Patent Eligible Subject Matter In the Biotechnological Arts

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Abstract

This paper compares the patentability of biotechnology inventions under the laws of the United States, Canada, Australia, and New Zealand. Five specific categories of biotechnology are examined: genes and DNA, microorganisms, plants and animals, human embryonic stem cells, and medical methods. The WTO-TRIPS agreement establishes the underlying framework followed by these countries. All of these counties allow patenting of genes and DNA as well as microorganisms. Plant and animal patents are allowed in all the countries except Canada. Surgical and medical methods are only patentable in the U.S. and Australia. Human embryonic cells are patentable in all jurisdictions, except for a limited prohibition on patenting totipotent stem cells in Australia. Finally, changes to the language of 35 U.S.C. §101 are proposed.
INTRODUCTION

Biotechnology

The word “biotechnology” was coined by a Hungarian scholar, Kark Ereky, as a word to describe a technology converting raw materials from living organisms to useful products.\(^1\) It was derived from the fermentation process known as zymotechnology in the eighteenth century and culminated with the inception of genetic engineering.\(^2\) While it is often associated with drugs and medicine, biotechnology also plays an important role in food and agriculture. Today, scientists refer to biotechnology as “the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.”\(^3\) Similarly, the U.S. Biotechnology Industry Organization characterizes biotechnology as “the use of cellular and biomolecular processes to solve problems or make useful products.”\(^4\) The United Nations Convention on Biological Diversity also includes a broad definition: “Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”\(^5\)

More so than inventions in other technological sectors, biotechnology frequently implicates ethics and safety concerns, especially when scientists attempt to alter life

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forms. Debates can be even more heated when considering patent rights on products of biotechnology such as transgenic organisms. Use of biotechnology raises concerns but also has great power to provide new therapies, food crops, and consumer goods. The high cost of research and risk of failure, combined with the potential for a spectacular invention, heightens the relevance of a patent monopoly for motivating biotechnology innovation.

This paper examines the choices that common-law countries—the United States, Canada, Australia, and New Zealand—have made regarding the patentability of biotechnology inventions. Comparing the decisions made by these common-law countries illustrates how legal systems with a common English law heritage reach different decisions in the complex and controversial area of biotechnology patents. To this end, international treaties such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) are examined. Next, five specific categories of biotechnology are examined: genes and DNA, microorganisms, plants and animals, human embryonic stem cells, and medical methods. Finally, differences are discussed and changes to the U.S. patent system are proposed that harmonize the U.S. with other countries and clarify U.S. law.

INTERNATIONAL TREATIES GOVERNING PATENT ELIGIBLE SUBJECT MATTER

WTO-TRIPS

The patent law of many nations has been moving gradually towards harmonization through establishing international treaties. Since its adoption in 1994, the
World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has influenced domestic patent laws of all WTO member states. Because all countries with significant patent activity are members of the WTO, the effect of TRIPS on harmonization is significant. One key principle embodied in TRIPS is equal treatment for all technologies.\(^6\) This requirement obligates member states to accommodate biotechnology inventions. Since TRIPS sets only minimum patentability and disclosure requirements, there is considerable variability between countries, e.g. in the definition of patent-eligible inventions. Part of the variation is adoption of optional exclusions from patentability of certain kinds of inventions. Under TRIPS “[m]embers 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.”\(^7\) “Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.”\(^8\) Thus TRIPS allows a member state to deny patents on surgical methods, plants and animals, as well as inventions deemed immoral.. All member states—including all jurisdictions considered in this paper—have allowed patents on microorganisms since 1994. The exclusions in TRIPS are based on the exclusions under the European Patent Convention and in the legislation of its signatory states.\(^9\)

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\(^6\) TRIPS Art. 27(1) “patents shall be available...without discrimination as to...the field of technology”

\(^7\) TRIPS Art. 27(2)

\(^8\) TRIPS Art. 27(3)

\(^9\) European Patent Convention, Rule 23b, 23c, 23d, and 23e
authors of the 2005, 10th Anniversary Report of the WTO said that there were to date no cases of a Member obtaining authority under the WTO to retaliate for a TRIPS violation.¹⁰

**TRIPS-plus**

In bilateral trade agreements with other nations, the U.S. and EU often require that the bilateral partner amend its patent laws to include a broader definition of eligible subject matter than the minimum set out under TRIPS. TRIPS itself sets a floor for intellectual property protection but does not set a ceiling. The dynamic at work in raising the floor internationally is one of developed nations with strong intellectual property laws insisting that trading partners also increase intellectual property protection as part of a bilateral trade agreement. Frequently these so-called “TRIPS-plus” agreements require protection for biotechnology or prohibit exclusions on patenting plants and animals.¹¹ For example, the free trade agreement between Jordan and the U.S. limits exclusions to patentable subject matter only to that which is necessary to protect “*ordre public* or morality”¹² and requires that “diagnostic, therapeutic and surgical methods for the treatment of humans or animals be patentable.”¹³

