn as good or better than Pioneer['s]."

Reverse palming off is essentially the defendant's unauthorized removal of plaintiff's product's identifying marks before reselling the goods. The doctrine includes situations in which a defendant markets another's product that has been only slightly modified and then relabeled.

As discussed above, the district court found that Holden possessed H3H/H43SZ7 in the form of LH38-39-40, and this finding is not clearly erroneous. It is uncontested that Holden marketed LH38-39-40 as an independently-developed product. Neither its advertising nor its registration under the Plant Variety Protection Act referred to the existence of Pioneer's genetic material in its pedigree. This misrepresentation as to the origin of LH38-39-40 implicates several concerns protected by the Lanham Act's prohibition of reverse palming off. For instance, Holden's claims of independent development denied Pioneer "the advertising value of its name and of the goodwill that otherwise would stem from public knowledge of the true source of the satisfactory product." "The ultimate purchaser is harmed as well by the loss of knowledge of and possible deception regarding the true source of the product or service." In light of these concerns and on the facts before it, the district court did not err in concluding that Holden violated the Lanham Act by reverse palming off Pioneer's genetic material as its own.

Holden also argues the Plant Variety Protection Act, 7 U.S.C. §§ 2321-2582, preempts state trade secret law as applied to sexually reproducing plants. Holden contends the available legislative history demonstrates Congress' intent that the Act be the sole legal protection for sexually reproducing plants. If clearly expressed, congressional intent to preempt state law will be given effect. However, neither the plain language of the Act nor the legislative history cited

46The district court found that Holden held out during all relevant times, "and still does now, that LH38 and LH39 were developed solely by Holden by the use of L120." The court cited testimony indicating that Holden marketed LH38 x B73, for example, by displaying it alongside Pioneer's 3541. According to the court, "the obvious intended message" was that Holden possessed its "own corn as good or better than Pioneer['s]."

47A plant reproduces sexually if the offspring results from the combination of male and female genetic contributions.
by Holden demonstrates any such intent.\textsuperscript{48} We read the House Report as reflecting Congress' determination that no patent or patent-like protection existed for sexually reproducing plants. The language simply does not show a legislative intent to preempt all state protection of plants. Congress merely acknowledged and addressed the absence of protection for sexually reproducing plants \textit{qua} plants. It did not suggest that state law could not address improper conduct that happened to involve plants or plant material. The Supreme Court has expressly held that trade secret and patent protection can "peacefully coexist." Moreover, this court should not lightly infer preemption. We have carefully considered Holden's preemption argument, and conclude it is without merit.

IV.

The district court bifurcated the liability and damage trials. After considering the various submissions of the parties in the separate damage trial, the court awarded Pioneer $46,703,230 in lost profits. The court further determined that, in the alternative, the proper damages under an unjust enrichment theory would be $21,174,913. The court also enjoined Holden from distributing or disposing of 177 inbred lines containing LH38-39-40 or their progeny, pending a determination of whether such lines should be turned over to Iowa State University.

The parties' dispute over damages involves three major issues: (1) Did the district court properly choose the "lost profits" theory, instead of an unjust enrichment or reasonable royalty measure? (2) If lost profits are the appropriate measure, did the district court use an acceptable methodology in computing the lost profits? (3) Did the district court err in denying Pioneer's request for prejudgment interest? [The Eighth Circuit affirmed in all contested respects.]

We affirm the district court's judgment and order of damages.

\textsuperscript{48}The House Report states:

Under patent law, protection is presently limited to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

This language provides the context for the Report's later statement that "legal protection for plant varieties is not now available" in the United States.
Soon after the Eighth Circuit issued its decision, Pioneer and Holden settled. Meanwhile, any industry-wide shift to hybrid plant breeding could pose a unique set of economic and environmental hazards. Only three percent of the corn genome is used to develop the inbred corn lines that dominate the market for proprietary seed corn in the United States. Such a limited gene pool exposes the entire American corn crop to a single, perhaps undeveloped and unknown disease. As a result, research into diversifying the genetic stock of American corn is forging ahead.

3. Contractual protection of plant breeders' rights

Plant breeders can protect themselves through contractual provisions that create a form of privately enforced intellectual property. These provisions frequently appear in one of three contexts:

- A purchase agreement incident to a sale of seed to a grower.
- A production contract under which a grower raises specialty crops.
- A production contract stipulating that the grower has no ownership interest in the seed that he or she plants.

