LEGAL STATUS AND PATENTABILITY OF HUMAN STEM CELLS: A COMPARATIVE ANALYSIS OF AUSTRALIA, THE UNITED STATES AND CANADA

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As for the argument that stem cell research can be abused for monetary gain or vanity, one must remember the adage that with great power comes great responsibility. The ability to create life, for example, was one of the most important discoveries in our evolution as a species because of its multiple uses that aided in survival: seeing in the dark, staying warm in freezing environments, and cooking meals to prevent illness. This important tool, however, was often abused and used to destroy villages or burn people at the stake. Does this mean humans would have been better off without its potential to be used as an unethical tool of destruction? It is a generally accepted reality that making progress coincides with taking risks.1 - Tyler Lanza

Abstract
The commercialisation of science and the patenting of human stem cells has become one of the most controversial debates of the decade. Thirty years ago, the case of Diamond v Chakrabarty introduced a new area of patent doctrine in which, for the first time, the court intended patentable subject-matter to 'include anything under the sun that is made by man'.2 The patenting of living organisms has now become routine, however, due to the exceptionally personal nature of human genetic material, the issue of patenting genes has sparked a controversy that spans legal, philosophical, and social concerns.3 The real issue here is deciding whether to permit patenting of human genes because it is necessary to promote research and investment in biotechnology that could potentially cure deadly diseases that would not otherwise be cured, or to forbid gene patenting on the ground that it violates human dignity and morals in principle. Tyler Lanza has argued that:

This debate is not about whether stem cell research is ethical or not. Rather, it is about whether or not we can trust ourselves as a society to handle its vast potential in an appropriate way. Humans are historically fallible, but human imperfections should not lead society to dismiss innovation. Instead, we must evolve as a species in order to adapt to our own advancements while working together to protect ourselves from ourselves, while paradoxically attempting to save ourselves from diseases and other ailments.4

This article draws attention to some of the challenges posed by the ethical and moral aspects of commercialising stem cells, which could be the most obvious barrier to their patentability. The article then considers some of the key judicial decisions related the patenting of human stem cells in order to analyse how the judiciary has responded to new scientific breakthroughs. The article also discusses recent developments in the patentability of stem cells by comparing legal issues in Australia, the United States, and Canada, with the aim of identifying the advantages and disadvantages of each approach. The overarching purpose of the article is to explore the benefits and drawbacks of human biological research and whether or not it should be patentable.

Introduction
The average adult human body is comprised of 50 million trillion cells of around 200 different types.5 Human development begins with the union of a sperm ( spermatzoon) and a secondary oocyte (ovum); this results

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1) Diamond v Chakrabarty, 447 U.S. 303 (1980). The US Supreme Court ruled that life forms can be patented if they are the products of human ingenuity.
in an embryo, which is the beginning of a new human being.\(^6\) Like embryonic germ (EG) cells, human embryonic stem cells (hESCs) are derived from embryos that can be propagated indefinitely in their primitive undifferentiated state while remaining pluripotent.\(^7\) Because hESCs have the potential to differentiate into almost all of the cell types in the body, they have exciting potential, both as a source of cells for regenerative medicine and as valuable tools for drug discovery and for understanding human development and disease.\(^8\)

Stem cell research has the potential to cure hundreds of debilitating and degenerative diseases, such as leukaemia, Parkinson’s disease, Alzheimer’s disease, diabetes and various cancers.\(^9\) According to the Stem Cell Research Foundation, stem cell research can create treatments that will help 58 million Americans with heart disease, 4.3 million with arthritis, 10 million with osteoporosis, 8.2 million with cancer, 4 million with Alzheimer’s disease, 1 million with juvenile diabetes, and 250,000 with spinal cord injuries.\(^10\) The most important potential use of hES cells is that they can be ‘grown’ to fit specific individualised genetic requirements, eliminating the risk that the host body will reject the organ. Adult stem cells can be used for this purpose (thereby eliminating the moral and ethical debate on the subject), but this method is not as effective as using embryonic stem cells.\(^11\)

Although human stem cell research is at an early stage of development, it has the potential to save lives and the development of stem-cell-based treatments will also promote the growth of the biomedical industry.\(^12\) Similarly, stem cell research promises to advance the science of stem cell biology science and cell regeneration. Understanding the processes by which stem cells remain unspecialised and self-renewing may lead to greater insights into how the human body repairs and replaces old and degenerated cells, as well as how it ‘pre-programmes’ the lifespan of certain cells.\(^13\) This knowledge may illuminate the complex process of differentiation that allows simple multi-cellular forms to develop into highly specialised and inter-coordinated tissues.\(^14\) This is a significant scientific milestone that has generated considerable excitement among researchers and scientists. In fact, the prestigious American journal Science described this area as the third great technology revolution, after the Industrial and Information technology revolutions.\(^15\)

Stem cell research also involves significant potential financial benefits. In 2004, for example, the potential of the stem cell research industry was forecasted to generate revenues in excess of US$10 billion by the end of 2013.\(^16\) Investments in stem cell research in the United States are projected to reach US$2.4 billion by 2015.\(^17\) California alone will invest US$3 billion in stem cell research over the next ten years.\(^18\) The United Kingdom must invest at least an extra £160 million in stem cell research over the next three years if it is to continue on its current trajectory as a leader in the field.\(^19\) In 2010, the Australian Government allocated A$21 million to Stem Cells Australia for a period of up to seven years to

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\(^14\) Ibid., at 79.

\(^15\) US semiconductor giant Motorola has declared that biotechnology will be its next major investment. This is the third major investment area for Motorola, following radio in the 1920s and semiconductors in the 1950s; quoted in Prime Minister’s Science, Engineering and Innovation Council, the paper was prepared by an independent working group for PMSEIC, 2000 at http://www.chiefscientist.gov.au/wp-content/uploads/20000130-Molecular-Medicine.pdf (last accessed on 24 January 2011).


\(^18\) UK stem-cell research needs £100m to retain world lead at http://www.timeshighereducation.co.uk/story.asp?storycode=401403 (last accessed on 27 February 2013).

\(^19\) Ibid.
continue stem cell research under the new Australian Research Council Special Research Initiative in Stem Cell Science (SRI), which commenced in July 2011. In the 2009/10 financial year alone, the Centre funded A$11.1 million of stem cell research across Australia.

The significant investments in hESC research have meant that stem cell technology is heavily reliant on patent protection. There has been rigorous debate about the extent to which patents are an adequate method to provide incentives for inventions related to higher life forms. Although 30 years have passed since Chakrabarty, judicialities around the world have been inconsistent with their decisions, which has created considerable uncertainty with regard to patenting genes. The courts have displayed mixed reactions to upholding the patentability of DNA.