**Draft Substantive Patent Law Treaty**

After major patenting nations including the U.S. clamored for substantive patent harmonization, the International Bureau of the World Intellectual Property Organization composed a draft Substantive Patent Law Treaty (SPLT) in 2001. Article 12 of the SPLT

¹¹ Grain, “*TRIPS-plus* through the back door: How bilateral treaties impose much stronger rules for IPRs on life than the WTO* (2001) (available at http://www.grain.org/briefings/?id=6, last visited September 26, 2007)
¹² The US-Jordan FTA, Article 18(a)
¹³ The US-Jordan FTA, Article 18(b)
sets out both a positive and negative definition for patent eligible subject matter. “Subject matter eligible for protection shall include products and processes [, in all fields of technology,] which can be made and used in any field of activity.” Specified exceptions are mere discoveries of natural phenomena, abstract ideas as such, scientific and mathematical theories and laws of nature as such, and purely aesthetic creations. These are almost identical to the exceptions under EU and U.S. case law. Disagreement between member states has put further discussion about the SPLT on indefinite hold. The original goal of creating a single set of patenting guidelines for the entire world has proved very difficult to achieve given the controversy over issues such as patenting plant and animal life. Progress may also be stalled due to pushback from developing countries who feel that TRIPS is already over protective of intellectual property.

USA

Statutory Limits on Patent Eligible Subject Matter

Unlike the other jurisdictions discussed in this paper, the U.S. has a mandate to provide protection for inventions and discovers as part of its constitution. In the U.S., 35 USC §101 contains a positive definition of eligible subject matter of utility patents.

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15 SPLT Art. 12(b)
18 “The Congress shall have power to … promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” U.S. Const. Art. I § 8 c 8
The statutory classes are process, machine, manufacture, or composition of matter.\textsuperscript{19} The U.S. Patent Office and the courts have interpreted the extent of patent eligible subject matter broadly. This broadness is reflected in the U.S. Supreme Court’s declaration that “anything under the sun that is made by man” is eligible subject matter under §101.\textsuperscript{20} The Court has also recently noted that “the language of §101 is extremely broad.”\textsuperscript{21} The other common law countries in this article have narrower definitions of patent eligible subject matter than the U.S.

**Case Law Limits on Subject Matter**

Courts have included negative definitions of patentable subject matter as part of U.S. case law. After finding that the correct statutory interpretation of §101 requires a broad construction of eligible subject matter, in the next paragraph the U.S. Supreme Court limited that breadth: “[t]his is not to suggest that §101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”\textsuperscript{22}

**Morality in U.S. Patent Law**

In the U.S., morality is often thought of as something best left to the legislature and kept out of patent law. When asked to consider the risks associated with genetically modified organisms, the U.S. Supreme Court’s position in *Chakrabarty* was that the

\textsuperscript{19} “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 USC § 101 (2004).


\textsuperscript{22} 447 U.S. at 309.
courts were “without competence to entertain [such] arguments.” In a 1977 study, Ronald Schapira found that most patent attorneys in the U.S. believe that the “American view” is that “morality should . . . have nothing to do with patents.”

However, judges have from time to time read morality into the requirement that an invention be useful. Justice Story (Judge Story at the time) wrote: “All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful,’ therefore, is incorporated into the act in contradistinction to mischievous or immoral.” (emphasis added) This thinking is not a mere relic of the 19th century. In 2002 a federal district court found that a patent possesses utility “if it will operate to perform the functions and secure the results intended, and its use is not contrary to law, moral principles, or public policy.” (emphasis added) Because there is a moral underpinning beneath the surface of U.S. patent law it is possible for a judge to find than an invention lacks utility because of moral concerns.

