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# Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Health Care and Biomedical Research

Ikechi Mgbeoji<sup>†</sup> & Byron Allen<sup>‡</sup>

## Introduction

One of the theoretical premises of the patent system is that it enhances the dissemination of valuable information by assuring creators of new inventions a limited monopoly for the exploitation of their inventions. As a tool of state policy, the patent system seeks to catalyze the industrialization of the state, disclosure of information by inventors, and ultimately, the enrichment of the public domain in a manner that benefits both the inventor and the society. Consequently, the patent system is often characterized as a form of contract between the inventor and the state.<sup>1</sup> As a consideration for disclosing the secret of the invention, so this theory says, the state grants the inventor limited monopoly over the use of the invention. The implicit assumption in this simplified theoretical construction of a complex system is that the inventor and the society benefits mutually from the bargain.

Although this theory, indeed romantic idealization of the patent system, has been assailed on several fronts by a formidable school of critical scholars<sup>2</sup> of the patent system,<sup>3</sup> it nonetheless constitutes the major rhetorical flag which advocates or supporters of the patent system readily wave before skeptics as the *raison d'être* of the patent system.<sup>4</sup> Without revisiting the merits or otherwise of this unresolved debate, the central and undisputed tenet of patent laws is that the exclusive rights granted by the patent are delimited and defined by the specification supporting the patent application. It is the utility embedded in the patent specification which acts as a consideration for the enormous limited monopoly conferred on the inventor and which the state is often willing to lend its authority and processes to protect and enforce.

In theory thus, patent holders may lawfully use this market exclusivity and assurance of state protection to generate profits and recoup the costs of the inventive

process. Implicit in this assumption is that the bargain would only be worthwhile if the disclosures made in the patent specification are of such character or quality as would confer a net value on the society, especially in respect of new technologies, industries, or research. In effect, beneath the apparent legalese of the patent system is a policy of encouraging disclosure of valuable information, enrichment of the public domain, and concomitant welfare of both the inventor and the larger society.

In recent times, however, developments resulting from the internationalization of the United States' patent law have encouraged biotechnology firms and pharmaceutical companies to argue in favour of stringent patent laws and broad patent claims.<sup>5</sup> In the same context, 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 demonstrable utility. There is an emerging consensus among scholars of the patent system that mechanical inventions receive a tougher scrutiny for utility than their genetic or biotechnological counterparts. The convergence of these strong undercurrents poses severe challenges to the social utility of patent regimes and the fairness of the patent system as a whole. Given that the normative basis or theoretical justification of the patent system is that patents are a contract between the inventor and the public for the disclosure of valuable information to the public and protection of the inventor's investments, a patent of uncertain utility is a fraud on the public. If the patent system performs its role, other inventors or researchers would be able to build upon valuable information to produce better products for the benefit of society. Genetic patents in particular are thus intended to provide access to innovations in health care and genetic research. Consequently, where patents are issued on genetic materials without demonstrable utility the society is short-changed, the public domain is cluttered

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with speculative patents, and the patent system becomes a clog rather than a catalyst for social welfare.<sup>6</sup> It is arguable that the contemporary trend in issuance of patents to genetic materials when such materials are not accompanied with sufficient disclosure of their utility encourages speculative patenting and eventually turns the patent system into rubbish.

In addition, the granting of speculative genetic patents which fail the requirement of the rules on specification of inventions<sup>7</sup> grossly distorts the evidential which is at the base of the integrity and efficiency of the patent system, particularly in patent validity litigations. This is the position notwithstanding the fact that section 53(1) of the Canadian *Patent Act*,<sup>8</sup> and similar provisions in other patent legislations across the world, provide that a patent is void “if the specification and drawing contains more or less than is necessary for obtaining the end for which they purport to be made and the omission or addition is willfully made for the purpose of misleading”.<sup>9</sup> In Canada, as in other patent law jurisdictions, the power to void or invalidate a patent rests with the Federal Court (or similar courts) and not with the individual member of the public who may believe that a particular genetic patent is of dubious validity.

Apart from the fact that courts are the ultimate determinants of the validity or otherwise of a patent issued by the pertinent patent office, it has to be emphasized that there is a statutory presumption of validity, albeit weakly worded, in favour of patents already issued by a patent office. In other words, no matter the reservations any person may have about a particular patent, such a patent is presumed valid until the courts say otherwise. According to s. 43(2) of the Canadian *Patent Act*,

[A]fter the patent is issued, it shall in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable.<sup>10</sup>

However, in Canada, opinion is divided as to whether the presumption in question is an evidential burden to be discharged by the defendant in a patent validity trial or an incidental burden of introducing preliminary evidence.<sup>11</sup> According to Dube J., “the burden is on the defendant challenging a patent to show, on the usual standard of the balance of probabilities, that a patent is invalid. The burden is heavy and is not easy to overcome”.<sup>12</sup> On the other hand, Pratte J. observed rather ambiguously in *Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd* that:

[O]nce the party attacking the patent has introduced the evidence, the Court, in considering evidence and in determining whether it establishes the invalidity of the patent must not take presumption into account. It cannot be said that the presumption created by [now 45] is, as a rule, either easy or difficult to overcome; in some cases, the circumstances may be such that the presumption will be easily rebutted, while in other cases the same result may be very difficult or even impossible to obtain.<sup>13</sup>

Interestingly, when this issue came up before the Canadian Supreme Court, the Court opined that “the presumption adds little to the onus already existing, in the usual way, on the attacking party”.<sup>14</sup> In effect, the preponderant judicial tenor in Canada is in favour of a presumption of validity of patents. What is more disturbing is the impression created by the courts across the world that a challenge to the validity of a patent is often the desperate argument of an infringer. In this context, the need for patent examiners to be very rigorous when evaluating the completeness of an application for patents, particularly in respect of genetic matter, can hardly be overemphasized. Members of the public rely on patent examiners to exercise their best possible judgment in the issuance of patents, especially genetic patents. Consequently, where patent offices are slack or lax in their responsibility to ensure that genetic patent applications satisfy the requirements of sufficient disclosure and utility, the patents issued unfairly place the burden on the person attacking the validity of the patent. In the light of these developments, the question arises as to what policies ought to be put in place to deal with the emergent trend of speculative genetic patents as they impact on the integrity of the patent system and on health care and research.

Increasing concerns over the legal validity of genetic patents and licensing of genes and genetic material transcend theoretical or scholarly discomfort with tardy application of patent law by patent examiners. Genetic testing and research has in modern times become increasingly critical to health care delivery. The broad interpretation that has been granted to gene patents and the creeping culture of patent now and litigate later, particularly in Canada and the U.S., has led to what many commentators feel is the emergence of a predatory patent regime. As restrictive licensing practices combine with heated races to the patent office by researchers, the immediate consequences include the monopolization of clinical testing, uncertainty of the scope of patents, excessive commercialization of research,<sup>15</sup> and distortion of the academic research agenda.

