

## Three Separate and Distinct Spheres: Patents, Regulation, and Liability

by  
Drew L. Kershen\*

In a recent newspaper article about food security and food shortages, Thomas Lumpkin, Director of the International Wheat and Maize Improvement Center in El Batán, Mexico (better known by its Spanish initials, CIMMYT) was quoted as saying, “We need science to come back to farming.”<sup>1</sup> Dr. Lumpkin’s statement is appropriate for the theme of this article about plant biotechnology and patents.

Agriculture needs science.<sup>2</sup> Plant biotechnology is a significant scientific technique for plant breeding that can put science back into farming.<sup>3</sup> A thesis of this article is that to put science, more particularly plant biotechnology, back into agriculture, it is important to keep three

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\* Earl Sneed Centennial Professor of Law, University of Oklahoma, College of Law.

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In a shortened, variant version, this article is also Chapter 5 in STUART SMYTH, A. BRYAN ENDRES, THOMAS REDICK, & DREW KERSHEN, *INNOVATION AND LIABILITY IN BIOTECHNOLOGY: TRANSNATIONAL AND COMPARATIVE PERSPECTIVES* (Edward Elgar Publishing, Ltd., 2010).

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<sup>1</sup> Javier Blas, *The End of Abundance: Food Panic Brings Calls for a Second ‘Green Revolution’*, FINANCIAL TIMES (London), June 1, 2008, available at [http://us.ft.com/ftgateway/superpage.ft?news\\_id=fto060120081432222607](http://us.ft.com/ftgateway/superpage.ft?news_id=fto060120081432222607).

<sup>2</sup> For a superbly informative discussion of the need for science, particularly plant biotechnology, in agriculture, see ROBERT PAARLBERG, *STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA* (2008).

<sup>3</sup> For a fascinating exploration of plant biotechnology for breeding improvements in agricultural crops (especially orphan crops), see JONATHAN GRESSEL, *GENETIC GLASS CEILINGS: TRANSGENICS FOR CROP BIODIVERSITY* (2008).

legal spheres – patents, regulation, and liability – separate and distinct. This article argues that the more these three legal spheres are conflated or confused, the less likely plant biotechnology will be used in agriculture – to the detriment of agriculture generally and to subsistence farmers particularly.

My thesis is not intuitively obvious. In this essay, I intend to defend my thesis with the goal of providing a thoughtful and (hopefully) persuasive analysis.

## **I. Patents**

I adopt a very utilitarian view of intellectual property rights, especially patents. By utilitarian view of patents I mean that society enters into a bargain with the patent holder. The basic terms of the patent bargain are as follows:

- Society will grant the patent holder exclusive control of the holder’s invention for a limited period of time – generally twenty years. By granting this time-limited exclusive control, the patent holder obtains the enhanced opportunity to recover the costs of research and development for the invention (investment recovery) and the costs of bringing the invention to market (innovation recovery). Once the patent expires, the patent holder will face economic competition whatever the consequences to the patent holder for further investment and innovation recovery.<sup>4</sup>

- Patent holders will disclose the invention in sufficient detail so that society knows what has been invented and so that others in the society are enabled to understand and to

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<sup>4</sup> The patent holder’s exclusive control is sometimes referred to as a “patent monopoly.” But a “patent monopoly” should not be confused with an anti-trust monopoly. While exclusive control can give rise to anti-trust concerns due to the holder’s anti-competitive behavior, the holder’s exclusive control is purposefully granted as a matter of social policy to give the holder an incentive and opportunity for enhanced investment and innovation recovery.

make the invention themselves. By disclosing the invention, society gains the benefit of increased knowledge that can be used immediately to create new inventions or new improvements, though those creating these new inventions/improvements usually need permission (a license) from the holder of the patent. Once the patent expires, the invention becomes part of the public domain and anyone can use the patent without needed to seek permission from the original patent holder.

Underpinning this bargain is the economic theory that if society provides legal and economic incentives for anything, society will get more of that “anything.” By providing legal and economic incentives through patents to inventors, society will get more inventions and their affiliated knowledge. If the patent system provides appropriate legal and economic incentives, the patent system should foster technological accumulation for societal benefit. Moreover, the bargain is just as valid for the field of biotechnology as for any other field of creativity. With biotechnology patents, society will get more biotechnology inventions and greater biotechnology knowledge; without biotechnology patents, society will get fewer biotechnology inventions and lesser biotechnology knowledge. While I am not competent to settle debates about the economic reality, as opposed to theory, of the bargain that I have just described,<sup>5</sup> I hold the opinion that the patent system is a good bargain for both societies and inventors, despite the tension between

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<sup>5</sup> For contrasting views in the area of plant breeding, compare Dermot Hayes, Sergio Lence, & Susana Goggi, *Impact of Intellectual Property Rights in the Seed Sector on Crop Yield Growth and Social Welfare: A Case Study Approach*, 12 *AgBioForum* 155 (2009) with Niels Louwaars, et al., *Breeding Business: the future of plant breeding in the light of developments in patent rights and plant breeder's rights* (Centre for Genetic Resources, Report 2009-14).

public and private interests arising from an intellectual property system.<sup>6</sup>

In light of the patent bargain just described, the separate and distinct sphere for patents is to determine whether the applicant for a patent has met the legal requirements for obtaining a patent. More particularly, the separate and distinct sphere for patents is accurately set forth in the Agreements on Trade-related Aspects of Intellectual Property Rights (TRIPS) Article 27(1) which states: “[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”<sup>7</sup> TRIPS Articles 28, 29, 30, 31 and 33 then complete the basic terms of the patent bargain by setting forth the rights conferred, the disclosure obligations, and the term of the exclusive control, respectively.

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<sup>6</sup> Note that I do not make a distinction about the patent bargain between public research and private research. The patent bargain provides legal and economic incentives for increased inventiveness regardless of where the funding for the research originated.

Publicly-funded research may address well the costs of research and development (investment recovery) but may struggle to address the costs of bringing the invention to market (innovation recovery). Private research often may better address both investment and innovation recovery. Moreover, private research allows anyone to become an inventor about anything; in contrast, public research assuredly is limited in funds and focus. On the other hand, private research often ignores identifiable public needs because the potential economic recovery is small or unattractive in other ways. Therefore, public research is essential to satisfy public needs that would otherwise go unmet.

Hence, I consider public research and private research as complementary approaches to achieving inventiveness. In my opinion, both are enhanced by the legal and economic incentives provided by patents.

<sup>7</sup> The author realizes that TRIPS Article 27(2) & (3) allow member nations to exclude from patentability certain subject matters that particularly impinge upon the field of biotechnology. In the patent bargain that means that by exercising these subsection options, societies are choosing to get fewer biotechnology inventions and lesser biotechnology knowledge than they would get if they did not use those subsection options. Societies certainly may exercise the allowable options of TRIPS Article 27(2) & (3), but those societies will also take the consequences by doing so. *See supra* Part II (discussion of *ordre public* or morality). *Cf. also* Andrew W. Torrance, *Metaphysics and Patenting Life*, 76 UMKC L. REV. 363 (2007).

Noticeably absent from the patent bargain I have described are several considerations. I have described a patent bargain that does not directly take into account issues of commercialization and safety related to the patented process or product. These considerations (commercialization and safety) are within the separate and distinct sphere of regulation that I will discuss in Part II of this essay. Nor does the patent bargain directly take into account responsibility for harms flowing from the use of the patented process or product. This consideration (responsibility for harm) is within the separate and distinct sphere of liability that I will discuss in Part III of this essay.

Most surprisingly to many, however, may be the absence from the patent bargain I have described of issues of justice that have been hotly debated about plant biotechnology, particularly issues related to biopiracy and to access and benefit sharing for plant genetic resources used to create new plants and new products. These are worthy of discussion in this Part I about patents in plant biotechnology.<sup>8</sup>

### *Biopiracy*

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<sup>8</sup> My academic interest in intellectual property arises from agricultural biotechnology (food and fiber primarily, with fuels coming into prominence in recent years) but plant biotechnology spans several other economic sectors – pharmaceutical, chemical, horticultural, cosmetic and personal care, and food and beverage. Each sector interrelates to plants, genetic resources, and biotechnology somewhat differently. *See generally* Secretariat of the Convention on Biological Diversity, *Access and Benefit Sharing in Practice: Trends in Partnerships Across Sectors*, Technical Series No. 38 (2008) (prepared by Sarah Laird & Rachel Wynberg) [hereinafter *ABS in Practice*]. *See especially id.* at 11-21, 100-17 (industry profiles)

For an overview discussion of intellectual property rights in genetic resources that I consider compatible with the views that I have expressed, see Grant Isaac & William Kerr, *Bioprospecting or Biopiracy? Intellectual Property and Traditional Knowledge in Biotechnology Innovation*, 7 J. WORLD INTELL. PROP. 35 (2004).

