

Biotechnology, Patents, and the Law:
Reform of the Intellectual Property Law of New Zealand
Ryan D. Jenlink

I. Introduction

Since its enactment in 1955, the Patents Act of 1953 (Patent Act) has governed the award of patents in New Zealand.¹ Although amended on several occasions since enactment², perhaps the most significant revision of the Patent Act to date is currently nearing completion.³ As the technologies with which the Patent Act must be equipped to deal have evolved, certain inadequacies and inabilities in the current system have been realized. Attempts to resolve such deficiencies are currently in motion, but whether these measures will remedy those shortcomings is yet only a product of speculation. This paper discusses the underlying New Zealand Patents Act 1953, the changes to it, and the likely effect these revisions may have on the patentability of innovations in the arena of genetics, biotechnology, and living matter.

II. The Patents Act of 1953

New Zealand's Patent system, like many others, is premised on the theory that by rewarding inventors with a limited monopoly, innovation and development will be encouraged. Without the potential to afford any such protection, inventors and those investing in invention, whether individuals or businesses, will have little incentive to sink time, effort and funds into research and development for fear that whatever development might be made could easily be

¹ 1 Patents Throughout the World (4th ed.) [hereinafter Patworld] § 123:2 Law (last updated November 2007).

² *Id.*

³ Ministry of Economic Development, Reform of the Patents Act 1953, http://www.med.govt.nz/templates/MultipageDocumentPage_____1457.aspx (last visited September 22, 2006).

acquired, utilized and commercially exploited by another.⁴ Patents award a limited monopoly with regard to a given invention in exchange for the grantee's divulging that innovation to society.⁵ In this way, society benefits from the awarding of a patent and the developer of an innovation is able to reap the benefits of his or her investment.⁶ As such, it is vitally important that patents be awarded in exchange for culturally or societal valuable innovation and that the award of patent not stifle further innovation of the economic well-being of society at large. In the alternative, however, where patents are granted for an invention that is not new or innovative, society does not benefit from the exchange; it gains no new knowledge or innovation for the limited monopoly it has granted⁷; thereby giving monopoly rights without any benefit inuring to society.

Until enactment of the reform legislation which is to be discussed hereafter, New Zealand's Patent Act provided for the granting of patent rights for inventions which are defined by section 2(1) of The Patent Act as: "any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies and any method or process of testing to the improvement or control of manufacture; and includes an alleged invention."⁸ In essence, New Zealand's Patent Act required two criteria of any manner of invention for which a patent was sought: first that the invention is new, and second, that it be a manner of manufacture.⁹

⁴ Ministry of Economic Development, The Present Patent System and Its Rationale, *supra* note 4.; See Andrew Brown QC, *Review: Intellectual and Industrial Property*, 2004 NZ Law Review 563, (2004).

⁵ Ministry of Economic Development, The Present Patent System and Its Rationale, *supra* note 4.

⁶ *Id.*

⁷ *Id.*

⁸ Ministry of Economic Development, Definition of Invention, http://www.med.govt.nz/templates/MultipageDocumentPage_____1458.aspx (last visited September 21, 2006).

⁹ Ministry of Economic Development, Patent Protection in New Zealand, http://www.med.govt.nz/templates/MultipageDocumentPage_____12975.aspx (last visited September 21, 2006).

To be “new” an invention or innovation simply must not have been published in New Zealand prior to the filing date of the application.¹⁰ Publications made outside New Zealand and not available within New Zealand¹¹ were not given consideration.¹² Therefore, it was possible that the details of a certain invention could have been fully known by the public virtually anywhere, if not everywhere, else in the world and yet that the invention might still be deemed “new” for purposes of gaining a patent in New Zealand.¹³ As previously discussed, award of a patent in such a scenario could not be expected to enrich the “state of the art”¹⁴ and therefore would be of little value if not, in fact, a hindrance to society.