Part I of this article provides an overview of human cell development, explains the arguments at the centre of the debate and discusses whether human stem cells ought to be patentable. Questions related to the legalities of the patentability of human stem cells have received less attention than the more popular social and moral issues. This article looks at the legal, ethical and moral aspects of commercialising stem cells as perhaps the most obvious possible barriers to the patentability of human embryonic stem cells. Part II considers a number of stem cell lawsuits around the world, in an attempt to determine how the judiciary has responded to the new scientific breakthroughs. Part III examines the current legal and policy stance on embryo research under different jurisdictions, and identifies the difficulties of patenting human stem cells. Finally, the article suggests that even though human genes themselves cannot be patented, it must be possible to patent the isolated DNA molecules engineered by humans, which are markedly different from naturally occurring DNA.

Analysing Arguments For and Against Patenting Higher Life Forms

The moral and ethical concerns related to human stem cell research have received a great deal of attention in the last few decades. In fact, there are myriad views on the status of an embryo and its patentability. One of the most prominent ethical issues regarding stem cell research is the need to destroy the embryo in order to isolate human ES cells. Once an egg is fertilised, it ceases to be an egg and instead becomes an embryo that is chromosomally diploid, possessing a full complement of genes derived from its parents. If implanted in a womb, the embryo has the potential to develop into a fetus and subsequently become a full human being. This raises an important issue: what is the legal status of an embryo, even if it will never be implanted?

At one end of the spectrum is the view that an embryo is nothing more than a collection of cells. The main attraction of using embryos is their pluripotency, which is the ability of the cell or cells that make up the embryo to grow and divide and differentiate into other kinds of cells. At the earliest stages, the embryonic cell is totipotent; from these few stem cells, it is able to make all the myriad other differentiated or specialised cells that will eventually make up the adult human body. In fact, embryos, particularly the very early pre-implantation blastocysts involved in stem cell research, do not, for instance, have consciousness, individuality, the ability to reason or the ability to form courses of action in life and choose between them. Consequently, many philosophers do not believe a fertilised, five-day-old human embryo before implantation satisfies the criteria of personhood. Not every embryo will result in a human being.

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21) Ibid.
23) The author supports the recent decision of the US Federal Circuit Court of Appeals in Washington, DC, in which the court found a distinction between a product of nature and a human-made invention.
24) Philosophically, a human embryo may be defined as a totipotent cell or a group of cells or a multi-cellular organism which has the inherent actual potential to continue organised human development in a suitable environment: Norman Ford SDB, 'Embryos, Cloning, Stem Cell Research and Ethics' (2004) Summer Chitham Health Ethics Bulletin 21.
26) Ibid., at 911.
27) Ibid., at 900.
29) Hug, Kristina, "Therapeutic Perspectives of Human Embryonic Stem Cell Research versus the Moral Status of a Human Embryo - Does one have to be Compromised for the Other?" (2006) 42(2) Medicina (Kaunas) 107, at 107 to 108.
At the other end of the spectrum is the religious immediate humanisation doctrine, which asserts that human life begins at the moment of conception. Christianity argues that, from the point of conception, an embryo acquires the full moral rights and attributes of every human being – the doctrine of ‘immediate Anthropogenesis’. In fact, biblical references mention God forming the human being in the womb. The Roman Catholic Church has said that that ‘the human embryo, from the moment of conception, has a right to its own life, and therefore every intervention which is not in favour of the embryo is an act which violates that right’. Christians believe it is immoral to destroy a life that has been conceived, because it belongs to God, in whose image it was made. However, this view is not consistent across all religions. For example, the Muslim perspective is that an embryo is only considered a human life after it is four months old, as a soul is believed to be introduced into the embryo at that point. From a Jewish perspective, ‘humanity’ starts after 40 days’ gestation, which suggests that embryos would not have ‘humanity’. Even though there are mixed religious views on the issue, a poll conducted in 2005 by the Genetics and Public Policy Center at Johns Hopkins University showed that 69 per cent of Roman Catholics, 74 per cent of Protestants, and 50 per cent of Evangelicals supported stem-cell research.

Another argument is that if a woman has the right to abort a foetus implanted in her womb at her absolute discretion at any time before 24 weeks, there should be no higher protection from destruction for the purpose of research than consent given within the same time-frame from the people who contributed genetically to the embryo. This is especially so if there is no reasonable possibility that the embryo will ever be implanted. In such circumstances, the choice is between destroying the embryo by thawing and subsequent disposal as waste tissue, or donating it to research. The failure of an embryo to implant in a woman’s uterus does not generally attract significant attention, nor is it considered as serious a death as that of a human life. Above all, hundreds of thousands of ‘surplus’ embryos are cryopreserved in IVF clinics around the world, some of which will remain in frozen storage for years and ultimately discarded by the intended couple when they are no longer needed for future IVF cycles. Approximately 25 per cent of frozen and thawed embryos do not survive between a first and second impregnation procedure.

Professor Janet Rowley said:

Many [embryos] are destined to be thawed and discarded and thus die. It is a true moral dilemma, but science offers a way to bring something good from a flawed situation. The parents of these embryos could allow them to die, or they could donate the embryos for research that someday might benefit patients with incurable diseases. This is a high purpose, one that promotes both human health and understanding.

The use and ultimate fate of embryos is a dilemma: they cannot be stored in cryogenic deep freeze indefinitely and ultimately, they will have to be used or discarded. Instead of being destroyed, they should be donated to science, if they can be used to treat someone with a terminal disease like cancer. The future of stem cell research depends not only on the abilities of scientists, but also on the wisdom of lawyers and judges to help transform this achievement into commercial products.

**Genetics, Genomics and Patentability Requirements**

Any discussion regarding gene patenting must begin with the science of genetics and genomics. Genomics, defined as the study of genes and their functions, along with related techniques, has the potential to offer new therapeutic methods for the treatment of some deadly diseases, as well as new diagnostic methods. The main difference between

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36) Ibid., at 911.
37) Hug, Kristina, Note 30 above, at 109 to 110.
genomics and genetics is that genetics scrutinises the functioning and composition of the single gene, whereas genomics addresses all genes and their inter-relationships in order to identify their combined influence on the growth and development of the organism. In fact, the information in the genome is stored as DNA (deoxyribonucleic acid), which is capable of transformation, comprises most of a chromosome and is the genetic material for all cellular organisms. Genes that are ordered sequences of nucleotides located in a particular position on a particular chromosome carry the blueprints for proteins; these make up less than 2 per cent of the human genome. DNA isolation refers to the process of extracting DNA from a cell in a relatively pure form; this technique involves separating DNA from other cellular components, such as proteins, RNA and lipids. The rope element (a strand) is composed of alternating molecules of sugar and phosphate. The double-stranded DNA molecule contains the four basic chemical units of life's code DNA: adenine (A), thymine (T), guanine (G) and cytosine (C). Moreover, detailed inspection of the patent description reveals that a type of isolated DNA molecule that is claimed in many patents is not genomic DNA but is actually complementary DNA (cDNA), which is prepared by an enzymatic process (reverse transcription) from isolated messenger RNA (mRNA); therefore, it is a human-made artificial construct. In fact, cDNA differs from naturally occurring genomic DNA that does not exist in nature and is not simply purified from nature.