Leaving aside the merits of specific claims of biopiracy,<sup>9</sup> biopiracy seems founded upon two interrelated assertions. Assertion one is that the nations of the south (less developed nations primarily in tropical Africa, Asia, and Latin America) are the biodiverse nations of the world whose genetic resources are necessary for plant biotechnology. Assertion two is that the nations of the north (developed nations primarily in North America and Europe) are the technologically-sophisticated nations of the world possessing plant biotechnology industries. Both assertions are likely becoming outdated and significantly inaccurate in the 21<sup>st</sup> century.

Beginning with genetic resources, one cannot deny the marvelous and wondrous biodiversity of the plant and animal species of tropical nations. While these plant genetic resources are valuable to plant biotechnology, their genetic necessity is lessened due to scientific discoveries about the vast genetic diversity in the microbial world of single-celled creatures. In a recent article,<sup>10</sup> this utterly astounding diversity was described as follows:

Scientists had known that there are more microbes in an ounce of soil than humans alive on the Earth, but that was just a measure of abundance. Pace's discovery demonstrated something new, a previously unfathomed repository of biodiversity. ...<sup>11</sup>

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<sup>9</sup> Scholars disagree on the merits of biopiracy claims. Compare Federico Lenzerini, *Traditional Knowledge, Biogenetic Resources, Genetic Engineering and Intellectual Property Rights*, in GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM ch. 6 (Daniel Wüger & Thomas Cottier eds., 2008) and David Conforto, *Traditional and Modern-Day Biopiracy: Redefining the Biopiracy Debate*, 19 J. ENVTL. L. & LITIG. 357 (2004) with Charles R. McManis, *Fitting Traditional Knowledge and Biopiracy into the Existing Intellectual Property and Unfair Competition Framework*, in INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES ch. 12 (Burton Ong ed., 2004) and Jim Chen, *There's No Such Thing as Biopiracy ... and It's a Good Thing Too*, 37 MCGEORGE L. REV. 1 (2006).

<sup>10</sup> Jonathan Shaw, *The Undiscovered Planet*, HARVARD MAG., Nov.-Dec. 2007, at 44.

<sup>11</sup> *Id.* at 46

... Each of these deep-branching divisions [on the diagrammatic three-domain tree-of-life] is thought to represent millions, if not hundreds of millions, of species. ... [Roberto] Kolter says, “So when you think about biodiversity, and the extent of diversity on the planet, you really get a sense of how little we know about this undiscovered world [of microbes]. We are at the stage of discovery where, everywhere we look, we see new species.”<sup>12</sup>

New discoveries in microbial science have likely made assertion one of biopiracy incorrect – the biodiversity of tropical nations is probably not necessary for biotechnology to flourish.<sup>13</sup> Genetic diversity is in abundance everywhere.

Moreover, advances in biology – among others, genomics, proteomics, synthetic and systems biology – mean now, and possibly even more so in the future, that those doing research and development in biotechnology can learn much from their presently available genetic resources. If sovereign nations make access to plant genetic resources difficult, biotechnology researchers may decide that they do not need wild germplasm or wild plants and animals to develop new plants and products for biotechnology industries.<sup>14</sup>

Moving to technological sophistication, one cannot deny that plant biotechnology requires technological sophistication and significant financial resources to produce a transgenic

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<sup>12</sup> *Id.* at 47.

<sup>13</sup> For additional support for this assertion, see the industry profiles in *ABS in Practice*, *supra* note 6, where the authors emphasize the importance in current practice of microorganisms for biotechnology over prospecting for genetic resources in plants and animals.

<sup>14</sup> *Id.* The authors discuss trends in research and development and demand for access to genetic resources. The authors highlight how the different sectors of biotechnology have different levels of reliance on wild resources. However, the authors point out that the trend, for various reasons, has been away from utilization of wild resources and more on technological advances using presently available resources. *See also* Manuel Ruiz Muller, *Keeping Pace with Technological Development*, BUSINESS.2010 (Secretariat of the Convention on Biological Diversity), Jan. 2008, at 27 (vol. 3, no. 1), *available at* <http://www.cbd.int/doc/newsletters/news-biz-2008-01-low-en.pdf>.

plant. What one can deny is that nations in the south lack the technological sophistication and the financial resources to create thriving plant biotechnology sectors. To name just four nations, Brazil, China, India, and the Philippines have well-trained scientists who are at the cutting-edge of plant biotechnology. Moreover, these four nations have committed significant financial resources, centered in public research, to develop plant biotechnology for agricultural improvement.<sup>15</sup>

Assertion two supporting biopiracy – the technological sophistication assertion – is inaccurate now and will become increasingly inaccurate within the next decade. Many nations in the developing world can be on the cutting edge of sophisticated, funded programs in plant

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<sup>15</sup> For Brazil, Larry Rohter, *Scientists Are Making Brazil's Savannah Bloom*, N.Y. TIMES, Oct. 2, 2007, available at <http://www.nytimes.com/2007/10/02/science/02tropic.html> (“Embrapa has in three decades become a world research leader in tropical agriculture and is moving aggressively into areas like biotechnology and bio-energy.”).

For China, Niu Shuping, *China to Promote More Genetically Modified Crops*, REUTERS, July 10, 2008, available at <http://www.flex-news-food.com/console/PageViewer.aspx?page=17675&str=> (“China’s cabinet has decided to give broad support for genetically modified crops, a move that follows a decade of research and which scientists say will likely speed commercial production of GMO rice or corn.”).

For India, *ICAR to Develop Transgenic Kind of 14 Crops*, FIN. EXPRESS, Mar. 10, 2004, available at <http://www.financialexpress.com/news/ICAR-To-Develop-Transgenic-Kind-Of-14-Crops/101055/> (“The Indian Council of Agricultural Research (ICAR) has decided to develop transgenic varieties of 14 select crops.”)

For Philippines, Jonathan L. Mayuga, *Biotech Products to Boost Agricultural Development*, BIOLIFE, Jan.-Feb. 2008, at 4, available at [http://www.biotechforlife.com.ph/images/biolife\\_jan\\_feb08.pdf](http://www.biotechforlife.com.ph/images/biolife_jan_feb08.pdf) (“‘Biotechnology,’ says Agriculture Undersecretary Jose Emmanuel Paras, ‘holds the key to the country’s survival ...’ In the Philippines, there are biotechnology products that are ‘proudly Filipino’ and help boost agricultural production.”)

Nor does the author consider these four nations as exceptions or anomalies. The author could provide citations to significant biotechnology programs in, among others, Argentina, Colombia, Indonesia, Kenya, Nigeria, Pakistan, South Africa, and Vietnam.

biotechnology, if those nations adopt a positive attitude towards science and plant biotechnology. What often keeps these countries from a sophisticated biotechnology sector is not technological domination by northern (i.e. developed) nations but their own fearful and precautionary attitudes towards biotechnology.

Biopiracy should be labeled for what it is: more political rhetoric than factual reality about the science and technology of plant biotechnology in the 21<sup>st</sup> century.<sup>16</sup>

*Access and Benefit Sharing (ABS)*

The Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) make clear that nations are sovereign over their genetic resources.<sup>17</sup> Hence, nations can control this resource just as they control their other resources such as timber, minerals, gas, and oil. Consequently, nations are likely to control this resource through permit systems,<sup>18</sup> regional initiatives,<sup>19</sup> nationalized corporations,<sup>20</sup> material

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<sup>16</sup> For a contrary view, see MICHAEL GOLLIN, *BIOPIRACY: THE LEGAL PERSPECTIVE*, (SEARCA Policy Brief Series No. 2007-4, Nov. 2007).

<sup>17</sup> Convention on Biological Diversity, June 5, 1992, pmbl. & art. 3, 31 I.L.M. 818 (entered into force Dec. 29, 1993); International Treaty on Plant Genetic Resources for Food and Agriculture, pmbl. & art. 10, *opened for signature* Nov. 3, 2001 (entered into force Jan. 29, 2004), *available at* <ftp://ftp.fao.org/ag/cgrfa/it/ITPGRRe.pdf>.

