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Stem Cell Patents and Related Policy Issues in Biotechnological Research

by
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I. INTRODUCTION

The bio-patent industry is distinctive from other patent industries because of the remarkable benefits and research possibilities it provides to humanity. Stem cell research is an ideal example of those possibilities as it promises to vitally improve medicinal studies and medical approaches towards genetic diseases at the molecular level. Researchers are using stem cells to grow organs in laboratories, to reverse physical trauma like spinal injury, and to cure congenital diseases. Parents are choosing to deposit their new-borns' umbilical cords in an "umbilical cord blood bank", for the purposes of preserving and using the stem cells to cure any fatal diseases their child may suffer from in the future. The regenerative and pluripotent properties of stem cells imply that there are infinite possibilities of research and medical applications based on them for the betterment of mankind. But the scientific community also agrees that these applications, for now, are just an exercise in creating a foundation for the advent of gene-based personalised medicinal techniques of the future.

Notionally, human embryonic stem cell research can lead to the understanding and discovery of cure for many diseases at the genetic level, but the challenge as well as the stigma lies in practically applying that research as diagnostic tools and therapeutic treatments. This requires "industrial application" of stem cell researches in the form of clinical field studies and eventually as clinical medicine.[1] Despite many doubts about its success and moral acceptability, the stem cell research has attracted enormous interest in the United States, the European Union and the rest of the world in last

several decades because of its scientific and medical potential, as well as commercial viability.

Although not much breakthrough research work seems to be happening in the field of stem cells and human embryonic cells in many developing nations, but notably in countries of Asia-Pacific region like China, India, Singapore and South Korea, the boom in *in vitro* fertilization clinics and laboratories have led to a considerable interest in the arena of stem cell research. In India, under the industry-academia partnership programmes, a few human embryonic stem cell (hESC) lines have been generated in some of the institutions in the country and deposited in UK Stem Cell Bank, to be used by the researchers across the world for research purposes. Yet, as stem cell based medical therapies progress into the later stages of development, the field will be confronted with many of the problems similar to the ones currently plaguing the pharmaceutical trials in these developing nations, pertaining to the distinctive combination of economy, politics and culture of these nations. Therefore, for the purposes of this article, and due to the lack of cases challenging the patentability of genetic and stem cell patents in developing nations like India, the judicial cases in the jurisdictions of the US and the EU would be held as relevant and as a source of guiding light, while discussing the patentability of stem cells.

As we already know that patents are designed to cultivate and encourage the research through exclusive market incentives and the security of recouping the investments for a certain period of time. But not all patent industries, for e.g. the biotechnology based industries, respond to the same categories of patent incentives. For patent law to be truly effective, an industry specific approach is required in order to take into account the special differences in various functional aspects of the biotech industry. Patent law should strive to maintain a balance between incentivizing investment in research and development activities and encouraging freedom in academic research in order to benefit the public from new discoveries.[2] Conversely, latest studies have started to trickle, showing that the biotechnology industry experts now claim and make the assertion that patent protection as a necessity for continued growth and development of new technologies does not hold true anymore.[3]

Such scepticism has risen because the biopatents often result in monopolies of fundamental research tools. Unlike the majority of patents, which may be invented around through analogical comparisons or may be reverse engineered to claim a new manufacturing process, the biopatents have

conventionally covered central or cardinal principles, which essentially allow the right holders to control the follow-on or derived development in biotechnological research. Stem cell patents perfectly exemplify this conundrum.

Because stem cell patents fall under the broad ambit of the prevalent, yet at times unsuitable, patent system, it is crucial to understand the state of current bioproduct regulation in the major jurisdictions worldwide, and primarily in the US, before applying the law to stem cell patents.

Therefore, this article shall mainly take into consideration the holdings laid down in the two landmark US cases *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*[4], and *Assn. for Molecular Pathology* v. *Myriad Genetics Inc.*[5] as likely to be applicable to the major types of stem cells (Human Embryonic Stem Cells, Induced Pluripotent Stem Cells, and Somatic Cell Nuclear Transfers) being currently used in research, and shall discuss why the courts and the governments worldwide must adopt a new approach towards remedying the ambiguities in the current biopatent law, which often leads to the ineffective or confusing coverage of the patentable subject matters, like in the case of stem cell research.

The main objectives of this article is to bring to notice the shortcomings in the current patent regime, to expose loopholes in regulations governing biotech research, and to provide recommendations for a better regulation pertaining to the biopatents.