The following contracts, based on models presented at the 1993 American Agricultural Law Association meeting by Neil D. Hamilton, exemplify each of the three types:

Purchase agreement

Supplier represents and Purchaser hereby acknowledges that Supplier is engaged in the business of developing and supplying for sale various varieties of seeds. Supplier has a substantial investment in the development and production of its seeds and in the use of


50 See Dirck Steimel, *Corn Breeders Pin Hopes on Some Exotic Seed Lines*, Des Moines Reg., Oct. 9, 1994, at 3G.
subsequent production of the seeds herein sold. Supplier has expended substantial effort in developing a market for its seeds. Supplier has existing contractual relationships with other purchasers and growers for the sale of its seeds and expectations of additional contracts for the sale if its seeds in the future.

In consideration of the foregoing and in consideration of the seeds herein sold, Purchaser hereby acknowledges and agrees that the production from the seeds herein sold will be used only for feed or processing and will not be used or sold for seed, breeding, or any variety improvement purposes. Purchaser acknowledges Supplier's proprietary interest in the use of subsequent production from the seeds herein sold, and agrees it would be a violation of this agreement to allow subsequent production of the seed herein sold to be used to create a seed variety or seed product from said production, which may be used for seed purposes by individuals or entities other than the Supplier. Purchaser agrees that any use of Supplier's seeds which is forbidden by this agreement will constitute a misappropriation of the personal property of the Supplier and will therefore result in a breach of the agreement.

Purchaser agrees that any use of Supplier's seeds forbidden by this agreement will damage Supplier's legitimate expectation of future sales of seed and any use of Supplier's seeds in violation of this agreement will constitute an attempt to intentionally injure or destroy Supplier's prospective business expectations in future sales of its seeds.

Purchaser agrees that any use of Supplier's seeds in violation of this agreement will cause substantial damage to the Supplier and that if subsequent production of the seed herein sold is used to create a seed variety or seed product substantial damage to the Supplier for all seed varieties or seed products thereby created will be caused. This agreement shall not limit any other rights, legal or equitable, that the Supplier has, but shall be accumulative.

* * * * *

Production contract covenant

Grower acknowledges that Integrator has a valuable proprietary interest in the parent seed and seed crop. Grower agrees that he will not use for seed except under this agreement, not sell to or permit any other person to use for seed any of the parent seed or seed crop. Grower acknowledges that the legal remedies in the event of any actual or threatened breach of this covenant, in addition to any other right or remedy which Integrator may have, Integrator shall be entitled to specific performance of this covenant through injunctive relief.
Production contract provision reserving title to seed

Grower agrees to accept, as a bailee, stock seed of Integrator, for seeding at the rate of ___ pounds per acre. Grower agrees to return all unused stock seed to Integrator within two (2) months from the date of receipt by Grower.

Grower agrees:

— That the stock seed furnished, the plant life produced and all seed grown under this agreement are and at all times shall remain the property of Integrator,

— That he will not use or sell or permit any other person to use or sell for seed any of the crops produced from the stock seed furnished by Integrator,

— That he will not allow any of the vegetative cuttings or plants from the stock seed to be removed from his fields or control, except with express written consent of Integrator, and further

— That he will not commit any act permitting any other party to obtain possession of the seed in any way whatsoever except as provided for hereunder.

The emergence of contracts such as these, of course, is directly linked to technological advances in plant genetics and the legal phenomenon of protecting these advances through intellectual property:

Neil D. Hamilton

*Why Own the Farm If You Can Own the Farmer (and the Crop)*:

*Contract Production and Intellectual Property Protection of Grain Crops*

73 Neb. L. Rev. 48, 89-90 (1994)

The trend toward contract production is directly related to development of improved plant
genetics which can produce high value crops and grains genetically engineered for special uses. There is also a direct link between the trend toward contract production and the intellectual property right protections available for agricultural crops. As genetic engineering and improved breeding creates the potential for added value in grains, it is only natural for the companies investing millions of dollars to develop new crops to want to protect their financial interests in what they create. Companies will look for ways to claim rights further out of the production flow of a crop in order to capture part or all of the value they contribute. That is why companies such as Du Pont have decided to enter directly into the production of grain by opening subsidiaries engaged in contract production.

It is increasingly clear seed companies will not be content to simply sell improved seeds and profit from the higher prices charged. Instead, they may look for ways to control production of value-added crops so a portion or all of the enhanced value added by their breeding goes to them. Companies can do this in several ways. First, they can own or rent land and raise the crop themselves, but this is costly and even illegal for some companies in many midwestern states. Second, the companies could sell the seed to farmers and then buy back the production in the open marketplace for further distribution. If farmers can save the seed and replant it, however, this method risks losing control over the specially tailored genetics, which in turn could reduce the company's future ability to sell the seeds and capture their added value. Open sale of the improved seeds may also result in the extra value being lost if the public marketplace did not provide a way to value the additional traits. In such a case, poultry growers who buy high-oil corn might get a better quality feed ingredient without having to pay anyone for the improvement. A third approach is to contract with farmers to raise the crops and then sell them exclusively to the company for further marketing. . . . In order to protect their interests in both the improved genetics and their ability to maximize the financial gains from the products, companies will utilize whatever laws are available. The laws which are most directly applicable are those for protecting intellectual property claims in seeds and plants. As a result, the increased use of contract production in grain requires consideration of the existing range of intellectual property right protections available along with the emerging legal issues in their use.