On both the legal and policy levels, the emergent trend threatens the integrity and essence of the patent regime. It is a fundamental policy of patent regimes that patentees, competitors, and the public are entitled to definite functions of a patent specification. Given that specification lies at the “heart of the patent system”,<sup>16</sup> there is a compelling need to rethink the excessively liberal construction of patent specifications and the laxity of the patent offices, particularly in respect of genetic matter. Unless the patent system is made to perform its vaunted function of enriching the public domain in exchange for limited monopolies, the public would suffer from a “bargain process” heavily weighted in favour of questionable patented genetic materials. As

the Canadian Supreme Court warned in *Apotex Inc. v. Wellcome Foundation Ltd.*:

[I]t is not enough for a patent owner to be able to buttress speculation with post-patent proof, and thereby turn dross into gold. Utility is an essential part of the definition of an invention. A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove invalidity, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner "by law" is required to refuse the patent.<sup>17</sup>

This paper will not directly address the ethical considerations of allowing patents on human genetic sequences, although this continues to be a controversial debate in itself.<sup>18</sup> Rather, the aim is to consider the legality of such gene patents and the effects such patents have on biomedical research and health care delivery in definitive terms through an analysis of current developments and research relating to the subject. The operation of current intellectual property regimes regulating such patents will be examined, and amendments to these legal systems will be considered. An emphasis will be placed on identifying practical concerns rather than broad, general issues that do not directly address practical implications. In concluding our analysis, we propose a set of policy options which the patent system and public institutions may pursue to mitigate the excesses of an exuberant and liberal patent system.

In the light of the recent sequencing of the human genome, and the concurrent genomic mapping of several other important organisms essential as research models in bioscience research, this topic is of considerable importance. As gene sequences and complementary protein structures are increasingly characterized in humans and other related organisms, the elucidation of basic molecular pathways and disease-related mechanisms will result in an exponential increase in biomedical and biotechnological innovations. The fundamental nature of health care will change as common diseases and genetic predispositions will be characterized and treated on a molecular level. It is therefore essential that the processes by which these innovations are developed and shared benefit both society and innovators to the greatest possible extent in a manner that is consistent with the tenets and policy anchors of patent law.

This paper is divided into five parts, of which part one is introductory. Part two examines the law on patentability of genetic sequences. It argues that in recent decades, patent law across the globe has been gradually diluted to accommodate the huge capital investment in biomedical research. The relaxation of the standards of patentability has in turn led to the proliferation of biomedical patents. Part three takes the analysis further by examining the impact of this trend on biomedical research, the public domain, and access to health care. In part four, we propose a set of solutions to the problems identified and analyzed earlier. The paper concludes its analysis in part five.

## Patentability of Genetic Sequences

Arguably, the patent system was not originally designed for protection of life forms.<sup>19</sup> Rather, early patent systems, especially in the United Kingdom, continental Western Europe, and North America were dominated almost exclusively by machines and mechanical devices.<sup>20</sup> Discoveries, principles of nature, and natural products were all debarred from the range of patentable subject-matter.<sup>21</sup> However, 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>22</sup>

Although the nature of this (r)evolution in the patent system is outside the scope of this paper, it suffices to note at this stage that the expansion of the patent system to accommodate growths in the chemical, pharmaceutical, and biological fields often emanated from judicial interpretation of patentable subject-matter rather than express legislative adjustments.<sup>23</sup> Thus, the exposition of what constitutes patentable subject-matter has largely remained a judicial creation rather than a legislative function. Attempts to limit the scope of patentable subject-matter to the express letters of the law have often come to a miserable end as courts often embrace interpretative techniques which yield modern meanings to what constitutes acceptable patentable subject-matter.

Hence, there is merit in the observation of the Canadian Patent Appeal Board in *Re Application of Abitibi* that "throughout the world various judicial bodies, without changes in legislation, have gradually altered their interpretation of statutory subject-matter to adapt it to new developments on technologies, and current concepts of industrial activity".<sup>24</sup> It was largely within this paradigm that the courts have, over the years, resolved many fundamental issues in patent law in favour of new industries. In modern times, the biotechnology and pharmaceutical industries have been the greatest beneficiaries of the inherent capacity of patent systems to embrace modern conceptions of patentable subject-matter.<sup>25</sup>

The predilection of the patent system to adjust to new conceptions of patentability is often reflected in the epochal deployments of capital in the society. In the past five or six decades, this phenomenon is probably best exemplified in the fine distinctions which the courts have gradually imposed on the patentability of purified products of nature on one hand and products of nature *per se* on the other hand.<sup>26</sup> Originally, patent systems across the world purported to debar the patentability of products of nature. However, with the rise of sophisticated methods of pharmaceutical research and manufacture, the major patent systems of the world have drawn a distinction between products of nature *per se* and refined products of nature. While the latter is patentable,<sup>27</sup> the former is not.

Interestingly, the patenting of refined or purified products of nature started with the patent on acetyl salicylic (aspirin) in 1910.<sup>28</sup> Thus, on the basis of the hypothesis that purified or refined natural substances are physically and chemically distinct from raw products of nature,<sup>29</sup> the courts in the United States of America and elsewhere have upheld the patenting of purified natural substances such as vitamin B12,<sup>30</sup> purified prostaglandins,<sup>31</sup> adrenalin,<sup>32</sup> et cetera.<sup>33</sup> Intriguingly, the argument that purified natural products are patentable was made in respect of purified tungsten<sup>34</sup> (in the case of *General Electric Co. v. Deforest Radio Co.*<sup>35</sup>) but the Court rejected it. It is on the theory that genetic materials are akin to chemical compounds that patents are increasingly issued to such genetic matter.

Given the current trend in patenting genetic matter, there remains a question on whether such materials are legally patentable.<sup>36</sup> It is not enough that a particular substance sought to be patented is a chemical, it must also have a demonstrable utility. Generally speaking, genes or genetic sequences as they exist *in vivo*, or as they exist in nature, are not *per se* patentable. However, on the basis that gene fragments are chemicals, patent protection is available for isolated and purified DNA fragments, full length genes, and the protein products of genes, provided their functions are known. In effect, modern patent law treats DNA material similarly to patentable chemical compounds that have been derived from natural resources, provided, of course, the function of such chemicals, albeit of biochemical origins, are known and specifically identified.<sup>37</sup>

By law, in order to receive a patent for a genetic sequence, the patent application must satisfy the requirements of novelty and utility under s. 2 of the Canadian *Patent Act*, and the non-obviousness requirement under s. 28.3.<sup>38</sup> The Canadian Intellectual Property Office position that genetic sequences may qualify as patentable subject matter was recently reinforced by the Canadian Federal Court of Appeal in a decision granting Harvard University a patent for claims on a transgenic mouse.<sup>39</sup> Justice Rothstein, speaking for the majority, stated that “DNA is a physical substance and is therefore matter”.<sup>40</sup> Although the decision was ultimately overturned by the Supreme Court of Canada, which held that higher life forms are not patentable subject matter under the definition of “invention” in s. 2 of the Act, the holding did not affect the current understanding that genetic sequences with known functions or utility are patentable subject matter under the Canadian *Patent Act*.<sup>41</sup>

However, what is troubling about some patented gene sequences is that unlike other chemicals with known utility, the functions of certain genetic materials are often unknown even when scientists know the function of a similar gene sequence. Yet, some patent offices have been issuing genetic patents on the basis of homology rather than specific and ascertained utility or function. This practice is inconsistent with patent law. As

the United States’ National Institutes of Health (NIH) and the Association of American Medical Colleges (AAMC) have recently argued, patents on homologous gene sequences (as they are called) are flawed because “a difference in a single base pair in a gene sequence can have important functional implications”.<sup>42</sup>