**Other Patentability Requirements Significant for Biotechnology**

Biotechnology and chemistry are treated as unpredictable arts. Compared to technologies such as mechanical engineering, the USPTO requires a stronger showing of enablement. The enablement requirement is often used to limit the scope of broad process or method claims. For some gene sequences, it can be easier to identify a new sequence than to identify a use for the sequence. Thus the utility requirement is

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23 447 U.S. at 317.
important in the patent law of the U.S. as well as other jurisdictions. The requirement for asserting a credible, specific utility limitation will prevent some biotechnology inventions from receiving U.S. patents. The written description requirement in 35 USC §112 can also be a barrier to patenting of some types of biotechnology. Courts question whether a person who does not know the sequence of biotechnological material (nucleic acid or protein) was in fact in “possession” of it. Some aspects of providing a written description are solved by submission of biological materials to an international depository approved under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

Genes and Nucleic Acid Sequences

Treatment of genes and DNA under U.S. patent law is largely analogous to the treatment of chemicals. There are no issues in terms of patent eligible subject matter, but speculative attempts to patent a gene without knowing a function will fail for lack of utility. The Court of Appeals for the Federal Circuit rejected an application claiming express sequence tags (ESTs), short pieces of DNA, finding that they lack specific and substantial utility. The court rejected this application for a patent on ESTs under §101.

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27 The U.S. Patent and Trademark Office has interpreted case law to require the applicant to identify a specific and substantial utility and disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological. Manual of Patent Examining Procedures §2107.01 (2006).
29 MPEP §2402 “The Deposit Rules”
30 See USPTO Notice on Utility Examination Guidelines (Friday, January 5, 2001) “If a patent application discloses only nucleic acid molecular structure for a newly discovered gene, and no utility for the claimed isolated gene, the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable.”
31 In re Fischer, 421 F.3d 1365 (2005).
for lack of utility—not for belonging to an ineligible class of subject matter—and for lack of enablement under §112, first paragraph.\textsuperscript{32}

**Microorganisms**

The U.S. has a long history of granting patents on microorganisms. In 1873, Louis Pasteur received U.S. Patent 141,072 on yeast free from germs or disease, as an article of manufacture. In 1980, the U.S. Supreme Court issued its now famous holding in *Diamond v. Chakrabarty*.\textsuperscript{33} Specifically it held that a living, genetically-altered bacterium was patentable subject matter. Due to the genetic alteration it was not a product of nature and was protectable as either a manufacture or a composition of matter.\textsuperscript{34} The potential for significant utility in Chakrabarty’s invention probably helped the Court reach a holding of patent eligible subject matter even though those are formally two distinct questions. As with all the countries compared in this paper, TRIPS 27(2) now requires that the U.S. recognize microorganisms as patentable subject matter.

**Plants and Animals**

Both plants and animals are clearly patentable in the U.S. After the holding in *Chakrabarty*, the U.S. Patent Office said that “the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability.”\textsuperscript{35} The U.S. Patent Office allowed a claim directed to a transgenic multicellular animal when it issued U.S. Patent 4,736,866 on the Harvard oncomouse on April 13, 1988. About a year before issuing the Harvard oncomouse patent, the USPTO issued a notice that it would consider

\textsuperscript{32} Id. at 1379  
\textsuperscript{33} 447 U.S. 303  
\textsuperscript{34} Id. at 309-310  
\textsuperscript{35} MPEP § 2105
nonnaturally occurring, nonhuman multicellular living organisms including animals to be patentable subject matter within the scope of 35 U.S.C. §101.\textsuperscript{36} Subsequently, there was great debate in the U.S. Congress about the morality of patenting animals. Of the bills that were introduced in response, one mandated a two-year moratorium on patenting new animals while Congress studied the issues\textsuperscript{37} and another simply banned such patents.\textsuperscript{38} Neither bill passed into law. In terms of plants, the U.S. Supreme Court recently confirmed that “[i]t has been the unbroken practice of the [U.S. Patent and Trademark Office] since [1985] to confer utility patents for plants…” under 35 U.S.C. §101.\textsuperscript{39}

\textbf{Human Embryonic Stem Cells}

In 1998, the U.S. Patent and Trademark Office issued a patent with claims directed to primate, including human, embryonic stem cells.\textsuperscript{40} Although this patent was held invalid in April of 2007, the reason was obviousness, not ineligibility of the subject matter. During the debate on this and other stem cell patents, the discussions have focused on the validity and scope of individual patents not on the patent eligibility of human embryonic stem cells.

\textbf{Medical Methods}

The U.S. is one of a few jurisdictions that allows patents on medical methods.\textsuperscript{41} However, a 1996 amendment to § 287 of the patent law exempted medical practitioners

\textsuperscript{36} Policy Statement on Patentability of Animals: Animals—Patentability, 1077 O.G. 24 (April 21, 1987)
\textsuperscript{37} HR 3119, introduced on August 5, 1987
\textsuperscript{38} S 2111, introduced on February 29, 1988
\textsuperscript{39} \textit{J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.}, 534 U.S. 124, 131 (2001)
\textsuperscript{40} Patent 5,843,780 issued to the Wisconsin Alumni Research Foundation
\textsuperscript{41} See Table 1, Selected Medical and Surgical Method Patents, 1846–1993, in W. Noonan, “Patenting Medical and Surgical Procedures,” 77 JPTOS 651 (Aug. 1995).
from liability for infringement.\textsuperscript{42} The Conference Report accompanying the amendment states that the exemption does not include a patent on a “biotechnological process” as defined in §103(b), or “a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated \textit{ex vivo} at the cellular or molecular level.”\textsuperscript{43}

