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Adam Crane

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# OF MICE AND “MAN”: PATENTABILITY OF GENETIC MATERIAL AND THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

ADAM CRANE<sup>†</sup>

*The patenting of genetic material raises a host of concerns such as moral and ethical issues, the weakening of the utility requirement and the blockage of downstream research. This article examines the patentability of genetic material in the United States, Canada and the European Union. It discusses the advantages and disadvantages of the current patent system in relation to patents on genetic material. The article concludes with suggestions regarding the protection of intellectual property rights in light of growing concerns.*

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<sup>†</sup> Adam Crane, B.A. (Acadia), LL.B. Candidate (2010) (Dalhousie). Adam would like to thank Professor Graham Reynolds and Professor Chidi Oguamanam for their inspiration and advice in preparation of this article. He would like to note that any shortcomings of the article are his own.

## INTRODUCTION

The biotechnology industry is still in its infancy, with many breakthroughs on the horizon. However, even in its early stages, we have witnessed many improvements in technology such as cloning and the mapping of the human genome under the Human Genome Project. The boom in the biotechnology industry is considered by many to have been ignited by the decision of the Supreme Court of the United States in *Diamond v. Chakrabarty*.<sup>1</sup> This growth within the biotechnology industry, especially in regards to patenting genetic material, has caused many people to criticize the current patent system. The system is being strained by recent developments in technology that were never initially contemplated. Ikechi Mgbeoji and Byron Allen have stated that “the patent system was not originally designed for protection of life forms. Rather, early patent systems... were dominated almost exclusively by machines and mechanical devices.”<sup>2</sup> They also mention that “as early industrialization evolved from machines and extended to chemicals, pharmaceuticals, and lately, biotechnology, the patent regime expanded its scope of patentable subject-matter to accommodate the claims of those emergent industries.”<sup>3</sup>

The intent of this paper is to examine the patentability of genetic material in the United States, Canada and the European Union and to discuss the advantages and disadvantages of the current patent system in relation to biotechnology. In the first section of this paper, relevant terminology will be defined and discussed to provide a technical background. Section II will examine the patentability of genetic material in the United States, Canada and the European Union through relevant jurisprudence and legislation. Concerns regarding patents on genetic materials will be examined in the third section. These concerns include moral and ethical issues, the

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1 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) [*Chakrabarty*].

2 Ikechi Mgbeoji & Byron Allen, “Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research” (2003) 2 C.J.L.T. 83 at 85.

3 *Ibid.* at 85.

weakening of the utility requirement for patentability and the blocking of downstream research and development. The fourth section will cover arguments in support of granting patents on genetic material, focusing on the need for patent protection to increase research and development. The fifth section will examine possible solutions to issues proposed in section III, in order to reconcile those concerns with the protection of biotechnology products and processes.

In addition to these concerns, there are other highly contentious issues surrounding biotechnological patents, such as the appropriation of indigenous knowledge and the genetic use restriction of agricultural products. These issues are beyond the scope of this paper and so will not be covered in this analysis. Detailed discussions of these issues may be found in academic commentary elsewhere.<sup>4</sup>

## I. BACKGROUND

Before engaging in a discussion dealing with highly technical terms, it is important to initially define the relevant terminology. For the purpose of this paper, *genetic material* includes “a gene, part of a gene, a group of genes, or fragment of many genes, a molecule of DNA, a fragment of DNA, a group of DNA molecules, or fragments of DNA molecules” and “[c]ould refer to anything from a small fragment of DNA to the entire genome of an organism.”<sup>5</sup> A *biotechnological innovation/invention* will include the

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4 For a detailed discussion on the appropriation of indigenous knowledge, see: Ikechi Mgbeoji, “Patents and Traditional Knowledge of the Uses of Plants: Is a Communal Patent Regime Part of the Solution to the Scourge of Bio-Piracy?” (2001) 9 *Ind. J. Global Legal Stud.* 163. For a detailed discussion on the genetic use restriction of agricultural products, see: Chidi Oguamanam, “Genetic Use Restriction (or Terminator) Technologies (GURTs) in Agricultural Biotechnology: The Limits of Technological Alternatives to Intellectual Property” (2005) 4:1 *C.J.L.T.* 59.

5 Biology Online, *Genetic Material*, online: Biology Online < [http://www.biology-online.org/dictionary/Genetic\\_material](http://www.biology-online.org/dictionary/Genetic_material)>.

production or processing of the genetic material outlined in the definition of genetic material.<sup>6</sup> Such innovations may take many forms, whether it be the development of a genetic test for diseases or the isolation and purification of genetic material. As will be discussed throughout this paper, patents on genetic sequences are quite controversial. A genetic sequence (also referred to as a DNA sequence) is “the precise ordering of the bases (A, T, G, C) from which DNA is composed.”<sup>7</sup> The following is an example of a genetic sequence:

AATGCTGATTTTGATGGA

The function of a genetic sequence is often unknown to scientists at the time of patent application.<sup>8</sup> This will be examined in section III under the lack of utility requirement.