The appropriate method for determining patentability over genetic material has been the subject of considerable debate. In fact, all member states of the World Trade Organisation are obliged to make patents available for all technological inventions, provided that they fulfill Article 29 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS); that is, novelty, non-obviousness and utility. The fact that requirements were enacted long before gene sequencing was possible or even predicted has made it difficult to apply the requirements to patent applications for genetic materials. In fact, patents claiming DNA sequences have been subject to extensive debate given the question of whether they meet the patentability requirements that apply to other mechanical inventions. The question centres on whether a gene sequence is merely a discovery or an invention.

For an invention to be patentable, it must meet several technical requirements: 'novelty' (it must be new, and not a product of nature in its 'raw state'); 'inventiveness' (there must be an element of non-obviousness to the invention); and 'usefulness' (it must have industrial application and functionality).

The requirement of novelty stops the patenting of everyday items or processes that are known to the public, and also the multiplicity of patents. In general, the novelty requirement mandates that claims for the subject of a patent application must be made on the basis that all prior information about the features of the invention (what has gone on before in the field, including what is generally known and documented) has been made publicly available. In the context of gene patents, the novelty requirement centres on whether genes, which already exist in nature, can truly be said to be new. Undoubtedly, the most difficult questions in gene patent claims are, first, whether genetic materials, as a product of nature, can meet the novelty requirement that applies to other inventions; and, secondly, the extent to which the spectrum of human
intervention should differ from the natural product in order for the result to qualify as a new invention.

In fact, the application of the novelty doctrine to biotechnology has been the subject of considerable debate at common law, most conspicuously in the United States. For example, the Supreme Court of the United States first addressed a patent claiming a purified product of nature in 1874, in American Wood-Paper Co. v. Fibre Disintegrating Co. The court rejected the patenting of isolated and purified products of nature, asserting that a patent for purified cellulose to create paper did not significantly differ in kind or substance from naturally occurring cellulose, and was therefore not novel. The court held that the paper pulp obtained from various vegetable substances was in common use before the original patent was granted, and that whatever the process for obtaining it, the product was in no sense new. Unfortunately, the court did not clarify when and how the purification or isolation of a natural product could result in patentable subject-matter.

The legal principles followed in American Wood-Paper Co. were later confirmed in American Fruit Growers v. Brogdex, which established that purifying an existing natural product could not transfer it into patentable subject-matter. The court found that impregnating fruit rind with borax to render it resistant to moulds did not make it a 'manufacture' or a manufactured article because it lacked the novelty factor. In fact, although the product in Brogdex undeniably possessed a new and distinct quality that changed the general character of the natural fruit, the court held that a 'sufficient change' was required in order to transform non-statutory subject-matter into statutory subject-matter. However, this case did not analyse the boundaries of patentable subject-matter; instead, it left uncertainty regarding what defined 'sufficient change' or what was the proper test to show that applicants had invented or discovered something new. This result showed that the common law concerning patents on biotechnology was more stern than previously believed, which overwhelmed the biotechnology industry with uncertainty.

The above decisions clearly show the lack of a clear direction in common law for determining whether biotechnological inventions are entitled to patent protection. In these cases, the patentability requirements regarding biotechnology were poorly defined and the courts generally tended to be especially firm when applying novelty requirement over natural phenomena. This, in turn, increased uncertainty about the scope of patents over biotechnology. Justice Frankfurter said that because these concepts could not establish the 'novelty' (inventive step) element, they would obstruct the effectiveness of the patent laws and deny the deserved protection for persons engaged in research and development of living subject-matter.

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57] Ibid., at 192.
58] 90 U.S. 566, 596 (1874).
59] 1932 283 USA.
60] 283 U.S. 1 (1933) at 11-12. "It said that addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange, fit only for the same beneficial uses as theretofore."
63] Ibid.
64] Ibid.
65] Ibid.
In 1980, however, the Supreme Court removed the opposition to plant biotechnology patents, in *Diamond v Chakrabarty*.67 In a surprising reversal from its prior decisions, the Supreme Court upheld the first patent on a newly-created living organism, ruling that as long as the organism is truly 'man-made', such as through genetic engineering, then it is patentable.68 *Chakrabarty* was one of the first stem-cell cases in the United States. Ananda Chakrabarty, who worked for General Electric, developed a bacterium that could break down multiple components of crude oil. He intended to use the bacteria to treat oil spills and applied for a patent in 1972. *Chakrabarty* was initially turned down by a patent examiner on the basis that the bacterium was a living organism, which could not be patented. He then appealed to the Board of Patent Appeals and Interferences, which agreed with the original decision. The case was then appealed to the United States Court of Customs and Patent Appeals, which found in Chakrabarty's favour and allowed the appeal. The Commissioner of Patents (Sidney Diamond) then appealed this decision to the Supreme Court, based on two main arguments. First, Diamond argued that the Patents Act had been designed in such a way that it did not include the ability to obtain patents over living organisms. The court rejected this claim on the basis that the patents were originally disallowed because they were natural and had not been modified. In this case, the bacterium had been significantly modified and was, therefore, not 'nature'. Diamond's second argument was that micro-organisms cannot qualify as patentable subject-matter until the legislature specifically authorises such protection. The court rejected this argument, noting that its role was to interpret statute and apply it. This was the process that was being undertaken and part of the process was to determine whether micro-organisms were included within the Patents Act provisions. The court also emphasised that if the legislature disagreed with its decisions, they could be overridden by the passing of legislation.

The *Chakrabarty* decision certainly heralded a new era to the field of biotechnology, pushing the borders of patent law to the extent that living organisms are allowed patentable status. In fact, more than 30 years after *Chakrabarty*, US courts have upheld thousands of patents since this decision. Despite this, court rulings have not brought any clarity on patentable subject-matter apart from making the patenting of living organisms much more difficult. For example, as opposed to the *Chakrabarty* precedent, in the 2010 case of *Association for Molecular Pathology v USPTO Myriad Genetics*,69 the District Court basically followed the Supreme Court's 1931 decision of *American Fruit Growers v Brodex*. The District Court ruled that isolated and purified DNA lacked 'markedly different characteristics' from native DNA and was therefore not a patentable composition under section 101 of the Patent Act. In fact, *Myriad* is the exclusive licensee of a series of patents claiming isolated DNA compositions, as well as methods for testing for the presence of genetic mutations that correlate with an increased risk of certain breast and ovarian cancers (the BRCA1 and BRCA2 genes).70 The inventors actually obtained a large collection of DNA samples from families with inherited breast and ovarian cancers and prepared the BRCA mutation sequence.71 The patent claims include methods of analysing and comparing a patient's BRCA sequence with the normal sequence and method claims covering the processes of detecting and screening for BRCA mutations.72 The District Court rejected the *Myriad* patent claim, arguing that, under the requirements of §101, purification of a product of nature, without more, does not count as a transformation of the product into patentable subject-matter because the isolated DNA for the BRCA test was not 'markedly different' from the naturally occurring mutations. However, it is necessary to understand that isolated DNA has never existed in nature and had only been extracted as a result of human intervention using advanced laboratory techniques. The isolated DNA actually changed the composition of an isolated strand of DNA from its counterpart in the human body and, therefore, the molecules do not actually exist in nature. The District Court's decision was tenuous, which certainly narrowed the scope of the patentability requirements over molecular biology and genetics.