<sup>18</sup> For a brief description of the permit system established in Australia, specifically the Northern Territory, see Geoff Burton, *Attracting Research and Business Investment*, BUSINESS.2010 (Secretariat of the Convention on Biological Diversity), Jan. 2008, at 4 (vol. 3, no. 1), *available at* <http://www.cbd.int/doc/newsletters/news-biz-2008-01-low-en.pdf>.

<sup>19</sup> Andean Pact Decision 391: Common System on Access to Genetic Resources, July 2, 1996, *available at* <http://www.comunidadandina.org/ingles/normativa/d391e.htm>. Andean Pact Countries are Bolivia, Colombia, Ecuador, Peru, and Venezuela.

<sup>20</sup> For example, Costa Rica created a governmental organization called InBio to assess Costa Rica's genetic resources and to control access to those resources in compliance with the

transfer agreements,<sup>21</sup> and private contractual relationships between the sovereign nation (and its domestic entities), and public and private institutions and entities of other nations.<sup>22</sup> In other words, once genetic resources are identified as a resource, access and benefit sharing becomes an issue emphasizing commercial relationships for mutual economic advantage of seller and buyer.<sup>23</sup>

Just as access and benefit sharing for oil resources is independent from patents related to petroleum processes and products, so access and benefit sharing of genetic resources may

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CBD.

<sup>21</sup> Parties to the ITPGRFA have adopted a standard Material Transfer Agreement (sMTA). *See* Standard Material Transfer Agreement, <ftp://ftp.fao.org/ag/cgrfa/gb1/SMTAe.pdf> (last visited May 17, 2009). The sMTA facilitates transfer of genetic materials within the multilateral system created by the Treaty for the crops brought specifically within the coverage of the Treaty.

<sup>22</sup> For two examples, see Franck Petersen & Thomas Kuhn, *How to Link Bioprospecting with Sustainable Capacity Building*, BUSINESS.2010 (Secretariat of the Convention on Biological Diversity), Jan. 2008, at 14 (vol. 3, no. 1), *available at* <http://www.cbd.int/doc/newsletters/news-biz-2008-01-low-en.pdf> (describing the relationship between China and Novartis), and Maureen Wolfson, *Perspectives on a Horticultural Agreement*, BUSINESS.2010 (Secretariat of the Convention on Biological Diversity), Jan. 2008, at 18 (vol. 3, no. 1), *available at* <http://www.cbd.int/doc/newsletters/news-biz-2008-01-low-en.pdf> (describing the relationship between South African National Biodiversity Institute and Ball Horticultural Company).

<sup>23</sup> For seven cases studies of ABS agreements, see *ABS in Practice*, *supra* note 6, at 40-98.

*Cf. generally* Greg Venbrux, *When Two Worlds Collide: Ownership of Genetic Resources under the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 6 U. PITT. J. TECH. L. & POL'Y art. 4 (2005), [http://tlp.law.pitt.edu/articles/Vol\\_9\\_Venbrux.pdf](http://tlp.law.pitt.edu/articles/Vol_9_Venbrux.pdf).

Despite these tensions, both treaties ultimately foster economic development through recognition of the role intellectual property rights play in protecting the interests of users [*sic*, suppliers] and consumers of genetic resources. Through a studied application of new and existing forms of intellectual property rights, biotechnology may someday make all countries winners in the eyes of the global economy.

*Id.* at 35.

become irrelevant to patents issued about plant biotechnology processes and products. Countries granting patents in biotechnology are unlikely to require access and benefit sharing as a prerequisite for obtaining patents in plant biotechnology.<sup>24</sup> Moreover, countries seeking benefit sharing are unlikely to undermine patents in biological resources because doing so would mean fewer benefits to share. Mutual commercial advantage may come to the fore and access and benefit sharing as a “patent” issue could recede to the background to become a contractual issue about the sharing of the enhanced opportunity for investment and innovation recovery arising from the exclusive control granted by patents.

Recognizing that biopiracy is a rhetorical word disconnected from scientific and technological reality, and that access and benefit sharing is ultimately about commercial relationships, patents emerge as a separate and distinct sphere that provide legal and economic incentives for more biotechnological inventions and greater biotechnology knowledge. Patents do so by focusing on the patent bargain itself. Patents should not be freighted with rhetoric and commercial negotiations. Patents should be left to do what patents can do well – encourage creativity and innovation of plant biotechnology for agricultural development.<sup>25</sup>

## **II. Regulation**

As a young lawyer one quickly learns that winning a law suit is only half the battle. The other half, often much more difficult, is enforcing and collecting the judgment. Winning, one

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<sup>24</sup> *TRIPs Council Once Again Marked by Divisions over Disclosure Amendment*, BRIDGES WKLY. TRADE NEWS DIG., Mar. 19, 2008, at 7, available at <http://ictsd.net/downloads/bridgesweekly/bridgesweekly12-10.pdf> (brief summary of the wide disparity in views about ABS and patent systems).

<sup>25</sup> For a similar view of the limits of copyrights, see Norman Siebrasse, *A Property Rights Theory of the Limits of Copyright*, 51 U. TORONTO L. J. 1 (2001).

learns, isn't everything, but enforcing and collecting are.

Patent holders quickly learn too that obtaining a patent is, at best, only half the battle. Having a patent entitles the patent holder only to negative rights – i.e. to prevent others from making, selling, or using the patented invention without having first obtained permission from the patent holder. In order to gain positive rights to make, sell, or use the patented invention, the patent holder often will have to gain regulatory approval prior to commercialization. In other words in many instances, getting a patent is like buying a lottery ticket – there is no economic payoff until a governmental regulatory agency validates your numbers.

Societies act sensibly by having regulatory regimes to assess safety and other societal concerns (e.g. efficacy, environmental impacts), prior to authorizing commercialization, of a particular patented invention. Plant biotechnology patents similarly face regulatory regimes that assess the safety, environmental impacts,<sup>26</sup> and efficacy<sup>27</sup> of the transgenic plants prior to the commercial release of those plants into farmers' fields.

As anyone even remotely aware of plant biotechnology knows, contentious and

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<sup>26</sup> E.g., the European regulatory regime found in Directive 2001/18/EC and Regulation (EC) No 1829/2003. The European Union also has Regulation (EC) No 1830/2003 dealing with traceability and labeling.

<sup>27</sup> For example, Seeds Act, R.S.C., ch. S-8 (1985) (Can.) and implementing Seeds Regulations, C.R.C., ch. 1400 (1985) (Can.). Seeds Acts and their implementing regulations provide for the testing of seeds prior to commercial release to assure varietal purity, graded pedigree, freedom from intermingled noxious weeds, freedom from disease, uniformity, germination rates, agronomic merit in comparison to seeds presently available on the market, and clear name identification to distinguish from other approved seeds. Seeds Acts confer no intellectual property on plant breeders and their plant and variety creations. However, even if a seed breeder has intellectual property rights in a variety, either a patent or a plant variety certificate, the seed breeder cannot release that variety for commercial sale to farmers until a regulatory agency has subjected the variety to the legal standards specified in the Seeds Acts.

exhausting debates presently exist about the appropriate model to use to regulate plant biotechnology.<sup>28</sup> From this author's perspective, the present, on-going debate about the appropriate model is whether to use a regulatory model that is excessively slow, excessively costly, and excessively burdensome<sup>29</sup> or to use a regulatory model that is somewhat less slow, somewhat less costly, and somewhat less burdensome.<sup>30</sup> Sensible, scientifically-sound regulatory regimes for transgenic plants are not on the immediate horizon.<sup>31</sup> The impacts of these regulatory regimes on plant biotechnology has been particularly severe for public research.<sup>32</sup>

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<sup>28</sup> E.g., Donald L. Uchtman & Gerald C. Nelson, *U.S. Regulatory Oversight of Agricultural and Food-related Biotechnology*, 44 AM. BEHAV. SCIENTIST 350 (2000); Maragaret Rosso Grossman & A. Bryan Endres, *Regulation of Genetically Modified Organisms in the European Union*, 44 AM. BEHAV. SCIENTIST 378 (2000). See generally *Special Issue on Sustainable Regulation of Biotechnology*, 8 ASIA PAC. J. ENVTL. L. 1 (2004).

<sup>29</sup> The European system described in Grossman & Endres, *supra* note 25.

<sup>30</sup> The U.S.A. system described in Uchtman & Nelson, *supra* note 25.