The second consideration, “manner of manufacture” referred to, in essence, any invention of human creation. Although the phrase seems simply directed toward manufactured products, “manner of manufacture” has come to include methods or processes of testing related to manufacture.¹⁵ It excluded, as interpreted by the Courts, “products of nature, mathematical operations, bare principles, mathematical algorithms, schemes, or plans and methods of medical treatment of humans.”¹⁶

This two-consideration approach to patentability, encompassing “newness” and “manner of manufacture”, stood in contrast to the three-criteria approach commonly adopted elsewhere and throughout the world; that an invention be new, involve an inventive step, and be useful^{17, 18}.

¹⁰ *Id.*

¹¹ New Zealand previously adopted and utilized a “local novelty” test in its determination of newness, as opposed to an absolute or universal novelty test which would find an invention to be new if not found anywhere.

¹² Ministry of Economic Development, Patent Protection in New Zealand, *supra* note 9.

¹³ *Id.*

¹⁴ In this context, “state of the art” refers to the novelty and inventiveness of an invention and is similar to the idea of “prior art”. Synonymous with Article 54(2) of the European Patent Convention (EPC) which states, “[the] state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”. European Patent Convention, 12th Edition (2006): Article 54(2).

¹⁵ Patworld § 123:7 What is Patentable? (last updated November 2007).

¹⁶ Ministry of Economic Development, Patent Protection in New Zealand, *supra* note 9.

¹⁷ The United States employs a patentability scheme which requires that inventions be of patentable subject matter, novel, non-obvious, useful. *See* 35 U.S.C. §§101-103 (2006).

Unlike most other countries, New Zealand's Patents Act contained no provision requiring inventions and innovations involve an inventive step or be useful in order to be granted a patent.¹⁹ New Zealand's requirement of newness finds a counterpart internationally in what most countries term the requirement for novelty; the usefulness requirement, found commonly in many other patent regimes across the globe, however, finds no functional counterpart in New Zealand.²⁰

In certain scenarios, the ability to gain a patent under New Zealand's laws might be negated by the very nature of the invention. Even where the criteria for patentability had been met, the Patent Commissioner had grounds to deny a patent on an application which was thought to be contrary to law of public morality, or, as it is termed, *ordre public*.²¹ Specifically, this exception to patentability regarded inventions so obviously contrary to established natural laws; for example, aggregates of the known properties of ingredients of food or medicine.²²

III. Reform of the Patent Code

As previously discussed, the criteria for gaining a patent in New Zealand have been such that it was quite possible to gain a patent for an invention that is not actually new, does not involve an inventive step, and may not be useful.²³ That New Zealand enabled the grant of patents over subject matter that was not necessarily useful or inventive could have resulted in the granting of patents for innovations that were, in fact, not genuinely innovative, thus burdening the economic system, discouraging growth and standing in direct contradiction to the generally-

¹⁸ Ministry of Economic Development, The Present Patent System and Its Rationale, *supra* note 4.

¹⁹ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

²⁰ *See Id.*

²¹ § 2, Patents Act 1953.

²² *See Id.*

²³ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

recognized purpose underlying the patent system.²⁴ The patent system functions to grant exclusive rights to the inventor in exchange for the receipt, by society, of valuable and beneficial information: the means to this new, inventive, and useful knowledge, *see supra*.²⁵ Granting patents for innovations that are not actually new and useful does not provide a benefit to society.²⁶ Because New Zealand may have in the past granted patents more readily than many of its trading partners, other countries would not grant a patent to an innovation that might receive patent protection in New Zealand.²⁷ Therefore, inventors might have received patent protection for information that is already globally available; as such New Zealand was not reaping any benefit for awarding these patents, but instead has born the burden of those awarded patents.²⁸ A realization that such benefits were being missed is one of the foremost factors which lead to the reform of the New Zealand Patent Act which might take measures to secure benefits to society in exchange for the grant of a patent.²⁹

In 1989, the Ministry of Commerce (as it was then known) began a review of the Patent Act.³⁰ That review process culminated in a 1992 discussion paper proposing a series of reforms to the Patent Act meant to address the shortcomings which have been herein discussed.³¹ Responses to the 1992 paper raised primarily two concerns about the proposed changes: first, that the proposed reformation failed to deal with the patentability of biological inventions and, second, that the changes further failed to address patentability of inventions based on traditional

²⁴ *See Id.*

²⁵ Ministry of Economic Development, The Present Patent System and Its Rationale, *supra* note 4.

