

(2005) 3:2 *GenEdit*, 1-13

## GENETIC RESEARCH TOOL, THE RESEARCH EXCEPTION AND OPEN SCIENCE\*

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\* This commentary will focus on the patenting of genetic material as research tools. The use of electronic and IT materials as research tools in genetic and genomic research will not be discussed.

**The extension of the patent system to cover living materials is in no way recent. In fact, the first patent relating to life forms dates back more than 150 years: it was issued in Belgium in 1833 for a variety of yeast. It may thus come as a surprise that patents over complete genes or gene sequences have recently generated so much controversy. In no area is this more true than in the area of gene sequences used as research tools.**

While there is no clear definition of what constitutes a research tool, they are, generally, resources used by scientists that have no immediate therapeutic or diagnostic value; rather, they are used in conducting scientific work. Genetic research tools are a type of research tool and can be classified into three broad categories: research techniques, research consumables, and research targets.<sup>1</sup> Some of the most important genetic research tools are fundamental research platforms that open up new and uncharted areas of investigation.<sup>2</sup> Shouldn't such basic scientific resources be deposited in the public domain?

Although some view any patent relating to DNA as controversial,<sup>3</sup> scientists and observers seem particularly concerned about genetic research tool patents. These patents are perceived as substantially increasing the cost of biomedical research to the point of slowing or, in the worst case, even stopping the advancement of science and the development of important clinical tools in large areas of biomedicine. Critics of genetic research tool patents have suggested a number of options to address these concerns.<sup>4</sup>

One of the most straightforward of these is for countries to adopt a legal exception to permit certain forms of scientific experimentation involving patented genetic inventions.<sup>5</sup> The exception could cover several specific uses of the invention such as experimental research on or in respect of the patented invention, research aimed at

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meeting regulatory requirements, philosophical inquiry, and so on.<sup>6</sup> In fact, most countries already have either a statutory or a common law research exception but their scopes differ markedly from jurisdiction to jurisdiction. The variety and imprecision of the language used to define the exception also makes it difficult for courts of justice to ensure judicial stability.<sup>7</sup>

This article will discuss the controversy surrounding genetic research tool patents and the research exception in light of a study of this exception in 27 selected countries.<sup>8</sup> The authors will argue for the adoption of well defined, statutory model of research exception within the international community. Considering the growing economic interconnections between nations in this era of globalization, individual countries will also need to harmonize already existing models of research exception to foster stability in both national and international laws<sup>9</sup>. We believe these two precautions could improve access to genetic research tools by academic researchers as well as reassure members of the scientific community.

#### **A. The Patentability of Genetic Research Tools**

Despite the various arguments put forward by gene patenting opponents, the consensus among the legal world is that genetic inventions, including genetic research tools, are patent-eligible.<sup>10</sup> As early as 1988, before the widespread grant of patents over genetic material, the three major patent offices (EPO, USPTO and the Japan Patent Office) took the following position:

*Purified natural products are not regarded under any of the three [European, US and Japanese] laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.*<sup>11</sup>

The European Union adopted the *Biotechnology Directive* in 1998 to harmonize the legislation of its Member States with respect to the patenting of biotechnological inventions. Member States were to transpose the *Directive* into their national legislation by July 2000. Despite this and a decade of negotiation preceding its adoption, several European countries view the *Directive* as controversial and have yet to transpose it.<sup>12</sup>

Germany presents an example of a country where the transposition of the *Biotechnology Directive* has raised controversy. While Germany has transposed most portions of the *Directive* without change, the new German *Biotechnology Patent Law* requires patent applicants to limit claims over human genetic inventions to particular, identified uses. Thus under German law, it would not be infringing to use a patented human DNA sequence for a second use that is not covered by the specific use included in the patent claim. This restriction arguably contradicts the language of the *Directive* to award patent rights over the genetic invention to its discoverer. Patents over products, such as genetic sequences, normally provides the patent holder with exclusive rights over *all* uses of the invention, not simply those listed in the application. Further, the German law provides that no patents may be awarded for germ line cells.<sup>13</sup> Germany's contentious position has been supported by a recent resolution from the European Parliament.<sup>14</sup>