Other forms of genetic material that will be covered throughout this paper include expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs). Patents have been granted on these materials in the United States, Canada and the European Union.<sup>9</sup> ESTs are defined as “a tiny portion of an entire gene that can be used to help identify unknown genes and to map their positions within a genome.”<sup>10</sup> They have aided scientists to discover and isolate genes that are involved with many diseases, including colon cancer and Alzheimer’s disease.<sup>11</sup> It is thus obvious that ESTs are important to assist with the research and development of innovative medicines and treatments. SNPs are also important in the identification of genetic diseases. They involve a variation

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6 Mona Frendo, “Intellectual Property Protection for Biological Innovations” (January 2001) online: Canadian Biotechnology Advisory Committee < <http://strategis.ic.gc.ca/epic/site/cbac-cccb.nsf/en/ah00417e.html>>.

7 *Webster’s New World Medical Dictionary*, 2d ed. (Hoboken, NJ: Wiley, 2003) s.v. “DNA sequence”.

8 Mgbeoji & Allen, *supra* note 2 at 86.

9 *Ibid.*

10 A Science Primer, *Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, ESTs: Gene Discovery Made Easier*, online: National Center for Biotechnology Information

< <http://www.ncbi.nlm.nih.gov/About/primer/est.html>>.

11 *Ibid.*

within a gene that can be linked to the development of certain diseases. Researchers believe that a genetic predisposition to a disease is not caused by one single nucleotide variation; however, SNPs over stretches of DNA may allow them to associate an SNP with a particular disease trait.<sup>12</sup> It is also believed that SNPs are “useful in helping researchers determine and understand why individuals differ in their ability to absorb drugs.... Therefore, the recent discovery of SNPs promises to revolutionize not only the process of disease detection but also the practice of preventive and curative medicine.”<sup>13</sup> Other technical terms are included throughout this paper and are defined in their relevant sections.

## II. PATENTABILITY OF GENETIC MATERIAL IN THE UNITED STATES, CANADA AND THE EUROPEAN UNION

### A. PATENTABILITY OF GENETIC MATERIAL IN THE UNITED STATES

In the United States, patentable subject matter is covered under the U.S. Patent Act, Title 35, § 101.<sup>14</sup> This section states that “[w]hoever invents or discovers any new or 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.”<sup>15</sup> This is, of course, subject to the requirements of novelty, non-obviousness and utility. These three requirements are not unique to the United States; they are a common feature of patent laws throughout the world. This section will focus on the development of U.S. patent law in relation to the patentability of genetic material through examining

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12 A Science Primer, *Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, SNPs: Variations on a Theme*, online: National Center for Biotechnology Information

< <http://www.ncbi.nlm.nih.gov/About/primer/snps.html>>.

13 *Ibid.*

14 35 U.S.C. § 101.

15 *Ibid.*

the groundbreaking *Diamond v. Chakrabarty* case, as well as patent applications for the Harvard Oncomouse and an invention of a half-human, half-animal creature.

### 1. Anything Under the Sun Made by Man

The leading case in the United States regarding patentable subject matter is *Diamond v. Chakrabarty*. Ananda Mohan Chakrabarty, a genetic engineer working for General Electric, developed a micro-organism that possessed the ability to decompose crude oil. Mr. Chakrabarty applied for a patent but was initially rejected by the United States Patent and Trademark Office (USPTO) and by the Board of Patent Appeals and Interferences on appeal. He then appealed to the United States Court of Customs and Patent Appeals. The Court allowed the appeal; however, the Commissioner of Patents and Trademarks appealed to the Supreme Court of the United States. In a 5-4 decision in 1980, the Court affirmed the previous decision and held that “[a] live, human-made micro-organism is patentable subject matter under § 101. [The] respondent’s micro-organism constitutes a ‘manufacture’ or ‘composition of matter’ within that statute.”<sup>16</sup> In its decision, the Court held that when codifying the U.S. patent laws in 1952, congress intended patentable subject matter to include “anything under the sun that is made by man.”<sup>17</sup> The decision in *Chakrabarty* caused great controversy throughout the biotechnology industry and academia. Many people criticized the decision by arguing that it would not provide a barrier to the patenting of “higher forms of life – such as plants, animals, and possibly human beings.”<sup>18</sup> The following two paragraphs will examine two applications of the *Chakrabarty* standard: one where the USPTO granted a patent on a mouse, and another where it denied a patent on human beings.

### 2. Mice, Man and Humanzee?

In 1988, the USPTO granted a patent to Harvard College for the Harvard Oncomouse. An Oncomouse is a transgenic mouse that has been genetically

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<sup>16</sup> *Chakrabarty*, *supra* note 1.

<sup>17</sup> *Ibid.*

<sup>18</sup> Daniel J. Kelves & Ari Berkowitz, “The Gene Patenting Controversy: A Convergence of Law, Economic Interests, and Ethics” (2002) 67 *Brook. L. Rev.* 233 at 234.

modified to carry an oncogene (a gene that contributes to the development of cancer) in order to further cancer research.<sup>19</sup> Genetically manipulating animals raises a host of ethical questions such as animal cruelty, as well as raising the issue of whether the patent meets the requirements of novelty, non-obviousness and utility. In coming to its conclusion, it appears that the USPTO did not consider ethical issues to be a relevant factor. Nonetheless, the USPTO ruled that humans would be excluded from patentability because of “moral and legal concerns about patents on human beings, and about modification of the human genome.”<sup>20</sup> The subsequent sections dealing with patentability of genetic material in Canada and the European Union will demonstrate how the Oncomouse patent application received more scrutiny in those respective jurisdictions than it did in the United States.