II. BACKGROUND OF THE RELEVANT PATENT LAW

Patent law does not directly deal with stem cell research, and so it is indispensable to first comprehend the various patent law principles, both the statutory and as well as the ones interpreted by the courts, before one can begin to discuss the consequences of patent law application on stem cell research.

A patent is a government granted intellectual property right of an inventor to exclude others from making, using, offering for sale, or selling or importing the invention for a designated period of time in exchange for public disclosure of the invention[6]. The justification behind establishing the patent systems is that they foster technological innovation and scientific

progress. The primary objective of patent law, as determined by the courts, is to benefit the general public rather than rewarding the inventor for the efforts they have put in.[7]

Notably, Article 1, Section 8, Clause 8 of the US Constitution states that Congress has the authority, "to promote the Progress of Science and Useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries". To that effect, the US Congress has enacted the federal Patent Act codified in §35 of the U.S.C.[8]

Section 101 of the said Patent Act postulates that "whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title." For an invention to be patentable, the invention must fit within the scope of patentable subject matter codified in 35 U.S.C. § 101, as interpreted by the courts[9]. Even if useful, novel, and non-obvious, the question remains whether a patent fits within the scope of §101. A patent examiner at the USPTO usually grants a patent to an invention which meets the criteria of utility, novelty, and non-obviousness in the eye of someone of ordinary skill in that branch of technology[10]. The claims elicited in the patent application should be documented in such a way or written in such an enabling detail that the person of ordinary skill in the art can duplicate the invention at the patent's expiry.[11]

Unlike the European Union, which has specific rules per industry, e.g. for patentability of business models and software products and for compulsory licensing of pharmaceuticals, the United States patent law does not provide directions and rules that are specific to an individual industry.[12] On the contrary, the United States encourages perfectly competitive market in setting price and demand on research patents and allows exclusive rights to innovators. In recent years, however, the US Supreme Court has given special attention to the patentability standards and requirements elucidated in the § 101, while dealing with the eligibility of biopatents.

Judging from the plain language of the relevant sections, legislative history, and relevant case laws, courts are able to decide what qualifies as

patentable under the US Patent Act and the policy levers.[13] Ultimately the decision has to be taken by the courts, however, the USPTO guidelines may serve as a suitable reference tool for the courts to decide whether a particular biotech invention lies under the domain of patentable subject matter of §101 of the Patent Act.

III. JUDICIAL APPLICATION AND INTERPRETATION OF 35 U.S.C. § 101

Normally, there are broad patent categories in usage, but there are three judicially created exclusions to patentability, namely, "laws of nature, physical phenomena, and abstract ideas".[14] Under the US constitution, it is mandated to promote progress in the useful arts, which encompasses the individual's right to reasonable access to basic knowledge.[15] Because the laws of nature, physical phenomena and abstract ideas comprise fundamental aspects of knowledge, the courts have made these non-patentable.

Even though the laws of nature, as mentioned earlier, are barred from being patented, products of nature and applications of laws of nature are not outrightly

barred from being patented. The court in *Diamond* v. *Chakrabarty* held that products of nature are patentable with additional human engineering making them "*markedly different compositions of nature*".[16] In this case, the court said that a patent claiming a genetically engineered bacterium was patentable because such kind of a new genomic composition in bacteria was unlike any found in the nature. The insertion of two plasmids coding for hydrocarbon degradation enzymes (useful in breaking down oceanic oil spills) had transformed the bacteria into a "new composition" not found in nature. Consequently, laws of nature are not patentable, but process claims involving laws of nature may be eligible for a patent protection.

Similarly, although physical phenomena and laws of nature are non-patentable, the Court in *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.* said abstract ideas that do more than simply stating the idea are not mechanically barred from patentability standards. "*An application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection*."[17] This implied that

"*a particular, inventive application of the law*" must have enough human involvement to make the matter eligible for patent protection.[18]

The above cases show that with the arrival of biotechnology, mankind is now able to manipulate, alter and re-design micro-organisms or living creatures resulting in patently different bioprocesses and bioproducts. Biopatents introduced a new category of patents, but the arrival of bioproducts has challenged the expediency of the judicially created tests meant to assess their patentability.[19] As the Supreme Court explained in *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*, the court's examination should not be restricted to some previously established tests and legal mechanisms alone.[20]

With the progression happening in the science and biotechnology at a high pace, it has become increasingly more difficult for courts to distinguish between patentable and non-patentable subject matters. Conventionally, the courts have relied on two major tests for judging patentability, the machine-or-transformation test and the pre-emption test. But more often than not, modern science manages to blur the lines of patentable subject matters that these tests seek to establish.