Our analysis of national legislation confirms the existence of a broad consensus on the patentability of genetic material.<sup>15</sup> DNA patent applications are subject to the traditional patent law requirements of novelty, industrial application (utility), inventive step (non obviousness) and disclosure. These criteria are increasingly more difficult to meet as genetic science advances. For example, it is not only harder to obtain patents over genetic inventions in the United States, but those that are granted are narrower in scope due to the application over the last few years of a more stringent utility requirement.<sup>16</sup>

In Europe, the situation is similar, with the European Patent Office's Opposition Division applying the inventiveness criteria more stringently.<sup>17</sup> In fact, recent American case law<sup>18</sup> along with the European Parliament's *Resolution on Patents on Biotechnological Inventions*<sup>19</sup> could signal the beginning of the end for patents on genetic research tools. If this trend persists, the case for a broad research exception may no longer be as strong as it was a few years ago.

It should be noted that in several developing countries surveyed for this article, human genetic research is still in its infancy. The legal validity of human DNA patents in those countries can only be presumed since there is a lack of both specific regulations and court decisions on the subject.<sup>20</sup>

## B. The Research Exception

Some authors<sup>21</sup> maintain that the patent system has a long and successful history of coping with new technologies and that biotechnology will be no exception. However, others have been much more critical of DNA patents.<sup>22</sup> Genetic research tool patents have been no exception to that trend; several authors claim they could have a strong negative impact on fundamental or applied biomedical research.<sup>23</sup> Heller and Eisenberg have suggested that biomedical research tool patents could create a tragedy of the anticommons (the underutilization of a scarce resource caused by multiple owners blocking each other) through a proliferation of fragmented and overlapping intellectual property rights.<sup>24</sup> Andrews has argued that commercial incentives (such as research tool patents) are responsible for significant delays in the publication of research findings and stifle collaboration, especially in the area of biomedicine.<sup>25</sup> Finally for Matthijs, genes and genetic sequences have unique informational content that makes it impossible for researchers to invent around them, creating a *de facto* "double" monopoly.<sup>26</sup>

These critics call for a defence to patent infringement that would protect academic research. HUGO, the international organisation of scientists involved in human

genetic research, recently argued in favour of such an exception stating that "freedom to undertake research in genomics is fundamental to the acquisition of further knowledge and the development of applications to benefit human health"<sup>27</sup> and that "researchers who wish to use patented technologies or products to further understanding in their work should not be unduly constrained by issues relating to licensing."<sup>28</sup> A Canadian report recently concluded that:

*As long as experimental use exceptions permit industry to obtain the substantial benefit of patent protection – that is, that they do not apply to all those who would otherwise purchase the product – there seems little rationale for not incorporating them in national legislation.<sup>29</sup>*

It should be noted that the emerging evidence about the impact of patents on fundamental biomedical research does not, to date, support criticisms of the current system<sup>30</sup>. In fact, the largest study on this topic concluded that the 414 biomedical researchers studied "through a combination of luck and appropriate institutional response ... appear to have avoided situations where a single firm or organization using its patents has blocked research in one or more broad therapeutic areas"<sup>31</sup> and that, "biomedical enterprise seems to be succeeding, albeit with some difficulties, in developing an accommodation that incorporates both the need to provide strong incentives to conduct research and development and the need to maintain free space for discovery."<sup>32</sup> This kind of evidence suggests that a dramatic change in patent policy may not be needed for the purpose of upstream research. However, as other studies highlight,<sup>33</sup> patents may have an impact on innovation downstream. The problem, of course, is that a research exception is much harder to justify in such contexts because it is generally closely related to commercial activity.

In fact, those opposed to an "academic research exception" have also been quick to point out the growing commercialisation of university research.