On appeal, however, the United States Court of Appeals for the Federal Circuit reset the button on the doctrine of patent eligibility, reversing the Southern District Court of New York's earlier ruling that isolated DNA would be considered patent-eligible if it was 'markedly different' from naturally occurring DNA. The judges noted that isolated DNA molecules that have been synthesised or removed from their native cellular and

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69) No. 10-1406 (Fed. Cir).
72) No. 10-1406 (Fed. Cir).
chromosomal environment by breaking covalent chemical bonds to produce a molecule a fraction of the size of the naturally occurring DNA are markedly different from DNA molecules that occur in nature. Without doubt, this decision has changed the nature and pace of bio-technology and will encourage biotechnology companies to invest billions of dollars in the development of future diagnostic tests, not only in America but also around the world. However, it is unlikely that this case will be the end of the matter, which will probably be appealed to the Supreme Court. It will be interesting to note whether the Supreme Court's decision will impact the approach that other countries take. Even though it is more than 30 years since the groundbreaking Chakrabarty ruling, the conflicting decisions noted above clearly show that court rulings have not promoted any clarity on products of nature doctrine, nor have they established a clear view of exactly how the novelty requirement applies to gene patenting. This leaves the doctrine's fate uncertain.

Another contentious issue of patent law is the 'inventive step' (or the non-obvious requirement), which is generally considered to be the most defining feature of an invention. Courts have tended rigidly or narrowly to define the non-obvious requirement, which has become the most critical propositions for an invention, especially one based on DNA molecules. In KSR International Co. v Teleflex Inc., the court radically changed the test for obviousness landscape. The court ruled that a particular combination of prior art elements was obvious because it would have been obvious to someone with ordinary skill in the art to attempt such a combination. KSR altered the non-obviousness analysis, holding that a patent claim cannot be proved obvious simply by showing that the combination of elements was 'obvious to try.' This case modified the obviousness standard used in patent cases in the history, arguing that the TSM Test should not be used as formalities to test obviousness. Instead, the case left substantial discretion to the later courts or the patent examiners to decide whether a claimed patent is obvious or not. Although the patent issue in KSR was unrelated to biotechnology, the KSR decision has created increased legal uncertainty over the 'obvious test', which has left judges to develop requirements for the obviousness standard. Although the Supreme Court in KSR seemed to suggest that a flexible approach of obviousness is desirable, the court did not define flexibility in any material way. This decision is clearly at odds with the prior precedents as well as the PTO's practices regarding obvious standard. This could have a negative impact on the validity of many of the genetic sequence.

In In re Kubin, the Federal Circuit followed the Supreme Court of the United States' new obviousness standard in KSR, affirming that claims to an isolated polynucleotide molecule excluding a polypeptide that was at least 80 per cent identical to a defined amino acid sequence in a known polypeptide was obvious over that known polypeptide and therefore unpatentable. Kubin isolated and cloned a human NAIL protein using an available antibody to the murine version of the protein, and a cDNA expression library generated from pooled mRNAs extracted from human NK cells stimulated with known activators that became the first to sequence both the cDNA and amino acid sequences of such a protein. However, the courts held that the claimed gene sequence was unpatentably obvious in light of abundant prior art. It is argued that:

The Federal Circuit's decision in Kubin generally means that to the extent a protein has been previously identified, its nucleotide sequence is no longer patentable. The broader application of Kubin will include attempts to reject or invalidate claims directed to biotech inventions that claim an outcome of experimentation from among a range of expected results, even though not expressly predictable. There will undoubtedly be an increase in invalidity challenges to existing gene patents by those seeking to market generic and follow-on biologics prior to patent expiration, in view of the likelihood that pending regulatory legislation also passes. Clearly, the patentability standard for gene sequences and the commercial exclusivity available for such biotech inventions have been dramatically altered by the Federal Circuit's In re Kubin decision.

74) Ibid.
76) Ibid.
The *Kubin* decision raised the non-obviousness bar for DNA patents to be granted, as opposed to earlier court decisions that had favoured DNA patenting. For example, in the 1993 American case *In re Bell*, the court held that a method of gene cloning, combined with a known partial amino acid sequence, did not render obvious DNA molecules encoding the protein; it merely rendered them 'obvious to try'. Basically, the court ruled that claims directed to nucleic acids encoding human insulin-like growth factors were not obvious, even though the amino acid sequences for such human insulin-like growth factors were disclosed in the prior art. The Federal Circuit further opined that the established relationship in the genetic code between a nucleic acid and the protein it encoded did not make the gene *prima facie* obvious over the protein for which it coded. In reaching this decision, the court approached the obviousness requirement by examining the characteristics of the isolated and purified DNA sequences and determining whether these sequences have properties or functions that would not have been obvious to a skilled geneticist prior to the discovery of that sequence.

In a similar decision (the case of *In re Deuel*), the United States Court of Appeals for the Federal Circuit considered whether knowledge of partial amino acid sequences from a protein, in conjunction with a general method of cloning, renders the sequence of a gene *prima facie* obvious. The Federal Circuit's decision reversed the Board's rejection of the applicant's claimed DNA sequence, based on the combination of a primary reference disclosing the partial amino acid sequence of protein encoded by the claimed DNA with a secondary reference describing a general method of gene cloning. The court confirmed that DNA molecules encoding the protein were non-obvious from their corresponding amino acid sequence, which meant that 'knowledge of a partial amino acid sequence for a protein did not make the corresponding gene obvious'.