<sup>31</sup> For three alternative models for appropriate regulation, see Monica Garcia-Alonso et al., *A Tiered System for Assessing the Risk of Genetically Modified Plants to Non-target Organisms*, 5 ENVTL. BIOSAFETY RES. 57 (2006); Kent Bradford et al., *Regulating Transgenic Crops Sensibly: Lessons from Plant Breeding, Biotechnology and Genomics*, 23 NATURE BIOTECH. 439 (2005); John Barton et al., *A Model Protocol to Assess the Risk of Agricultural Introductions*, 15 NATURE BIOTECH. 845 (1997). For two recent criticisms of the present regulatory systems, see Shane H. Morris, *EU Biotech Crop Regulations and Environmental Risk: A Case of the Emperor's New Clothes?*, 25 TRENDS IN BIOTECH. 2 (2007); Henry I. Miller & Gregory Conko, *AgBiotech Evolution Needs a Regulatory Revolution*, ISB NEWS REP. (Info. Sys. for Biotech.), Dec. 2006, at 3, available at <http://www.isb.vt.edu/news/2006/Dec06.pdf>.

<sup>32</sup> Dr. Ingo Potrykus, co-creator of a transgenic rice called "Golden Rice," has been particularly outspoken about over-regulation of transgenic crops and its impact on public research. See e.g., Ingo Potrykus, *Is GMO Over-regulation Costing Lives?* (Apr. 2005) (PowerPoint presentation for bioVISION 2005 at Lyon, France), available at [http://www.goldenrice.org/PDFs/Potrykus\\_BioVision\\_Lyon\\_April\\_2005.pdf](http://www.goldenrice.org/PDFs/Potrykus_BioVision_Lyon_April_2005.pdf).

For an excellent, detailed review of an agricultural biotechnological regulatory system as applied to a specific transgenic crop, see BHAGIRATH CHOUDHARY & KADAMBINI GAUR, *THE DEVELOPMENT AND REGULATION OF BT BRINJAL IN INDIA* (ISAAA Brief No. 38, 2009). See

In contrast to plants created through other breeding techniques (e.g. mutagenic techniques), plants created through biotechnology face special regulatory regimes at national<sup>33</sup> and international levels.<sup>34</sup> Indeed, the special regimes for transgenic plants have deterred and distorted plant breeding as plant breeders look for ways to create new plants without incurring the delaying, costly, burdensome oversight of special regimes for transgenic plants.<sup>35</sup>

Obviously, the contrasting regulatory regimes that apply to plant biotechnology can significantly affect the adoption rate of science, in the form of plant biotechnology, for agriculture. However, the regulatory regimes just described for plant biotechnology are separate and distinct, as they should be, from the patent system. The regulatory regimes address safety and other societal concerns as their separate and distinct sphere without interfering with the separate and distinct sphere of patents.

By contrast, some commentators on patents and biotechnology, including plant biotechnology, argue that the patent system itself should take into account a wide spectrum of

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especially *id.* at Part IV (“*Bt* Brinjal: The Regulatory Framework in India”). In February 2010, the Environmental Minister of India blocked the commercial release of *Bt* brinjal (eggplant), despite approval by the Genetic Engineering Approval Committee (GEAC) that had considered *Bt* brinjal for almost a decade before issuing the approval.

<sup>33</sup> For example, the European Union has agricultural biotechnology specific legislation for regulatory approval, food labels, and traceability. For a description of the EU regulatory system, see Grossman & Endres, *supra* note 28. However, many other nations also have regulatory laws that focus specifically on agricultural biotechnology.

<sup>34</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027.

<sup>35</sup> For example, some scientists are using chimeraplasty and cisgenics to breed new plants because they assert that these breeding techniques are outside the special regimes designed for transgenic plants. For a discussion of this attitude and its consequences, see GRESSEL, *supra* note 3, at 382-85.

public policy concerns – e.g. morality, ethics, human rights, environmental risks, animal welfare, social structures, and economic impacts. These commentators reject the idea that the patent system is a utilitarian bargain between society and the patent holder. For these commentators, the patent system should involve an evaluation and a judgment about the desirability and worth of an invention before society would grant the invention legal protection under a patent.<sup>36</sup> To distinguish this non-utilitarian view of patents from the utilitarian patent bargain, I name this non-utilitarian view a “technology assessment.”

While the United States patent statutes and regulations do not have an explicit reference to public order or morality as a criteria for considering patent applications,<sup>37</sup> TRIPS Article 27(2)

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<sup>36</sup> E.g., Donna Dickenson, *Ethics Watch: Patently Paradoxical? “Public Order” and Genetic Patents*, 5 NATURE REVS.: GENETICS 86 (2004); Hope Shand, *Corporations Grab Climate Genes*, FOREIGN POL’Y IN FOCUS, May 13, 2008, <http://www.fpif.org/fpiftxt/5223> (“Governments must respond urgently by . . . [s]uspending all patents on climate-related genes and traits and conducting a full investigation of the potential environmental and social impact of transgenic abiotic stress-tolerant seeds . . . .”) For a general discussion arguing for the patent system as a technology assessment system, see Gionathan Curci Staffler, *Towards a Reconciliation Between the Convention on Biological Diversity and TRIPS Agreement 19-23* (n.d.) (unpublished Ph.D. thesis, University of Geneva), *available at* <http://www.botanischergarten.ch/Patents/Staffler-CBD-TRIPS.doc>.

<sup>37</sup> In the Policy on Patenting Animals, the U.S. Patent & Trademark Office stated, “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.” Policy on Patenting Animals, 1077 Off. Gaz. Pat. & Trademark Office 24 (1987).

The European Patent Convention and the European Union Directive on Biotechnology contain exclusions from patentability related to the human body and human beings. See Convention on the Grant of European Patents (European Patent Convention) R. 28, 29, Nov. 29, 2000 (entered into force Dec. 13, 2007), *available at* <http://www.epo.org/patents/law/legal-texts/epc.html>; Council Directive 98/44, arts. 5, 6, 1998 O.J. (L 213) 13 (EC).

This article focuses on plant biotechnology. The analyses and arguments should be understood in the context of plant biotechnology. This article is not addressing issues related to the human body and its genes, human cloning, or human stem cells. I agree that moral, ethical,

does:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.<sup>38</sup>

By citing *ordre public* or morality, supporters of a patent system evaluating and judging an invention's desirability and worth argue that the statutory language should be interpreted to mandate that the patent system become a technology assessment.

In the plant biotechnology field, patent offices, administrative tribunals, and courts have been uniformly unfavorable towards the view that the patent system is a technology assessment.<sup>39</sup> In European venues, where these issues have been most fiercely contested, the flavour of this rejection is best captured by quoting from these three sources.

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and human rights concerns are more clearly and more substantively relevant to "human" patents than to plant patents.

Two excellent presentations about public order and morality with regard to stem cell patents were made to the Haifa Conference, where this article also began as a presentation. See Ingwer Koch, The European View on the Patenting of Inventions Involving Human Embryonic Stem Cells (June 17, 2008) (slide presentation at the Haifa Conference), *available at* [http://law.haifa.ac.il/events/event\\_sites/biosciences/](http://law.haifa.ac.il/events/event_sites/biosciences/) (follow "Presentations" hyperlink; then follow "Mr. Ingwer Koch" hyperlink); Geertrui Van Overwalle, Stem Cell Patents and Ethics from an International Perspective (June 17, 2008) (slide presentation at the Haifa Conference), *available at* [http://law.haifa.ac.il/events/event\\_sites/biosciences/](http://law.haifa.ac.il/events/event_sites/biosciences/) (follow "Presentations" hyperlink; then follow "Prof. Dr. Geertrui Van Overwalle" hyperlink).

<sup>38</sup> The European Patent Convention (2000) has an equivalent exception to patentability that reads: "European patents shall not be granted in respect of (a) inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States." European Patent Convention art. 53(a).

<sup>39</sup> For a thorough discussion of the relevant legal developments in the European context, see Farhana Yamin, *Intellectual Property Rights, Biotechnology and Food Security* 17-36 (Inst. Dev. Studies Working Paper No. 203, 2003).