According to them, especially in the life sciences and biotechnology sectors, universities are no longer ivory towers interested only in fundamental knowledge with little or no commercial interest. Indeed, universities have had to face an unprecedented push from governments and funding agencies to commercialize their research<sup>34</sup>, however they still remain modest players in the patent race. According to the Association of University Technology Managers, universities still occupy only a limited portion in the North American patent market.<sup>35</sup> In Europe, the fragmentary evidence is even less convincing of a claimed overriding commercial interest by universities. The authors of one of the only studies on the subject state that “American universities have been much more active than their European counterparts in enforcing and exploiting IPRs on the research carried out by their faculties.”<sup>36</sup>

The majority of the countries surveyed for this article already possess a statutory exception from patent infringement for research or experimental use.<sup>37</sup> This type of exception to patent infringement is standard in most European countries. In fact, article 31 of the *Community Patent Convention* stipulates that the right conferred by a patent does not extend to “acts done for experimental purposes relating to the subject matter of the patented invention.”<sup>38</sup>

Although there remains variation in the interpretation of the research exception among the different members of the European Union, it constitutes an important mechanism to permit experimentation made on patented genetic research tools. Nonetheless, the European research exception is not unlimited: it only applies to research *on* the patented research tool and does not include research *using* the tool.<sup>39</sup> It is debatable whether this is a wise limitation, for while permitting researchers to *use* a research tool will certainly undermine the market value of the patent on the tool (as the exception exempts all those wishing to make ordinary use of the tool from the scope of the patent), it would benefit academic researchers who are unlikely to be able to afford the licence fees connected with the research tools. Patent owners would not

have much to lose (in the way of profits) in providing these researchers with free access.<sup>40</sup> Simple reliance on the good sense of patent holders may not, in itself, provide sufficient assurance to researchers. Thus, a statutory exception is called for.

Interestingly, the statutory exception of a number of surveyed countries did not link experimental use to non-commercial purposes. For the most part, these countries treat the private/non-commercial condition as an independent exception to patent infringement. In some of these countries, it seems that the “commercial” nature of contemporary academic research does not automatically preclude the application of the research or experimental use defence to patent infringement. However, in others, the research exception has been interpreted restrictively by the judiciary as limited to non-commercial purposes.<sup>41</sup>

Generally, surveyed countries of the common law legal tradition had judicially-created exceptions applicable to non-commercial research use. However, much uncertainty persists in those countries regarding the nature and extent of the exception.<sup>42</sup> In the United States, the scope of the common law research exception has been debated by the judiciary in the last few years. Although the exception had previously been seemingly reduced to the point of virtual non-existence by two decisions from the United States Court of Appeals for the Federal Circuit,<sup>43</sup> a recent decision from the United States Supreme Court<sup>44</sup> along with a strong dissent in another Court of Appeals’ decision<sup>45</sup> could be a signal that the courts now recognise a broader exception. In Australia and South Africa, the existence of a judicially-created exception itself is subject to debate within the judiciary.<sup>46</sup>

In Canada, a recent report to the Canadian Biotechnology Advisory Committee recommended the enactment of a broad research exception that would permit researchers to conduct experiments with a patented research tool without infringing the patent.<sup>47</sup>

The enactment of a statutory exception similar to the European model in countries of common law legal tradition would have a clarifying effect on the law.

Certain of the developing countries surveyed (Argentina, Brazil, India and Uruguay) had broad statutory research exceptions that did not require the experimental use to be “related” to the subject matter of the patented invention. However, the lack of legal precedents on the topic of the research exception in those countries makes it difficult to foresee how the courts will interpret these broad exceptions.

## Conclusion

There is an obvious need for additional empirical data regarding the impact of research tool patents on biomedical research. A recent study concluded that although in most situations the parties came to workable solutions allowing them to avoid the problems related to research tool patents, it was impossible to rule out the possibility of future problems.<sup>48</sup> According to the authors of the study, there is a “continuing need for the active defence of open science.”<sup>49</sup> Consequently, the authors recognized the importance of the research exception for allowing open science to proceed relatively unencumbered and recommended that “policymakers ensure an appropriate exception for research intended for the public domain.”<sup>50</sup> Indeed, although there exist other solutions to ensure that university researchers have access to all the tools required for them to conduct biomedical research, the use of a statutory research exception may be the most straightforward solution to ensure both certainty and an ‘open science’ environment in the biomedical research community at little or no cost to the private sector.

Currently, the research exception differs in its nature, scope and judicial interpretation between the various members of the international community. This situation creates uncertainties in both national and international laws that foster a climate of apprehension among members of the biomedical research community.