Analysing the applicability of the above mentioned tests, the Supreme Court in *Bilski* v. *Kappos* said the machine-or-transformation test is not the only test for determining the patentability of a process. There are several exceptions where some inventions are non-patentable even though they may satisfy the test while other inventions may are patentable even though they don't satisfy the test.[21] Rather it is "*a useful and important clue, an investigative tool, for determining whether some claimed inventions are patent-eligible processes*."[22] Although this test dates back to the 19th century and was formally articulated in a government brief in *Gottschalk* v. *Benson*[23], the Court in *Bilski* v. *Kappos*[24] pointed out that the machine-or-transformation test does not work for all cases and rejected the patent application claiming process patent on a method of hedging losses on the basis that the abstract strategy of investment was not a patentable subject matter. The Court noted

that the machine-or-transformation test had explicitly been refused to be relied upon as a sole test even in earlier cases, like in *Gottschalk* v. *Benson*.

Now looking at the second test, i.e. the pre-emption test, which questions whether a patent could prohibit another inventor from employing a fundamental principle that would be indispensable for further scientific progress. Under this test, Courts enquire if a given invention has patent claims that may 'pre-empt' or anticipate ideas employing fundamental principles of nature already in "the storehouse of knowledge of all men", which are essential for other innovators to use in their research. Otherwise, inventing or researching based on a patented fundamental principle of science would nearly be impossible.[25] This includes abstract ideas and basic scientific tools and techniques which are not patentable because such claims prevent the scope of future inventions and therefore must remain in the public domain.[26]

In *Bilski* v. *Kappos*, the Court found that the process claims fulfilled the machine-or-transformation test, but were still not patentable because they covered fundamental principles pre-empting any future innovation in the relevant field. Conversely, a patent for the use of a familiar mathematical formula in a procedure for curing synthetic rubber was granted in *Diamond* v. *Diehr* because the Court established there was no pre-emption issue as a machine controlled by a computer program was no more just a mathematical formula in the abstract sense and hence patentable.[27]

IV. EMERGING LEGAL TRENDS IN THE FIELD OF BIOPATENTS

Since the *Diamond* v. *Chakrabarty* decision in 1980, which said products of nature are not patentable without additional human engineering making them "*markedly different compositions of matter*", the US Supreme Court had not touched upon the patentability of life issues. However after three decades, on June 28, 2010, the Court in *Bilski* v. *Kappos*, held that the established 'machine-or-transformation' test was not fool proof or determinative.

Biopatents, including stem cells patents, can be classified into two sub-groups: (1) process claims involving laws of nature; and (2) product claims in the nature of compositions of matter. The patentability of biotech based

process patents was addressed by the Supreme Court in the year 2012 in *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*, holding them patentable if they do more than state a law of nature and demonstrate its utility and application. The Court said that applications of laws of nature to known structures or processes are patentable if they go beyond just describing the law and establish its verifiable utility or industrial application. This controversial yet major holding, that an application of a law of nature must fulfil the requirement of 'inventive step' which is noteworthy and separate from the natural law itself and which must be limited in scope so as not to broadly pre-empt the use of the law, would certainly apply to stem cell patentability as well.[28]

In the year 2013, the Supreme Court in a unanim nature" but said that Myriad's synthetically created DNA, also known as complimentary DNA ("cDNA"), is patentable because it does not occur naturally[29]. Although to date, there has been no lawsuits concerning stem cell patents, but as stem cell therapies would sooner or later hit the markets, the stem cell patent rights will be scrutinised and challenged in the same light.

The Supreme Court addressed the eligibility of composition of matter patents in

Myriad, holding them patentable if the final product is not found in nature in its patented form. Although much of the Supreme Court's reasoning in *Mayo* laid the foundation for its *Myriad* decision, unlike the patent holder in *Mayo* who had claimed a process involving a law of nature (claims with respect a method of administering a drug to a patient, measuring metabolites of that drug, and with a known threshold for efficacy in mind, deciding whether to increase or decrease the dosage of the drug, were held to be non-patentable subject matter), *Myriad* claimed a process for isolating and creating cDNA and claimed the individual compositions of matter.[30]

Interestingly, in the *Myriad* case, the Federal Circuit had previously held both the isolated DNA and the cDNA patentable, finding that isolated DNA is chemically distinct from naturally occurring DNA and cDNA is both biologically and chemically distinct from its natural form.