Granting patents on gene sequences with unknown functions, even when the function of a gene homologue is known, is speculative and presumptuous. In effect, such a patent becomes a fishing or hunting licence, an instrument of speculation, rather than performing its avowed role as a facilitator of disclosure of specific and useful information by inventors to the public.<sup>43</sup> Simply put, the patenting of gene fragments of unknown utility flies in the face of basic patent law and short-changes the public. The impact of such speculative and uncertain patents on the larger society is decidedly negative. As Binnie J. warned in respect of patents with indeterminate and unknown functions:

[T]he patent system is designed to advance research and development and to encourage broader economic activity. Achievement of these objectives is undermined however if competitors fear to tread in the vicinity of the patent because its scope lacks a reasonable measure of precision and certainty. A patent of uncertain scope becomes a public nuisance. Potential competitors are deterred from working in areas that are not in fact covered by the patent even though costly and protracted litigation (which in the case of patent disputes can be very costly and protracted indeed) might confirm that what the competitors propose to do is entirely lawful. Potential investment is lost or otherwise directed. Competition is ‘chilled’. The patent owner is getting more of a monopoly than the public bargained for.<sup>44</sup>

In addition to patents on full gene sequences, patents have been granted in Canada and the U.S. for expressed sequence tags (ESTs), complementary DNA (cDNA), and single nucleotide polymorphisms (SNPs).<sup>45</sup> ESTs are short fragments of larger genes that have a variety of uses in molecular biology, including the identification of complementary full length genes and similar, homologous gene sequences within and among species. cDNA is a widely used research tool for methods such as genome mapping. SNPs constitute single nucleotide variations within genes between and among organisms. Single nucleotide variation within a gene can result in disease development and is implicated in certain cancer development and genetic predispositions to disease. SNPs are used frequently to locate chromosome markers to identify genes implicated in disease.

Of late, however, the position in the United States<sup>46</sup> and Germany<sup>47</sup> is that the patent offices will henceforth apply a stricter regime on patentability of gene sequences. This welcome return to a more rigorous standard of patentability is largely born out of the concern that, apart from their apparent illegality, broad gene patents hinder the exploitation of newly discovered functions for DNA sequences. In addition, there is a growing apprehension that broad gene patents stifle research in

the biomedical and pharmaceutical fields.<sup>48</sup> These concerns deserve a closer analysis.

## Effects of Broad Genetic Patents on Health Care and Biomedical Research

There is an increasing number of patents being issued in the U.S., Canada, and abroad covering patents implicated in human disease, and diagnostic tests developed for these diseases are being commercialized by biotech companies. Many laboratories have avoided offering such diagnostic tests and developing further research on these genes because of concerns of patent infringement. This has also raised concerns by numerous groups that such restrictions will inevitably inhibit further research into disease-related mechanisms of gene function. There is thus a compelling need to strike the appropriate balance between public and commercial interests.<sup>49</sup>

Emerging evidence shows that public and private laboratories may be restricted from offering certain diagnostic tests for disease and genetic predisposition due to costly licence and royalty fees. This is of particular importance to national health care systems. Canada's social policy towards health care subsidizes a significant proportion of health care treatment. The Canadian health care system is in a financial crisis, and providing access to innovative medical treatments and diagnostics in some instances has proven extremely costly.<sup>50</sup>

In 2002, the Ontario provincial government refused to recognize patents held by a U.S.-based biotechnology firm, Myriad Genetics.<sup>51</sup> Myriad Genetics holds nine U.S. patents on BRCA1 and BRCA2, genes involved in breast and ovarian cancer susceptibility, and similar patents have been granted in Canada and Japan and filed in the United Kingdom and Europe. The test costs approximately \$1,150 in Ontario in Canadian dollars. Myriad notified the provincial government of the firm's patent rights and mandated that the province send samples to Myriad laboratories for testing, costing approximately \$3,850 in U.S. dollars for each test.<sup>52</sup>

The British Columbia government has ceased diagnostic testing for BRCA1 and BRCA2, and has suspended funding for the test across Canada. Quebec has agreed to send samples to Myriad laboratories, and Alberta has continued to provide testing. The remaining provinces are not offering the diagnostic test. The significance of Myriad's refusal to license the BRCA1 and BRCA2 tests cannot be underemphasized given the prevalence of breast and ovarian cancer among women.<sup>53</sup> Early diagnosis and knowledge of genetic predisposition considerably increases treatment effectiveness. These reasons may have compelled research institutions in Germany, the Netherlands, and France to challenge Myriad's BRCA patent applications.<sup>54</sup>

The implications of overly broad gene patents on health care across the globe are gradually moving from the periphery to the core of rising concerns on the future of public access to health care. A recent study researched the adoption and use by U.S. laboratories of genetic testing for a common hereditary disorder.<sup>55</sup> The results found that 30 percent of the laboratories surveyed ceased to provide or develop the test as a result of an exclusive licence granted on the patents for clinical testing services.<sup>56</sup> A similar study was conducted to research the licensing activities of private firms holding patents on genetic diagnostic tests.<sup>57</sup> The results found the patents included in the study that had been licensed were entirely under exclusive terms.<sup>58</sup> These results and other published data<sup>59</sup> on genetic patents involving disease illustrate a trend toward a monopolization of diagnostic, therapeutic, and research purposes concerning a particular gene. Access to genetic-based diagnostics and therapies will become increasingly important as biomedical research and development provides an entirely novel approach to disease treatment. Beyond issues of access to health care, it is becoming obvious that, rather than promote research and inventiveness as most proponents of the patent system assert is its *raison d'être*, broad gene patents issued on genetic sequences of doubtful or unknown utility stifle and hamper research.

Some studies have shown that patents on genetic material have affected researchers' willingness to explore new areas of research and reduced the level of communication within the scientific community.<sup>60</sup> In a survey of approximately 2,100 life science researchers, 19.8 percent of the respondents reported delaying publications of research results for greater than six months in order to prepare and file patent applications, to provide time for patent prosecution, to protect their intellectual property rights, or to resolve contentious intellectual property ownership issues. The study also found that research teams actively pursuing commercialization of university research and partnered with private firms were correlated with significant publication delays. Variables associated with the practice of refusing to share results included human genetic research and involvement in university research commercialization. The researchers concluded that withholding results was not a common practice among life science researchers, but was much more prevalent among faculty research groups pursuing university technology transfer opportunities and corporate partnerships. What makes the situation even more outrageous is that a large number of the patented gene sequences were obtained at a time when patents were granted on gene sequences without identified functions. As Bruce Alberts and Sir Aaron Klug have rightly pointed out:

[T]he intention of some university and commercial interests to patent the DNA sequences themselves, thereby staking claim to large numbers of human genes without necessarily having a full understanding of their functioning, strikes us as contrary to the essence of patent law.<sup>61</sup>

Apart from bringing the patent system to disrepute, the emergent practice flies in the face of common notions that patents constitute a form of fair bargain and contract between the inventor and the society. The reality with such gene patents is that they often short-change the society by granting the inventor large and expansive rights over “areas” or “spaces” which have indeterminable boundaries and thus unfairly constrict the ability of members of the public in conducting research in such “areas” or “spaces”. As Bruce Alberts and Sir Aaron Klug again observe:

[T]hose who would patent DNA sequences without real knowledge of their utility are staking claims not only to what little they know at present, but also to everything that might later be discovered about the genes and proteins associated with the sequence. They are, in effect, laying claim to a function that is not yet known or a use that does not yet exist. This may be in current shareholders’ interests. But it does not serve society well.<sup>62</sup>

Given that scientists are still at the very early stages of understanding the human genetic sequence, it is vital that researchers have access to the full genome without the encumbrances of overly broad genetic patents.<sup>63</sup> The effects of patenting genetic material also affect research agendas within universities, especially in Canada and the U.S. This relates to the growing relationships between private industry and university research, especially in the areas of biotechnology and biomedical research. However, a full treatment of the complex issues arising out of corporate-university relations is beyond the scope of this paper.<sup>64</sup>

There are also issues of inefficiency in resource allocation raised by overly broad genetic patents. Thus, some commentators have analyzed the current trend in genetic patent grants in terms of resource allocation and control.<sup>65</sup> During the second half of the 20th century the original “commons model” of biomedical research, in both Canada and the U.S., has developed into the current “privatization model”.<sup>66</sup> Under the commons model a significant amount of upstream biomedical research was developed from public research institutions and universities and results were circulated widely within the scientific community.<sup>67</sup> Most research and development was published and remained in the public domain, and commercial downstream products arrived.<sup>68</sup>

The 1970s and early 1980s witnessed a move towards private sector research and development, and with this trend arose the importance of protecting intellectual property with patents. A necessary consequence of privatization was a large influx of capital from the private sector, and a concurrent decline in public funding. A similar trend has occurred within university departments, as private funding of university research projects and growing university-corporate ventures have changed the fundamental nature of university research. As private control of biomedical research and development continues, a rapid increase in patents on upstream

genetic patents, including patents on ESTs and partially characterized gene sequences, may be hindering the development of downstream research products. Upstream intellectual property rights delay the development of effective treatment methods involving that specific gene, and may further interfere with research involving related pathways that involve the patented subject matter.<sup>69</sup>

In practical terms, the exclusive rights granted by patents restrict use of patented subject matter and increase transaction costs necessary to access such information. Biomedical research necessarily requires access to a number of resources, and patent protection may often become an obstacle to access. The effective result is an under use of restricted resources because of expansive, if not dubious patents. In biomedical research the effects can be demonstrated through the proliferation of overlapping patent claims and licences. Patents covering characterized, full length genes may provide viable commercial products, including diagnostic genetic tests and therapeutic treatments including pharmaceuticals.

However, both the Canadian Intellectual Property Office (CIPO) and the United States Patent and Trademark Office (USPTO) have issued patents on ESTs. The corresponding gene, protein product, and biological role of gene fragments are not fully characterized, and generally only putative functions are proposed on the basis of homology-based comparisons with conserved gene families. As shown earlier, slight differences in gene homology may produce radically different results. Preliminary sequence information is invaluable in preliminary research initiatives, but granting exclusive intellectual property rights over isolated gene fragments does not afford valuable commercial products and research benefits to the scientific community. The research and development necessary to produce biomedical diagnostic genetic tests and therapeutic treatments requires the use of multiple gene fragments. Access to gene sequences requires significant transaction costs under an intellectual property regime in which patents are granted on multiple gene fragments.<sup>70</sup>

The development of novel therapeutic agents by private firms requires a process of receptor screening. An established practice in the pharmaceutical industry is the screening of large numbers of drug candidates in order to assess possible effects on cellular function. Similarly, candidates that are selected for further pre-clinical research are screened with classes of receptor families to assess therapeutic effects. Use of patented receptors requires obtaining an extensive group of licensing agreements to avoid patent infringement suits, and private firms cannot qualify under research exemptions in developing commercial products. Consequently, pharmaceutical and biotechnology firms normally pursue research involving fewer patent licensing restrictions or proceed

further into clinical testing without adequate *in vitro* studies.<sup>71</sup>

A further implication of granting patents over current gene fragments involves licensing agreements and research ventures entered into during the period between the filing of a patent application and the patent issuance. The rapid development of industry research necessitates that firms and universities enter into licensing agreements and develop research strategies based on pending patent applications. Research groups establishing research and development protocols are restricted further by possible patent claims covered by pending applications.

Further, patent licensing of upstream genetic sequences may result in numerous overlapping rights in downstream commercial products. License agreements may contain conditions granting the licensee royalties in future commercial products developed by licensors, reciprocal licences on commercial developments, or options to acquire reciprocal licences.<sup>72</sup> Practical conflicts can arise when overlapping claims to downstream products are created. In effect, upstream genetic patent holders may acquire rights to subject matter outside of the original patent claims, and exert control over downstream research and product development.

Patents over gene sequences may prevent other researchers from collaborating and contributing to proteomics research, the characterization of protein structure and function. The field of proteomics will eventually replace genomics as the major field of biomedical research, and will provide a novel array of protein-based platform technologies and products. Patents conferring intellectual property rights on protein-based therapeutics will have significant implications for health care treatment and delivery.<sup>73</sup>

Again, overly broad gene patents have the potential of skewing research agendas. A critical underlying principle in the enforcement of intellectual property regimes regarding genetic sequences is the significant potential for economic gain. A significant portion of biomedical research is private, and the primary impetus for continued private research and innovation is capital earnings. As a result, research efforts are primarily directed at projects designed to develop and market commercial products. Such commercially-oriented research does not generally produce the innovative impact within the scientific community as research designed at characterizing basic biochemical and genetic processes. In addition, the exclusive monopoly granted by genetic patents delays general research into further study of biochemical and genetic mechanisms. Basic molecular research that is not predicated on producing commercial products will likely provide a more distinct scientific understanding of biochemical pathways and significant contributions to advances in biomedical research.<sup>74</sup>

Universities have historically provided significant contributions to basic research initiatives. Recently, a

number of universities have entered into corporate relationships and developed university technology transfer initiatives.<sup>75</sup> As public research funding continues to diminish and universities continue to pursue commercial research agendas, fundamental biochemical research will be limited. Commercially-oriented research will not provide broad-based contributions to science, and likewise innovations with maximum benefit to society will be limited.<sup>76</sup> These wide implications of speculative and overly broad genetic patents compel a need to rethink contemporary practices and laws surrounding the issuance of genetic patents.

## Proposed Solutions to the Problems Associated With Speculative Genetic Patents

The Canadian Biotechnology Advisory Committee (CBAC)<sup>77</sup> and the Government of Ontario have recently issued reports concerning genetic patents containing a number of recommended amendments to existing Canadian patent law.<sup>78</sup> These responses take the form of changes to patent office practice, judicial treatment and application of the law, and new legislation or regulatory schemes introduced by Parliament. Although some groups have called for a complete restriction on patenting of any genetic material, this alternative is impractical and may not be necessary. As noted by a group of well-known commentators in this area, "... a radical alteration in patent law ... is unlikely to be tenable, because there are too many forces pushing the patent agenda forward".<sup>79</sup> In the next pages, we outline considerations of several proposed and critical amendments to current intellectual property regimes. We also examine the proposed regulatory framework for genetic patents.