²⁶ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

²⁷ *Id.*

²⁸ *See Id.*

²⁹ *See Id.*

³⁰ *Id.*

³¹ *Id.*

knowledge^{32, 33} These objections to the Patent Act overhaul resulted in the effective indefinite postponement of the reform effort.³⁴

In August of 2000, renewed interest in efforts to secure the societal and economic benefits of the patent system stirred New Zealand's Government restart the process of reforming the Patent Act.³⁵ In the time between the postponement of the reform effort and its revitalization, the only changes to the Patent Act occurred in 1992 when New Zealand accepted the terms of the Patents Cooperation Treaty (PCT) and in 1994 when New Zealand joined TRIPS³⁶. Upon the reconsideration of the proposed corrections to the Patent Act, the Government agreed to impose a series of changes: a proposed three-stage restructuring process focused on implementing many of the suggestions made previously in the 1992 paper.

Stages 1 and 2, which have now been completed, were aimed at securing the benefits to be realized by New Zealand upon the grant of a patent; that New Zealand might truly encourage growth and economic prosperity through the grants of patent.³⁷ The amendments to the Patent Act proposed by Stages 1 and 2 changed the novelty requirements.³⁸ Following those changes, an invention will only be considered "new" if no description of the invention has been published anywhere worldwide prior³⁹ to the filing date.⁴⁰ This change will abandon the local novelty

³² See generally Ryan D. Jenlink, *Māori Claims to Traditional Knowledge of New Zealand* (2008).

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization (WTO) and negotiated in 1994 during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) sets down minimum standards for the protection of intellectual property by requiring that the laws of member nations reflect certain minimum standards for protection. Of particular importance is the requirement found in Article 27(1) that "patents shall be available for any inventions . . . in all fields of technology. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994), available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

³⁷ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

³⁸ *Id.*

³⁹ Under the International Convention, priority must be claimed with 12 months of the first Convention filing.

⁴⁰ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

standard in favor a standard of absolute novelty.⁴¹ The proposal also requires that an invention now involve an inventive step, which will likewise be judged against the worldwide body of knowledge.⁴²

Although questions about how the proposed Patent Act would deal with patentability of inventions dealing with living matter and inventions based on traditional knowledge had caused the reform effort to stall several years earlier, the change agreed upon by the government did not address any of these recurring issues.

The third and final stage of the Patent Act Revision is aimed at addressing several substantive and controversial issues, perhaps most importantly, the boundaries to patentability, moral issues related to the patentability of biological inventions, cultural claims to inventions of traditional knowledge⁴³, and New Zealand's International Treaty obligations.⁴⁴ Stage three is anticipated to also address:

- the interaction between the Patents Act and the Plant Variety Act of 1987⁴⁵;
- the patentability of business methods and computer software related inventions;
- the patentability of methods of medical treatment of humans;
- the stringency⁴⁶ of the tests used to determine whether a patent should be granted.⁴⁷

⁴¹ See Brown, *supra* note 4, at 563.

⁴² *Id.*

⁴³ See Jenlink, *supra* note 32.

⁴⁴ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

⁴⁵ See generally Ryan D. Jenlink, *Protecting Plant Varieties in New Zealand* (2008).