\section*{CANADA}

\subsection*{Statutory Limits on Patent Eligible Subject Matter}

Patent eligible subject matter was first defined by the Canadian Parliament in 1869.\textsuperscript{44} That definition borrowed language from U.S. law and has remained essentially unchanged. The current Patent Act states that: “‘invention’ means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”\textsuperscript{45} The main prohibitions, or negative definitions, exclude patenting a “theoretical principle or a product occurring in nature” and “higher life forms.”\textsuperscript{46}

\subsection*{Morality in Canadian Patent Law}

There are no morality provisions in the Canadian Patent Act. The Supreme Court in \textit{Harvard College v. Canada} unanimously held that the Commissioner of Patents has no

\textsuperscript{42} 35 USC 287(c) “With respect to a medical practitioner's performance, of a medical activity that constitutes an infringement under section 271 (a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.”
\textsuperscript{44} Patent Act, S.C. 1869, c. 11, s. 6
\textsuperscript{45} Patent Act, R.S. 1985, c. P-4, s. 2
discretion to refuse a patent on the basis of public policy considerations independent of any express provision in the Patent Act.\textsuperscript{47} Even so, the court denied the patent in a split decision. The influence of French civil law tradition may be responsible for some courts including a flavor of moral judgment when evaluating patents. Canada Patent Office examiners have no discretion to consider morality in making patentability decisions.\textsuperscript{48}

**Genes and Nucleic Acid Sequences**

Patent protection for genes and DNA in Canada is very similar to the U.S. Subject matter is not an impediment, but failure to state or show utility can preclude patenting.\textsuperscript{49} The Supreme Court of Canada recognized the validity of a gene patent in an infringement case involving genetically modified canola.\textsuperscript{50}

**Microorganisms**

Canadian courts have long held engineered microorganisms patentable.\textsuperscript{51} The Canadian Patent Appeal Board also held that a mixed fungal yeast culture system was patentable subject matter.\textsuperscript{52} The Manual of Patent Office Practice (MOPOP) provides that “uni-cellular life forms which are new, useful and inventive are patentable.”\textsuperscript{53} Uni-cellular life forms provided by way of example include microscopic algae, moulds and yeasts, bacteria, viruses, cells in culture, transformed cell lines, and hybridomas. The

\textsuperscript{47}2002 SCC 76, 116-121 per Bastarache J., and 89-102 per Binnie J.
\textsuperscript{48}T. Caulfield et al., Biotechnology Patents and Embryonic Stem Cell Research: Emerging Issues (Part I), 1 JIBL 98, 102 (2004).
\textsuperscript{49}See MOPOP Chapter 17 “Biotechnology” and Chapter 12.03 “Utility”
\textsuperscript{50}Monsanto Canada Inc. v Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34 (CanLII) [Schmeiser]
\textsuperscript{52}See Re Abitibi Co., 62 C.P.R. (2d) 81 (1982)
same section further provides that “[i]n general, a process to produce, or which utilizes these organisms is patentable.”

**Plants and Animals**

Canada is one of the few jurisdictions, along with Taiwan and China, to find that the Harvard Oncomouse is not eligible subject matter for patenting. Claims 1 through 12 in the Canadian patent application are identical to the claims in the U.S. application. The majority of the Canadian Supreme Court reasoned that the word “matter” as found in the statutory language “composition of matter,” does not accurately encompass higher life forms. “Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed.” Hence patenting can apply to lesser life forms but not to higher life forms. Even though the Patent Act does not explicitly differentiate between lower and higher life forms, making such a distinction, according to the five justices on the majority, “is nonetheless defensible on the basis of common sense differences between the two.” The four justices in the minority had a different understanding of common sense.

Interestingly, the five-four split is exactly along the lines of the justices’ legal background. The majority consisted entirely of judges trained in the civil law tradition, while the minority consisted entirely of judges with a background in the British common law. The civil law majority may have been discomfited by the morality of animal patents, using a narrow statutory interpretation of “invention” to effectively reject the

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54 Id.
55 US 4,736,866
56 *Harvard College v. Canada*, 2002 SCC 76, Para. 148-150 per Bastarache J.
57 Id. at Para. 199
oncomouse patent on moral grounds.”

