The Countervailing Interests of the Progression and Application of Biotechnological Innovation Supporting the Modification of Current Exclusionary Property Rights

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I. Introduction

Deeply rooted exclusionary property rights in all fields of research and development permit inventors and licensors to both protect their innovations and to reap the fruits of their labor. Yet, in certain fields, countervailing interests, such as the continuing progression and application recent of biotechnological innovation, necessitate change in current policies. In Moore v. Regents of the University of California, the court rendered its decision by considering both the value of property rights and the promotion of valuable research, but this decision has, in effect, slowed the advancement of scientific research because of the assignment of property rights to researchers.¹ The court concluded that if fewer entities had fractional interests in intellectual property rights, then research would increase; however, at best, this holding may have only simplified the determination of property rights. Both adoption of the decision by other states and federal policies building upon the case have slowed research. Observers, on the other hand, believe that exclusive intellectual property rights are counterproductive to innovation in biotechnology, and, further, the evolution of science transpires most rapidly when researchers enjoy free access to new materials.²

Improvements in molecular biology have empowered and continue to empower us to combat diseases and ailments in new ways. Notably, stem cells, and more specifically, embryonic stem cells, show considerable promise in fighting disease through gene therapy and organ transplantation and repair.³ In 1968, stem cells were used in the first successful bone

¹ Moore v. Regents of the Univ. of California, 793 P.2d 479 (Cal 1990), 51 Cal. 3d 120 (Cal. 1990) (holding that a donee of cells has no property rights in his donated cells).

² See Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1017, n.2 for examples of such perspectives.

³ See infra pp. 6-7 for a discussion on the difference between stem cells and embryonic stem cells.
marrow transplant to combat leukemia.\textsuperscript{4} In October 2006, scientists grew the first “artificial” liver cells using stem cells.\textsuperscript{5} And recently, in March 2008, doctors performed the first successful cartilage regeneration in a human knee using stem cells.\textsuperscript{6}

The history of stem cells research gives reasonable hope that soon we can replace failing hearts, kidneys, and livers, repair spinal cord tissue, and regenerate muscle.\textsuperscript{7} Additionally, innovations in stem cell research may lead to the production of new pharmaceuticals and hormone replacement therapy.\textsuperscript{8}

A primary goal of public health policy involves increasing access to medicine, as well as improving the quality and success of medical treatment. Stem cell research can do this by increasing the volume of transplants and producing new pharmaceuticals. Organ transplant surgery can be cost-prohibitive to most patients, particularly those without insurance, with prices

\textsuperscript{4} University of Minnesota Pediatric Bone Marrow Transplant Program, \url{http://www.med.umn.edu/peds/hemonc/education/hemoncfellow/bmtprogram/home.html} (last visited Jan. 15, 2009).


\textsuperscript{6} Christopher J. Centeno et al., \textit{Increased Knee Cartilage Volume in Degenerative Joint Disease using Percutaneously Implanted, Autologous Mesenchymal Stem Cells}, 11 \textit{Pain Physician} 33, 343 (2008), available at \url{http://www.painphysicianjournal.com/2008/may/2008;11;343-353.pdf}.

\textsuperscript{7} Though it is expected that advancements will eventually lead to these treatments, estimates vary as to when such therapies will be available. \textit{Compare} Stem Cell Basics, \url{http://stemcells.nih.gov/info/basics/basics6.asp}, (last modified Apr. 18, 2009) (“… significant technical hurdles remain that will only be overcome through years of intensive research.”) with Telephone Interview with Rachel Laing, Ph.D student in Medical and Molecular Pharmacology, in L.A., Cal. (Jan. 15, 2009) (stating that such technologies will begin to develop in the next decade).

\textsuperscript{8} \textit{Cf.} Stem Cell Basics, \textit{supra} note 7.
ranging from between $246,000 to $908,000 for single organs.\textsuperscript{9} Despite the high costs of surgery, recipients still must wait for a donor organ availability. With over 84,000 people waiting on such lists,\textsuperscript{10} many potential recipients do not live long enough to ever receive an organ. And, even if a patient has the money and is high up on the list, the organ must not only match,\textsuperscript{11} but the patient must take immunosuppressant drugs.\textsuperscript{12}

With advancements in stem cell technology, scientists will have the tools to grow organs for patients using the DNA from the same patients. This has the potential to eliminate donor lists and obviate the need for a lifetime regimen of immunosuppressants.\textsuperscript{13} Over time, the price of a transplant might decline because surgery may no longer be required.

In addition, we will see overall improvement in the development of pharmaceuticals. For instance, instead of taking prescriptions for life, a person with deficient thyroid production may receive a simple injection that will “cure” his thyroid. Such an injection composed of stem cells could repair or replace the damaged tissue. Further, because of the resulting increased access to organs from genetic engineering, more extensive testing will occur on pharmaceuticals with

\textsuperscript{9} Transplant Living, \url{http://www.transplantliving.org/beforethetransplant/finance/costs.aspx} (last visited Jan. 15, 2009).

\textsuperscript{10} The Gift of a Lifetime, \url{http://www.organtransplants.org/understanding/unos/} (last visited Jan. 15, 2009).