⁴⁶ The Stringency test refers to the degree of certainty that a given patent might be later held invalid by the courts which IPONZ requires to not grant that patent. New Zealand has in the past only failed to grant patents where it is "practically certain" that it would later be invalidated, however, New Zealand is considering a recommendation to move to the "benefit of doubt" criterion used in Australia; see Ministry of Economic Development, Stringency Test for Patentability, http://www.med.govt.nz/templates/MultipageDocumentPage___1463.aspx (last visited September 22, 2006).

⁴⁷ *Id.*

In this era of rapid technological development, the reform of New Zealand's patent legislation will presumably allow New Zealand to reap the benefits of its innovations and encourage the growth of national innovation, research, and invention.⁴⁸

The Ministry of Economic developments cites five points in support of the rationale for reform: 1) to ensure that patents are granted for genuine innovations only, 2) to contribute to economic development and the development of a "knowledge economy", 3) to provide incentives to international innovators to bring technologies to New Zealand, 4) to deal with concerns expressed by the native Māori about the patenting of living organisms and genetic material, and 5) the settle moral and cultural concerns regarding the patenting of living organisms or genetic material.⁴⁹

Whatever changes may be made to New Zealand's patent law, those changes will need to be consistent with New Zealand's international obligations.⁵⁰ As a party to the World Trade Organization (WTO) Agreement on Trade Related Intellectual Property Rights (TRIPS),⁵¹ and to the Paris Convention for the Protection of Industrial Property, New Zealand, like many other countries, must seek to conform its standard of intellectual property protection to several international norms.⁵²

IV. Biotechnology, Genetic Material, and Research

Amid concerns about patents regarding genetic material and products of biotechnology, and at a time when New Zealand seeks to execute the most extensive overhaul system in

⁴⁸ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

⁴⁹ *Id.*

⁵⁰ Ministry of Economic Development, Executive Summary, http://www.med.govt.nz/templates/MultipageDocumentPage___1159.aspx (last visited September 22, 2006).

⁵¹ *Id.*

⁵² Ministry of Economic Development, Patent Protection in New Zealand, *supra* note 9.

decades, New Zealand is faced with a series of questions pertaining to exactly how it will choose to treat patents arising in such fields of technology henceforth.⁵³ Significant consideration has been given to exactly how the patents regarding genetic material should be approached during the reform process.⁵⁴ As yet, many questions remain unanswered. Should biotechnological inventions be patentable? If so, to what degree and would such patents be contrary to the public good? Further, would biotech patents have the effect of encouraging or inhibiting technological development and thus economic growth?

New Zealand is a world leader in the realm of biological, agricultural, and biotechnological research.⁵⁵ The biotechnology industry, in particular, is well established in New Zealand. Because of the importance of primary production in these areas in New Zealand's economy, patents restricting the availability of such innovations have been often met with hostility.⁵⁶

Perhaps of foremost importance is the question of how, exactly, New Zealand will choose to treat genetic material with regard to patentability.⁵⁷ Under the pre-reform Patent Act, genetic material was not specifically excluded from patentability.⁵⁸ The working definition of a patentable invention, found in § 2 of the Patent Act of 1953 did not specifically exclude genetic material.⁵⁹ The Intellectual Property Office of New Zealand (IPONZ) established a policy of refusing patents which might incorporate human beings in their scope.⁶⁰ However, IPONZ embraced attempts to patent innovations pertaining to non-human animals; for example New

⁵³ Ministry of Economic Development, Should Genetic Material Be Excluded from Patentability?, http://www.med.govt.nz/templates/MultipageDocumentPage___1163.aspx (Last visited September 21, 2006).

⁵⁴ *See Id.*

⁵⁵ Ministry of Economic Development, New Issues in Patentability 1: Biotechnological Patents, http://www.med.govt.nz/templates/MultipageDocumentPage___1460.aspx (last visited September 22, 2006).