The Supreme Court's decision, though, largely reflected Federal Circuit Judge Bryson's dissent. The court noted that "*extracting a gene is akin to snapping a leaf from a tree*"[31]. The judgement reasoned that isolated DNA should not be patentable because the nucleotide sequence found in isolated

DNA, which codes for the proteins that make up the BRCA 1/2 genes, appears identically in isolated DNA as it does in naturally occurring DNA.[32] But, the Supreme Court unanimously held cDNA to be patentable as "*compositions of matter distinct from natural DNA as a result of human intervention into nature*"[33], which implies that cDNA is artificially synthesized through the splicing of genetic material (synthesized post-transcription from mRNA, in which non-coding intron sequences are naturally cut out).[34] Therefore, the Supreme Court affirmed in part and reversed in part.

Therefore, though the US Supreme Court has not directly addressed stem cell patentability criteria, but as stem cells comprise a specific category of biopatents, the legal principles postulated in the aforementioned two landmark cases would outline the future eligibility of stem cell patents.

Interestingly in a recent development, in a similar case as the one brought against the *Myriad Genetics* in the United States (*D'Arcy* v. *Myriad Genetics Inc.*), the Full Bench of the Australian High Court came to the opposite conclusion of the US Supreme Court, maintaining the decision from the Federal Circuit Court of the United States.[35]

The Court primarily adopted the approach taken by Lourie J. of the US Federal Circuit, deriving its reasoning from the patent's claims to isolated nucleic acids, DNA or RNA, and that these isolated nucleic acids would have different structural and functional properties to the equivalent nucleic acid sequence in the naturally occurring genome or within a cell. It was not disputed that locating the BRCA1 gene for breast cancer within a previously known region of chromosome 17 was inventive and useful. By isolating the nucleic acids *Myriad* had created an artificial state of affairs with economic value.[36]

Probably in the *Mayo* and *Myriad* cases, the US Supreme Court reached the correct legal conclusion by suitably applying all cardinal tests while judging the eligibility of biopatents, however the "correct" holding (as in the Australian *Myriad* case) may have immense negative consequences for the advancement of scientific innovation and access to affordable as well as reliable medical care for the consumer.

Contrastingly, if we analyse the other key jurisdictions, for e.g. the European Union, to study the vagueness and uncertainty in the field of biotechnological inventions and stem cell patents, we'll find that there are

several noteworthy differences in the approach towards biotech patents that EU takes when compared to the approach taken by the US. One of the major differences between the two approaches is the EU's consideration towards *ordre public*, or *morality* (similar cautious approach is adopted by the Indian patent system vide clauses (b), (c), (j) of Section 3 of the Indian Patents Act 1970).[37]

In Paragraph 36 of the EU Directive, it cross-references to how the TRIPs Agreement[38] may choose to exclude inventions from patentability that they believe go against *ordre public*, "including to protect human, animal or plant life or health or to avoid serious prejudice to the environment".[39] Exclusions include processes for cloning humans or for modifying the germ line genetic identity, as well as uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals that would cause them suffering without causing any substantial scientific benefit.[40] Paragraph 37 also references that inventions must be excluded from patentability if the commercial exploitation goes against *ordre public*. The importance of *morality* is very important and has been pointed out in specific ways in the Directive.

While, as stated previously, the EU has followed in the steps of TRIPs, it has gone even above and beyond their standards for *ordre public* and *morality*.[41] While Article 27(2) of the TRIPS Agreement states that Members, "may exclude from patentability inventions, prevention of commercial exploitation of which is necessary to protect *ordre public* or *morality*, it states in Article 6 of the Directive, inventions "shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or *morality*."[42]

Nevertheless, morality does not seem to be as relevant in the United States' eyes as it is in the E.U.'s. The United States chooses to take on quite an aggressive approach with biotech patents. Therefore, it can be seen that they are willing to grant anything a patent as long as it fulfils the prescribed requirements of a patentability and is able to progress the technology forward that is significant for the advancement of the biotech industry.[43]

V. LIKELY ADVERSE EFFECTS OF BIOPATENTS ON INNOVATION AND SCIENTIFIC PROGRESS

Patents grant market monopoly to inventors enabling them not only to regain their invested capital in research and development activities but also to make profits from their innovation. Multiple studies analyzing the correlations between innovation and patent protection have depicted that in certain scenarios, rather than speeding up the innovation, patents slow it down.[44] If the patent system is only valid as long as it spurs progress, then it is high time for the governments globally to reassess the current patent regime and see if the regime is still constitutionally valid and commercially viable, specially with regards to the fast developing biotechnological sector.