In both cases, the Federal Circuit established that a DNA molecule is obvious only if it is structurally similar to prior art products, even if someone skilled in the art would consider it obvious to obtain the DNA molecule using familiar prior art methods. In many ways, the facts of *Deuel* were analogous to the facts of *Kubin*, but the latter case certainly indicates that it will be increasingly difficult to obtain patents for DNA sequences. Both the *Bell* and *Deuel* decisions appear to have somewhat softer interpretation over non-obvious requirement. These decisions clearly show that whether biological invention is obvious has become a question of law. In particular, the obvious to try test in the context of gene patents had caused considerable trouble for patent claims in biotechnology in the United States because patents were refused for DNA sequences coding for amino acid sequence, where the protein amino acid sequence had been in the prior art or published. However, it is important to understand that the purified substance does not simply occur in nature and that the extraordinary or unexpected results can be achieved when the substance is isolated or purified. Harold Edgar, professor of law at Columbia University, said:

> A patented gene differs from its intracellular counterpart in that it is no longer part of a chromosome. Also, a patent typically claims only the protein-encoding part of a gene, not the regions without apparent function. When you isolate something as it appears in its natural state you change it, even if the only change is the isolation. You have left behind the natural product and created something artificial. No isolated gene sequence occurs in nature.
The final requirement in the patent process is that of utility, which has also become a hurdle to patenting gene-based inventions. A patent may not be granted for an invention unless a substantial or practical utility for the invention has been discovered or disclosed. Although this condition is usually easy to meet for inventions in non-biological areas, utility has become a real obstacle in seeking patent protection for biotechnology inventions. In fact, the United States has seen a series of inconsistent decisions related to the utility requirement in the area of biotechnology. For example, the Supreme Court articulated a relatively strict utility standard in its 1966 decision in Brenner v. Manson, in which the applicant sought to patent his process of creating a steroid that was a homologue to a steroid being studied at the time for anti-cancer treatment. In rejecting the claims, the court held that simply being similar to a compound of known utility did not pass the utility threshold, and that the applicant needed to show that the compound has a ‘sufficient likelihood that the steroid yielded by his process would have similar tumor-inhibiting characteristics.’ The court went on to say that a novel process for making a known steroid did not satisfy the utility requirement because the patent applicants did not show that the steroid served any practical function. The court was clear that a mere interest in research or further investigation was not sufficient to assess the utility of a chemical compound, and required that a patent applicant must establish that the invention has ‘substantial utility’ that benefits the public before a patent can be granted.

The judicial interpretation of the utility requirement has faced considerable criticism due to its strict utility analysis in Brenner. In fact, Brenner created a more meticulous test, namely that an invention or discovery’s utility be ‘specific and substantial’ in analysing a patent application that certainly lessens the opportunities of scientists to obtain patents over biological inventions. At times, a protein or nucleic acid whose function is not known, and whose only use would be as a subject of further research, would not display a substantial utility. The utility requirement should not preclude the patenting of research tools whose only function relates to the development or research of commercial applications. It is questionable whether strict utility requirements should be applied to genetic inventions in much the same way as they have been to mechanical inventions. It has been argued that the usefulness criterion does not require that an invention be useful in the sense that it is worthwhile or commercially practical; only that if a particular result is claimed, it must be achievable.

This strict utility requirement was employed again in In re Fisher, where the Court of Appeals for the Federal Circuit found that, despite having several potential uses as research tools, ESTs lacked a ‘specific and substantial utility’, which is required for patentability. The court outlined that ‘to be patentable, claimed invention must have substantial and specific “utility,” i.e., invention must have significant, well-defined, and real world benefit to public, and its claimed use must be so vague as to be meaningless’. Whilst this decision was not directly related to gene patent applications, it does highlight the increased difficulty in applying ‘utility’ requirements for biological inventions.

Even though the utility requirement has been canvassed in the United States, it remains largely unexplored in other jurisdictions. For example, in the United Kingdom and Europe, Article 53(3) of the Biotechnology Directive requires that all gene patents must disclose the invention’s ‘industrial applicability’ in the patent application. The utility requirement (known as industrial applicability in Europe) requires that the patent in question has some commercial value. However, the
strict application of the US utility requirement differs fundamentally from that of industrial applicability in Europe, where an industrial applicability requirement is interpreted more leniently given that substantial or practical utility is not required. In Australia, this requirement is dealt with partly through the ‘manner of manufacture’ test. In Australia, the Australian Patent Office considers that patentable gene sequences must have a definite industrial use. However, it has not followed the USPTO in requiring a demonstration of ‘specific, substantial and credible’.

The above discussion clearly shows that the judiciary has been inconsistent and provides no stable guidance as to how to draw the patentable subject-matter boundaries over gene patenting. Judiciaries around the world could and should have made different choices regarding the strength of gene patents. Instead, they have failed to develop the steady common law concepts in patent protection of human genes in the ways advocated.

Any novel gene or a new set of genes that have been sufficiently altered by human effort that are not found in nature must meet the patentability requirements. The reason for this is the difference between knowledge of nature and reducing a portion of nature to concrete form; the latter is what patent laws seek to encourage and protect. Richard Hamer, from the Law Council of Australia, argued:

As a principle you can get a patent for isolating something which has never been isolated before. The isolated compound is something that you can do something with – something that you cannot do when it is in the body. For example, you can use an isolated gene sequence in a test kit. You cannot use it in a test kit when it is in the patient’s body. It is capable of uses that are not there in the body and that is because it has been isolated. It is also different chemically because it is separated from the other components.

The biotechnology has presented a number of interesting challenges in patent law and there is a clear mismatch and fundamental discrepancy between the original operation of patent law and its relevance in biotechnology. It is necessary to understand that the subject-matter of human biology was not addressed by legislation when patent laws were originally drafted. Applying the same patentability requirement to genetic inventions, in much the same way as it has been applied to other technologies, will not address the problem.

Recent Developments and Patenting of Human Stem Cells

As discussed above, the question of whether human genes should be patentable has been subject to vigorous debate; as a result, countries vary considerably in terms of policy and regulations on patentability of human genes. In most jurisdictions, the question of whether inventions concerning human genes are patentable remains unclear. This section of the paper considers the legal framework of stem cell research and its patentability in various jurisdictions.