As a result of Harvard College, the MOPOP guides examiners to exclude from patentability all higher life forms including animals, plants, seeds, and mushrooms. However, “a process for producing a higher life form may be patentable provided the process requires significant technical intervention by man and is not essentially a natural biological process which occurs according to the laws of nature.”

**Human Embryonic Stem Cells**

Neither the courts nor the Canadian Intellectual Property Office have commented directly the patentability of stem cells. However, patents that claim stem cells have issued.

**Medical Methods**

A method or process of surgery or therapy on living humans or animals is not considered to be within the scope of “invention” as defined by section 2 of the Patent Act. However, methods of treating animals to derive an economic benefit as well as methods of diagnosing a disease or medical condition in a human being are patentable.

**AUSTRALIA**

**Statutory Limits on Patent Eligible Subject Matter**

Patent law in Australia traces back to English law and the Statute of Monopolies.

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59 MOPOP Chapter 12.04.01 “Living matter”
60 Id.
61 See e.g. CA 2,476,553, CA 2,479,510, and CA 2,537,861
63 MOPOP Chapter 12.04.02 “Medical treatment”
In Australia, patent eligible subject matter is defined as “any manner of new manufacture the subject of letters patent and grant of privilege within Section 6 of the Statute of Monopolies, and includ[ing] an alleged invention.” Despite the antiquity of the “manner of manufacture” test from the nearly 400-year-old Statute of Monopolies, recent reports considering reform of Australian patent law recognize that this requirement has served its purpose well and should remain as the touchstone of patentability. The High Court of Australia held that “[f]or a process to fall within the limits of patentability which the context of the Statute of Monopolies has supplied, it must be one that offers some advantage which is material in the sense that the process belongs to a useful art as distinct from a fine art, that its value to the country is in the field of economic endeavour.”

Section 18 of the Patents Act sets out both positive and negative definitions for eligible subject matter. The positive definition is “manner of manufacture” from the Statute of Monopolies and the negative definition provides that “[h]uman beings, and the biological processes for their generation, are not patentable inventions.” The Australian Patent Office Manual of Practice and Procedure (Patent Manual) includes a negative definition very similar to U.S. case law. It says that “mere ideas, mere schemes and plans, scientific theories and mathematical algorithms … have traditionally been regarded as not per se patentable, because they do not exhibit the requirements of a manner of manufacture.”

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64 21 Jam. 1, ch. 3 (1623)
65 Patents Act, 1990, ch. 83, § 18(1) (Austl.)
67 National Research Development Corporation v. Commissioner of Patents, 102 C.L.R. 252, 253 (1959)
68 Patents Act § 18(1)
69 Id. § 18(2)
71 Patent Manual § 2.9.2.5 Discoveries, Ideas, Scientific Theories, Schemes and Plans
Morality in Australian Patent Law

Australia while clearly recognizing moral limits to patenting such as human beings, shares the view of U.S. jurisprudence that judges should not interject their moral views into determinations of patent eligibility. Justice Finkelstein in the Australian case of Bristol-Myers Squibb v. F H Faulding & Co. Ltd. stated that: “Judges should not be called upon to resolve moral questions and, speaking generally, legal principles are not to be ascertained by reference to standards of ethics or morality.”72 This is very similar to the view expressed by Justice Berger in Chakrabarty.73 Even though the Statute of Monopolies74 has a general inconvenience exclusion that is incorporated into the Patents Act of 1990, and despite suggestions that this provision could be interpreted to require consideration of public policy or moral issues, “it seems unlikely that unless directed, the courts or the Patent Office would be willing to enter into such debates.”75

Genes and Nucleic Acid Sequences

In Australia, there is no court decision that explicitly considers whether gene sequences are inventions or discoveries.76 However, this issue was looked at by the Deputy Commissioner of Patents in Kirin-Amgen Inc v. Board of Regents of University of Washington77 during opposition proceedings against Kirin-Amgen's EPO patent. The Deputy Commissioner accepted that a claim directed to naturally-occurring DNA would likely be claiming no more than a discovery per se and not be a manner of manufacture. However, it was sufficient that the patent claimed a purified and isolated sequence. The

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72 (2000) 97 FCR 524, 559-60
73 447 U.S. at 315
74 § 6, 1623, 23 Jac 1, c 3
75 Dianne Nicol, On the Legality of Gene Patents, 29 Melb. U. L. Rev. 809
76 Id.
77 (1995) 33 IPR 557
court held that these claims did not extend to the naturally-occurring chromosome, or any other naturally-occurring entity. By being directed to a purified and isolated DNA sequence they claimed “an artificially created state of affairs,” even though a sequence itself was claimed.  