European Patent Office (EPO) Guidelines in vigor in the year 2000 stated,

A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of a patent right would be inconceivable. ... Patent law is not an appropriate instrument for regulating the development of new technologies and that the legislature should determine whether a certain technology is so dangerous and unacceptable to the public that it should be suppressed.<sup>40</sup>

The EPO Enlarged Board of Appeal, in the *Novartis AG/Novartis II* decision upholding a patent for transgenic plants, wrote,

¶ 3.9 The objections to patentability submitted by Greenpeace under Article 53(a) EPC fall outside the scope of the referred questions. The Board recognises that these objections raise questions which are of interest to many members of the public. It is, therefore, appropriate to note that Article 52(1) EPC expresses the general principle of patentability for inventions which are industrially applicable, new and inventive. The EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas and of restricting the field of patentable subject-matter accordingly. ... [T]here is no consensus in the Contracting States condemning genetic engineering in the development of plants under the above criteria [ordre public or morality]. On the contrary, the Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions ... establishes that promotion of innovation in this field is considered necessary in Europe.<sup>41</sup>

In a lawsuit by the Kingdom of the Netherlands against the European and Council Directive 98/44 (on the legal protection of biotechnological inventions), the European Court of Justice denied all challenges while writing paragraphs that endorsed the EPO *Novartis AG/Novartis II* ruling of 1999 that the patent system has a utilitarian focus.<sup>42</sup> In addition, the

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<sup>40</sup> *Id.* at 29.

<sup>41</sup> Transgenic plant/NOVARTIS II, Case Number G 0001/98 (European Patent Office, Enlarged Bd. of Appeal, Dec. 20, 1999), *available at* <http://legal.european-patent-office.org/dg3/pdf/g980001ex1.pdf>.

<sup>42</sup> Case 377/98, *Netherlands v. Parliament*, 2001 E.C.R. I-7079, paras. 35-40.

European Court of Justice further opined,

¶ 79. Reliance on this fundamental right [of human integrity and free and informed consent] is, however, clearly misplaced as against a directive which concerns only the grant of patents and whose scope does not, therefore, extend to activities before and after the grant, whether they involve research or the use of the patented products.

¶ 80. The grant of patent does not preclude legal limitations or prohibitions applying to research into patentable products or the exploitation of patented products ... The purpose of the directive is not to replace the restrictive provisions which guarantee, outside the scope of the directive, compliance with certain ethical rules which include the right of self-determination by informed consent.<sup>43</sup>

These European legal authorities, about the meaning of the words “*ordre public* or morality” in patent statutes, emphasize that the patent system is neutral towards the broader societal concerns that may affect plant biotechnology. Those broader societal concerns are in the separate and distinct sphere of competent administrative agencies with their regulatory powers.

These European legal authorities also stress that the broader social concerns are for the political realm where legislatures can decide, if so inclined, to restrict or prohibit the utilization of particular technologies, such as plant biotechnology. Of course, if a society enacts laws or regulations prohibiting the use of a particular technology, the impact of that enactment is that the society gets fewer biotechnology inventions and lesser biotechnology knowledge. Scientists are unlikely to do research and inventors are unlikely to seek patents in a society where the utilization of the research or creation is against the law. Society has made its choice and will live with the consequences.

However, even if a sovereign nation proscribes the utilization of a particular technology, the TRIPs patent system can remain neutral because applicants meeting the statutory

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<sup>43</sup> *Id.* paras. 79-80.

requirements (new, inventive, industrially applicable) are entitled to a patent even though “the exploitation is prohibited by law or regulation.”

The argument being presented is not that societies cannot build a technology assessment into their patent systems – a technology assessment that gives a wide scope to concepts of public order and morality. The argument is that societies should not do so. The argument is that societies should interpret the discretion that TRIPs 27(2) allows to protect public order and morality to decide for neutrality in patent systems or, at most, to allow a narrow scope to concepts of public order and morality.<sup>44</sup> The argument is that the broader the scope a society gives to a technology assessment within the patent system, the fewer technological inventions and the lesser scientific knowledge the society will gain. Societies with a neutral or narrow scope to public order and morality will have more technological inventions and greater scientific knowledge. Societies make the choice, but the utilitarian patent bargain applies regardless.

What justification exists for the patent system maintaining its neutrality in the face of a prohibition by law or regulation? There are good and wise justifications for the neutrality of the utilitarian patent bargain. Is the utilitarian patent bargain immoral and unresponsive to societal concerns? The patent system is moral and responsive to societal concerns.

The good and wise justifications for patent system neutrality arise from the fact that the politics of a society changes and can change rapidly with the rise and fall of governments.

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<sup>44</sup> As for the narrow scope for public order and morality, the presentations by Koch and Van Overwalle, *see supra* note 34, both focus on stem cell research and its interrelatedness to human beings and human dignity. Professor Van Overwalle clearly is more inclined to support a wider scope for public order and morality (e.g., public interest, social goals, ethics) within the patent system. *See also* Geertrui Van Overwalle, *Biotechnology and Patents: Global Standards, European Approaches and National Interests*, in *GENETIC ENGINEERING AND THE WORLD TRADE SYSTEM*, *supra* note 7, at ch. 4.

Applicants for patents should be allowed a patent with the anticipation that the political climate may change and, in response, administrative agencies will reevaluate their understanding of *ordre public* or morality. Even if the politics of a particular society do not change, the applicant should be allowed a patent because the politics of other societies are different and may be more accepting of the patented invention. Therefore, patent applicants should be allowed to enter the patent lottery – to be ready whenever and wherever the opportunity emerges to work the patent.<sup>45</sup>

The utilitarian patent bargain, with its neutrality towards a particular technology, is moral and responsive to societal needs at a deeper level than passing, passionate political debates. Even if the invention never gains acceptance for commercial use, society worldwide has gained the knowledge described within the patent application. Even in the storm of an antagonistic political climate, the utilitarian patent bargain benefits society by affirming that society needs more inventiveness and more innovation lest the society stagnate and loses its capacity to respond to the unforeseen and unforeseeable challenges of the future.<sup>46</sup> The utilitarian patent bargain makes no claim to evaluate and judge the desirability and worth of particular inventions precisely because the future needs of society are unknown.

By focusing on the utilitarian patent bargain, rather than technology assessment, the patent system favors scientific queries (the expansion of knowledge) and scientific quests (the expansion of technology). The utilitarian patent bargain responds with neutrality toward societal

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<sup>45</sup> The opinion by European Union Advocate General F.G. Jacobs in the *Netherlands v. Parliament* case argues the same good and wise justifications for granting patents in the face of prohibitory laws or regulations. Case 377/98, *Netherlands v. Parliament*, 2001 E.C.R. I-7079, paras. 103-107.

<sup>46</sup> Evolution does demand that we all be Red Queens who must keep running faster just to keep up. Stagnation is not a very effective or sensible survival option.

qualms about inventions and technology so that it may affirm a presumption in favor of liberty – the freedom of scientific inquiry and the freedom of human creativity. By affirming the presumption in favor of inventive and innovative liberty, the patent system provides resiliency to society to adapt and to thrive in the face of whatever the future brings.

Regulation and patents are and should be distinct and different spheres. Regulation is to manage our fears and our doubts. Patents are to encourage our hopes and our dreams. Certainly in agriculture where “We need science to come back to farming,”<sup>47</sup> patents should encourage our hopes and our dreams for plant biotechnology.

### **III. Liability**

In the litigious United States, it is certainly a truism that if a product causes an identifiable and real harm, the legal system will provide a damage remedy. As an American lawyer, I hold the opinion that products that cause identifiable and real harms should bear the cost to remedy those harms and to repay damages incurred. In addition to the common law causes of action based in tort, including torts for toxic substances, the United States also has well-developed bodies of law on product liability and environmental restoration. Hence, the United States has a legal system that has the capacity and the willingness to remedy harms caused by plant biotechnology.

After fifteen years (1994-2009) of commercial production of transgenic crops in many nations, plant biotechnology has not caused any identified, real harm to human health, animal

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<sup>47</sup> Thomas Lumpkin, quoted in Blas, *supra* note 1.

health, food safety, ecosystems, or biological diversity.<sup>48</sup> Moreover, despite being grown on hundreds of millions of hectares and consumed by humans and animals in billions of human meals and animal feedings, there has not been a single identified, real harm from plant biotechnology anywhere in the world. In fact, as the decade-plus evidence has accumulated, the agronomic and scientific reports verify the benefits to human health, animal health, food safety, the environment, and biological diversity.<sup>49</sup> Without any identified, real harm to human health,

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<sup>48</sup> After the recall of a transgenic corn, called StarLink™, some persons claimed that they suffered allergic reactions to this unapproved-for-food corn. The U.S. Centers for Disease Control and Prevention (CDC) studied these claims and concluded,

An FDA laboratory developed an enzyme-linked immunosorbent assay (ELISA) method to detect antibodies to the Cry9c protein. ... The ELISA method found that none of the CDC-submitted samples reacted in a manner consistent with an allergic response to the Cry9c protein. These findings do not provide any evidence that the reactions that the affected people experienced were associated with hypersensitivity to the Cry9c protein.