In an attempt to spur the debate on morality of biotechnology, social activist Jeremy Rifkin and scientist Stuart Newman subsequently applied for patent protection for the invention of a half-human, half-animal labelled the “Humanzee.”<sup>21</sup> In 1998, the USPTO issued one of its many rejections on the basis that the claim “embraced a human being”, therefore, rendering its subject matter unpatentable.<sup>22</sup> The USPTO issued the following statement in one rejection of the invention:

The presence of some nonhuman primate cells does not make a human embryo nonhuman... Contrary to the argument that the claimed animal was never exclusively human in origin, i.e., that the chimeric embryo never existed as a human embryo, the specification states: “the invention relates to chimeric embryos and chimeric animals created from human embryos.”... The Office does not agree that humans are patentable subject matter.<sup>23</sup>

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19 WIPO Magazine, “Bioethics and Patent Law: The Case of the Oncomouse” *WIPO* (June 2006), online: WIPO <[http://www.wipo.int/wipo\\_magazine/en/2006/03/article\\_0006.html](http://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html)>.

20 *Ibid.*

21 Brock Heathcotte & Jason Scott Robert, “The Strange Case of the Humanzee Patent Quest” (2006) *National Catholic Bioethics Quarterly* 51 at 52.

22 *Ibid.* at 53.

23 *Ibid.* at 53.

A chimera is an animal with genetic material from two or more species. Combining genetic material from a human and an animal is clearly an ethical concern. The decisions by the USPTO in both the Harvard Oncomouse and Humanzee patent applications demonstrate that patentable subject matter does not extend to human beings. Through an examination of those patent applications, as well as the Supreme Court’s ruling in *Chakrabarty*, it is evident that patentable subject matter under U.S. patent law includes the fundamental building blocks of genetic material, including gene sequences, ESTs, SNPs and higher life forms such as plants and animals.

### **B. PATENTABLE SUBJECT MATTER: THE CANADIAN DEBATE**

Canadian patent law is governed by the *Patent Act*.<sup>24</sup> Section 2 of the Act outlines patentable subject matter; it states that an “‘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.”<sup>25</sup> As in the U.S., in order to be granted a patent in Canada, an invention must be novel and non-obvious, and must have utility. The Canadian *Patent Act* is similar to U.S. patent law under Title 35; however, Canada and the U.S. have different conceptions of acceptable patentable subject matter. The difference in the patentability of genetic material will be examined by exploring Canadian jurisprudence. The two major cases that have outlined patentable subject matter in Canada are *Harvard College v. Canada (Commissioner of Patents)*<sup>26</sup> and *Monsanto Canada Inc. v. Schmeiser*.<sup>27</sup>

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24 *Patent Act*, R.S.C. 1985, c. P-4.

25 *Ibid.* at s. 2.

26 *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45 [*Harvard College*].

27 *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 [*Monsanto*].

## 1. Higher Life Forms vs. Lower Life Forms

The *Harvard College* case resulted from the rejection of the patent application for the Harvard Oncomouse by the Canadian Patent Office. The decision was appealed to the Federal Court of Appeal where the appeal was allowed; however, that decision was appealed to the Supreme Court of Canada (SCC).<sup>28</sup> In a 5-4 decision, the SCC overturned the Federal Court of Appeal's decision and rejected the patent. The SCC held that the transgenic mouse constituted a higher life form and that higher life forms are not patentable subject matter under the s. 2 definition of inventions, thereby departing from the U.S. position.<sup>29</sup> Justice Bastarache, for the majority, held that he:

[C]annot...agree with the suggestion that the definition is unlimited in the sense that it includes "anything under the sun that is made by man". In drafting the *Patent Act*, Parliament chose to adopt an exhaustive definition that limits invention to any "art, process, machine, manufacture or composition of matter". Parliament did not define "invention" as "anything new and useful made by man". By choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act. This should be kept in mind when determining whether the words "manufacture" and "composition of matter" include higher life forms.<sup>30</sup>

The majority held that "the Court does not possess the institutional competence to deal with issues of this complexity" and that it should be up to Parliament to decide whether higher life forms may be patented.<sup>31</sup>

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28 WIPO, *supra* note 19.

29 *Harvard College*, *supra* note 26.

30 *Ibid.* at para. 158.

31 *Ibid.* at para. 183.

The dissenting judges agreed with the majority that the decision to include higher life forms under patentable subject matter should be left to Parliament. However, they stated that “neither the Commissioner of Patents nor the Court have the authority to declare, in effect, a moratorium on [higher] life form patents until Parliament chooses to act.”<sup>32</sup> The dissent found no requirement in the *Patent Act* for examining public order and morality, nor any provisions excluding the patentability of higher life forms.