* * * * *

4. The Federal Seed Act

Although the Federal Seed Act\textsuperscript{51} does not, strictly speaking, establish a type of agricultural intellectual property, it is essential to the marketing of proprietary seed, however such seed is protected. This statute protects buyers from defective or contaminated seed by

\textsuperscript{51}7 U.S.C. §§ 1551-1611.
requiring seed producers and distributors to comply with labeling and disclosure requirements. These requirements are usually enforced through private actions that often invoke the Uniform Commercial Code's implied warranty of merchantability\textsuperscript{52} and other state laws concerning the labeling and sale of seeds:\textsuperscript{53}

**Dessert Seed Co. v. Drew Farmers Supply, Inc.**

Supreme Court of Arkansas

248 Ark. 858, 454 S.W.2d 307 (1970)

BROWN, Justice.

This litigation was initiated by six commercial tomato growers in Drew County and against Drew Farmers Supply, Inc. The growers ordered "Pink Shipper" tomato seed. The seed shipped was so designated, but when the crop began to mature it was discovered that the farmers had received seed of a variety substantially unmarketable in their area. (The variety could not be detected by visual inspection.) Drew Farmers Supply filed a third party complaint against its supplier, Service Seed Company, a distributor headquartered in Mississippi. Service Seed interpled the seed grower in California, Dessert Seed Co., Inc. When the taking of evidence was completed all parties moved for directed verdicts. Thereupon the court held: (1) That the tomato growers were entitled to recover against Drew Farmers Supply. . . ; (2) That Drew Farmers Supply was entitled to judgment over against Service Seed, the claimed limitation of liability being invalid; and (3) That Service Seed was entitled to judgment over against Dessert Seed, finding that Dessert's disclaimer of liability as a defense was invalid both as to Service Seed's cause of action based on warranty and its action based on negligence asserted against Dessert.

Drew Farmers Supply did not appeal from the judgments against it by the growers. Service Seed, the distributor, appeals from the judgment over awarded against it in favor of Drew Farmers Supply; and Dessert Seed, the grower, challenges the judgment against it in favor of Service Seed. The two appeals of necessity must be treated separately.

\textsuperscript{52}See U.C.C. § 2-316.

I. SERVICE SEED-DREW FARMERS SUPPLY TRANSACTION

Drew Farmers Supply is a cooperative member of Southern Farmers Association, with headquarters in North Little Rock. Drew Farmers purchased most of its seed through Southern Farmers. It was stipulated that the two organizations were to be treated as one for the purposes of the lawsuit. In January 1967, Southern Farmers telephoned a rush order to Service Seed Company for tomato seed of the Pink Shipper variety. The seed was shipped forthwith and a six-pound bag was forwarded by Southern Farmers Association to Drew Farmers Supply. The tag attached by Service Seed recited that the bag contained Pink Shipper variety tomato seed. The face of the tag contained this fine print:

Subject to the limitation of liability herein set forth, we warrant that seeds or bulbs sold are as described on the container, within recognized tolerances. Our liability on this warranty is limited in amount to the purchase price of the seeds or bulbs. In no way shall we be liable for the crop.

For some eight years Drew Farmers Supply and/or Southern Farmers had been fairly regular seed customers of Service Seed. In the course of those transactions the buyer received Service Seed's price lists and invoices. Those instruments contained substantially the same wording as that which we have reproduced from the tag, as did its letterheads. Service Seed therefore argues that the totality of the recited evidence indicated an awareness by Drew Farmers Supply of the existence and meaning of Service Seed's disclaimer. Therefore, argues Service Seed, those facts place the case within the provisions of the Uniform Commercial Code, § 2-316(4), permitting limitations on remedies for breach of warranty. The cited section has to be applied in accordance with the provisions of §§ 2-718 and 2-719.