Firstly, most technological innovations are incremental in nature and new technologies are built by developing upon the previous innovations. A broad based

protection on upstream innovation through patent can altogether hinder the subsequent innovations.[45] Secondly, from the cost benefit analysis perspective, the cost of detailed disclosure required for patents might outweigh the benefits of retaining a patent monopoly for a limited amount of time.[46] Additionally, any likely value that patents provide must also be measured against the potential harms of granting such patents, specifically with regards to the biopatents. The adverse effects of biopatents, which include restricting the patients' access to secondary medical opinions and affordable medicine and treatments, are clearly against the public policy.

Therefore, the concerning aspect of biopatents is that they result in certain groups of the populations being prevented from accessing the approved medical treatments and diagnostic tests at affordable prices. As previously discussed, biopatents have the potential to thwart the necessary follow-on research.

Without this follow-on research, doctors and medical experts have no way to assess the effectiveness of the treatment or diagnostic test in higher risk or less responsive population groups. This very problem resulted from Myriad's BRCA 1/2 cancer test.[47] There is often more than one way to approach any set of medical facts and doctors may misdiagnose a condition. Biopatents are particularly concerning because they may deny patients access to secondary medical opinions. Because of Myriad's patents, researchers were prevented from conducting further clinical trials

on higher-risk population groups to better understand the test's efficacy.[48] Courts have consistently recognized a patient's right to a second medical opinion as a matter of public policy.[49]

On the other hand, the bioproduct manufacturers claim that patents are necessary to recover research and development costs, thereby enabling the manufacturers to offer drugs and treatments at affordable prices. But the industrial trends and predictions overwhelmingly indicate that in practice, patents greatly increase the medical and treatment costs.[50] This result, however, should not be surprising.

VI. CONCLUSION

From the detailed discussion of the holdings of the two most prominent US cases, i.e. *Myriad* along with *Mayo*, a sense can be attained regarding the great degree of impact these cases would have in shaping the future of stem cell patentability. Notably, the courts over the years have relied on the various sections of the patent statute found in §§ 112, 101, 102, and 103 as policy levers. This trend points towards the courts' willingness to follow an industry specific approach in the application of patent law in stem cells research.

As we know, the patent law derives its force from the constitution "to promote the Progress of Science and useful Art" but if the constitutional mandate to further progress and innovation is no longer fulfilled and the biopatents violate public policy, then relevant changes must be made to the existing framework of the patent law, across various major jurisdictions of the world, either through the legislature or through judicial application.

This change ought to come from the legislature and the courts may also carve out an exception directing the law-makers to come up with a *sui generis* arrangement for the remaining eligible stem cell patents, if courts find that they violate other public policies.

Notably, in 1984, the US Congress acted to safeguard consumer access to healthcare by enacting the "Drug Price Competition and Patent Term Restoration Act of

1984" (the Hatch-Waxman Act). This step undertaken by the Congress sped up the timeframe in which drug manufacturers could provide safe, effective, low cost alternatives (or the generic drugs)

to the general public as against the company advertised branded drugs.[51] Therefore, it would not be the for first time, if a government had to act to protect the interests of medical consumers in the field of stem cell based therapies in the future.

Similarly, compulsory licensing for stem cell gene patents would enable medical consumers an easy access to inventions, as intended. Compulsory licensing would not only increase downward flow of research and innovation but would also maintain patent incentives. Moreover, in exchange for reasonable compensation, compulsory licensing is automatically granted to the government for the use of any patented innovation.[52] Courts may also use compulsory licenses to remedy anti-competitive practices, thereby giving necessary impetus to the market economy.[53]

Arguably, the fate of stem cell patents is not yet certain. The adverse effect biopatents have on public health warrants special exceptions to the biotechnology industry. As we all know, the US Supreme Court ruled out the patentability of method claims involving laws of nature in *Mayo* and compositions of matter in *Myriad*. Because of their countless medical applications, stem cells are possibly one of the most critical and crucial research tools for the future, and therefore their arises a dire need to upgrade and revise the patent regulatory guidelines in order to support the blooming biotech industry, as well as to safeguard the public health concerns.