**Microorganisms**

Like all WTO member states, TRIPS obligates Australia to provide patent protection for microorganisms. A microorganism is patentable if it has been isolated from the natural environment, or has been synthetically or recombinantly produced. As in the U.S., an applicant must also show a utility for any microorganism in order to receive a patent under Australian Law.

**Human Embryonic Stem Cells**

Australian treatment of stem cell patent applications is unique. Because of the statutory prohibition on patenting human beings in §18(2) of the Patents Act, certain types of stem cell patents are prohibited while others are allowed. According to the Patent Manual, the key issue with when considering inventions that relate to human stem cells is “whether the stem cells are inherently capable of forming a human being. Totipotent stem cells can developed into a human being are not patentable, whereas pluripotent and multipotent stem cells (ones that can only form certain tissues) are patentable.”

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78 *Id.*
80 Patent Manual § 2.9.5.1 Stem Cells
inherently capable of forming a human being and thus not patentable under the Australian rational.

**Plants and Animals**

Australia recognizes a type of “petty-patent” called an “innovation patent” as well as a standard patent equivalent to a U.S. utility patent. For innovation patents “plants and animals, and the biological processes for the generation of plants and animals” other than microbiological processes are not patentable, but this exclusion does not apply to standard patents.\(^{81}\) The High Court of Australia confirmed the patentability of life forms as manners of new manufacture eligible for standard patents in *National Research Development Corporation v. Commissioner of Patents*.\(^{82}\)

**Medical Methods**

Australia is a jurisdiction that allows patents on medical methods. “It is Patent Office practice that no objection is to be taken to methods or processes for the treatment, medical or otherwise, of the human body or part of it, only on the basis that the human body is involved.”\(^{83}\) The Patent Manual points out to examiners that “[t]he approach of the PCT and in some foreign jurisdictions, such as the EU, is to treat inventions of this type as non-patentable subject matter.”\(^{84}\) The High Court of Australia found that a method of cosmetic treatment for the human body was inherently patentable because of its commercial significance.\(^{85}\) More recently, a High Court decision to allow a patent on

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81 *Id.* § 18(3) and § 18(4)
82 102 CLR 252. (1959)
83 Patent Manual § 2.9.2.13 Treatment of Human Beings
84 *Id.*
a method for administering an anticancer drug held that medical methods are inherently patentable in Australia.\footnote{86}{Bristol-Myers Squibb Company v. FH Faulding & Co. Ltd. 46 IPR 553 (2000)}

\section*{NEW ZEALAND}

\subsection*{Statutory Limits on Patent Eligible Subject Matter}

The patent law of New Zealand is very similar to Australian patent law. Both came from English common law and the courts in New Zealand will look to Australia for guidance when there is no New Zealand case law on an issue. The patent statute in New Zealand is the Patents Act of 1953. In recent years the Ministry of Economic Development has undertaken a review of patent law and released a draft patents bill in 2004.\footnote{87}{Charles Tansey and Gareth Dixon, \textit{Continuing Progress Toward New Zealand's New Patent Act}, IP News, January 2007, p. 6.} The draft bill is anticipated to pass into law in early 2008.\footnote{88}{Id.}

As in Australia, the law of New Zealand invokes section 6 of the English Statute of Monopolies in the definition of invention.\footnote{89}{The Patents Act 1953, § 2(1)} The Statute of Monopolies limits patent eligibility to only those things “not contrary to the law, nor mischievous to the state. . . or generally inconvenient.”\footnote{90}{21 Jam. 1, ch. 3 (1623)} The Commissioner of the Patent Office may also deny patents that are contrary to morality.\footnote{91}{The Patents Act 1953, § 17(1)}

\subsection*{Morality in New Zealand Patent Law}

The patent law itself explicitly allows for the rejection of an application on the basis of morality.\footnote{92}{Id.} When faced with an opportunity to allow patents on methods of
medical treatment of humans, the Court of Appeal deferred to the legislature for these types of policy choices. In a separate medical method case, the court recognized that New Zealand prohibits patenting of some subject matter solely upon policy and ethical grounds.

**Genes and Nucleic Acid Sequences**

Applications for patents on isolated genetic material removed from its natural state are allowed. Some had hoped that the upcoming revision of New Zealand’s Patent Act would exclude genetic material from patentability. The Ministry decided to continue allowing patents on genes and DNA because there is a large amount of material already patented and refusal to do so may be in conflict its TRIPS obligations. As in other nations, the hurdle in patenting genes is not the subject matter but rather meeting the requirements of novelty, inventiveness, sufficient and fair description in order to be a manner of new manufacture under the Statute of Monopolies.