The widespread adoption of a statutory research exception modelled after the one currently used by members of the European Union (exception for acts done for experimental purposes relating to the subject matter of the patented invention without regard to commercial interest) could reassure the scientific community. This would clearly benefit all parties since “the industry benefits from the knowledge that is created by the research being done on technology that the industry has patented.”<sup>51</sup> Eventually, policymakers will also have to decide if the exception should be expanded to cover all *uses* of the patented invention or simply those that relate to working on the tool itself and its properties. These are hard questions, but they will need to be answered if we value the importance of a dynamic, functional biomedical research sector in academia that continues to work in the spirit of open science.

**TABLE 1.**  
**DNA Patents and the Research Exception in Selected Countries**

Country	DNA patents	Research exception		
		Statutory	Judiciary	Uncertain/None
Argentina	Yes	X Non-commercial research on or with a patented tool		
Australia	Yes			X
Belgium	Yes	X Experimental research on or a patented tool		
Brazil	Yes	X Experimental research on or with a patented tool		
Canada	Yes	X (limited) For regulatory approval only		X Possible judiciary exception
China	Yes	X Experimental research on or with a patented tool		
Denmark	Yes	X Experimental research on a patented tool		
Finland	Yes	X Experimental research on a patented tool		
France	Yes	X Experimental research on a patented tool		
Germany	Yes (some limitations)	X Experimental research on a patented tool		
Hungary	Yes	X Experimental research on a patented tool		
India	Yes	X Experimental research on or with a patented tool		

Israel	Yes	X Experimental research on or with a patented tool		
Italy	Yes	X Experimental research on a patented tool		
Japan	Yes	X Experimental research on or with a patented tool		
Mexico	Yes	X Non-commercial research on or with a patented tool		
Netherlands	Yes	X Experimental research on or with a patented tool		
New Zealand	Yes		X Non-commercial research on a patented tool	
Romania	Yes			X
South Africa	Yes			X None
South Korea	Yes	X Experimental research on or with a patented tool		
Spain	Yes	X Experimental research on a patented tool		
Sweden	Yes	X Experimental research on a patented tool		
Switzerland	Yes			X Possible implicit exception in the patent law
United Kingdom	Yes	X Experimental research on a patented tool		
United States of America	Yes	X (limited) For regulatory approval only	X (limited) Strictly philosophical and non-commercial enquiries	
Uruguay	Yes	X Experimental research on or with a patented tool		