## 2. In Reverse, but not Reversal

The dissent in *Harvard College* paved the way for the SCC’s backtracking in *Monsanto*. In this case, Monsanto Canada Inc. (Monsanto) sued farmer Percy Schmeiser over his unlicensed use of Monsanto’s seed which was marketed as Roundup Ready Canola. The seed contained a gene patented by Monsanto that aids in controlling weeds because it prevents crops from being damaged by certain herbicides. In *Monsanto* the SCC split 5-4 and found that Mr. Schmeiser infringed Monsanto’s patent under s. 42 of the *Patent Act*. The essence of the majority decision was that even though a higher life form cannot be patented, the patent protection for the genetic material that makes up the higher life form may extend to protect the higher life form itself. The Court’s decision in *Monsanto* therefore marked a departure from the Court’s line of reasoning in *Harvard College*. However, it was not a reversal of its previous decision, at least in the eyes of the Court. One of the reasons for the Court’s departure may have been its change of personnel. Justices Gonthier and L’Heureux-Dubé of the majority in *Harvard College* had retired from the Court, while Justices Fish and Deschamps joined the Court and aligned with majority in *Monsanto*.

The current position on the patentability of genetic material is that higher life forms still cannot be patented but the “fundamental building blocks of the human body – DNA, RNA, proteins and genes – can be patented in Canada if they meet the statutory criteria of novelty, utility and non-obviousness.”<sup>33</sup> In order to receive a patent on a genetic sequence, it must

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32 *Ibid.* at para. 114.

33 Frenco, *supra* note 6.

be isolated or purified from its natural source within the body and it must meet the requirements for non-obviousness and utility.<sup>34</sup> This position was upheld in the Federal Court of Appeal decision in *Harvard College* and was affirmed upon appeal to the SCC; it was also upheld in the SCC's decision in *Monsanto*.

### **C. PATENTING OF GENETIC MATERIAL IN THE EUROPEAN UNION: A MORAL DECISION?**

The patenting of genetic material in the European Union has been quite controversial. As in Canada and the U.S., one of the most controversial patent applications has been for the Harvard Oncomouse. As discussed above, the patent had previously been granted in the United States and would later be rejected in Canada. Harvard College filed a patent application in 1985. The application was rejected by the European Patent Office (EPO) in 1989 on numerous grounds, one of them being a "European prohibition against the patenting of animals."<sup>35</sup> The Oncomouse patent was not initially rejected for being contrary to "ordre public" or morality under article 53(a) of the *European Patent Convention (EPC)*. Article 53(a) states that:

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 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.<sup>36</sup>

The decision by the Examining Division of the EPO was appealed to the Board of Appeals, where the Board decided that the Examining Division

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34 *Ibid.*

35 Baruch Brody, "Intellectual Property and Biotechnology: The European Debate" (2007) 17:2 Kennedy Institute of Ethics Journal 69 at 91.

36 Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, 13 I.L.M. 268, Article 53.

erred in rejecting the Oncomouse patent.<sup>37</sup> The Board of Appeal sent the case back to the Examining Division in 1992 and provided it with a three part test to examine the patentability issue in order to reconcile it with Article 53 of the *EPC*. The test consisted of the balancing of risks and detrimental effects associated with an invention against its benefits. The three interests the Examining Division considered were: “(1) the interest in remedying human disease, (2) the interest in protecting the environment from the uncontrolled spread of unwanted genes, and (3) the interest in avoiding cruelty to animals.”<sup>38</sup> In 1992, the Examining Division granted the patent on the transgenic mouse stating that:

In the overall balance the Examining Division concluded that the present invention cannot be considered immoral and contrary to public order. The provision of a type of test animal useful in cancer research and giving rise to a reduction in the amount of testing on animals... can generally be regarded as being beneficial to mankind.<sup>39</sup>

Over the next 12 years, the Examining Division’s decision was challenged on numerous occasions. In July 2004, the EPO issued its final decision on the Harvard Oncomouse patent by upholding the patent, but limiting it to mice.<sup>40</sup> Throughout the time period that the Oncomouse patent was challenged, the European Parliament and European Council worked on a biotechnology directive to address the patentability of biotechnological inventions, including genetic material. This directive will be examined in what follows.

### **1. European Biotechnology Directive, 98/44/EC**

On July 6, 1998, the European Parliament and European Council issued the *European Directive 98/44/EC on the Legal Protection of Biotechnological*

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37 Brody, *supra* note 35 at 91.

38 Margo A. Bagley, “Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law” (2003) 45 *Wm. & Mary L. Rev.* 469 at 520.

39 Jaenichen, H., *The European Patent Office’s Case Law on the Patentability of Biotechnology Inventions*, (Köln: Carl Heymanns Verlag, 1993), cited in Brody, *supra* note 44 at 94.

40 Brody, *supra* note 35 at 98.

*Inventions*.<sup>41</sup> The issuance of the *Directive* was met with criticism by many of the EU member states. Within three months, the government of the Netherlands challenged the *Directive*. It argued that the *Directive* should be annulled because it was too vague regarding whether patents would be denied based on ethical grounds. It also argued that the *Directive* allowed patents to be granted on isolated genetic material, which it considered to be a violation of human dignity.<sup>42</sup> In 2001, the European Court of Justice (ECJ) rejected the Dutch government's challenge, confirming the validity of the *Directive* and stating that both Article 5 and Article 6 of the *Directive* addressed Dutch concerns about human dignity and public morality.<sup>43</sup> The Court acknowledged that Article 5 appropriately addresses the concerns about human dignity by excluding certain elements of the human body from patentability:<sup>44</sup>

#### Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequences or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequences of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application.<sup>45</sup>

Article 6 of the *Directive* was aimed at giving effect to ethical concerns

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41 Council Directive (EC) 98/44 of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L213/13 [*Directive*].