**Microorganisms**

Memberships in the WTO obligates New Zealand to provide patent protection for microorganisms. Claims for microorganisms as they are found in nature are not allowed, but naturally-occurring microorganisms that have been isolated and altered are eligible for patenting. The a draft patents bill would require all microorganisms be submitted to a prescribed depository before filing an application.

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97 Draft for Consultation: Patents Bill § 37(3) and 38(1).
Human Embryonic Stem Cells

The patenting policy toward human embryonic stem cells is unclear.\textsuperscript{98} In New Zealand patents have issued with claims directed toward non-embryonic human stem cells, mammalian neural crest stem cells, and methods of obtaining embryonic stem cells.\textsuperscript{99} Neither the law nor policies of the Intellectual Property Office preclude patent applications for human embryonic stem cells. Even so, patents can be denied if the subject matter is generally inconvenient or contrary to morality.\textsuperscript{100} Since one survey found that about two-thirds of New Zealanders approve of using stem cells extracted from embryos to treat diseases is may be unlikely that a morality rational is used to reject patent applications for human embryonic stem cells.\textsuperscript{101}

Plants and Animals

In New Zealand, genetically modified plants and animals are patentable, but plants and animals as they occur naturally cannot be patented.\textsuperscript{102} One important exception is that genetically modified human beings are not patentable.\textsuperscript{103} Genetically modified parts (organs) of plants or animals are also acceptable subject matter for patents.\textsuperscript{104}

\textsuperscript{98} Stem Cell Research in New Zealand: Challenges and Opportunities for the Research Sector, Ministry of Research Science and Technology, December 2006.
\textsuperscript{99} See NZ 517002, “Multipotent adult stem cells and methods for isolation”, NZ 256154, “Mammalian multipotent neural stem cells”, and NZ 504784 “Pluripotent embryonic stem cells and methods of obtaining them”
\textsuperscript{100} The Patents Act 1953, § 17(1)
\textsuperscript{104} Id.
Medical Methods

Applications for medical methods to treat human suffering are not acceptable in New Zealand. The Court of Appeals in Pfizer Inc. v. Commissioner of Patents (New Zealand)\textsuperscript{105} upheld its ruling from two decades earlier in Wellcome Foundation Ltd. v. Commissioner of Patents\textsuperscript{106} that methods of treating illness or disease in humans are not patentable. The court in Pharmaceutical Management Agency Ltd. v. Commissioner of Patents\textsuperscript{107} noted activities in other jurisdictions such as the change in U.S. law to exempt medical practitioners from liability for patent infringement, and the language TRIPs permitting exceptions for diagnostic, therapeutic and surgical methods for the treatment of humans.\textsuperscript{108}

Some medical methods are patentable in New Zealand. New methods of treatment of animals (other than humans) are allowed.\textsuperscript{109} Claims to methods for treating humans are also allowed if the human is not ill; the condition is not an “illness” such as baldness, obesity, ageing, dandruff, and acne; the treatment is elective and does not target an illness such as treatments to quit smoking or contraception; the treatment kills bacteria on or in the body, or lice without treating the human itself; the active ingredient is in over-the-counter products like toothpaste; or the treatment is part of health and hygiene products.\textsuperscript{110} This policy puts New Zealand in position of using the patent system to encourage innovation for methods of treating relatively minor ailments like baldness but not for major illness like cancer.

\textsuperscript{105} (2004) 60 IPR 624
\textsuperscript{106} (1983) NZLR 385
\textsuperscript{107} (2000) 2 NZLR 529
\textsuperscript{108} Id. at para. 28
\textsuperscript{109} Swift and Co. v. Commissioner of Patents, [1960] NZLR 775
\textsuperscript{110} The Commissioner of Patents v. The Wellcome Foundation Ltd., (1983) FSR 593
The scope of patentable subject matters for these common law countries varies depending on each jurisdiction’s rules and policy concerns. Generally, patentable subject matter must possess utility (industrial applicability), novelty and non-obviousness in all jurisdictions. Compared to other countries, the U.S. has the most liberal standard on patent eligible subject matter. The statute and case law provide that almost all useful subject matter, even the most controversial human embryonic cells are patentable. This is consistent with the spirit of the U.S. Constitution to “promote the progress of science and useful arts.”