- <sup>1</sup> *Research techniques* include inventions that cover laboratory techniques used in research by molecular biologists, such as the Cohen–Boyer techniques (for gene-splicing) and polymerase chain reaction (PCR) methodology (for DNA amplification). *Research consumables* include inventions that cover particular enzymes or reagents used in the laboratory, such as Taq polymerase (used in PCR) and restriction enzymes (used in cloning and other applications). *Research targets* include inventions that cover genetic materials targeted in research, for example genes for receptor proteins used in designing new drugs or vaccines, such as the HIV-receptor CCR5. This category also includes expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), which can be targets of research or used to target other genetic materials; Austl., Australian Law Reform Commission, *Gene Patenting and Human Health* (Discussion Paper 68) (Sydney: Australian Government, 2004) available on line : <<http://www.austlii.edu.au/au/other/alrc/publications/dp/68>> at 12.28-12.30.
- <sup>2</sup> Arti K. Rai, "Genome Patents: A Case Study in Patenting Research Tools" (2002) 77:12 *Academic Medicine* 1369.
- <sup>3</sup> See for example, Jeremy Rifkin, *The Biotech Century* (New York : Putnam book, 1998) pp. 37-67.
- <sup>4</sup> Lori B. Andrews, "The Gene Patent Dilemma: Balancing Commercial Incentives With Health Needs" (2002) 2 *Houston Journal of Health Law & Policy* 65-106. Kate Murashige, "Patents and Research—An Uneasy Alliance" (2002) 77 :12 *Acad. Med.* 1329–1338.
- <sup>5</sup> E. Richard Gold et al. *The Research or Experimental Use Exception : A Comparative Analysis*, (Montreal: Centre for Intellectual Property Policy / Health Law Institute, 2005) available on line : < (<http://www.cipp.mcgill.ca/db/published/00000008.pdf>)> pp. 1-52.
- <sup>6</sup> In the context of this article, "research exception" will be used to refer to the component of the research exception that covers scientific research or experiments.
- <sup>7</sup> For more on the judicial interpretation of the exception see Matthew Rimmer, "The Freedom to Tinker: Patent Law and Experimental Use" (2005) 15:2 *Expert Opin. Ther. Patents*. 167-200.
- <sup>8</sup> Argentina, Australia, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Hungary, India, Israel, Italy, Japan, Mexico, Netherlands, New Zealand, Republic of Korea, Romania, South Africa, Spain, Sweden, Switzerland, United Kingdom, United States, Uruguay. See Table 1 and also Centre for Intellectual Property Policy, *Overview of Patent Regimes* (Montreal: Centre for Intellectual Property Policy, 2005) available on line: <<http://www.ipgen.umontreal.ca/>> as well as World Intellectual Property Organization, *Collection of Laws for Electronic Access*, available on line : <[http://www.wipo.int/clea/en/clea\\_tree1.jsp](http://www.wipo.int/clea/en/clea_tree1.jsp)>
- <sup>9</sup> Keith E. Maskus, *Intellectual Property Rights in the Global Economy* (Washington DC: Institute for International Economics, 2000) pp 3-6.
- <sup>10</sup> Timothy Caulfield, E. Richard Gold, Mildred K. Cho, "Patenting Human Genetic Material: Refocusing the Debate" (2000) 1 *Nature Reviews Genetics* 227-231.
- <sup>11</sup> Trilateral Co-operation of the US, European, and Japanese Patent Offices, (1988) 7 *Biotechnology Law Review* 163.