Courts should put forth their verdict that on public policy grounds, the holdings of *Mayo* and *Myriad* are not conclusive of patentability criteria, as was done by the US Supreme Court with the machine-or transformation test in *Bilski* v. *Kappos*. Rather than only focusing on the application of § 101 of the Patent Act, as courts currently do, the courts must also take into account the public policy effect of bioproduct patents when considering patentability of the stem cell patents.

It can be tentatively concluded, that if the judgements in *Mayo* and *Myriad* cases are not deemed conclusive on the matter of patentability, the courts would be able to stretch their judicial interpretation of the relevant laws to balance the public policy aspect of biopatents, particularly in the cases of stem cell patents. The medical applications of bioproduct research warrant special judicial balancing of public policy considerations when determining biopatent eligibility and validity. For e.g., in 1996, the US patent Act was amended to immunize medical professionals against patent

infringement cases of patented surgical techniques as a matter of public policy to meet the requirement of easy access to affordable healthcare for public.[54]

Regrettably, biopatents, and in particular stem cell patents, bring out public policy concerns in several ways. As put forth in the discussion earlier, the studies show that biopatents impede further innovation and progress by preventing follow-on research, increase medical costs, act as a roadblock for minority populations to access medical treatments and diagnostic tests, and deny patients the access to second medical opinions. The aforementioned public policy concerns require special consideration to be

given to patentability criteria of the biopatents. After all, the intended motive behind the patent law is for the benefit of the society at large, than rewarding the inventor alone for his or her efforts.

Hence it can be inferred, that future patentability in stem cell researches may depend on how the courts would interpret the holdings in *Mayo* and *Myriad* cases. The research in the biotechnology field is quite expensive, unprofitable and often unsuccessful since it undertakes massive investments with vague and uncertain returns. Therefore, the biotechnology industry has to rely on intellectual property protection, mainly patents, in order to make up for the costly investments they make and to generate licensing revenue in order to cover the cost of long and stretched bioproduct research and development.[55] Some stem cell researchers fear, due to the inadequate funding for stem cell studies by governments, the future economic growth and development of stem cell research and its application will come to a complete standstill if stem cells become ineligible for protection through patent.[56]

For now it seems that the courts alone are tasked with the burden to balance public policy concerns when determining patentability standards for biopatents. The courts may take an industry-specific approach to apply current patent law in order to remedy the public policy violations resulting from granting of biopatents. Although the courts, while making determinations, already balance the various statutory provisions of the patent law and the interests of the researchers. However, additional public policy considerations by the courts, the governments and the concerned international bodies are necessary to reach the correct conclusion for the benefit of the public at large, as was originally intended to be achieved by the application of the patent law.

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[4] *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*, 2012 SCC OnLine US SC 28 : 182 L Ed 2d 321 : 132 SCt 1289 : 566 US 66 2012.

[5] Assn. for *Molecular Pathology* v. *Myriad Genetics Inc.*, 2013 SCC OnLine US SC 47 : 186 L Ed 2d 124 : 133 SCt 2107 : 569 US ___ (2013).

[6] See United States Patent And Trademark Office (March 2016), available at <http://www.uspto.gov/patents/index.jsp>

[7] Rebeca Echevarria, *Can Biopatents Survive as a Matter of Public Policy*?, 4 (Wake Forest University of Arts and Sciences North Carolina, 2014).

[8] *See* 35 U.S.C.

[9] *See* 35 U.S.C. §101.

[10] Simone A. Rose, *Semiconductor Chips, Genes, and Stem Cells: New Wine for New Bottles ?*, 38 AM. J. OF L. 113, 116 (2012).

[11] *See* 35 U.S.C. §112.

[12] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1634 (2003).

[13] *Id.* at p.133.

[14] *Diamond* v. *Chakrabarty*, 1980 SCC OnLine US SC 128 : 65 L Ed 2d 144 : 447 US 303 1980.

[15] *See* Rose, *supra* note 10, at p. 121.