### Stringent Utility Requirements

Amendments should be made to promote further innovation in downstream research development by restricting the patenting of certain upstream gene sequences. Patents granting exclusive rights on genetic material that has not been fully characterized inhibits, or at the very least, delays further research concerning a gene and its related biological mechanisms. Restricting patents on partially characterized sequences and gene fragments diminishes overlapping claims and provides a clear scope for patent rights. This aim could be achieved by mandating that patent offices issue patents only in cases where the gene sequence has been sufficiently characterized and a substantial utility has been clearly identified.<sup>80</sup> It 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 adopted in respect of genetic patents.



The USPTO has recently issued utility examination guidelines with respect to biotechnology patent applications.<sup>81</sup> These guidelines call for stricter application of the utility requirement. The guidelines mandate that a patent applicant provide in the patent claims and supporting written description a “specific and substantial utility” that would be considered credible by a person of ordinary skill in the art.<sup>82</sup> The credibility is assessed from the perspective of a person of ordinary skill in the art provided with the patent application and any relevant evidence on record, including experimental data, expert opinions, and previous scientific literature.<sup>83</sup> Only one credible “specific and substantial utility” is required for a patent application. As a result of these guidelines, a patent application for a gene sequence that has a claimed utility in hybridization techniques for identifying a particular gene marker must be able to identify a specific gene loci.<sup>84</sup> The USPTO guidelines may also further require that the gene probe be related to specific disease research or a specific application.<sup>85</sup> For example, a gene probe may be required to identify a specific disease-related gene mutation. The specific and substantial utility requirement is intended to prevent “throwaway”, “insubstantial”, or “non-specific” uses from fulfilling the utility requirement under § 101 of the U.S. *Patent Act*.<sup>86</sup>

If the “specific and substantial utility” requirement is not met, examiners are instructed to reject the application under § 101 for lack of utility and under § 112 for failure to fully disclose the invention in the specifications due to a lack of a specific and substantial utility. A patent rejection based on § 101 and § 112 places the burden on the applicant to provide further evidence to “establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention”.<sup>87</sup> In circumstances where the examiner has concluded the applicant has not provided a specific and substantial utility, a *prima facie* showing must establish that it is more likely than not that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial.<sup>88</sup> This *prima facie* showing must include a full explanation of reasoning supported by factual findings, and an assessment of relevant evidence on record, including any utilities from previous relevant art.

The guidelines also stipulate that statements of fact made by applicants in relation to utilities asserted in the claim must be considered true statements unless evidence to the contrary exists that would provide a legitimate basis for a person of ordinary skill in the art to doubt the validity of such factual statements. Examiners must also accept qualified expert opinion based on relevant facts unless there is a basis to question the accuracy of such expert opinion. Several commentators submit that the scope of a genetic patent claim should be restricted to those uses that are disclosed in the patent application and satisfy the utility requirement. This suggestion accords with the law in respect of patents on mechanical inventions and ought to be applied with

equal rigor to genetic patents. Under present patent law an application that satisfies the utility requirement for a genetic patent restricts all other parties from using the genetic material in any method. The monopoly granted thereby restricts further research in areas of biomedicine and biotechnology that involve the subject matter of the patent.

This argument has been refuted by noting that a new use for that genetic material may qualify for a separate patent application, regardless of the fact that the gene itself has been patented in a previous application. Inasmuch as this accords with the law,<sup>89</sup> this reasoning ignores the reality that new uses for genetic material invariably require research using the patented material. University and public research institutions may qualify under an experimental use exemption to conduct research on patented genetic material. If a new use is discovered, normally a patent application will be filed on the basis of this new use. Commercial marketing of the patent will likely be pursued as a means for recovering research expenditures and funding further research.<sup>90</sup> In such circumstances, the original patent holder likely has a basis for a patent infringement suit, as research exemptions are generally limited to *bona fide* research uses that are not designed for profit taking.

For private research groups, no such protection is possible. Research into new uses for gene sequences in biotechnology, and particularly medical research, cannot viably be pursued without infringing exclusive patent rights. This may have dramatic consequences in delaying advances in health care that are based on genetic research, as patent holders effectively control not only the marketing of a specific genetic patent, but can restrict further research within entire fields of study for patented gene sequences that are involved in numerous other biochemical and disease-related pathways.

This argument is further supported when considering that a patent on a specific genetic sequence essentially grants a twenty-year monopoly to a patent holder on further uses that may not have been contemplated by the applicant at the time of the original application. While a patent holder is granted exclusive rights to research a particular gene sequence, any further substantial uses that arise from additional research may be monopolized by a firm or group of firms holding exclusive licences. Although this seems readily justified, it must be considered that other research groups are effectively prevented from furthering scientific progress within exclusive patent protected areas of research. It is not unlike the effects of granting a limited monopoly on a mere scientific principle, and allowing limited firms access to research and patent innovations based on that basic principle. DNA sequences form the foundation of all biochemical processes. DNA and RNA constitute the underlying framework for protein production, enzyme and hormone regulation, and basic cellular processes.

Granting somewhat exclusive rights to such principal subject matter carries significant consequences.<sup>91</sup>

Concern has also been expressed over the use of computer analysis of genetic sequence data based upon homology, or sequence similarity, to previously discovered gene sequences and patent utility submissions based on such data. Gene homology comparison is a regularly used tool in studying gene and protein function. The sequence of a gene or gene fragment, or the protein product sequence of the gene, can be compared, using online research tools, with all other previously sequenced and characterized gene families to determine sequence homology. Preliminary gene functional assignments are made based on substantial homology with conserved families of genes that share biological functions. There is credible scientific concern that sequence homology analysis is unreliable and should not form the basis of an alleged assignment of gene function. Even in circumstances where such analysis provides a reasonable general function, commentators have argued such putative assignment does not assess the actual biological role of the gene sequence and protein product and therefore patent examiners should not consider such evidence in determining utility requirements. An additional submission is that if such homology-based utility analysis is employed, the genetic sequence should be considered obvious with respect to prior art.

The claim that an alleged utility based on homology data would render a genetic patent application obvious with respect to previous art can be dismissed by noting that assessing the non-obviousness requirement is a completely separate determination from analyzing the utility requirement. The basis for the rejection of a patent application must include reasoned determinations based on the facts, with reliance on scientific data and evidence. Structure and function assignment derived from sequence homology data is a widely used research tool that is grounded in plausible scientific principles. Examiners must consider such data in assessing the utility requirement in a patent application. Such evidence is not conclusive in satisfying utility requirements and should be provided in conjunction with other evidence by the applicant.

Without sufficient evidence to rebut homology-based putative functional use claims, the data should be accepted and considered together with the materials submitted with a patent application. The utility requirement should not be satisfied simply on the basis of a putative, general biological function derived from a homology search. An applicant would be rewarded with exclusive rights to a genetic sequence before a complete understanding of a biochemical role, and research into possible therapeutic and diagnostic applications, has been elucidated. This situation is clearly contrary to the function of patent law in stimulating innovation. A private research group that receives a patent on a gene sequence based simply on homology analysis will in

effect be granted a monopoly on future uses and functions that have not been contemplated at the time of application. In addition to flying in the face of patent law, such a scheme is contrary to scientific innovation and the interests of society. It replaces certainty with conjecture.