Europe

The Convention on the Grant of European Patents of 1973, commonly known as the European Patent Convention ('the EPC'), is the authoritative legal instrument on patent protection in Europe. The EPC is a multilateral treaty that grants European patents for inventions in all fields of technology that are novel, susceptible to industrial application and involve an inventive component. However, Article 53 of the EPC excludes patentability inventions that are contrary to public order or morality. In fact, the new Rule 23(d) of the EPC explicitly states that European patents shall not be granted in respect of biotechnological inventions that concern using human embryos for industrial or commercial purposes. This clearly excludes from patentability all claims to the industrial or commercial use of human embryos and also all claims to associated products necessitate the direct and unavoidable use of a human embryo, such as embryonic cells. The exclusions found in Rule 23(d) of EPC and Article 6(2) of the EU Biotech Directive are identical in terms of the words, with the sole exception that EPC has implemented the recitals texts, which explain a process for cloning and adds that therapeutic or diagnostic purposes in the use of human embryos are acceptable.
The EPC's stance on patentability of human genetic materials is supported by Article 5(1) of the EU Directive, which clearly stipulates that the 'human body at the various stages of its formation and development, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.'\textsuperscript{113} Contrary to the above, Article 5(2) of the Directive states that an element isolated from the human body or otherwise produced by means of a technical process can be patented, provided that the regular patentability requirements are met.\textsuperscript{114} These are distinctly contradictory interpretations and the two provisions conflict with one another. The uncertainly caused by the EU Directive has been criticised by the Danish Council of Ethics, which argued that 'you cannot simultaneously forbid patents on the human body or elements thereof and then permit a sequence or partial sequence of a human gene, albeit isolated from the human body, to be patented'.\textsuperscript{115}

The EU Directive also contains exemptions from patentability, including Article 6(2), which states that inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public or morality. In particular, Article 6(2) states that European patents shall not be granted in respect of biotechnological inventions that specifically concern the following:

(a) processes for cloning human beings,
(b) processes for modifying the germ line genetic identity of human beings,
(c) uses of human embryos for industrial or commercial purposes,
(d) processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animals and also animals resulting from such processes.

The above list cannot be seen as exhaustive. In fact, Article 6(2)(c) leaves open the question of the patentability of cells obtained from donated embryos and does not precisely state which embryos are subjected to exclusion.\textsuperscript{116} The scope of exclusions of Article 6(2)(c) has created an imprecise definition of the concept of a human embryo and 'uses of human embryos'. In particular, neither the EU legislator nor the EPC has chosen to define the term 'embryo'.\textsuperscript{117} As a result, different countries have interpreted Article 6(2)(c) differently. There is a need for a definition of Article 6(2)(c) that clarifies whether this exclusion applies to any research involving human embryos or only allows embryonic stem cell procedure.\textsuperscript{118} In fact, one of the main criticisms of the EC Directive is that it does not specify which elements from human origin are patentable.

With the exception of Estonia, all countries in Europe prohibit human reproductive cloning. However, the positions of the EU Member States on stem cell research vary significantly. For example, the majority of countries in Europe (namely Denmark, France, Georgia, Hungary, Iceland, Latvia, Holland, Portugal, Russia, Slovakia, Switzerland and Spain) have made it illegal to undertake research cloning, although the derivation of embryonic stem cell lines from 'excess' ART embryos is permissible under certain conditions.\textsuperscript{119} The most restrictive countries – Austria, Germany, Ireland, Italy and Norway – all prohibit experiments on embryos, regardless of intention. On the other hand, Belgium, the United Kingdom (discussed further below) and Finland are the most liberal nations regarding embryonic research. These countries allow the destruction of human embryos for the derivation of ES cells and also permit research cloning under licence.\textsuperscript{120} This shows that the regulations on patents on stem cell research not only differ greatly among countries but have also produced different results for the same priority in the same country. It is argued that 'the controversies surrounding patents on hESCs in Europe point to a complex and deeply fragmented legal map for stakeholders to navigate'.\textsuperscript{121} The next sections explore the unravelling global patent trends in emerging fields of stem cell research and how various countries have reacted to the tertiary challenge.
United States of America

The United States has a powerful and well organised conservative Christian voice that has significant power over the development of policy in relation to gene patenting. In 2004, the Senate debated a Bill introduced by Sam Brownback that prohibited all forms of cloning, including therapeutic cloning, and would have imposed a $1 million fine on any doctor or patient who participated in any therapy that derived or originated from the cloning. Although this legislation did not succeed, it is indicative of the significant opposition to stem cell research and cloning in America.122

Under the presidency of George W. Bush, US policy restricted federal funding only to embryonic stem cells that were derived by or on 9 August 2001.123 In November 2004, voters in California approved Proposition 71, the California Stem Cell Research and Cures Act.124 This legislation created the California Institute for Regenerative Medicine (CIRM), which administers $3 billion of state bond-funded stem cell research for ten years, with a focus on embryonic stem cells.125 On March 8, 2009, President Obama revoked the eight-year-old policy enacted by President Bush that limited federal funding of stem cell research, as well as the 2007 executive order directed toward developing alternative methods of deriving hESCs.126 It is hoped that the Obama administration will support relaxing the federal restrictions on this type of research.127

Article I, Section 8 of the United States Constitution gives Congress broad power to promote the progress of science and useful arts, by securing for limited times to inventors the exclusive right to their respective discoveries. The first Patent Act of the US Congress128 defined the subject-matter of a US patent as 'any useful art, manufacture, engine, machine, or device, or any improvement thereon not before known or used'. In 1952, patent laws were re-codified and Title 35 U.S.C. section 101 of the Patent Act 1952 still governs US patent law. Section 101 of the Act classifies that an invention to be patentable and requires that the invention meets several requirements, including 'novelty', 'inventiveness', 'usefulness', and is fully disclosed. Once the patent issues, the owner enjoys the right to exclude others from making, using, selling, offering to sell, or importing the patented invention into the United States.129

In the landmark Supreme Court ruling in Diamond v Chakrabarty, US courts argued for the first time that intended patentable subject-matter would 'include anything under the sun that is made by man'. It is clear from the Supreme Court decision that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability.130 This decision has had a major worldwide impact on the idea of patenting living organisms, and this has certainly promoted biotechnology industry. The Chakrabarty decision was later confirmed by the Commissioner of the USPTO, which issued a notice stating that non-naturally occurring, non-human multicellular living organisms, including animals, were patentable subject-matter.131 In fact, 'the U.S. Congress created the Court of Appeals for the Federal Circuit to promote greater uniformity in the application of patent law and to reduce the possibility of forum shopping by parties seeking favorable courts'.132 In fact, the holding in Chakrabarty has been interpreted quite broadly, both by the USPTO and later by courts facilitating the patenting of a wide range of biotechnological inventions.133 For example, the USPTO has granted more than 20,000 patents claiming isolated DNA molecules since the 1980s, almost 4,000 of which claim isolated human DNA encoding proteins.134 One of the significant distinctions in US patent law is that it does not contain any morality provisions to deny patent protection on moral grounds, while moral exclusions are now a fixture of all other jurisdictions. The United States' unique stance on the 'morality clause' has


128) It was passed on 10 April 1790.


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undoubtedly had the effect of providing international corporations an additional incentive to seek protection first in the United States, where morality is not a factor. 135

Even though this is the case, it is also important to note that the stand US common law stand on gene patent acknowledges uncertainty and there has been an inconsistent application of patentability requirements to human genes through its decisions, as discussed above. The mixed reaction of common law to gene patenting leaves open a number of important questions regarding whether the Judiciary should take the lead in prohibiting the patenting of genetic material through its decision or whether it is totally up to Congress.