42 Duncan Curley and Andrew Sharples, "Patenting Biotechnology in Europe: The Ethical Debate Moves On" (2002) 12 Eur. I.P. Rev. 565 at 565-566.

43 Conference Report, "The Trials and Tribulations of the Biotech Patent Directive" *Academy of European Law* (July 2006), online: Academy of European Law <[http://www.era.int/web/de/resources/5\\_1095\\_2867\\_file\\_en.3961.pdf](http://www.era.int/web/de/resources/5_1095_2867_file_en.3961.pdf)>.

44 *Ibid.*

45 *Directive*, *supra* note 41 at Article 5.

about the patenting of certain genetic material:

#### Article 6

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
  - (a) processes for cloning human beings;
  - (b) processes for modifying the germ line genetic identity of human beings;
  - (c) uses of human embryos for industrial or commercial purposes;
  - (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.<sup>46</sup>

Despite the ECJ ruling, the *Directive* remained controversial. By 2003, only eleven European Union member states had adopted the *Directive*.<sup>47</sup> France initially refused to adopt the *Directive* because of concerns over the patentability of genetic sequences without actual proof of their utility.<sup>48</sup> However, in 2004, both France and the Netherlands, two of the most vocal of the opponents to the *Directive*, implemented the *Directive* into their national patent law.<sup>49</sup> Despite the reluctance by many of the nations over concerns about morality and utility, all European Union members had

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46 *Ibid.* at Article 6.

47 European Commission, “State of Play of the Implementation of Directive 98/44/EC” (15 January 2007), online: European Commission < [http://ec.europa.eu/internal\\_market/indprop/docs/invent/state-of-play\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/invent/state-of-play_en.pdf)>.

48 Matthias Herdegen, *Patenting Human Genes and Other Parts of the Human Body under EC Biotechnology Directive*, online: Pharmedicalensing.com < [http://pharmedicalensing.com/public/articles/view/1008262393\\_3c18dcf915ce1](http://pharmedicalensing.com/public/articles/view/1008262393_3c18dcf915ce1)>.

49 European Commission, *supra* note 47.

adopted the *Directive* by 2007.<sup>50</sup>

### III. CONCERNS REGARDING THE PATENTING OF GENETIC MATERIAL

Altering the genetic make-up of humans, animals and plants raises many ethical issues. In an article published in the *Ottawa Citizen* in 1994, “The Biology Business,” some of the general concerns that were raised include the threat of “genetic accidents,” the use of animals in research experimentation, genetic discrimination and the patenting of animal species or genes.<sup>51</sup> As mentioned previously, some of these concerns are considered during the patent assessment process in the European Union. On a deeper level, many more issues arise when addressing the question of the patentability of genetic material. Some major concerns regarding include the weakening of the utility requirement, the question of whether such patents are contrary to morality, and the concern that granting patents on genetic material will hinder biotechnological research rather than advance it.

#### A. WEAKENING OF THE UTILITY REQUIREMENT

One major concern regarding the patentability of genetic materials is that patents may be issued without fully satisfying the utility requirement. There is a “growing concern among patent lawyers and policy-makers that the major patent offices of the world are relatively lax and permissive in issuing patents on biotechnological products without showing demonstrable utility.”<sup>52</sup> As mentioned previously, this was one of the many

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50 *Ibid.*

51 “The Biology Business” *The Ottawa Citizen* (8 January 1994), cited in Hartley Gorenstein, “The Regulation of Biotechnology in Canada: Social and Moral Issues” (1996) 2 *Medical Law International* 169, at 176-177.

52 Mgbeoji & Allen, *supra* note 2 at 83.

complaints that EU member nations made about the *Directive*. If one were to compare patents on mechanical and biotechnological inventions, it is arguable that biotechnological patents are examined more favourably when it comes to meeting the utility requirement. Mgbeoji and Allen suggest that “[i]t is common knowledge that the patent offices would not issue patents to mechanical inventions of dubious or uncertain utility. There is no reason why a comparative attitude or stance should not be interpreted with respect of genetic patents.”<sup>53</sup>

Patents on genetic sequences as well as ESTs and SNPs have been granted in the United States, Canada and other international jurisdictions. Many of these patents have been granted without fully meeting the utility requirement. Patent offices have granted patents based on the homology of a sequence rather than a proven use.<sup>54</sup> Homology refers to the similarity between two distinct things based on their common origin.<sup>55</sup> In relation to genetic sequence patents, a patent would be issued on a genetic sequence based on its being homologous to another sequence that has a specific use. One reason why these patents may not meet the utility requirements is that “a difference in a single base pair in a gene sequence can have important functional implications.”<sup>56</sup> There has been some effort to reiterate the importance for a genetic material invention to have a specific utility before receiving patent protection. Article 5(3) of the *Directive* addresses the issue of genetic sequences by stating that the industrial application must be disclosed in the patent application. However, many efforts like these have failed in preventing the granting of patents that lack utility.

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53 *Ibid.* at 90.

54 *Ibid.* at 86.

55 *Dictionary.com*, s.v. “homology”, online: Dictionary.com <<http://dictionary.reference.com/browse/homology>>.

56 David Dickson, “NIH Opposes Plans for Patenting ‘Similar’ Gene Sequences” (2002) 405 *Nature* 3, cited in Mgbeoji & Allen, *supra* note 2 at 86.