The USPTO guidelines state that the nature and degree of sequence homology data will be considered by examiners, and in circumstances where a class of genes share a specific, substantial, and credible utility, assignment of a gene included in a patent application to the class based on homology will impute the shared specific, substantial, and credible utility to the assigned gene. This stipulation is important, as simply imputing a biological role based on sequence homology will not satisfy the utility requirement unless the class of genes share a specific, substantial, and credible utility. The USPTO Utility Guidelines state that “reasonable assignment of a new protein to the class of sufficiently conserved proteins” will impute the same specific, substantial, and credible utility to the novel protein.<sup>92</sup>

In circumstances where the protein products of a family of genes share major structural features but do not share a specific, substantial, and credible utility, assignment of a gene to the class will not impute a specific, substantial, and credible utility to the novel gene. The interpretation of “reasonable assignment” is not expanded upon, and no quantitative basis for satisfying this requirement is mentioned. Certainly a gene may share certain conserved domains with a family of conserved genes, but the degree of homology must be substantial in order for a putative function to be assigned based on the comparison. The opportunity exists for patent applicants to base an alleged utility solely on homology with a class of sufficiently conserved proteins that share a specific, substantial, and credible utility, in circumstances of low homology that do not in fact support a proper basis for the alleged utility.

As recently suggested by the Government of Ontario in their report, the Canadian Intellectual Property Office should adopt guidelines similar to those of the USPTO.<sup>93</sup> Although such guidelines do not have the force of law, such reform could be readily accomplished within existing intellectual property laws and would not require extensive legislative measures.

## Legislative Reform

The Supreme Court of Canada recently held in *Harvard College* that it is Parliament’s role, and not the role of the Canadian Patent Office or the courts, to determine the question of whether higher life forms are patentable.<sup>94</sup> The role of the patent office is simply to determine whether patent applications meet the requirements of novelty, non-obviousness, and utility under the *Patent Act*. The Supreme Court of Canada resolved the issue of whether higher life forms are

included under the definition of “invention” in s. 2 of the *Patent Act*. Clearly, the patentability of genetic sequences is a complex issue and requires carefully drafted legislative responses. A required element of legislative reform is a redrafted research exemption in the Canadian *Patent Act*. Considering the necessity of information and technology sharing for innovation and development within biomedicine and biotechnology, a compulsory licensing system including private and public research firms must be established. Further, a patent pool for genetic patents must be contemplated, considering the benefits possible from regulated technology patent pools.

## Amendments to Research Exemptions

Preliminary studies and evidence suggest that considerations of potential patent infringement with the lack of a clear research exemption have detracted from basic research.<sup>95</sup> Lack of a clear definition of patent infringing activity within the research community has also led to a general lack of disclosure in the scientific community. The Canadian *Patent Act* must therefore be amended to include a specific research exemption that clearly outlines the boundaries of such an exemption. The purpose of this exemption will ensure that researchers have a clear understanding of their rights, but more importantly, will prevent the forestalling of significant and essential medical research.

In *Smith Kline & French Inter-American Corp. v. Micro Chemicals*,<sup>96</sup> the Supreme Court of Canada dealt with an alleged infringing use of a patent and fashioned an experimental use exemption. The licensee had infringed the patent through experimental use prior to the effective date of a compulsory licence. The Court held that the use of the patent was not for profit but rather a *bona fide* use to ensure the licensee could commercially manufacture the product in accordance with the specifications of the licensor's patent. The Court held this was a logical result of the right to apply for a licence and could not constitute an infringing use. The scope of protection afforded under the experimental research exemption in *Smith Kline* is unclear, especially since compulsory licensing provisions have been removed in Canada.

The *Patent Act* was amended in 1993 to include statutory experimental exemptions under s. 55.2.<sup>97</sup> Section 55.2(6) does not clarify the extent of the exemption in the context of biomedical and biotechnology research.<sup>98</sup> The exemption in s. 55.2(1) was enacted for the purpose of the generic pharmaceutical industry, and states that it is not a patent infringement to make, construct, use or sell a patented invention involving research required to satisfy federal or provincial regulatory guidelines with respect to a product. The said provision reads thus:

**S. 55.2 (1)** It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and

submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.<sup>99</sup>

Commentators have also called for amendments to U.S. law with regard to research exemptions.<sup>100</sup> Although there is a limited statutory experimental research exemption in U.S. law permitting clinical trials under § 271(e)(1), there is no general statutory experimental use exemption. According to this provision,

§ 271(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.<sup>101</sup>

The patent laws of the United Kingdom and Germany contain research exemptions broader than those under the Canadian *Patent Act*. The United Kingdom, Germany, and other European countries conform to the principles of the Convention for the European Patent for the Common Market (CPC).<sup>102</sup> Under Article 31 of the CPC, experimental exemptions are granted for uses of patented subject matter of a private and non-commercial nature, and for experimental research relating to the subject matter of the patent.<sup>103</sup> The CPC has not been ratified by countries of the European Community. If ratified it will provide effective patent protection for an applicant in all countries of the European Union.<sup>104</sup>

The United Kingdom *Patents Act* provides for experimental use exemptions under two categories.<sup>105</sup> Under s. 60(5)(a), exemption is provided for acts “done privately and for purposes which are not commercial”.<sup>106</sup> Under s. 60(5)(b), experimental exemption is also provided for acts “done for experimental purposes relating to the subject matter of the invention”.<sup>107</sup> These provisions exempt experimental research designed to improve or modify the patented subject matter in order to examine the extent of the patent claims, but prohibit research examining commercial production of the patented subject matter.<sup>108</sup> German patent use exemptions protect personal use in the private sphere that is non-commercial.<sup>109</sup> Experimental uses relating to the subject matter of a patent are exempt, including uses for determining the scope of the patent claims and for determining methods for patenting around the invention. The Japanese *Patents Act* provides an exemption for “the working of the patented invention for experiment or study”.<sup>110</sup>

The s. 55.2 amendments to the Canadian *Patent Act* have been noted in recent reports by the Canadian Biotechnology Advisory Committee and the Government of Ontario as being insufficient in affording protection for researchers from patent infringement suits.<sup>111</sup> The spe-

cific content of a newly proposed experimental use exemption in Canadian law would require input from a number of interested parties, including private firms, public researchers, and legal professionals. Such an exemption would attempt to balance the commercial interests of the private sector while providing the means for continued innovation through necessary research.

An inherent problem in drafting an experimental research exemption to satisfy these conflicting interests is the economic and commercial potential that exists for current research in biotechnology and biomedicine. Obviously, private biotechnology firms could not avail themselves of an exemption to use patented subject matter for the purpose of commercializing further innovations. The exemption would be primarily designed for research centers conducting basic research in fundamental molecular biology, including public research centres and universities. However, the close relationships that have developed between corporate firms and universities create at the very least the potential for commercial products to develop from university research.<sup>112</sup>

In a recent report, the Canadian Biotechnology Advisory Committee recommends that the *Patent Act* be amended with a research and experimental use exemption that includes the following language:

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>113</sup>

The first clause restates the private and non-commercial exemption from s. 55.2(6) of the *Patent Act*. The second clause expands upon the exemption in s. 55.2(6) “for the purpose of experiments that relate to the subject-matter of the patent”.<sup>114</sup> The proposed exemption is more expansive in the use of the term “study”, and on a literal interpretation offers greater latitude for researchers, especially private firms, to use patented subject matter in developing further commercial products.