⁵⁶ *Id.*

⁵⁷ *See Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

Zealand patent 243908 includes within its scope a transgenic mouse.⁶¹ Under the pre-reform Patent Act, gene sequences were patentable.⁶²

The rationale for patenting genetic material seemed to mirror the patenting of a chemical substance which occurs in nature.⁶³ Proponents of patenting genetic material argued that, like such chemical substances, a gene or gene sequence is only patentable when it is isolated and purified⁶⁴.⁶⁵ An isolated and purified gene is patentable in that it does not exist in nature in the isolated and purified form and is thus not a product of nature.⁶⁶

Despite the fact that much genetic material has been allowed patent to date and the seemingly established practice of allowing patents on purified and isolated genetic material, concerns over the patents covering genetic material continue to exist.⁶⁷ Some would like to see a ban on patents related to genetic material incorporated into the reform process. Opponents to patentability contend that while the patent system is designed to spur innovation, some evidence suggests the patenting of genetic material may work to hinder research.⁶⁸ They further argue that patents covering genetic material may be too broad or the patent owners may restrict access to those patents; either scenario likely impeding scientific progress.⁶⁹ For example, an overly broad patent could mean that researchers would need to obtain licenses before secondary uses of a patented gene could be research or discovered.⁷⁰ They also raise foreseeable concerns that

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Isolated and purified means that the genetic material, whether it be an entire genome, a single gene, a gene fragment, DNA, RNA, or mRNA, has been extracted from the cell and is purified apart from the environment where it would naturally occur.

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *See Id.*

⁶⁸ *Id. citing*, Mildred K. Cho et al, "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services", JMD 2003, Vol. 5.

⁶⁹ Ministry of Economic Development, Background, http://www.med.govt.nz/templates/MultipageDocumentPage___1161.aspx

⁷⁰ *See Id.*

patents over genetic material would restrict access to medical treatments and increase the cost of health care.⁷¹ Arguments have been advanced that genes or gene sequences are not patentable on the basis that they do not meet patentability requirements.⁷² That is, because genes exist in nature, they would seem to fail novelty test.⁷³ Further, one who discovers a gene invents nothing; discovery is not invention.⁷⁴ Gene sequencing is not an inventive process.⁷⁵ However, New Zealand has, for some time, taken the view that genetic material is patentable where isolated and purified.⁷⁶

In 2002, New Zealand's Ministry of Economic Development outlined several reasons that genetic material should not be excluded from the possibility of patent protection:

- Patents on genetic material have previously been awarded and to abandon this practice would introduce an element of inconsistency,
- "Broader" patenting issues unrelated to genetic material exist,
- It is very difficult to determine exactly what constitutes "genetic material" or living matter,
- Internationally, the exclusion of genetic material from patenting is unsupported,
- New Zealand's international obligations under TRIPS likely preclude any attempt to outright exclude genetic material from patentability, and
- New Zealand's biotechnology industry would likely suffer from any attempt to exclude genetic material from patentability.⁷⁷

In June of 2004, the Ministry definitively announced that it would not recommend that genetic material be excluded from patentability.⁷⁸ It based its decision on the difficulties that would be associated with the definition of genetic material, the large number of pre-existing patents on genetic material, and that to exclude genetic material from patentability might very

⁷¹ An intellectual property guide for the life sciences in New Zealand (Callus et al. eds.).

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *See supra.*

⁷⁷ Ministry of Economic Development, Background, *supra* note 69.