## B. CONTRARY TO PUBLIC MORALITY

This concern is perhaps the most widely published in relation to the patentability of genetic material. Both proponents and opponents of genetic biotechnology recognize that a host of ethical issues arise. Harley Gorenstein suggested that “[t]he rapid advancement of biotechnology raises profound questions about how society will deal with social, moral, environmental and ethical issues arising from new and powerful techniques to manipulate life.”<sup>57</sup> Margo Bagley points out in her article, “Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law,” that there are no statutory morality requirements under U.S. patent law and that the patent system is one of “patent first, ask questions later.”<sup>58</sup> She recommends that a new system should be adopted to deal with the ethical concerns of genetic material patents. Despite the concerns that have arisen over the past thirty years, patent offices around the world have “continued to award patent rights over DNA sequences and other products of biotechnology while [the] academic and social debate [continues to] rage.”<sup>59</sup>

## C. GENETIC MATERIAL PATENTS:

### “A TRAGEDY OF THE ANTICOMMONS”<sup>60</sup>

One of the greatest concerns associated with patenting genetic material, especially the fundamental building blocks of the human genome including DNA sequences and ESTs, is the possible concomitant restriction on downstream research and development. These types of basic genetic material can be viewed as the platform for biotechnological research. The

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57 Harley Gorenstein, “The Regulation of Biotechnology in Canada: Social and Moral Issues” (1996) 2 *Medical Law International* 169 at 169.

58 Bagley, *supra* note 38 at 494.

59 Richard E. Gold & Alain Galloch, “The European *Biotech Directive*: Past As Prologue” (2001) 7 *Eur. L.J.* 331, cited in Richard E. Gold, “From Theory to Practice: Health Care and the Patent System” (2003) *Health L.J. Special Edition* 21 at 30.

60 The phrase “A Tragedy of the Anticommons” was established in an article by Michael A. Heller, “The Tragedy of the Anticommons: Property in the Transition from Marx to Markets” (1998) 111 *Harv. L. Rev.* 621, then used by Michael Heller and Rebecca Eisenberg in an article titled “Can Patents Deter Innovation? The Anticommons in Biomedical Research” (1998) 280:5363 *Science* 698.

material once existed under a commons model, meaning many researchers had relatively unrestricted access to it. However, the commons model for biotechnological research that existed in the second half of the 20<sup>th</sup> century has been pushed aside in favour of the current privatized system of biotechnological research.<sup>61</sup> This section will examine the anticommons theory and how it relates to the patenting of genetic material.

In an article titled, “Can Patents Deter Innovation? The Anticommons in Biomedical Research,” Michael Heller and Rebecca Eisenberg discuss a theory put forward by Garret Hardin, which stated that a “tragedy of the commons” occurs when there is an overuse of common resources.<sup>62</sup> On the contrary, the anticommons involves the underuse of a scarce resource because too many people have been granted an exclusive right and have the ability to prevent its use by others.<sup>63</sup> The tragedy of the anticommons has become a more pressing concern because of the shift from the commons model to a privatized scheme marked by private investment rather than governmental sponsorship.<sup>64</sup> More funding is received by the biotechnology firms because of the privatization of the industry. However, “privatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research.”<sup>65</sup>

As mentioned in the introduction to this section, the obstacle caused by patenting genetic material is that downstream technology and improvements may be prevented because exclusive patents are granted on platform innovations. One example of the effects on downstream research is a phenomenon known as a patent thicket, which involves “[a]n overlapping set of patent rights requiring those seeking to commercialize new technology [to] obtain licenses from multiple patentees.”<sup>66</sup> The problem caused by patent thickets is that it may be too costly to obtain licenses from each firm that

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61 Mgbeoji & Allen, *supra* note 2 at 88.

62 Heller & Eisenberg, *supra* note 60 at 698.

63 *Ibid.*

64 *Ibid.*

65 *Ibid.*

66 Cambridge Health Institute, “Biopharmaceutical Law & Intellectual Property Glossary and Taxonomy” (22 October 2007), online: Cambridge Health Institute <[http://www.genomicglossaries.com/content/intellectual\\_property.asp](http://www.genomicglossaries.com/content/intellectual_property.asp)>.

owns individual patents. Innovative products are delayed due to licensing issues. Not only does the tragedy of the anticommons have an effect on the commercialization of revolutionary medicines; it also has an effect on applied research. Researchers may be less willing to conduct research in areas that are covered by patents.<sup>67</sup> Another issue that occurs is that many laboratories are prevented from performing tests to discover genetic diseases or the predisposition to those diseases because it is too costly.<sup>68</sup> Solutions to these problems are examined in section V.

#### IV. IMPORTANCE OF GENETIC MATERIAL PATENTS

Notwithstanding concerns over the patenting of genetic material, the patent system was developed as a reward system to promote innovation. Innovation in biotechnology has the potential to lead to groundbreaking inventions that may contribute to improved health care and human development. Schulman suggested that “[w]hile patenting DNA runs the risk of diminishing respect for human dignity, some risk might be acceptable if the end result were an increase in human well-being.”<sup>69</sup> This was the result that can be seen in the Harvard Oncomouse patent case examined by the EPO. Ethical concerns may be overlooked if the benefit to mankind outweighs the detrimental effects of a certain invention. Additionally, it is believed that without the reward conferred by patent protection of genetic material, investors would be reluctant to invest in biotechnological and pharmaceutical firms for the development of new technologies and drugs.<sup>70</sup> This would have an unfavourable effect on society. However, this does not mean that ethical and developmental

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67 Mgbeoji & Allen, *supra* note 2 at 87.