It is clear that drafting an experimental exemption requires at some point a choice between the competing values of promoting research while protecting intellectual property rights. In circumstances of public research conducted by university departmental projects that receive partial or complete private funding from private interests, it is difficult to identify research that has non-commercial purposes. In addition, a research department may receive corporate funding for certain projects, and maintain separate research-exempt projects designed for non-commercial purposes. It is not difficult to imagine a patent holder commencing litigation for patent infringement under such circumstances regardless of the assumed research exemption, especially if the corporate firm funding the related research is a competitor. Patent infringement suits may arise in circumstances where experimentally exempt university research provides

potential for commercial marketing involving university-industrial technology transfer. Although university research departments are generally engaged in basic research rather than commercially oriented ventures, there is a growing trend to commercialize basic institutional research through university-industrial transfer programs.

The issue of distinguishing between basic research and research with commercial interests was explicitly avoided by the Canadian Biotechnology Advisory Committee in their recent report.<sup>115</sup> Despite the difficulty of resolving these distinctions in drafting an experimental use exemption, it is essential that a clearly outlined amendment be introduced. A possible remedy for these conflicts is provision for a licensing or royalty scheme within an experimental research exemption. Such a provision could provide the patent holder with a financial portion of the economic capital from commercial products produced as a result of patent use under the experimental use exemption. Clearly, the structure of an experimental exemption must be designed to serve the purpose of promoting further research in biotechnology and genetics, and must address the problem of access to platform biotechnology that has arguably inhibited general research progress within the scientific community.

## Compulsory Licensing Requirements

Some groups have called for the implementation of mandatory licensing schemes that would ensure broad access to novel therapeutics and diagnostic tests.<sup>116</sup> Licensing requirements would also provide research firms with access to genetic-based technologies and allow for greater exploitation of genetic resources through non-exclusive resource development. Mandatory licensing requirements may be included within a patent pool regulatory scheme involving public and private research centers.

## Biotechnology Patent Pools

The USPTO has recently examined the application of patent pools to biotechnology patents,<sup>117</sup> which involve “the aggregation of intellectual property rights which are the subject of cross-licensing, whether they are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool”.<sup>118</sup> Under a biotechnology patent pool, patent holders would engage in cross-licensing agreements, facilitating the dissemination of technological innovations within the fields of biotechnology and biomedical research.

The fundamental notion in support of patent pools is the principle that the benefits of genetic resources will be exploited to a greater extent by groups of researchers and organizations rather than through exclusive development. Patent holders will be inclined to form patent pools that provide capital through licensing fees. The

Cohen and Boyer patents, involving recombinant DNA technology, owned by Stanford University, represent a licensing scheme that has benefited all licensee organizations, Stanford University, and the entire biotechnology industry.<sup>119</sup> From 1981 to 1995, Stanford generated \$139 million in royalties from licensing agreements.

The success of this non-exclusive licensing arrangement was based on three essential factors. First, the licensing fees were inexpensive. Stanford was able to generate large amounts of capital return because of the enormous volume of licences granted. This vast market was available because of the second essential element that no other alternative technologies were available. Third, the technology was essential to advancing research methods in biotechnology and molecular biology.

As a result, the broad, non-exclusive nature of this licensing scheme allowed the recombinant DNA industry, and further biotechnology and biomedical research, to develop at an exponential rate during the 1980s and 1990s. It is clear that not all licensing schemes have such potential, as most innovations are not as critical to their respective industry or as widely applicable, and alternative technologies commonly exist. However, such a licensing arrangement outlines the potential benefits to patent holders and further industry innovation from a patent pool, while avoiding restrictions on development and significant transaction costs resulting from exclusive technology ownership.

A primary concern in a patent pool system is the potential for anti-competitive behaviour practised by participating organizations. The U.S. Department of Justice and the U.S. Federal Trade Commission recently set forth *Antitrust Guidelines for the Licensing of Intellectual Property (IP Guidelines)*.<sup>120</sup> These policies are structured to ensure that patent pools provide positive competitive effects and facilitate the advancement of technological innovation. According to the *IP Guidelines*, intellectual property pooling will provide a positive competitive environment through the formation of synergies among related technologies, reduction of transaction costs, effective allocation of technological resources, and by precluding litigation proceedings. The *IP Guidelines* also note that anticompetitive behaviour may be practised through the exclusion of organizations from a patent pool.

The U.S. Department of Justice has further submitted the following guidelines with regard to the approval of patent pools: the pool participants are restricted from aggregating competing technologies for the purpose of anticompetitive pricing; the pool patents must be valid; independent determinations are necessary to identify those patents essential to creating synergies among complementary technologies; and the patent pool participants must not attempt to affect market prices on downstream products.<sup>121</sup>

A patent pool system structured under the above guidelines, specific to patents on genetic material, would maximize the social and economic benefits to innovators and the state, the parties subject to the contract of a patent. Such a regime could be introduced not only at a national level, but also possibly as an extension of current international agreements such as the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).<sup>122</sup> The introduction of an intellectual property pool for genetic patents would alleviate problems caused by the existence of overlapping patents and stacking licences. The development of future biotechnological and biomedical innovations requires the assimilation of data from a number of genetic sequences. However, there has been a proliferation of patents granted on genetic sequences in a number of organisms. As a result, private firms and research groups are restricted in accessing proprietary genetic subject matter. Moreover, many patents have been granted on early stage, or upstream, genetic sequences that require further research before downstream practical innovations are developed.

The rights in such upstream patents could be licensed to private firms or public and university research groups, with provision for reach-through license agreements that provide royalties to the licensor on any downstream innovations that arise from the initial subject matter. A patent pool regime would provide research groups with access to platform technologies necessary to pursue further developments in particular fields. Licensors would be granted license fees or cross-licences, and the overall development of genetic innovations would be augmented through the cooperative research of patent pool members.

Economic benefits would accrue under a patent pool system as transaction costs could be greatly reduced. The significant costs of patent infringement litigation are reduced under such a system. In addition, research firms may obtain an entire portfolio of licences under a particular technology and avoid the extensive costs of separate licences. The leverage of certain patent holders exercising exclusive rights over core technologies is eliminated, and provisions could be included to impose reciprocal licensing of any innovations arising from licensed technologies.

A further benefit proposed may exist in the distribution of risk inherent in the research and development process in biotechnology. The obvious benefit is for medium and small biotechnology firms and research centres that are provided the incentive of offsetting the associated financial risks. However, such benefits would only be possible under a patent pool regime that provided a relative equal value for all patents and uniform access to technologies within the system. It seems apparent that large pharmaceutical and biotechnology firms would be reluctant to allow smaller enterprises to offset their financial risks through partnership. Pharma-

ceutical and biotechnology firms that hold significant patent portfolios, and consistently develop products closer to market realization, can expect to receive greater benefits from their intellectual property rights than firms with less resources and lower potential for patent commercialization. A patent pool regime required to induce the involvement of such firms would require a benefit sharing system that accounts for initial intellectual property investment.

There are reasons to doubt that the benefits realized from patent pools will translate directly into the field of biomedical research. Intellectual property rights form the basis for the economic value of pharmaceutical and biotechnology firms, and private firms may prefer the economic gains available from exclusive patent ownership. In addition, the lack of alternative technologies in biomedical research will provide unequal bargaining power among participants. Firms may be encouraged to enter a patent pool and introduce invalid patents in an attempt to prevent litigating the validity of such patents. Further, firms could receive licensing fees for technology that is properly part of the public domain. This situation could readily be prevented through the use of independent expertise to determine only those patents essential to complement technologies in the pool, as noted in the U.S. Department of Justice guidelines.