Service Seed's argument overlooks some essential facts. Drew Farmers Supply placed its order for these Pink Shippers by telephone. There was nothing said about a limited warranty. There was testimony that at least one of Drew Farmers' agents had before seen the limitation of warranty wording on tags on previous orders; but that fact is of little importance here. We are concerned with the particular order and acceptance of the particular seed. It was undisputed that these two companies negotiated oral "spot orders," as distinguished from written contractual orders containing limitation of liability clauses. There was testimony that not all tags carried printed limitations. Mr. Osborne, division manager for Southern Farmers, testified that Southern did business with suppliers from throughout the United States and that dependence was placed, "not on fine print," but upon the integrity of the supplier; and that the paramount concern of the buyer is such items as variety, purity, and germination. The fact finding tribunal — the trial court — evidently found that the limitation of warranty was not a basis of the bargain and there was substantial evidence to support that finding.
Additionally, [U.C.C. § 2-316] requires that a writing purporting to exclude or modify an implied warranty of merchantability "must mention merchantability" and "must be conspicuous." Service Seed's tag did not comply with either requirement. Moreover, in capital letters on the tag, Service Seed certified the seed to be Pink Shippers. That representation was a warranty as a matter of law. Thus it is apparent that Drew Farmers had the protection of both the law of express and implied warranties, and it is certainly not unreasonable to conclude that Service Seed failed to show that those rights were unmistakably negated.

II. DESSERT SEED CO.-SERVICE SEED CO. TRANSACTION

Dessert Seed is a seed grower in the west coast area. Early in 1966, Service Seed placed a substantial order for various seeds needed by it for the crop year 1967. Before the final consummation of that order there were a number of documents which passed from Dessert Seed to Service Seed, such as a letter, a price list, and a confirmation of the order in detail. All of those documents contained a finely printed limitation of liability clause. Likewise, items of correspondence which Service Seed sent to Dessert Seed contained the same type of printing whereby Service Seed purported to limit its liability. Finally, there was a contract order and agreement detailing the quantity, kind and variety of various seeds; describing the alternative terms of payment; protecting the seller in case of partial or total crop failure; relieving Dessert for liability from negligence; and limiting Dessert's liability in any event to a refund of the cost of the seed. The contract was prepared by Dessert and signed by officials of both companies.

With respect to the seed Pink Shipper, a mistake was made in Dessert's shipping department and the wrong seed was packed. Dessert explained it in a letter to Service Seed:

You had your order placed with us for Tomato Pink Shipper and the stock girl who lists the numbers [stock numbers] for the items to be shipped saw the Pink Tomato Deal and due to the similarity of the name she used that stock number. When this went out to the shipping department again they just picked up the lot number and made the same error in regard to the name.

Unfortunately for all parties concerned the seed was sent out under a shipping tag showing the tomato seed to be Pink Shippers. Also on that tag was a warranty clause in such fine print as to be barely legible:

We warrant to the extent of the purchase price that seeds we sell are as described by us on our container within recognized tolerances. Our liability, whether contractual or otherwise, is limited in amount to the purchase price of the seeds
under all circumstances and regardless of the nature, cause or extent of the loss. Seeds not accepted under these terms and conditions must be returned at once in original unopened containers and the purchase price will be refunded.

Dessert Seed argues that there are a number of reasons why Service Seed was bound to be aware of the limitation of liability invoked by Dessert Seed. It was printed on various items of correspondence; it was in the contract order and agreement; it was called to Service Seed's attention in 1966 when a question arose about a previous shipment of cantaloupe seed; Service Seed used a similar limited warranty clause (without mentioning negligence); and it had become a common usage of trade within the industry.

Dessert Seed contends on appeal that it validly limited its liability to Service Seed to the amount of the purchase price of the seed. Dessert concedes that it warranted the seed to be Pink Shipper but argues that, according to the contract, the exclusive remedy would be for a recovery of the purchase price. Service Seed was relegated to the same remedy, Dessert argues, even if the wrong seeds were negligently shipped. We first examine the defense of immunity from negligence. There are three essential factors which, when combined, compel us to the conclusion that public policy forbids that we sanction immunity from negligence in this type of transaction. They are (1) the legal requirements of certification, (2) the wording on the certification tag, and (3) the damaging results which the negligence is likely to cause to a community of growers.

(1) The Legal Requirement of Certification and its Effect on Immunity from Negligence. In certifying on the shipping tag the contents of the container, Dessert was performing a duty imposed by statute. 7 U.S.C. § 1571. In addition to the federal law, under which the shipment was made, many agricultural States, California and Mississippi included, have enacted the same requirement. Other States, such as ours, have delegated to appropriate State boards the authority to regulate labeling requirements. We are convinced that such labeling requirements are generally followed in the seed industry. We are not unmindful of the general rule that in many instances liability for negligence may be avoided by contract. On the other hand, the same authority enumerates many exceptions to the rule. For example it is there stated: "[T]he law will not sustain a covenant of immunity which . . . relieves one of a duty imposed by law for the public benefit." . . . [T]his court upheld the avoidance of a negligence immunity clause[. reasoning] . . . that appellant [an electric utility] could not by contract relieve itself of negligence in not keeping the proper temperature for eggs stored by appellee. It was there pointed out that such clauses of immunity are not productive of "caution and forethought by those in whose control rest the agencies that may cause damage."