Canada

Section 2 of the Canadian Patent Act 1985 defines ‘invention’ as any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter. Like legislation in other countries, the Canadian Patent Act requires an invention to have novel, non-obviousness and utility in order for it to qualify as a patentable invention. However, the Canadian Patent Act contains no specific reference to the inclusion or exclusion of human beings and/or their biological processes from patentable subject-matter. Nonetheless, any inventions relating to stem cells derived from human embryos are restricted by the Assisted Human Reproduction Act 2004, which clearly states that no person shall knowingly: (a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device; or (b) create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures; or (c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or fetus or transplant an embryo so created into a human being. 136 This is a clear indication that the Canadian legislature has refused to grant patents for human genes.

Judicial interpretation regarding whether a live, human-made micro-organism constitutes patentable subject matter in Canada comes down to consideration in Application for Patent of Abitibi Co 137 in 1982, where the company's patent claims to microbial culture had been rejected by the patent examiner on the grounds that living matter is not patentable. 138 One of the arguments was that micro-organisms cannot meet the criteria as patentable subject-matter until the legislature specifically authorises such protection. However, the Canadian Patent Appeal Board rejected this argument. It reviewed recent decisions in other jurisdictions and held that micro-organisms could be the subject of patent applications. 139 However, the patentability of higher life forms was not properly challenged in Canadian courts until Harvard College v Canada (Commissioner of Patents), 140 which is the only Canadian common law case to date to touch on the issue of patenting human genes. 141 In this case, the Harvard researchers developed a process by which they could breed genetically altered mice that would possess a cancer-promoting gene. 142 The gene was introduced into the chromosomes of mice to predispose them to developing malignant cancer. Harvard College applied to the Commissioner of Patents for patents over the 'oncomouse' and the process by which the college had created it. These applications were rejected on the basis that higher life forms were not inventions under the Canadian Patent Act, which defines an invention as 'any new or useful improvement, in an art, process, machine, manufacture or composition of matter'. 143 However, Harvard College then appealed this patent rejection. As Justice Binnie outlined:

We are asked to determine whether the oncomouse, a genetically modified rodent with heightened genetic susceptibility to cancer, is an invention. The legal issue is a narrow one and does not provide a proper platform on which to engage in a debate over animal rights, or religion, or the arrogance of the human race.

This tightly argued case was decided five to four in favour of the Commissioner of Patents. The majority of the court held that higher life forms were not patentable. The focus was on whether the words 'manufacture' and 'composition of matter' in the Patent Act included higher life forms. The majority held that the mouse was not composed just of matter and, as a higher life form, it possessed qualities that transcend the genetic materials of which it was composed.

136 Section 5(1).
139 Ibid., at 41.
141 Section 5(1) of the Act.
Therefore, the judges held that the patenting of a life form was outside the purpose of objectives of the Patent Act and to do so would be beyond the authority of the court. The judges suggested that this issue should be settled by the legislature and that specific legislation should be enacted to deal with the issue. This decision is completely contradictory to the United States' approach, where the mouse and other animals are patentable.

The case included a strongly written dissent from Binion J (with whom McLachlin, Arbour, and Major JJ agreed) that criticised the distinction between 'composition of matter' and biological life. The judges also criticised the majority of the court on the basis that the legislature, not the judiciary, should determine exceptions to the Patent Act. The issue of whether human genes were patentable was discussed but the Supreme Court refused to make a definitive statement, stating that Rothstein JA's claim that the Canadian Charter of Rights and Freedoms prevented the patenting of human genes or products was misguided and that this was an issue for the Canadian Parliament to resolve. Nonetheless, the majority of the Federal Court of Appeal, which found that the Patent Act did apply to higher life forms, was compelled to draw a distinction between higher life forms and human beings. In doing so, it merely substituted one line—that between humans and animals—for the line preferred by the Patent Office between higher and lower life forms.

In fact, the Harvard Mouse case is an interesting one, for a number of reasons. Firstly, the decision was very close (5 to 4 in favour of the Commissioner of Patents), which makes it possible that a future court could find differently if a matter on this topic is heard again (especially in light of the decision in Monsanto v Schmeiser, discussed below). Secondly, both parties relied heavily on arguments related to the role of the judiciary and legislature in their submissions; they argued essentially the same thing (that it was the role of the legislature, not the judiciary) but reached completely different conclusions. Finally, this decision is at odds with a number of other countries, including the United States, which generally allows patents of stem cells. This gives the United States a strategic and commercial advantage regarding the commercialisation of this type of research. Therefore, it will be important to follow this case and see whether it is upheld or whether future courts determine things differently.

In 2004, however, two years after Harvard, patents on genetically modified plants extended to the plants themselves as well as the gene sequences in Monsanto Canada Inc. v Schmeiser. The decision relates not just to the patentability of stem cells but to the patentability of genetically modified plants. However, this case shows an interesting approach to the issue of patentability of nature in Canada. The case was an action brought about by Monsanto against Percy Schmeiser, who had grown Monsanto's genetically modified canola without a licence. The canola was particularly valuable because Monsanto had used genetic engineering to insert a gene into it that made it resistant to certain herbicides. Monsanto had been given a patent over the modified gene in the canola. The legal issue was whether Schmeiser had breached the patent by growing canola that included the patented gene. The majority (McLachlin CJ and Major, Binion, Deschamps and Hsh JJ) held that Schmeiser had breached the patent by growing the canola, including the modified gene, because his actions had deprived Monsanto of their monopoly over the canola plant. Interestingly the judges held that no damages should be awarded as Schmeiser had not made any profit that resulted directly from the invention itself. In comparison, the minority (Arbour J, writing for Iacobucci, Bastarache, and LeBel JJ) closely followed the focus in Harvard College v Canada, where the judges continued the approach that higher forms of life cannot be patented. As Schmeiser grew the canola plant as a whole and did not just use the modified gene, the minority judges held that he had not breached the patent by growing the canola.

From the outset, the cases seem to be very similar making it difficult to justify the different outcome. However, in the Harvard case, the patent was applied for over the entire mouse, as opposed to the genetically modified genes inside that mouse. In the Schmeiser case, Monsanto only applied for a patent over the modified gene. The action of growing the canola with the modified gene in it was sufficient to violate the patent. The location of the line between unpatentable nature and patentable inventions will continue to be part of public and policy conversation. Therefore, it will be interesting to see how the Canadian judiciary deals with a patent application over a modified gene of an animal and whether it follows the approach in Harvard or Schmeiser. Having said that, there is no finding on the patentability of human genes in Canada.

145) ibid.