[16] *Diamond* v. *Chakrabarty*, 1980 SCC OnLine US SC 128 : 65 L Ed 2d 144 : 447 US 303, 310 (1980).

[17] *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*, 2012 SCC OnLine US SC 28 : 182 L Ed 2d 321 : 132 SCt 1289, 1293-94 : 566 US 66 2012.

[18] *Id.* at p. 1290.

[19] *See* Echevarria, *supra* note 7.

[20] *Mayo Collaborative Services* v. *Prometheus Laboratories Inc.*, 2012 SCC OnLine US SC 28 : 182 L Ed 2d 321: 132 SCt 1289 : 566 US 66 2012.

[21] *See* Echevarria, *supra* note 7, at p. 9.

[22] *Bilski* v. *Kappos*, 2010 SCC OnLine US SC 89 : 177 L Ed 2d 792 : 130 SCt 3218, 3226 : 561 US 593 2010.

[23] *Gottschalk* v. *Benson*, 1972 SCC OnLine US SC 222 : 34 L Ed 2d 273 : 409 US 63 1972 (held that, "a method for converting binary coded decimal numbers into pure binary numbers, to be used as programming technique in general purpose digital computers, is merely a mathematical calculation and hence not patentable").

[24] *See* Bilski, *supra* note 22.

[25] Dreyfuss, Rochelle & Evans, James, *From Bilski Back to Benson: Preemption, Inventing Around, and the Case of Genetics Diagnostics*, 63 Stan. L. Rev. 1349, 1352 (2011).

[26] *Bilski* v. *Kappos*, 2010 SCC OnLine US SC 89 : 177 L Ed 2d 792 : 130 SCt 3218, 3225 : 561 US 593 2010 (*quoting Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 1948 SCC OnLine US SC 22 : 92 L Ed 588 : 333 US 127, 130 (1948)).

[27] *Diamond* v. *Diehr*, 1981 SCC OnLine US SC 41 : 67 L Ed 2d 155 : 450 US 175, 186 (1981).

[28] *Consumer Watchdog* v. *Wisconsin Alumni Research Foundation*, No. 13-1377 (Fed Cir 2013).

[29] Assn. for *Molecular Pathology* v. *Myriad Genetics Inc.*, 2013 SCC OnLine US SC 47 : 186 L Ed 2d 124 : 133 SCt 2107, 2114 : 569 US ___ (2013).

[30] *See* Echevarria, *supra* note 7, at 14.

[31] *See* Myriad, *supra* note 29.

[32] *Id.* at p. 2116.

[33] Id.

[34] Id.

[35] *D'Arcy* v. *Myriad Genetics Inc.*, 2015 HCA 35.

[36] Anton Jackson-Smith, *Myriad Claims: Discovery, Invention and Innovation in Biotechnology*, 37 University of Ortago (2014).

[37] Section 3, Indian Patent Act, 1970 ("what are not inventions").

[38] Agreement on the Trade Related Aspects of Intellectual Property Rights (1995).

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[45] *Id.*

[46] *See* Echevarria, *supra* note 7, at p. 33.

[47] *See* Echevarria, *supra* note 7, at p. 38.

[48] Shobita Parthasarathy, *Building Genetic Medicine: Breast Cancer*, Technology, and the Comparative Politics of Health Care, MIT PRESS (2007).

[49] *Rush Prudential HMO Inc.* v. *Moran*, 2002 SCC OnLine US SC 63 : 153 L Ed 2d 375 : 122 SCt 2151, 2178 : 536 US 355, 400 (2002).

[50] A. Saha, H. Grabowski, et.al., *Generic Competition in the US Pharmaceutical Industry. Int. J. Econ. Bus. 13*, 15—38 (2006).

[51] United States Food & Drug Admin., *Development and Approval Process* (Department of Health & Human Services 2013), available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm>

[52] Report of the National Institute of Health Working Group on Research Tools (1998) (accessed Jan 2017).

[53] *Innogenetics* v. *Abbott Laboratories*, (Fed Cir 2008).

[54] Cynthia Ho, Patents, *Patients, and Public Policy: An Incomplete Intersection*, 33 U.C. Davis L. Rev. 601 (1999-2000) (discussing 35 U.S.C. § 287(c) & 35 U.S.C. § 287(c)(2)(A)).

[55] *See* Rose, *supra* note 10, at p. 120.

[56] *See* Ho, *supra* note 54.