A primary criticism of patent pool regimes is the potential for monopoly pricing and the encouragement of anticompetitive price fixing practices. A strict application of guidelines similar in principle to those under the *IP Guidelines* and from the U.S. Department of Justice would prevent anticompetitive behaviour. A parallel scheme of antitrust legislation would provide for prohibitive measures and penalties. Despite the problems inherent in structuring a complex patent pool for genetic patents, and the potential for anticompetitive practices, further research is necessary to assess patent pools as a viable solution to the problem of access to platform biotechnologies.

## Conclusion

**W**e have examined how the patent system evolved to accommodate the claims of the biotechnology industry across the globe.<sup>123</sup> In Canada, it is no longer in doubt that genetic materials are patentable. However, the majority decision of the Supreme Court in *Harvard College* to the effect that higher life forms do not fall under the definition of “invention” in s. 2 of the *Patent Act* still leaves ample room for debate on the broader legal and social implications of genetic patents.<sup>124</sup> In tune with emerging global concerns on indiscriminate issuance of patents, the Supreme Court, per Bastarache J. observed that patents may deter future biomedical

research and downstream product development, particularly within the field of biotechnology, and articulated the importance of maintaining access to platform technology within biomedical research. Similarly, the plurality of the Court noted that the scheme of the current *Patent Act* does not contain a sufficiently clear research exemption. In addition, the court expressed concerns over the potential high costs of diagnostic tests and therapeutic agents and the implications for Canadian health care. The plurality of the Court raised these concerns to illustrate that the current Act is not well designed to address the unique concerns and issues surrounding the patenting of higher life forms.<sup>125</sup>

These and other issues raised by the Court in respect of the dramatic expansion of the traditional patent system<sup>126</sup> underscore the need for a bold rethinking of the legislative scheme necessary to govern patents on life forms. In promoting ingenuity, novel ideas on this issue must balance the interests of the society with those of the industry. While it is not the province of the courts or the patent office to rewrite or amend the norms of science,<sup>127</sup> it is certainly their bounden duty to enforce extant laws with vigilance and even-handedness bearing in mind the essence of the patent regime. Of particular importance in this context is the objective of promoting the notion of universal health care in Canada. In this biomedical age, the Canadian philosophy of universal health care is severely threatened by the indiscriminate granting of overly broad and speculative genetic patents.

These unique concerns raised by the majority of the Supreme Court in *Harvard College* regarding the issue of patenting higher life forms likewise support the position that the current *Patent Act* is not well designed to accommodate genetic patents. The reasoning of the majority in *Harvard College* also supports the submission that novel legislative schemes are required to properly govern the patenting of genetic sequences. Further, such specific legislative responses must balance protection of exclusive intellectual property rights under the current regime against promoting the fundamental notion of universal health care in Canada.

The 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 patent laws. The basic framework for understanding biochemical processes and human disease, the human genome, has just recently been disclosed. The future of research will involve characterizing thousands of genes and protein products and myriad synergistic biochemical processes. In order for this endeavour to effectively advance, which requires providing incentive for scientific innovation and benefits to medicine and biotechnology, access to research tools is essential.

## Notes:

- <sup>1</sup> See, for example, Samuel Oddi, "Beyond Obviousness: Invention Protection in the Twenty-First Century" (1989) 38 *The American University Law Review* 1097. In the mellifluous words of Justice Binnie, "a patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*. The public should not be expected to pay any elevated price in exchange for speculation ... the patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosure". *Apotex v. Wellcome Foundation Ltd.* (2002), 21 C.P.R. (4th) 499; (2002), 219 D.L.R. (4th) 660.
- <sup>2</sup> Sir Arnold Plant, "The Economic Theory Concerning Patents for Inventions" (1934) *Economica* 30; Fritz Machlup, *An Economic Review of the Patent System*, [Study of the Sub-Committee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, Second Session, Study No. 15].
- <sup>3</sup> Samuel Oddi, "The Un-Unified Theories of Patents — The Not-Quite-Holy-Grail" (1996) 71 *Notre Dame Law Review* 267; Ulf Anderfelt, *International Patent Legislation and Developing Countries* (The Hague: Martinus Nijhoff, 1971); Edith Penrose, *The Economics of the International Patent System* (Connecticut: Greenwood Press, 1974).
- <sup>4</sup> Owen Lippert, "One Trip to the Dentist is Enough" in Owen Lippert, ed., *Competitive Strategies for the Protection of Intellectual Property* (Vancouver: The Fraser Institute, 1999) at 131; Robert Sherwood, et al., "Promotion of Inventiveness in Developing Countries Through a More Advanced Patent Administration" (1999) 39 *The Journal of Law and Technology* 473; Robert Sherwood, "Human Creativity for Economic Development: Patents Propel Technology" (2000) 33 *Akron Law Review* 1.
- <sup>5</sup> Amy Carroll, "Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law" (1994-5) 44 *American University Law Review* 2433.
- <sup>6</sup> John Golden, "Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System" (2001) 50 *Emory Law Journal* 101.
- <sup>7</sup> Bruce Alberts & Aaron Klug, "The Human Genome Itself Must Be Freely Available To All Humankind" [2000] 404 *Nature* 325. Under patent law, an applicant for a patent must comply with the requirements of s. 27 of the *Patent Act* on specification. A patent specification contains two separate but interrelated parts, the disclosure and the claims. Section 27(3) of the *Patent Act* provides thus:
- S. 27** (3) Specification — The specification of an invention must
- (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
- (b) set out clearly the various steps in a process, or the method of constructing, making, compounding, or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;
- (c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and
- (d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.
- Section 27(4) provides for the "claims" component of a specification. It reads thus:
- [T]he specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed.
- <sup>8</sup> See *Patent Act*, R.S.C. 1985, c. P-4, ss. 27, 28.3.
- <sup>9</sup> *Patent Act*, *Ibid.* It is an axiom of patent law that the "patentee must particularly describe and ascertain the nature of his invention. In order that, after this privilege is expired, the public may be able to do what the patentee has invented, he must particularly describe and ascertain the manner in which the same is to be performed". See *Beecham Canada Ltd, et al. v. Procter & Gamble Co.* (1982), 61 C.P.R. (2d) 1 at 8.
- <sup>10</sup> *Patent Act*, *Ibid.* See also *Whirlpool Corp. v. Canco Inc.*, [2000] 9 C.P.R. (4th) 129; S. 45 of *Patent Act*, *Ibid.*
- <sup>11</sup> *Martinray Industries Ltd v. Fabricants National* (1991), 41 C.P.R. (3d) 1 at 20.
- <sup>12</sup> *Airseal Controls Inc. v. M & I Heat Transfer Products Ltd.* (1994), 53 C.P.R. 259 at 274.
- <sup>13</sup> (1972), 8 C.P.R. (2d) 6 (F.C.T.D.), at 14.
- <sup>14</sup> See Binnie J. in *Apotex v. Wellcome Foundation*, *supra* note 1 at 12.
- <sup>15</sup> David Dickson, "NIH Opposes Plans For Patenting 'Similar' Gene Sequences" (2000) 405 *Nature* 3.
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