- <sup>12</sup> E. Richard Gold, Alain Gallochat, "The European Biotech Directive: Past as a Prologue" (2001) 7:3 *Eu L.J.* 331-366. IPR Helpdesk, *The EC Directive on the Legal Protection of Biotechnological Inventions*, (Alicante: IPR Helpdesk, 2004) available on line: <[http://www.ipr-helpdesk.org/documentos/docsPublicacion/pdf\\_xml/8\\_BPBiotechMain\[0000001087\\_00\].pdf](http://www.ipr-helpdesk.org/documentos/docsPublicacion/pdf_xml/8_BPBiotechMain[0000001087_00].pdf)> p. 1-9; European Commission, *Industrial Property : Eight Member States Referred to Court for Failure to Implement Directive on Legal Protection of Biotechnological Inventions* (Strasbourg: European Commission, 2003) available on line: <<http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/03/991&format=PDF&aged=1&language=EN&guiLanguage=en>> pp. 1-3.
- <sup>13</sup> *Patent Act* (Text of December 16, 1980, as last amended by the Law of February 28, 2005); Ned Stafford, "German Biopatent Law Passed" (2004) *The Scientist*, available on line: <<http://www.the-scientist.com/news/20041209/01>>; Graham Dutfield, Uma Suthersanen, "DNA Music: Intellectual Property and the Law of Unintended Consequences" (2005) 18:1 *Science Studies* 15-16.
- <sup>14</sup> European Parliament, *European Parliament Resolution, Patents on Biotechnological Inventions*, (Strasbourg: European Parliament, 2005) available on line : <<http://www.europarl.eu.int/omk/sipade3?TYPE=DOC=TA&REF=P6-TA-2005-0407&MODE=SIP&L=EN&LSTDOC=N>>. This resolution affirms that germ cells are not patentable and that the European Patent Office should grant patents on human DNA only in connection with a concrete application and for the scope of the patent to be limited to this concrete application so that other users can use and patent the same DNA sequence for other applications.
- <sup>15</sup> See Table 1.
- <sup>16</sup> *Utility Examination Guidelines* 66:4 Federal Register (United States Patent and Trademark Office, 2001).
- <sup>17</sup> David Cyranoski, "High Flying Patents Get Their Wings Clipped in Europe" (2004) 10:9 *Nature Medicine* 882; Yann Joly, Bartha M. Knoppers, "BRCA Gene Patents and the European Patent Office" (2004) 4:2 *The Law and Bioethics Report*, available on line: <<http://www.louisville.edu/medschool/ibhpl/images/pdf/Lab%20Report%20win%2004.pdf>> 6.
- <sup>18</sup> *In Re Dane K. Fisher and Raghunath v. Lalgudi*, No. 04-1465, Fed. Cir.; 2005 US App. LEXIS 19259.
- <sup>19</sup> *Supra*, note 16.
- <sup>20</sup> For example, in Mexico, Uruguay and Argentina, see : International Association for the Protection of Intellectual Property, *Mexico report Q 150 – Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes* (Sorrento: AIPPI, 2000) available on line: <<http://www.aippi.org/reports/q150/gr-q150-e-mexico.htm>>; International Association for the Protection of Intellectual Property, *Uruguay report Q 150 – Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes* (Sorrento: AIPPI, 2000) available on line : <<http://www.aippi.org/reports/q150/gr-q150-e-uruguay.htm>>; International Association for the Protection of Intellectual Property, *Argentina Report Q 150 – Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes* (Sorrento: AIPPI, 2000) available on line: <<http://www.aippi.org/reports/q150/gr-q150-e-argentina.htm>>
- <sup>21</sup> Berthold Rutz, Siobhan Yeats, "The Importance of Being Inventive" (2004) 5:2 *European Molecular Biology Organization* 119-123; Sharon Farnley, Pamela Morey-Nase, Diana Sternfeld, "Biotechnology -A Challenge to the Patent System" (2004) 15 *Current Opinion in Biotechnology* 254-257.
- <sup>22</sup> Lori B. Andrews, Jordan Paradise, "Gene Patents: The Need for Bioethics Scrutiny and Legal Change" (2005) 5 *Yale J. Health Pol'y L. & Ethics* 403; Mildred K. Cho, "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services" (2003) 5:1 *Journal of Molecular Diagnostics* 3.
- <sup>23</sup> Arti K. Rai "Genome Patents: A Case Study in Patenting Research Tools" (2002) 77:12 *Academic Medicine* 1369; K. Murashige, *supra* note 6, at 1329.