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Australia

Australia has always been at the forefront of scientific development. In fact, Australia is one of the growing list of countries that allows the generation of embryonic stem cells from surplus IVF embryos. However, there is a fundamental ambiguity in the Patents Act 1990 (Cth) as to whether human stem cells are patentable subject-matter. Section 18(2) of the Act states that 'human beings, and the biological processes for their generation, are not patentable inventions'. However, the Act contains no explicit guidelines as to whether the exclusion of human beings would extend to prohibit the patenting of human gene sequences. Due to the inherent difficulty of defining the exclusion, it is widely assumed that this provision may prevent patent protection being available for inventions involving human embryonic stem cells in Australia.

In addition, section 50(3)(a) of the Patents Act provides that the Commissioner of Patents has the discretion to refuse an application for a standard patent on the grounds that its use would be 'contrary to law'. The manual states that the discretionary power conferred on the Commissioner of Patents under section 50(3)(a) should be invoked only 'in the clearest of circumstances'. However, this section only governs inventions for which there are no lawful uses. One commentator has argued that 'gene-related inventions are not made unlawful under any existing Australian regulations, and courts have been reluctant to refuse patentability on the ground of generally inconvenient, believing it is best left to parliament to decide whether matters of ethics or social policy are to have any impact on what is patentable'. It is also clear that Australian patent law does not provide a clear ruling about rejection of patents on ethical or moral grounds. This also provides an uncertain result about the patentability of genetic material under Australian law. On the one hand, the adoption of such a provision to the Act on the grounds of 'ordre public and morality' would help Australia come into line with some European countries, the TRIPS agreement, and the Australia–US Free Trade Agreement. Both of these agreements state that members may exclude from patentability inventions and prevent commercial exploitation within their territory as necessary to protect 'ordre public or morality'. On the other hand, the consideration of 'ordre public and morality issues on biotechnology may interfere with improvement in genetic engineering inventions.

The Patent Amendment (Human Genes and Biological Materials) Bill 2010 proposed to amend subsection 18(2) of the Patent Act so that the following are not patentable inventions: (a) human beings and the biological processes for their generation; and (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature. Although this definition is obviously much broader than section 18(2) of the Patent Act, it does not interpret what is meant by 'identical or substantially identical'. The new amendments also leave Australia's position against the patentability of human stem cells uncertain unless it explicitly includes or excludes the patentability of gene materials. Given the unfortunate absence of the clarity, there may be a further period of uncertainty. If passed in its current form, the amendments will also have a far-reaching negative impact on Australian medical research.

The Bill is a direct attack on IP Australia's interpretation of views and the subsequent division of human genes and stem cells into patentable and non-patentable categories under the Patent Manual of Practice and Procedure. In its submission to the Senate Community Affairs Committee (SCAC) 2010 Report on Gene Patents, IP Australia adopted the position that there is no basis for it to refuse to grant a patent over human genes and genetic materials; it argued that as long as the application of human ingenuity to a discovery could result in an invention, producing a new and useful result, it may be
patentable. On this basis, a claim to isolated or purified gene sequences may become a patentable invention, through the involvement of an artificially created state of affairs (human involvement and ingenuity). In response, SCAC stated that:

... in the Committee’s opinion, there is substantial doubt that IP Australia’s approach to the granting of patents over genes conforms with the general prohibition in law on the patenting of a discovery or product of nature. While the Committee acknowledges IP Australia’s defence of the current approach as being analogous to other classes of patents, such as chemical products, the Committee strongly rejects the reasoning which says that, for the purposes of the Patents Act 1990 (the Act), genetic information that is isolated from its naturally occurring state in the human body may be classed as an invention, and therefore properly be the subject of a patent (where the other requirements of patentability are satisfied). The Committee considered this objection to be the strongest justification for recommending that the Act be amended to include an express prohibition.

Enacting the Patent Amendment (Human Genes and Biological Materials) Bill (2010) in its current form would have a profound effect on the biotechnology in Australia. However, the recent ruling in Association for Molecular Pathology v USPTO Myriad Genetics 2011 in the United States will have an enormous impact on the proposed Patent Amendment Act and could dramatically change the legal status of gene patents in Australia. ALRC has made the following point:

Whatever the merits of that argument, the Inquiry was faced with the fact that since the 1980s—in Australia and internationally—large numbers of patents have been granted on genetic sequences, provided they have been isolated from their natural state and otherwise satisfy the statutory requirements for patentability. The Inquiry ultimately concluded that if there had been a time to recommend that gene sequences should not be patentable, that time had long since passed. Rather, it was preferable to focus on reforms that would make the system work better.

At the other end of the spectrum, there is no definitive Australian common law judicial consideration of section 18(2) PA or of human gene patentability. However, the Deputy Commissioner of Patents did consider this issue in Kirin-Amgen Inc v Board of Regents of the University of Washington in 1995, accepting that a claim directed to naturally occurring DNA would likely claim no more than a discovery per se and would not be a manner of manufacture. Nonetheless, recent case law demonstrates that Australian courts will uphold claims to human DNA sequences. In Genetics Institute Inc v Kirin-Amgen Inc., the court held that a patent over recombinant procedures that enables the production of polypeptide proteins, specifically the use of recombinant DNA techniques to produce commercial quantities of erythropoietin, was valid. In addition, the Synoptic Pharmaceutical Corporation v Astra Aktiebolag decision clearly shows that, in most circumstances, the inventive step is likely to be satisfied by identifying and isolating genetic material. Even though these decisions held that the isolation of a natural product from its native environment can lead to a patentable invention, there is no explicit rule in Australia that genes are patentable. The Australian courts have avoided definitive views on the patentability of human genes and shifted the onus onto their respective parliaments.

In Australia, it may be helpful to examine the approaches that other jurisdictions have taken before enacting the proposed Act. Such examination would help Australia to develop a law that considers the natural progression of research and development in molecular biology.

Conclusion

In common law, the patenting of human genes follows decades of debate over gene patenting. The judicial failure adequately to explain its position on gene patenting has
sparked great uncertainty worldwide. There is strong evidence that the courts have not been reliable in all applications of the law, and there is wide confusion over the scope of the principle in common law. For example, the District Court decision in the "Myriad" gene patent litigation in 2010 is quite different from that taken by the Federal Circuit on appeal.

There is ongoing debate as to whether the law goes far enough, or whether a political dimension needs to be added to reignite the debate on whether human genes should be patentable with judicial and/or administrative consideration of statutory consistency. Certainly, patent law requires adjustment to accommodate genetic inventions. There is clearly a mismatch and fundamental discrepancy between the genomic patents and conventional law, as articulated in the traditional threshold requirement for patentable subject-matter. In order for the law to keep pace with technological development, it will undoubtedly need to be updated, either by amending the existing legislation or introducing a new self-contained statutory framework that deals exclusively with genetic patents. One way out of this impasse, as shown in this article, is to treat genomic processes as patentable inventions per se for the purposes of the law.

Bibliography


- Senate Community Affairs Committee, Gene Patents, November 2010, pp 75 – 7.