Similar to the U.S., Australia also has a broad scope of patentable subject matters. The only restrictions in the Australian Patent Law are on patenting human beings and the biological processes of creating them. Accordingly, totipotent human embryonic stem cells, because of the potential to develop into a human being, are unpatentable in Australia. However, Australia does not prohibit the patentability of human pluripotent or multipotent embryonic stem cells. In Canada, there is a strong policy against patenting both human and non-human higher life forms. Accordingly, higher life forms (plants and animals) cannot be patented in Canada. An example is the Harvard oncomouse, for the Canadian Supreme Court denied a patent because it was not patentable subject matter. In addition, the case law in Canada provides that surgical methods cannot be patented in Canada, as that is neither an art nor a process. One possible explanation for greater restrictions in Canada may be the influence of the French civil law tradition.

111 Art. I §8 c 8
In summary, all of the common law jurisdictions examined here permit patent protection on genes and DNA as well as microorganisms. Plant and animal patents are granted in the U.S., Australia, and New Zealand but are disallowed in Canada. Surgical and medical methods are eligible for patents in the U.S. and Australia but not in other jurisdictions. Human embryonic cells are patentable in all jurisdictions, except for a prohibition on patenting totipotent stem cells in Australia.

**Proposed Changes to Existing 35 U.S.C. §101**

This comparison of common law jurisdictions, suggests ways to clarify the scope of patentable subject matter under U.S. law by a modification of 35 U.S.C. §101 which incorporates the rules from other jurisdictions and U.S. case law. The goals with the proposed changes are multifold:

1. to promote development of biotechnology by maintaining a broad definition of eligible subject matter and maintaining the predictability of the current patent law;

2. to harmonize the patent laws regarding subject matters with other jurisdictions by recognizing value judgments inherent in the use of biotechnology, and using other aspects of patent law such as enablement, utility, and written description to exclude a subject matter from patent protection when appropriate.

With these goals in mind, it is proposed to amend 35 U.S.C. §101 to read:

(a) Whoever invents or discovers any process, machine, manufacture, or composition of matter, or any improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
(b) Excluded from patent protection are laws of nature, physical phenomenon and abstract ideas and, any invention that is injurious to the morals, the health, or the good order of society.

While the current 35 U.S.C. §101 provides a only a positive definition for eligible subject matter, this proposal includes a negative definition similar to the draft SPLT. Addition of this negative definition as §101(b) is not intended to change U.S. law substantially. It would only codify exceptions the U.S. Supreme Court identified in Chakrabarty, and morality concerns expressed by federal courts as part of utility analysis. Adding morality to the statute will give the U.S. greater currency in negotiating for substantive patent law harmonization. A finely tuned morality provision was codified in Article 6 in the Biotech Directive in 1999, so Europe will likely remain committed to morality checks in patent law. This proposed change will show the importance the U.S. places on harmonizing with other nations.

Morality is an important part of regulating biotechnology beyond just the patent law. When expressly included in the law, morality is framed differently in each country. Often moral views are not concretely written down in statutes. Morality may be one of the most difficult issues to harmonize because it is tied to the culture and beliefs of a nation. This proposal to include “morals” and “good order of society” into the U.S. patent law will show a recognition of the issue while still allowing the USPTO and U.S. courts flexibility when interpreting the law. Allowing the USPTO and courts to make case-by-case patentability decisions on the basis of morality would exceed a straight interpretation of what the law is. This might trouble some who feel that moral judgments should be made by the legislature not by courts or administrative agencies. This is a reasonable

112 Art. 12
concern. The courts and the USPTO have already shown a willingness to reject some patents on the basis of morality. It is better to explicit reject a patent on moral grounds than to reach the same end through a tortured interpretation of patentability requirements such as obviousness or enablement.

This proposal can be characterized as a “tweaking” rather than a reworking of the U.S. standard for patent eligible subject matter. The proposed changes are not major, but recognizing morality does validate the concerns many inside and outside the U.S. have about biotechnology. Current U.S. law is correct in allowing a broad class of biotechnological inventions to receive consideration for patenting. A broad definition of eligible subject matter is the correct approach because patents provide only a right to exclude not a right to exploit or practice an invention. The U.S. should continue to push for other nations to adopt broader definitions of patent eligible subject matter through TRIP-plus bilateral treaties and international harmonization efforts. The first hurdle to get in the door of a patent office should be set low. Biotechnology invention applications can be rejected for many reasons other than subject matter ineligibility. Each application should be judged on its novelty, nonobviousness and, if appropriate, morality. Furthermore, even if a jurisdiction allows patenting it can prohibit exploitation of the patent through other laws or prevent enforcement of the patent as the U.S. does with medical method patents. Minor changes to current U.S. law that incorporate existing common law limitations on patent eligible subject matter into §101 will clarify U.S. law and provide a meaningful gesture to other nations as all jurisdictions continue the slow march towards substantive patent law harmonization.