CTRS. FOR DISEASE CONTROL, INVESTIGATION OF HUMAN HEALTH EFFECTS ASSOCIATED WITH POTENTIAL EXPOSURE TO GENETICALLY MODIFIED CORN 3 (2001), *available at* <http://www.cdc.gov/ncet/ehhe/cry9creport/pdfs/cry9creport.pdf>.

Regarding biological diversity, there has also been considerable controversy about Mexican corn landraces and whether imported transgenic corn has interbred with the landraces. The controversy has had two distinct threads. One thread is whether interbreeding has occurred. Assuming that interbreeding has occurred, the second thread is whether this interbreeding would constitute an undesirable or a desirable development for the landraces. While the literature on this controversy is extensive, one can gain a good understanding of the issues by reading *Transgenic DNA in Mexican Corn Landraces*, <http://www.cls.casa.colostate.edu/TransgenicCrops/hotmaize.html> (last visited May 17, 2009); Peter H. Raven, *Transgenes in Mexican Maize: Desirability or Inevitability?*, 102 PNAS 13,003-04 (2005), *available at* <http://www.agbioworld.org/pdf/raven081505.pdf>; and EKIN BIROL, ERIC RAYN VILLALBA & MELINDA SMALE, *FARMER PREFERENCES FOR MILPA DIVERSITY AND GENETICALLY MODIFIED MAIZE IN MEXICO* (Int'l Food Pol'y Res. Inst. Discussion Paper No. 00726, 2007).

<sup>49</sup> *E.g.*, OLIVIER SANVIDO ET AL., *ECOLOGICAL IMPACTS OF GENETICALLY MODIFIED CROPS: EXPERIENCES FROM TEN YEARS OF EXPERIMENTAL FIELD RESEARCH AND COMMERCIAL CULTIVATION* (ART-Schriftenreihe 1, 2006) (prepared on behalf of the Swiss Export Comm. for Biosafety), *available at* [http://www.art.admin.ch/dms\\_files/03017\\_de.pdf](http://www.art.admin.ch/dms_files/03017_de.pdf); JORGE FERNANDEZ-CORNEJO & MARGRIET CASWELL, U.S. DEP'T OF AGRIC., *THE FIRST DECADE OF GENETICALLY*

animal health, food safety, ecosystems, or biological diversity, there are no examples of plant biotechnology incurring legal liability for torts, product liability, or environmental remediation.<sup>50</sup>

Lawsuits have been filed for claims relating to property damage and economic losses stemming from transgenic traits failing to have approval for use in food or in export markets.

Probably the most famous of these cases, and the only successful case to date, is the *In re*

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ENGINEERED CROPS IN THE UNITED STATES (Econ. Info. Bulletin No. 11, 2006), *available at* <http://www.ers.usda.gov/publications/eib11/eib11.pdf>; Graham Brookes & Peter Barfoot, *Global Impact of Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use*, 9 *AGBIOFORUM* 139 (2006), *available at* <http://www.agbioforum.missouri.edu/v9n3/v9n3a02-brookes.pdf>; Steven Naranjo, Graham Head, & Galen Dively, *Field Studies Assessing Arthropod Nontarget Effects in Bt Transgenic Crops: Introduction*, 34 *ENVTL. ENTOMOLOGY* 1178 (2005).

<sup>50</sup> There is a distinction between legal liability for harms and administrative liability. Biotechnology companies have been held liable in a number of cases for violations of administrative regulations regarding permit compliance. These administrative cases imposed liability for failure to comply with regulatory requirements relating to permits for field trials or commercial release, not for an identified, real harm to human health, animal health, food safety, ecosystems, or biological diversity.

There are also several cases in Germany where beekeepers sued German State Research Centers for Agriculture in opposition to transgenic maize research. In both decided cases, the beekeepers lost their lawsuits. In one case, the Bavarian Higher Administrative Court ruled that the EU legislation does not prohibit trace amounts of transgenic material in honey. *Court Ruling on GM Maize Trial in Germany*, *GMO COMPASS*, June 28, 2007, <http://www.gmo-compass.org/eng/news/messages/200706.docu.html>. In the second case, the court in Kitzingen ruled that the beekeeper had not proved any damage from trace amounts of pollen and that there was no proof that honey was unsafe for human consumption. *German Beekeeper Loses Complaint Against GM Field Trials*, *GMOBELUS*, Feb. 19, 2009, <http://www.gmobelus.com/news.php?viewStory=352>. Yet, a third undecided law suit against the Bavarian State Research Center for Agriculture mirrors the two decided lawsuits. Whether the third time's a charm for beekeepers before the German courts cannot be known until the court issues its judgment. Uwe Buse, *Monsanto's Uphill Battle in Germany*, *SPIEGEL ONLINE*, Mar. 5, 2009, <http://www.spiegel.de/international/germany/0,1518,611582,00.html>. Note that all three of these German cases are against state research institutions, not Monsanto; but, obviously, a decision imposing liability upon the state research institutions would have significant negative impact upon the growing of transgenic crops in Germany.

*StarLink Corn Products Liability Litigation*,<sup>51</sup> where the Cry9c protein had not gained U.S. regulatory approval for its presence in foods. When the unapproved Cry9c protein was found in food, the food was legally adulterated food that had to be recalled. Aventis CropSciences USA, the developer of the transgenic maize StarLink™, ultimately settled the case for US\$ 110 million.<sup>52</sup>

By contrast to the *StarLink* litigation, one American court<sup>53</sup> and one Canadian court<sup>54</sup> rejected claims filed by farmers and others seeking to impose legal liability upon biotechnology companies for the commercial release of crops containing approved transgenic traits. In these two cases, the farmer did not allege physical injury or property damage to their crop, their land, or human/animal health, rather they alleged solely monetary losses related to commodity market declines or market rejection in some export markets (primarily the European Union). These farmers claimed damages simply from the release of the approved transgenic crop and alleged disruptions caused to their market hopes and expectations. In other words, the farmers in the *Hoffman* case and the *Sample* case sought damages for what is called “pure economic loss.”<sup>55</sup>

Finally, farmers and others have filed lawsuits related to transgenic rice, from field trials,

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<sup>51</sup> 212 F. Supp. 2d 828 (N.D. Ill. 2002).

<sup>52</sup> For a thorough discussion of this case, see D.L. Uchtman, *StarLink™ – a Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159 (2002).

<sup>53</sup> *Sample v. Monsanto*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003).

<sup>54</sup> *Hoffman v. Monsanto Canada*, [2005] S.K.Q.B. 225, *aff'd on appeal*, [2007] S.K.C.A. 47, *leave for appeal dismissed*, Sup. Ct. of Can. (Dec. 2007).

<sup>55</sup> “Economic-loss rule. *Torts*. The principle that a plaintiff cannot sue in tort to recover for purely monetary loss – as opposed to physical injury or property damage – caused by the defendant.” BLACK’S LAW DICTIONARY 552 (8th ed. 2004).

that was found in commercial seed stocks, allegedly causing property damage, market losses, export rejections, and other economic or related damages.<sup>56</sup> As of January 2009, these case are in the early stages of litigation, meaning that the courts have issued no substantive rulings about the legal validity of any of the claims presented.<sup>57</sup> Whether this transgenic rice litigation will result in judgment of legal liability or settlement (as occurred in the *StarLink*<sup>TM</sup> litigation) or the denial of legal liability (as occurred in the *Sample* and *Hoffman* litigations) is yet to be determined.<sup>58</sup>

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<sup>56</sup> *In re Genetically Modified Rice Litigation*, 06-MD-1181 (E.D. Mo. filed May 17, 2007); see GM Rice Litigation, <http://www.bayerricelitigation.com> (last visited May 18, 2009). This lawsuit is by farmers against the Bayer CropScience.