(2) The Wording on the Certification Tag. Dessert warranted that the seed conformed to the description on the container "within recognized tolerances." Then in large type appears this wording: "Kind and Variety, TOMATO – PINK SHIPPER." . . . [W]e recognize that utmost
reliance can be placed on the certification; ... we [have] held that the certification, as a matter of law, warrant[s] the contents of the bag. It would certainly dilute the strong reliance to which the warranty has been properly elevated if the packer could be shielded from negligence in packing the wrong seed, particularly when the word "negligence" does not appear on the tag.

(3) The Damaging Results which are Likely to Flow from Misbranding. Neither Service Seed, Drew Farmers Supply, nor the six growers who purchased seed from this shipment could detect the variation in variety by visually examining the seed. The revelation could reasonably come about only when the plants had matured to the extent that the variation was visible from the formation of the plant. Then it is too late in the season to correct the harm. When an entire community of growers is thus placed at the mercy of the seed grower-packer the law should encourage "caution and forethought" on the part of the latter. To uphold the negligence clause in the contract would be more likely to produce the opposite result.

Service Seed in its pleadings placed in issue the negligence of Dessert Seed. In support of that contention Service introduced a letter written by Mr. Dessert ... and which explained the mistake. In addition to admitting the error of the stock clerk, Mr. Dessert left the definite impression that the particular employee was not experienced. He said "experienced clerks are hard to come by these days when everyone wants to make a lot of money and do very little work." There was substantial evidence to support a finding of negligence.

To hold that Service Seed is limited to a recovery of the purchase price of the seed in the face of established negligence would be unreasonable, unconscionable, and against sound public policy. We declare the principle to be the law of our forum and it is applicable notwithstanding the contract was made in another State.

Affirmed.

* * * * *
Before GODBOLD, GARZA and RANDALL, Circuit Judges.

GODBOLD, Circuit Judge:

Gibson, a resident of Texas, bought from Worley Mills at its plant in New Mexico, a large quantity of a "pasturage mixture" of rye and barley seed. Gibson supplied wheat seed, which Worley cleaned and added to the rye-barley mix that it sold. Gibson hired a contract planter to sow the three-seed mixture on his land in Texas for the purpose of growing forage for the feeding of livestock. When the sowing operation was almost completed the planter discovered that the mixture also contained the seed of bindweed, a highly noxious plant. Later bindweed was found growing on the seeded land.

Bindweed has good protein content and is readily eaten by cattle, but it is highly undesirable. It has deep roots, is very difficult to eradicate, and tends to choke out other plants.

Plaintiff sued Worley in United States District Court in Texas under theories of negligence, strict liability, and breach of implied warranty. The case was submitted to the jury on special interrogatories . . . . The jury found that the mixture sold by Worley contained bindweed seed. It found that the mixture was to be used by Gibson for planting and growing forage for the feeding of livestock, that Worley knew or should have known of Gibson's intentions, and that the mixture was fit for this intended purpose. It found that Gibson relied on the skill and judgment of Worley in selecting the ingredients for the mixture, other than the wheat. It found that it was reasonable for Gibson to use the pasturage mixture without inspecting it to determine if it had any defect. The jury also found that the bindweed seed was the producing cause of damage to Gibson's land. Last, it found that the reasonable cost of eradicating the bindweed was $20,000. The court entered judgment for Worley. Gibson appealed. We reverse and remand with directions to enter judgment for Gibson.

Sale of any agricultural seed containing bindweed seed is forbidden by federal law, 7 U.S.C. §§ 1561 & 1571, Texas law, and New Mexico law. Sale of the seed by Worley was negligence as a matter of law because Gibson was in the class of persons that all of these statutes were designed to protect. The jury excluded contributory fault on the part of Gibson by finding that he acted reasonably in not inspecting the mixture.
The only remaining element of Gibson's action in negligence was proximate causation. This element may be established as a matter of law by a showing of causation in fact and foreseeability. The existence of a statute forbidding some activity because of the harm that may result acts at least as a guide to the existence of foreseeability. The jury finding that the bindweed seed in the mixture was the "producing cause" of the damage to Gibson's land excluded the possibility that the source of the bindweed either was seed already present in the soil or was some other source than the pasturage mixture. Thus the jury found causation in fact.

Moreover, proscriptions against the sale of agricultural seed containing bindweed seed are not imposed because bindweed seed is dangerous when ingested, or because it will injure persons who handle it, or because it will produce a plant poisonous to livestock, but because bindweed adversely affects the land. The harm that occurred to Gibson is clearly the foreseeable result which the statutes were designed to prevent. Thus there was proximate cause as a matter of law.

With cause in fact and damages found by the jury, and negligence and proximate causation present as a matter of law, the court was required to enter judgment for Gibson.