68 *Ibid.*

69 Miriam Schulman, “Of SNPS, TRIPS and Human Dignity: Ethics and Gene Patenting” *Markkula Center for Applied Ethics* online: Santa Clara University <<http://www.scu.edu/ethics/publications/submitted/schulman/genepatenting.html>>.

70 *Ibid.*

concerns should be ignored.<sup>71</sup> Consideration must be given to where the bar is set. “[I]f the bar is set too high... pharmaceutical and biotechnology companies will not put the vast sums necessary into research because they will have no way to protect their investment.”<sup>72</sup> On the other hand, if the bar is set too low, society will run the risk of over patenting genetic materials which will lead to a “tragedy of the anticommons.”

### A. BIOTECHNOLOGY IS BOOMING

In an article published by the World Intellectual Property Organization (WIPO), “Bioethics and Patent Law: The Relaxin Case”, it was stated that “[b]iotechnology is booming. Innovation in biotech is producing new medicines, treatments and processes with the potential to save or transform the lives of millions.”<sup>73</sup> The biotechnology industry has contributed to the development of over 200 new vaccines and products, as well as 400 others that are in clinical trials, with the majority of those being targeted at devastating diseases such as AIDS, cancer and heart disease.<sup>74</sup> In the World Health Organization’s (WHO) 2004 world health report, these three diseases were listed in the top ten diseases throughout the world.<sup>75</sup> It is imperative that patents are granted to support the intellectual property rights of the companies that produce these new medicines, treatments and processes. The research and development of genetic material products and processes is incredibly expensive. In 2006, approximately \$29 billion was spent on research and development within the industry.<sup>76</sup> In receiving a patent on genetic material, biotechnology firms are given exclusive rights

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71 *Ibid.*

72 *Ibid.*

73 WIPO Magazine, “Bioethics and Patent Law: The Relaxin Case” *WIPO* (April 2006), online: WIPO <[http://www.wipo.int/wipo\\_magazine/en/2006/02/article\\_0009.html](http://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html)>.

74 Biotechnology Industry Organization (BIO), *Biotechnology Industry Facts*, online: Biotechnology Industry Organization <<http://www.bio.org/speeches/pubs/er/statistics.asp>>.

75 WHO, *The World Health Report 2004* (Geneva: WHO, 2004).

76 Battelle Technology Partnership Practice, *Technology, Talent and capital: State Bioscience Initiatives 2008*, online: BIO at ES-3 <[http://bio.org/local/battelle2008/State\\_Bioscience\\_Initiatives\\_2008.pdf](http://bio.org/local/battelle2008/State_Bioscience_Initiatives_2008.pdf)>.

over the material and so become more attractive to private investors.<sup>77</sup> In 2006, the biotechnology industry received more than \$24.8 billion in private investments.<sup>78</sup> Larger biotechnology firms are not the only ones that require substantial amounts of funding to conduct pioneering research. Start-up companies, with the potential to commercialize similar biotechnology products, rely on venture capitalists to fund their research and development. However, “[v]enture capitalists generally require a potential for exceptionally high rates of return in exchange for funding.”<sup>79</sup> Patents on genetic materials are therefore required to secure investment. Without patent protection, potentially life-saving medicines and treatments would not be commercialized. Venture capitalists provide approximately one third of the funding towards biotechnology firms. In 2007 alone, venture capitalists contributed a total of \$11.6 billion towards biotechnology firms, which was an increase of \$600 million from 2000.<sup>80</sup>

## V. SUGGESTIONS FOR RECONCILING THE PATENT SYSTEM WITH THE PATENTING OF GENETIC MATERIAL

Since the biotechnology industry is still in its early stages, it is important to consider some of the solutions that have been proposed to address the problems identified above. Heller and Eisenberg suggest that “[p]olicy-makers should seek to ensure coherent boundaries of upstream patents and to minimize restrictive licensing practices that interfere with downstream product development. Otherwise, more upstream rights may lead paradoxically to fewer useful products for improving human health.”<sup>81</sup>

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77 Michael S. Mireles, “An Examination of Patents, Licensing Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation” (2004) 38 U. Mich. J.L. Ref. 141 at 154.

78 BIO, *supra* note 74.

79 Mireles, *supra* note 77 at 163.

80 Battelle, *supra* note 76 at ES-3.

81 Heller & Eisenberg, *supra* note 60 at 701.

This section will discuss some of the potential suggestions to the current problem faced by the industry, including patent pooling, stronger utility requirements and the development of new research exemptions.