In a second lawsuit arising from the same transgenic rice incident, farmers are suing Riceland Foods, the farmer cooperative, involved in the commercial sales of the rice seed containing the transgenic trait. Chuck Bartels, *Lawsuit Targets Riceland in Modified Rice Claim*, ASSOCIATED PRESS, July 3, 2008, available at <http://news.ino.com/headlines/?newsid=6891768698280..>

<sup>57</sup> Rickmers Reismuehle GMBH has sued Riceland Foods and Producers Rice Mill for selling rice to Rickmers that did not meet its contract specifications calling for rice that was in conformity with EU approvals for imported agricultural products. *German Company Sues U.S. Rice Millers over Modified Rice*, ASSOCIATED PRESS, Aug. 24, 2007, available at [http://www.agbios.com/static/news/NEWSID\\_8746.php](http://www.agbios.com/static/news/NEWSID_8746.php). The Rickmers lawsuit is a contractual claim based in warranty clauses and product specification clauses in the contract. Consequently, the Rickmers claim is not be barred by the tort doctrine of pure economic loss that courts may apply to the lawsuits brought by the farmers against Bayer CropScience and Riceland Foods. The pure economic loss doctrine is a doctrine in torts, not in contracts.

<sup>58</sup> There is a substantial body of legal literature discussing legal liability issues related to agricultural biotechnology. Access this literature by consulting the Agricultural Law Bibliography, <http://www.nationalaglawcenter.org/bibliography> (follow “Browse Categories” hyperlink; then follow “8-Biotechnology” and “42-Torts, Insurance” hyperlinks) (last visited May 18, 2009).

The New Zealand Royal Commission on Genetic Modification also studied the issue of legal liability and concluded,

The Commission considers it is unnecessary to recommend legislation providing special remedies for third parties, where they may have been affected by the release of a genetically modified organism. As technology advanced with ever-increasing pace throughout the 20th century, the common law (that is, law based on court decisions, as distinct from statute law) showed it was well able to

In contrast to the several cases seeking to impose civil legal liability – the cases discussed in the preceding paragraphs about cases in Canada, Germany, and the United States --, there have been a goodly number of law suits brought by biotechnology companies against farmers for patent infringement. These lawsuits have two fact patterns in Canada and the United States. In the most common fact pattern, the companies alleged that farmers had saved and replanted patented seed in violation of the license (a technology use agreement) to grow a crop with the patented seed for food and feed purposes only.<sup>59</sup> In the second fact pattern, the companies alleged that the farmer acquired patented seed without obtaining a license and grew a crop in violation of their patent rights.<sup>60</sup> In all but several of these cases, the farmers admitted to having saved seed and contested the lawsuit, not on the facts, but on whether or not their replanting of the patented seeds constituted infringement under the patent laws. The companies have won

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mould new remedies for novel situations. Parliamentary intervention has rarely been needed in this area. From a legal liability perspective we have not been persuaded there is anything so radically different in genetic modification as to require new or special remedies.

REPORT OF THE ROYAL COMMISSION ON GENETIC MODIFICATION 328, ¶ 80 (2002) (from chapter 12, “Liability Issues”), *available at* <http://www.mfe.govt.nz/publications/organisms/royal-commission-gm/chapter-12.pdf>.

<sup>59</sup> *E.g.*, *Monsanto Co. v. Scruggs*, 459 F.3d 1328 (Fed. Cir. 2006), *cert. denied*, 127 S. Ct. 2062 (2007); *Monsanto Co. v. McFarling*, 488 F.3d 973 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 871 (2008); *Monsanto Co. v. McFarling*, 363 F.3d 1336 (Fed. Cir. 2004), *cert. denied*, 545 U.S. 1139 (2005); *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002), *cert. denied*, 537 U.S. 1232 (2003). The *Scruggs* case (and its related litigation) and the *McFarling* cases are probably the most prominent cases of fact pattern one.

<sup>60</sup> By far the most prominent case of this second fact pattern is from Canada: *Schmeiser v. Monsanto Canada, Inc.*, [2004] 1 S.C.R. 902, *affirming in part and reversing in part*, [2003] 2 F.C. 165, *affirming* 2001 F.C.T. 256.

every case thus far on the infringement issues.<sup>61</sup>

What has been described thus far in this **Part III Liability** is nothing beyond the ordinary, traditional parameters of liability for developers and users of new technologies – environmental damage claims, civil liability claims, and intellectual property (infringement) claims. However, there is an attempt to create a new connection between patents (or more specifically, patent holders) and liability that is uniquely worthy of discussion in this article about the three separate and distinct spheres. This is an attempt to make intellectual property rights themselves an autonomous source of liability for those holding intellectual property rights.<sup>62</sup>

The Cartagena Protocol on Biosafety contains an Article 27 on Liability and Redress that seeks “the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of” genetically modified organisms.<sup>63</sup> In 2004, the governing body of the Protocol (Meeting of the Parties) established a

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<sup>61</sup> For discussion of the results, see Drew L. Kershen, *Monsanto vs. U.S. Farmers: Commentary on the Center for Food Safety Report*, ISB NEWS REP. (Info. Sys. for Biotech.), Apr. 2005, at 6, available at <http://www.isb.vt.edu/news/2005/Apr05.pdf>; Norman Siebrasse, *Comment on Monsanto Canada Inc. v. Schmeiser*, 83 CANADIAN B. REV. 967 (2005). For broader commentary, compare Drew L. Kershen, *Of Straying Crops and Patent Rights*, 43 WASHBURN L. J. 575 (2004); Norman Siebrasse, *Patent Use, Intent and Remedy in Light of Monsanto v. Schmeiser*, 22 CANADIAN INTELL. PROP. REV. 453 (2005).

<sup>62</sup> For contrasting views about the desirability of creating a connection between having an intellectual property right and liability arising from having the intellectual property right itself, compare Elizabeth F. Judge, *Intellectual Property Law as an Internal Limit on Intellectual Property Rights and Autonomous Source of Liability for Intellectual Property Owners*, 27 BULL. SCI., TECH. & SOC’Y 301 (2007) (favoring liability for holders of intellectual property rights *qua* intellectual property right holder; focused on patents) with Norman Siebrasse, *A Property Rights Theory of Limits of Copyright*, 51 U. TORONTO L. J. 1 (2001) (opposed to creating liability for copyright holders *qua* copyright holders; focused on copyrights).

<sup>63</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 27, Jan. 29, 2000, 39 I.L.M. 1027.

Working Group on Liability and Redress (WGLR) to undertake the development and negotiation of the Article 27 liability and redress regime. As of March 2009, the WGLR was still in the process of developing and negotiating the regime.<sup>64</sup>

As the WGLR undertook to survey the various options for liability and redress related to transgenic crops,<sup>65</sup> proposals were brought forth that would have created liability for holders of intellectual property rights in transgenic organisms arising solely from being the holder of the intellectual property right.<sup>66</sup> To make this point clearly, it is best to read together several of the key proposals that would have established this new form of liability for intellectual property holders.

Damage:

A. Optional components of the definition of damage.

Operational Text 2

The instrument shall apply to:

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<sup>64</sup> For a report about the most recent (Mexico City, February 2009) session of the WGLR, see *Summary of the First Meeting of the Group of Friends of the Co-Chairs on Liability and Redress in the Context of the Cartagena Protocol on Biosafety: 23-27 February 2009*, EARTH NEGOTIATIONS BULL., Mar. 2, 2009, at 1 (vol. 9, no. 457) [hereinafter *Summary*], available at <http://www.iisd.ca/download/pdf/enb09457e.pdf>.

<sup>65</sup> Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, Curitiba, Braz., Mar. 13-17, 2006, *Report of the Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Cartagena Protocol on Biosafety on the Work of Its Second Meeting*, U.N. Doc. UNEP/CBD/BS/COP-MOP/3/10 (Feb. 24, 2006) [hereinafter *Curitiba Report*], available at <http://www.cbd.int/doc/meetings/bs/mop-03/official/mop-03-10-en.pdf>.

<sup>66</sup> As of March 2009, the proposals quoted in the body of the article have moved to the background or margins of the Article 27 Liability and Redress discussions. See *Summary*, *supra* note 61, to see that the present discussions are focused on an administrative liability approach that models after the European Directive on Environmental Liability. Hence, the presentation of these quoted proposals does not imply that these proposals are likely to be adopted. Rather, the presentation of these proposals illustrates the attempt by some groups to create an autonomous source of liability for those holding intellectual property rights.

(c) socio-economic damage, which shall include but not be limited to:

- (i) loss of income
- (ii) loss of cultural, social, traditional and spiritual values
- (iii) loss of food security
- (iv) loss of economic markets;<sup>67</sup> loss of competitiveness.<sup>68</sup>

### III. Causation

Issues for further consideration

Operational text 9

4. There shall be a presumption that:

- (a) the living modified organism which was the subject of the transboundary movement caused the damage where there is a reasonable possibility that it could have done so; and
- (b) that any damage caused by a living modified organism which was the subject of a transboundary movement was the result of its biotechnology-induced characteristics.