Some of the answers to interrogatories on the warranty theory of the case are inconsistent with what we have said. A new trial is not required, however, because these interrogatories and the accompanying instructions, to which Gibson objected, confused the ordinary usage issue. The interrogatories submitted to the jury inquiring as to whether the seed mixture was reasonably fit for the purpose intended, was fit for ordinary purposes, and fit for planting and growing forage, should not have been submitted, because they were not necessary to the decision of this case. When bindweed seed is included in a seed mixture to be planted on the land, the mixture cannot be reasonably fit because it damages the land that it is planted on.

Our conclusion concerning the negligence theory makes it unnecessary to discuss the strict liability theory.

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5. State statutes protecting local specialty crops

States have enacted statutes protecting local specialty crops. After asserting the state's or an in-state region's economic stake in the crop, these statutes typically impose a labeling requirement and sanctions for violations of that requirement.
§ 2-14-130. Short title.

This article shall be known and may be cited as the "Vidalia Onion Act of 1986."


As used in this article, the term:

(1) "Person" means an individual, partnership, corporation, association, or any other legal entity.

(2) "Vidalia onion production area" means a production area which encompasses only the State of Georgia or such lesser area as may be provided for pursuant to subsection (a) of Code § 2-14-133.

(3) "Vidalia onion variety" means all Yellow Hybrid Granex and Granex 33 onions or other existing Granex varieties.

§ 2-14-132. Use of term "Vidalia."

Only onions which are of the Vidalia onion variety and which are grown within the Vidalia onion production area may be identified, classified, packaged, labeled, or otherwise designated for sale inside or outside this state as Vidalia onions. The term "Vidalia" may be used in connection with the labeling, packaging, classifying, or identifying of onions for sale inside or outside this state only if the onions are of the Vidalia onion variety and are grown in the Vidalia onion production area.

§ 2-14-133. Rules and regulations; enforcement of article.

(a) The Commissioner of Agriculture is authorized to prescribe rules or regulations which may include, but not necessarily be limited to, quality standards, grades, labeling, and marketing practices for the marketing of onions in this state and such other regulations as are necessary to administer properly this article. The Commissioner may also prescribe rules or regulations establishing a registration, inspection, and verification program for the production and marketing of Vidalia onions in this state and, after hearing and public comment, further limiting the Vidalia onion production area as defined in paragraph (2) of Code § 2-14-131. Pursuant to such rules, regulations, and conditions as may be prescribed by the Commissioner, the Commissioner is
authorized to grant variances in the production area requirements of this article to any producer who has produced in Georgia, marketed, and labeled onions of the Vidalia onion variety as Vidalia onions prior to January 31, 1986. Such rules or regulations may include within the definition of Vidalia onion variety as defined in paragraph (3) of Code § 2-14-131 other hybrids or varieties of onions which may be developed and which have characteristics similar to the Vidalia onion variety. All onions sold must conform to the prescribed standards and grades and must be labeled accordingly.

(b) The Commissioner and his agents and employees are authorized to enter any premises or other property where onions are produced, stored, sold, offered for sale, packaged for sale, transported, or delivered to inspect such onions for the purpose of enforcing the provisions of this article and the rules and regulations promulgated under this article.

§ 2-14-134. Violations; criminal penalties.

(a) It shall be unlawful for any person to sell or offer for sale either inside or outside this state any onions as Vidalia onions unless such onions are of the Vidalia onion variety and were grown in the Vidalia onion production area.

(b) It shall be unlawful for any person to package, label, identify, or classify any onions for sale inside or outside this state as Vidalia onions or to use the term "Vidalia" in connection with the labeling, packaging, classifying, or identifying of onions for sale inside or outside this state unless such onions are of the Vidalia onion variety and were grown in the Vidalia onion production area.

(c) Any person who violates subsection (a) or (b) of this Code section shall be guilty of a felony and, upon conviction thereof, shall be punished by a fine of not less than $1,000.00 nor more than $5,000.00 or by imprisonment for not less than one nor more than three years, or both.

(d) It shall be unlawful for any person to sell onions in a manner which does not comply with the rules or regulations established by the Commissioner under authority of Code § 2-14-133.

§ 2-14-135. Civil penalties; injunctions.

(a) Any person who violates any provision of this article or who violates any rule or regulation issued by the Commissioner pursuant to this article shall be liable for a civil penalty in an amount not to exceed $5,000.00 for each and every violation thereof, the amount of such penalty to be fixed by the Commissioner after notice and hearing as provided in . . . the "Georgia Administrative Procedure Act," for contested cases. Each day of violation shall constitute a
separate violation for purposes of this subsection but in no event shall the penalty exceed $20,000.00. Any moneys recovered pursuant to this Code section shall be deposited in the state treasury.