### A. PATENT POOLING AND CROSS-LICENSING

One particular way in which patent thickets may be prevented is through the development of a patent pooling system. This system would involve the “pooling” of intellectual property rights possessed by each biotechnology firm facilitated by a cross-licensing scheme which would provide a greater opportunity for researchers to take advantage of their access to a wide range of patented genetic materials.<sup>82</sup> Patent pooling systems have proven to be successful in many other technological areas including the automobile, semi-conductor and the aircraft industries.<sup>83</sup> Licensing schemes have even been successful in a small sector of the biotechnology industry, which is evident from licensing agreements that existed between Stanford University, Cohen and Boyer and also other licensees.<sup>84</sup> Even though patent pooling is an attractive and viable option for the industry, there are concerns over the outcome of these pools. One major concern is that patent pooling will encourage anti-competitive behaviour between firms, which could result in higher costs to consumers.<sup>85</sup> In response to this concern, the U.S. Department of Justice issued guidelines to be followed before a patent pool will be approved: “[t]he pool applicants are restricted from aggregating competing technologies for the purpose of anticompetitive pricing...and the patent pool participants must not attempt to affect market prices on downstream products.”<sup>86</sup> Failing an industry-wide patent pooling system, cross-licensing schemes may be promoted between two separate biotechnology firms. The benefits conferred on researchers would be limited to the firms involved with the agreement; however, it is still a step in the right direction, that is, a

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82 Mgbeoji & Allen, *supra* note 2 at 93.

83 Graham Reynolds, *Nanotechnology and the Tragedy of the Anticommons: Towards a Strict Utility Requirement* [unpublished] at 61.

84 Mgbeoji & Allen, *supra* note 2 at 94.

85 *Ibid.* at 94.

86 *Ibid.* at 94.

step away from the restriction placed on research and development by anticommons and patent thickets.

## **B. STRONGER UTILITY REQUIREMENTS**

As mentioned above, the current patent system is being chipped away at because of the lax utility requirements for patents on genetic materials. Patent offices throughout the world should enforce stronger utility requirements before issuing patents on biotechnology inventions. Stringent utility requirements benefit downstream research because they prevent the abundant overlapping of claims over genetic sequences without those claims' having been proved useful.<sup>87</sup> A more stringent utility requirement will also ensure that society will receive the benefit of the patented invention while the inventor retains the right to exclude others and to recoup their investment.<sup>88</sup> Since genetic sequences and ESTs have been patented based on homologous grounds, patent applications for many these genetic materials may be rejected if they are subjected to more rigorous utility requirements.

## **C. FAIR USE AND RESEARCH EXEMPTIONS**

Similarly to copyright law in Canada and the U.S., a fair use exemption has been suggested to help researchers overcome the anticommons problems that exist.<sup>89</sup> Professor Maureen O'Rourke argued that fair use may be used to "excuse infringement by researchers attempting to invent around the patent even when the eventual end product is to be marketed commercially."<sup>90</sup> As with copyright law, the fair use exemption is used as a defence to infringement of copyright or it may be used as a user's right. If it is classified only as a defence, it would be a reactionary measure which would put more of a strain on the court system and may cause researchers

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<sup>87</sup> *Ibid.* at 89.

<sup>88</sup> Mireles, *supra* note 77 at 195.

<sup>89</sup> *Ibid.* at 201.

<sup>90</sup> Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 Colum. L. Rev. 1177 (2000) at 1238.

to second guess whether that excuse may apply to them. The major difference between copyright law and patent law is that receiving copyright protection is relatively costless, while the process for obtaining a patent is costly.<sup>91</sup> A fair use doctrine may not be the ideal alternative to alleviate concerns regarding genetic material patents, but it does have the potential to prevent the stifling of research and development.

Perhaps a more appropriate method would be for legislatures in all jurisdictions to adopt a broader scope for the research exemption. In 2002, the Canadian Biotechnology Advisory Committee (CBAC) recommended that the Canadian *Patent Act* be amended to include the following provision:

It is not an infringement of a patent to use a patented process or product either:

Privately and for non-commercial processes, or  
To study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.<sup>92</sup>

Adoption of the CBAC’s recommendations would provide researchers with more leverage when using patented genetic material.<sup>93</sup> At the same time, adoption of these recommendations would grant researchers more certainty when dealing with patented subject matter. This would contribute to the advancement of more applied research and development beyond the initial platform stage. However, there are objections to the research exemption suggestion. It may result in a reduction of disclosures for genetic material research tools such as ESTs and SNPs,<sup>94</sup> which, in turn, would be detrimental to the development of applied research. Therefore, if legislatures attempt to amend research exemptions, they must be cautious in their approach, in order to avoid contributing to the tragedy of the anticommons. Although academics believe that a broader research

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91 Mireles, *supra* note 77 at 204.

92 Canadian Biotechnology Advisory Committee. *Patenting Higher Life Forms and Related Issues* (Ottawa: CABC, 2002), cited in Mgbeoji & Allen, *supra* note 2 at 93.

93 Mgbeoji & Allen, *supra* note 2 at 93.

94 Mireles, *supra* note 77 at 216.

exemption is better than a fair use exemption, patent pooling, which would provide the biotechnology firms with more of an opportunity to recover their investment through a licensing system, seems to be the preferable route of reform.<sup>95</sup>

## CONCLUSION

It is evident that biotechnology patents on genetic material are essential to help promote the research and development of groundbreaking medicines, treatments and procedures. Many academics believe that “[t]he field of biotechnology and biomedicine is at an early stage and its immense promise should not be aborted by a lax interpretation and application of contemporary laws.”<sup>96</sup> The current patent system must therefore be improved in order to prevent the blockage of future research and development, while balancing the need to reward innovation and thus encourage it.

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95 *Ibid.* at 216.

96 Mgbeoji & Allen, *supra* note 2 at 95.