- <sup>24</sup> Michael A. Heller, Rebecca Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 *Science* 698.
- <sup>25</sup> *Supra* note 6.
- <sup>26</sup> Gert Matthijs, "Patenting Genes May Slow Down Innovation, and Delay Availability of Cheaper Genetic Tests" (2004) 329 *BMJ* 1359.
- <sup>27</sup> HUGO Intellectual Property Committee, *Statement on the Scope of Gene Patents Research Exemption, and Licensing of Patented Gene Sequences for Diagnostics* (London: The Human Genome Organisation, 2003) available on line : <<http://www.hugo-international.org/PDFs/Statement%20on%20the%20Scope%20of%20Gene%20Patents%20Research%20Exemption.pdf>>
- <sup>28</sup> *Ibid.*
- <sup>29</sup> *Supra* note 7, at 51-52.
- <sup>30</sup> John P. Walsh, Charlene Cho, Wesley M. Cohen, "View from the Bench: Patents and Material Transfers" (2005) 309: 5743 *Science* 2002-2003.
- <sup>31</sup> John P. Walsh, Wesley M. Cohen, Ashish Arora, "Research Tool Patenting and Licensing and Biomedical Innovation" in Wesley M. Cohen and Stephen A. Merrill, eds. *Patents in the Knowledge-Based Economy* (Washington DC: National Academy Press, 2003) p. 335.
- <sup>32</sup> *Id.* 335-36.
- <sup>33</sup> M.K. Cho, *supra* note 24.
- <sup>34</sup> Case in point, "in Canada, in 2002 the Federal Industry Minister, Alan Rock suggested that there is a need to commit academic institutions 'to a link between public funding and economic outcomes'. Many of Canada's major public research funding entities such as the Canadian Institutes of Health research (CIHR), now have a formal commercialization mandate. For example, the enabling legislation of the CIHR states that the CIHR should 'encourage innovation, facilitate the commercialization of health research in Canada and promote economic development through health research in Canada.'" Tim Caulfield, "Policy Conflicts: Gene Patents and Health Care in Canada" 2005 8(4) *Community Genet.* 224.
- <sup>35</sup> Association of University Technology Managers, *AUTM Licensing Survey: FY 2003* (Northbrook: The Association of University Technology Managers, 2004) available on line: <[http://www.autm.net/events/File/Surveys/03\\_Abridged\\_Survey.pdf](http://www.autm.net/events/File/Surveys/03_Abridged_Survey.pdf)>.
- <sup>36</sup> Aldo Geuna, Lionel Nesta, "University Patenting and its Effects on Academic Research : The Emerging European Evidence" (2005) forthcoming in *Research Policy*.
- <sup>37</sup> *Supra*, note 16.
- <sup>38</sup> *Convention for the European Patent for the Common Market*, (Community Patent Convention), 1976 O.J. (L 17) 1; although this Convention never entered into force because it was not ratified by a sufficient number of countries, it has a considerable influence on the shape of European patent law.
- <sup>39</sup> *Supra* note 9, at 185.
- <sup>40</sup> A. K. Rai, *supra* note 25, at 1368.
- <sup>41</sup> See Table 1 and Rimmer, *supra* note 9.
- <sup>42</sup> Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues*, (Ottawa: Canadian Biotechnology Advisory Committee, 2002) p. 16; Ursula M. McGuinness, "Experimenting with Infringement" (2004) 7:7 *July Biotechnology Focus* 15 available on line: <http://www.bioscienceworld.ca/view.html?id=305>
- <sup>43</sup> *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349, 55 U.S.P.Q. 2d 1161, 1163 (Fed. Cir. 2000); *Madey v. Duke University*, 307 F.3d 1351, 64 U.S.P.Q. 2D (BNA) 1737 (Fed. Cir. October 3, 2002). In the *Embrex* case, the Federal Circuit Court held that : "the defence is very narrow and limited to actions performed for amusement to satisfy idle curiosity, or for strictly philosophical enquiry" and in *Madey* it added that: "regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in the furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical enquiry, the act does not qualify for the very narrow and strictly limited experimental use defence."
- <sup>44</sup> *Merck KGAA v. Integra Lifesciences I, Inc.*, 2005 WL 1383624, \*1, 8 (U.S. June 13, 2005). "Although the Supreme Court chose not to comment on the applicability of U.S.C. §271(e) (1) to research and experimentation involving "research tools", the Court did seem to agree with Justice Newman from the Federal Circuit that a distinction could be made between the study of a "research tool" and the use of a tool in one's research. It is also telling that the Supreme Court chose to quote from Justice Newman's strong dissent (in the 2003 appeal of the *Merck* case) wherein she argued that narrowing the common law research "exception" was "ill-suited to today's research-founded, technology-based economy" and that "prohibition of all research into patented subject matter is as impractical as it is incorrect." Yann Joly, *Integra v. Merck : The resurrection of the American research exemption?* (Montreal: Centre for Intellectual Property Policy, 2005) available on line: <<http://www.cipp.mcgill.ca/db/news/00000025.pdf>> .
- <sup>45</sup> *Integra Lifesciences I, Ltd. v. Merck KgA*, 331 F.3d 360, 66 U.S.P.Q. 2D (BNA) 1865 (Fed. Cir. June 6 2003) 12.
- <sup>46</sup> See *Monsanto v. Stauffer* [1988] FSR 57 for South Africa and M. Rimmer, *supra* note 9, at 185-193 for a discussion on Australia.
- <sup>47</sup> Expert Working Party on Human Genetic Materials, *Human Genetic Materials : Making Canada's Intellectual Property Regime Work for the Health of Canadians*, (Ottawa: Government of Canada, 2005) x.
- <sup>48</sup> J.P. Walsh, *supra* note 33, at 285.
- <sup>49</sup> *Ibid.* 335.
- <sup>50</sup> *Ibid.*
- <sup>51</sup> Biotechnology Industry Organization, *Statement of the Biotechnology Industry Organization (BIO) Submitted to the Subcommittee on Labor, Health and Human Services, Education of the Senate Appropriations Committee Hearing Regarding Commercial Development of Pluripotent Stem Cell*, (Washington DC: Biotechnology Industry Organization, 1999) available on line: <[http://www.bio.org/bioethics/background/stemcell\\_testimony.asp](http://www.bio.org/bioethics/background/stemcell_testimony.asp)>