(b) Whenever in the judgment of the Commissioner any person has engaged in or is about to engage in any act or practice which constitutes or will constitute any violation of this article, the Commissioner may make application to the superior court of the county where such person resides or, if a nonresident of this state, to the superior court of the county where such person is engaged in or is about to engage in such act or practice, for an order enjoining and restraining such act or practice. If it appears to the court, upon any application for a temporary restraining order or upon any application for an interlocutory or permanent injunction, after evidence is received, that any person has engaged in or is about to engage in any act or practice which constitutes or will constitute any violation of this article or any rule or regulation duly issued by the Commissioner under this article, then the court shall enjoin the defendant from committing further violations. It shall not be necessary in such event to allege or prove lack of an adequate remedy at law.

(c) In any court action brought by the Commissioner to enforce any of the provisions of this article or any rule or regulation issued by the Commissioner, the judgment, if in favor of the Commissioner, shall provide that defendant pay to the Commissioner all costs and expenses incurred by the Commissioner in the prosecution of such action.

(d) The Commissioner may file in the superior court of the county wherein the person under order resides, or, if the person is a corporation, in the county wherein the corporation maintains its principal place of business, or in the county wherein the violation occurred or in which jurisdiction is appropriate, a certified copy of a final administrative order of the Commissioner unappealed from or a final administrative order of the Commissioner affirmed upon appeal, whereupon the court shall render judgment in accordance therewith and notify the parties. Such judgment shall have the same effect, and all proceedings in relation thereto shall thereafter be the same, as though the judgment had been rendered in an action duly heard and determined by such court.

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Hawaii Kona coffee statute
HAW. STAT. § 486-120.6

KONA COFFEE; MINIMUM CONTENT AND LABELING REQUIREMENTS.

(a) In addition to all other labeling requirements, all roasted or instant coffee which is produced in whole or in part from Kona coffee beans shall meet the following:

(1) Identity statement:

(A) Only roasted or instant coffee which contains one hundred per cent Kona coffee by weight may be labeled or advertised as roasted or instant Kona coffee.

(B) Roasted or instant coffee containing not less than ten per cent but less than one hundred per cent Kona coffee by weight shall be labeled or advertised as "Kona coffee blend," "Kona blend coffee," or "blended Kona coffee." In addition, the following statement shall appear on the front panel of the label: "contains not less than ten per cent Kona coffee"; however, the actual percentage may be substituted in the statement.

(2) Each word in the identity statement shall be contiguous and conspicuously displayed without any intervening material. Upper and lower case letters may be used interchangeably in the identity statement.

(b) It shall be a violation of this section:

(1) To use the term "Kona coffee," "100% Kona coffee," or similar terms in labeling or advertising unless the package of coffee contains one hundred per cent Kona coffee.

(2) To use the term "Kona" in labeling or advertising, including in conjunction with a coffee style or in any other manner, if the roasted or instant coffee contains less than ten per cent Kona coffee by weight.

(c) For the purpose of this section:

(1) "Kona coffee" means coffee that is grown in the geographical regions identified as North Kona and South Kona districts on the island of Hawaii and which meets the grade standard requirements as adopted under chapter 147.
(2) "Per cent Kona coffee by weight" means the percentage calculated by dividing the weight in pounds of roasted Kona coffee used in a production run of roasted or instant coffee, by the total weight in pounds of the roasted coffee used in that production run of roasted or instant coffee, and multiplying the quotient by one hundred.

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In France, the United States, and other nations, viticulture enjoys special legal protection for the multinational system of geographic "appellations of origin." In France, the Institut National des Appellations D'Origine enforces the rules that entitle only wine producers to label their products "cognac," "bordeaux," or "champagne." The United States operates a similar, albeit less stringent system of appellations of origin. Internationally, appellations of origin are recognized and protected as a distinct form of intellectual property under the most recent version of the General Agreements on Tariffs and Trade.

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6. Copyright protection for biotechnology

Finally, as an exercise in innovative lawyering or legal scholarship, consider the possibility of copyrights on biotechnology. The following excerpt explores this intriguing prospect, which has not been tested in the courts:

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54 For further information, contact the Institut at 138, Champs Élysées, 75 008 Paris, FRANCE.


56 See General Agreement on Tariffs and Trade, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 22 (World Trade Organization April 15, 1994) ("Protection of Geographical Indications").

Molecular biologists and genetic engineers may be surprised to learn (as may most everyone) that their expressions of intracellular genetic information, novel or otherwise, within living microorganisms or eukaryotic cells are also works of authorship protected from unauthorized reproduction by the terms of the Copyright Act of 1976. Although this conclusion may appear startling, a careful examination of the statutory and constitutional requirements for copyright protection indicates its likely validity. The central theses of this article are that virtually all original works of a genetic scientist are copyrighted automatically when he creates them; the scientist generally can enforce his copyrights; those copyrights may provide more effective protection than other forms of intellectual property in many circumstances; and copyright protection for genetically engineered works appears within the constitutional limits on Congressional power.