⁷⁸ Brown, *supra* note 4, at 563-64.

well be inconsistent with New Zealand's obligations under TRIPS.⁷⁹ The changes implemented as a part of the reform process, specifically, the addition of a usefulness requirement, will have a dramatic effect on the patentability of genetic material, thereby likely addressing, although indirectly, many of the concerns posed by critics of the decision not to outright exclude genetic material from patentability.⁸⁰

The subject of genetic material patentability garnered much debate, both in New Zealand and internationally, following the receipt and enforcement of patent protection for genes encoding breast and ovarian cancer (BRCA 1/2).⁸¹ The issue remains unaddressed in the Patents Act or in any review of the Patent Act which has thus far occurred.⁸²

In many countries, a usefulness or utility requirement often entails three levels of consideration: credible utility, specific utility, and substantial utility.⁸³ *Credible utility* is found where a person of ordinary skill in the relevant technology would find that the utility is believable.⁸⁴ *Specific utility* requires that the invention claimed be related to a specific use; for example, it is not enough that a fragment of genetic material be claimed useful as a probe or marker, it must be found to be a probe or marker for a specific gene or trait. *Substantial utility* requires that the invention have an actual use capable of being implemented.⁸⁵

The usefulness requirement will change the light in which pending applications for patent of genetic material will be viewed, even though it will have an effect on the way in which all pending applications are evaluated.⁸⁶ Because patents will no longer issue without a disclosed use, issued patents will have a greater societal value; patents will be more readily translatable

⁷⁹ *Id.* at 564.

⁸⁰ Ministry of Economic Development, Background, *supra* note 69.

⁸¹ *Id.*

⁸² *Id.*

⁸³ Callus, *supra* note 67, at 42.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Ministry of Economic Development, Reform of the Patents Act 1953, *supra* note 3.

into societally valuable products.⁸⁷ Further, the requirement may help to narrow the scope of patents, discouraging researchers from seeking a patent over a given fragment of purified and isolated genetic material without knowledge of its function.⁸⁸

The Patent Act has no specific bar to the patenting of human beings or biological material derived from human beings.⁸⁹ However, speculation suggests that any patent which might include human beings within its scope would be denied by IPONZ on the basis that it is not a “manner of manufacture”.⁹⁰ New Zealand’s Royal Commission on Genetic Modification proposed in recommendation 10.2 that human beings and related biological processes be excluded from patentability by amendment to the Patent Act.⁹¹ New Zealand’s government agrees that the Patent Act should be so amended.⁹² While genetic material may also be excluded from patentability where their commercial enforcement may be contrary to morality,⁹³ it seems unlikely that IPONZ would refuse patents covering any and all genetic material⁹⁴ and IPONZ seems apprehensive to overturn the standing precedent or to challenge New Zealand’s international treaty obligations.

Stemming from the question of whether to exclude genetic material from patentability is the question of what effect genetic patents would have on New Zealand’s research industry. Many countries include a “research” or “experimental use” exception within their patent law.⁹⁵ Such an exception works to allow non-commercial research to continue without the threat of

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Ministry of Economic Development, Background, *supra* note 69.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Ministry of Economic Development, Addressing Ethical Concerns, http://www.med.govt.nz/templates/MultipageDocumentPage___1170.aspx (Last visited September 21, 2006).

⁹⁴ *Id.*

⁹⁵ Ministry of Economic Development, Addressing the Effects of Genetic Patents on Research, http://www.med.govt.nz/templates/MultipageDocumentPage___1167.aspx (Last visited September 21, 2006).

patent infringement.⁹⁶ In New Zealand, as in several other countries such as the United States and Australia, this exception is derived from judicial interpretation.⁹⁷ New Zealand's Ministry of Economic Development has recommended that the exception be made a permanent part of New Zealand's statutory patent law.⁹⁸ Such an exception would allow researchers working for non-profit purposes to continue their work without need to seek licensing from the patent owner.⁹⁹

V. Conclusion

New Zealand's Patents Act 1953 has served with little revision since its enactment. This patent system is in need of change to meet the demands presented by newly emerging technologies and the desire to patent the innovative products of these technologies. New Zealand faces a variety of questions concerning how it will approach patenting genetic material, biotechnology products, and other living matter. New Zealand must consider these questions against a backdrop of reaping the societal benefits of the patents it chooses to award, comports with international obligations under such agreements as TRIPS, encouraging research and industry, and protecting the public morality.

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*