5. To rebut the presumption, a person must prove to the standard required by the procedural law applied that the damage was not due to the characteristics of the living modified organism resulting from the genetic modification, or in combination with other hazardous characteristics of the living modified organism.<sup>69</sup>

### IV. Channelling of Liability, Role of Parties of Import and Export, Standard of Liability

B. Issues relating to civil liability

2. Standard of liability and channelling of liability

(b) Strict Liability

Option 1. Liability to be channelled to one or more of the following persons, including persons acting on his or her behalf, on

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<sup>67</sup> Curitiba Report, *supra* note 62, at 22.

<sup>68</sup> *Id.* at 21.

<sup>69</sup> *Id.* at 34.

the basis of prior identification:

- (a) The developer
- (b) The producer
- (c) The notifier
- (d) The exporter
- (e) The importer
- (f) The carrier
- (g) The supplier.<sup>70</sup>

Putting these proposals together using one example combination, these proposals mean that a developer (i.e. the holder of the patent) would be strictly liable, with a presumption of causation for reasonably possible events, for loss of economic markets and loss of competitiveness. Consequently, a holder of a patent on a transgenic crop would be liable to farmers who claim that they have lost a market because of the approved commercial release or approved field trial of a transgenic crop<sup>71</sup> simply based on the fact of being the holder of the patent. Furthermore, a holder of a patent on a transgenic crop, *qua* holder, would be liable to farmers growing conventional crops who lost their competitiveness to farmers of transgenic crops with superior traits and cheaper costs of production. Obviously, companies develop transgenic crops and farmers grow transgenic crops because the transgenic crop offers improved agronomic, economic, and environmental benefits.

Those who favor creating an autonomous liability based on being the holder of an intellectual property right offer several justifications for this new form of patent holder liability. First, they assert that patent holders of transgenic crops have been given too many rights vis-a-vis

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<sup>70</sup> *Id.* at 41.

<sup>71</sup> Think back to the *Hoffman, Sample*, and LLRice 601 lawsuits discussed earlier in Part III (“Liability”).

farmers and society and that this autonomous liability properly balances, in a fair and moral way, responsibilities with these patent rights.<sup>72</sup> Second, they assert that this autonomous liability is needed to assure full cost internalization of damages (broadly defined) based on the proponents asserted understanding of the polluter pays principle.<sup>73</sup> Third, they assert that this autonomous liability is needed to assure that someone is available to insure that someone with resources is available to provide compensation for damages (broadly defined).<sup>74</sup> Finally, the tone and tenor of these proposals clearly imply that this autonomous liability is a facet of the precautionary principle. In other words, autonomous liability would mean that developers of transgenic crops should not develop those crops unless they are willing to accept autonomous liability for any and all damages (broadly defined).

While each of the asserted justifications for autonomous liability based on being the holder of patent on a transgenic crop could be debated and critiqued, this article is not the place for that debate and critique. Rather, this article focuses simply on the impact that this autonomous liability for patent holders has upon the patent system itself. By connecting liability to patent holders qua patent holders, the incentive for invention and innovation almost completely disappears. If you invent a product and introduce it to society, you are liable for basically anything and everything that flows from your invention and innovation. The message

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<sup>72</sup> Jeremy de Beer, *The Rights and Responsibilities of Biotech Patent Owners*, 40 U.B.C. L. REV. 343 (2007); Jeremy de Beer, *Biotrespass*, 27 BULL. SCI., TECH. & SOC'Y 287 (2007).

<sup>73</sup> Curitiba Report, *supra* note 62, at 44 (Greenpeace International comment); *id.* at 45 (South African Civil Society comment).

<sup>74</sup> *Id.* at 44 (Greenpeace International comment); *id.* at 45 (South African Civil Society comment).

of this proposal to establish autonomous liability within the patent law system is clear to would-be inventors and innovators: Best to be dumb and stagnant rather than creative and progressive; Do the latter and you will be impoverished through civil liability lawsuits.

Moreover, the autonomous liability proposed in the Cartagena Article 27 discussions is even more antagonistic to scientific research and technological development than may at first reading be apparent. There are two additional impacts worth explicit recognition.

Additional antagonism one. Patents are a limited-time monopoly. Patents on transgenic crops come to an end (usually after twenty years). After the end of the limited-time monopoly, anyone can become a generic maker of the formerly patented transgenic crops. Those generic makers of the formerly patented transgenic crops may often be farmers who are now legally allowed to save seeds. No matter what these generic makers do with the crop (e.g. ignoring refugia obligations or geographical restrictions), the original patent holder will be the liable party under the proposed autonomous liability regime as the party of last resort with the resources to compensate for damages (broadly defined).

Additional antagonism two. Under present regulatory systems governing transgenic crops, regulatory approvals are also time limited.<sup>75</sup> Hence, if a transgenic crop loses its regulatory approval, the transgenic crop is likely to become a heritage crop – i.e. a crop that has been superseded by newer, more recently developed and approved crops. Developers of the heritage crop will see no economic reason to pay the costs to obtain a renewed authorization from regulatory agencies for the heritage crops. At the same time, generic makers of the crop (now

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<sup>75</sup> E.g., the European Union grants authorization for ten years. Council Directive 2001/18, arts. 15(4), 17, 2001 O.J. (L 106) 1 (EC) (Renewal of Consent); Council Regulation 1829/2003, arts. 7(5), 11, 2003 O.J. (L 268) 1 (Renewal of Authorization).

off-patent) are unlikely to see any need to seek renewed regulatory approval. From the perspective of generic makers the seeking of renewed regulatory approval only imposes regulatory costs upon their generic product without offering any benefit aside from legality. But why should generic makers worry about legality when the autonomous liability regime imposes liability upon the original patent holder (as developer) for loss of economic markets? If a country rejects a shipment of an approved transgenic crop for having intermingled unapproved heritage transgenic crops, the original patent holder is the liable party. Why should the generic maker care or worry?

Under the proposed autonomous liability regime, it is bad enough for the patent holder to be liable for everything. It is even worse under the proposed autonomous liability regime for the patent holder to be liable for everything done by everybody.

With these impacts of the autonomous liability regime articulated, one can see that the proposed autonomous liability regime, despite the purported justifications for establishing a patent liability regime, is in reality an attempt to thwart and destroy any scientific research and technology that comes within the patent liability regime. In light of the incredibly negative impact on inventiveness and innovativeness that a patent liability regime establishes, the thesis of this article becomes clear – patents and liability ought to be separate and distinct spheres. Patents should be about incentives for inventiveness and innovativeness. Liability ought to be about real, identified harms for those who can justly be held to have caused the real, identified harms to the environment, biodiversity, human health, and property damage. To conflate the patent system with legal liability is to undermine the rationale for a patent system and to deform a liability regime into a regime of punitive sanctions for those who would dare to be creative and curious.

#### IV. Conclusion

In a thoughtful report by Dr. Michel Trommetter, Director of Research, Institut National de la Recherche Agronomique (INRA),<sup>76</sup> he wrote:

There are thus not one but several stakes for intellectual property rights in agricultural biotechnologies. In the market context, intellectual property is a necessary but insufficient condition for creating incentive to develop innovation in agricultural biotechnologies. So the definition of optimal IPR is linked to other necessary but insufficient conditions, such as the size of market demand for the innovation.<sup>77</sup>

In this article, it is argued that intellectual property rights are a necessary condition for gaining the socially-optimal level of freedom for scientific research (inventiveness) and technological development (innovation) that society needs and deserves. At the same time, this article argues that intellectual property rights can be undermined and, ultimately, destroyed if intellectual property rights are not kept separate and distinct from excessive concerns about biopiracy, access and benefit sharing, morality, regulation, technology assessments, and an autonomous patent legal liability regime.

Ultimately an intellectual property rights system is not just about patents and plant biotechnologies, nor about science and technology in agriculture. Ultimately an intellectual property rights system is about societal attitudes towards science and technology or inventions and innovations. Society can choose to create a necessary condition of encouragement for science, technology, invention, and innovation. Or to the contrary, society can choose to create

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<sup>76</sup> MICHEL TROMMETTER, INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL AND AGRO-FOOD BIOTECHNOLOGIES TO 2030 (2008), *available at* <http://www.oecd.org/dataoecd/11/56/40926131.pdf> (prepared on behalf of the OECD International Future Project on “The Bioeconomy to 2030: Designing a Policy Agenda”).

<sup>77</sup> *Id.* at 27.

barriers of discouragement. Society will choose.