Shock value to the reader aside, what is the value in copyrighting genetic information? The answer is that it depends! Under certain circumstances, from a practical as well as legal viewpoint, copyright protection may be the only or the most effective way an "author" can protect a valuable genetic "work." Furthermore, even when forms of legal protection other than copyright suggest themselves as generally more appropriate, the unusually attractive remedies and long life of copyright protection may tip the scales in its favor. A few examples will illustrate the attractiveness of copyright protection.

At this time, two of the major methods for recombinant DNA engineering with greatest commercial potential appear to be hybridoma methodology and the Cohen-Boyer process of

8DNA, deoxyribonucleic acid, is the primary genetic material of all cells. It is composed of a five-carbon sugar, phosphoric acid and four bases or nucleic acid molecules, adenine, guanine, cytosine and thymine. These components are arranged in repeating units called nucleotides which are attached in linear chains. These chains are in the form of a double helix, a ladder-like configuration rotated on a central axis. Recombinant DNA is "a synthetic DNA molecule containing genes from two or more different organisms."

9The hybridoma process is the fusion by chemical means of a cell from a malignant tumor with a normal cell whose function is to produce a useful protein, such as an antibody for a specific disease. The fused cell reproduces with the rapidity of cancer cells and produces the useful antibody, not the cancerous protein.
DNA cleavage and ligation or gene splicing. The Cohen-Boyer process has been patented and licensed widely by the assignee, Stanford University. Hybridoma techniques are apparently in the public domain as a consequence of their publication.

Policing a patented process or method of manufacture that is carried out within the quiet of an infringer's plant usually is either impossible or too expensive to justify. The Cohen-Boyer process creates an exception to this wisdom because of its pioneering nature. Absent a decision to give the process away and absent the possibility of effectively policing a pioneering process, however, the only way an inventor or his investors can benefit from a novel genetic engineering process is to maintain it as a trade secret. The owner of a trade secret can either use it exclusively or license it to others for use (with appropriate restrictions to maintain secrecy).

Assume the secret process allows the owner to create two genetically novel microorganisms, A and B. The first, A, is both novel and nonobvious to a microbiologist of ordinary skill and therefore patentable. The second, B, is both novel and valuable, but obvious to those of ordinary skill and, therefore, unpatentable. How can A and B best be protected so as to provide their creator and his financial backers an appropriate return on their efforts, money, and risk-taking?

The answer for protecting A, patentable though it may be, cannot be patenting if the process for making it is to be kept secret. To obtain a valid patent, the applicant will have to disclose in the patent, and thus to the world, how to make A. The trade secret in the process for making A will be lost. That secret process may be far more valuable as a "golden goose" than any of the individual golden eggs it lays.

A and B probably cannot be protected as trade secrets themselves, since the use of DNA sequencing and DNA-DNA hybridization may well disclose their DNA code. Copyright, however, can protect both DNA sequences to the extent that others will not be allowed to plagiarize (by culturing or otherwise) the organism in which the genetic information is fixed. On the other hand, if others independently invent a process (different from or the same as the secret

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10 A cell will function in precisely the way in which its DNA molecule directs it to. Artificial or synthetic DNA molecules can now readily be created by the Cohen-Boyer process. One natural DNA molecule in a test tube is broken at a predetermined site simply by mixing a specific protein (restriction enzyme) with it. The same thing is done to another natural molecule in another test tube. After the cleavage of the two, they are combined in one test tube where, in the presence of a ligating enzyme and with some shaking of the tube, the DNA fragments recombine. Many of the new combinations comprise fragments from the different molecules; they form an artificial, spliced DNA sequence.
one) for making A and B, then their use of that process to create and reproduce A and B will not infringe the copyrights to A and B, so long as they did not use the copyrighted work as a guide to compiling the genetic information needed to make A or B. In short, "a work is original and may command copyright protection even if it is completely identical with a prior work provided it was not copied from such prior work but is rather a product of the independent efforts of its author."

To further demonstrate the benefits of copyright protection, assume a microbiologist engineers an organism that is superior in important ways to previously engineered microorganisms or to naturally occurring microorganisms. As with microorganism B, the organism's advantageous properties may not be so dramatic as to make it patentable; it may be obvious to those skilled in the art. Nonetheless, it may be quite valuable commercially and much time, effort, insight, and money may have been expended to create it.

Although the scientist may not be able to obtain a patent, he may be able to secure a copyright. The copyright precludes another from using the DNA sequence that the scientist originated and fixed in the microorganism to make an identical or substantially similar copy. Preventing others from reproducing the DNA information fixed in the organism can be very profitable, even though the scope of protection may be narrower than that afforded by patent. . . .

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