\textsuperscript{12} Transplant Living, \url{http://www.transplantliving.org/afterthetransplant/stayinghealthy/preventingRejection.aspx} (last modified Jun. 4, 2008). Not only are immunosuppressants costly, but among their side effects, prevent patients’ immune systems from fighting many types of diseases.

\textsuperscript{13} See Transplant Living, \url{http://www.transplantliving.org/afterthetransplant/medications/typesofsuppressants.aspx} (last modified May 17, 2007).
these organs, with fewer potentially harmful human trials, ultimately leading to the creation of safer drugs. As an ancillary, the freedom to research in more areas can occur because of more expendable resources through cost-savings.

While great potential exists, several hurdles delay progress in the field. Broadly speaking, these hurdles can be categorized as technological, financial, and legal. Among the legal problems, we see conflicts among the states, differing policies between state and federal governments, and judicial opinions that have not kept pace with changes in the structure of scientific research.

This paper will describe current hurdles in stem cell research and determine the legal landscape necessary to facilitate advancements in the field with a specific emphasis on Moore v. Regents of the University of California, its progeny, and applicable federal policies. This article will begin with an introduction to the scientific significance of stem cells and the tools that scientists require to perform genetic research, describe the barriers impeding research, examine recent changes in policy, and propose modifications to policies to maximize growth in the field.

II. The Tools that Scientists Require to Perform Genetic Research

In a laboratory setting, the first step in researching a genetic disease generally involves finding a gene. This involves isolating the DNA sequence from a cell and creating markers, which are compared to mutated or normal sequences. If the sequence encodes a protein,
researchers can cultivate cell lines containing the protein to try to develop drugs or strategies for gene therapy.  

A cell line comprises of cells isolated from a specific tissue or organism and can grow indefinitely. Cell lines can incorporate different genes and produce a variety of proteins. An embryonic stem cell line is a specific cell line derived from an embryonic stem cell. These cell lines, though not limited to, can be used to prevent or cure diseases and injuries, repair or replace damaged tissue, or overcome immunity rejection when transplanted.

In 1993, Kary Mullis received the Nobel Prize in Chemistry for his creation of polymerase chain reaction (“PCR”). Prior to this technique, replicating DNA, a necessary step in many biotechnological applications such as sequencing a gene, was a slow and complex process. PCR revolutionized molecular biology by exponentially replicating fragments of DNA in a very short period of time. This important technique shortens the time needed for scientists to perform the first steps of quickly sequencing unknown DNA or to detecting diseases through the

16 Telephone Interview with Rachel Laing, supra note 7.

17 Id.


19 Basics of Stem Cell Research, supra note 18.


amplification known DNA sequences. The use of PCR is a necessary component of genetic research.

Other techniques are used by scientists to help cure diseases. Somatic cell nuclear transfer ("SCNT")\textsuperscript{23} was used to clone a primate stem cell line in June 2007 and to clone human blastocysts from human fibroblasts\textsuperscript{24} in January 2008. SCNT essentially requires two cells, one complete cell with a nucleus, which contains the DNA, and an egg cell, which contains no nucleus. The nucleus from the complete cell is transplanted to the enucleated egg cell. This newly nucleated cell can now replicate and grow into an embryo. Scientists can harvest the cells from these embryos to create new embryonic stem cell lines. These embryonic stem cell lines can be created using cells linked to a particular disease in order to study the disease or created using healthy cells for cell-based transplant therapy to avoid immunity rejection. SCNT, however, is a complex process and its biochemical mechanisms are not completely understood.

Stem cells, also used for genetic research, have the ability to go through multiple cell divisions while remaining undifferentiated. Undifferentiated cells have not yet been “programmed” as a certain type of cell and can mature into any type of cell. For instance, after conception, cell division produces the morula, a ball of twelve embryonic stem cells. Embryonic stem cells are totipotent. In other words, they can form all types of embryonic and extraembryonic cells, and each can individually create a complete organism. After subsequent cell divisions increase the number of cells to about 100, the embryo reaches the blastocyst stage, a structure resembling a ball. At this stage, the cells in the inner mass of the ball then lose their totipotency. Pluripotent cells can be derived from the blastocyst and can form into all kinds of

\textsuperscript{23} U.S. Patent No. 7,304,204 (filed Nov. 21, 2001).

\textsuperscript{24} Fibroblasts are types of cells found in the connective tissue of animals.
embryonic cells. They cannot, however, form extraembryonic cells, like the placenta, yolk sac, and umbilical cord. Thus, pluripotent cells cannot form a complete organism but are still considered embryonic stem cells.

Scientists can extract stem cells from a variety of different tissues such as the embryo, bone marrow, or after-birth. Research, however, has shown that the greatest promise for advancement lies with embryonic stem cells—perhaps because they originated as stem cells immediately after conception, unlike, for instance, stem cells from bone marrow, which were created after birth. The figure above depicts the derivation of different types of stem cells from different stages of the embryo. Against, scientists can use embryonic stem cells to create cell lines.

III. Barriers to Research

25 Picture by Mike Jones (May 3, 2006), available at http://upload.wikimedia.org/wikipedia/commons/3/3c/Stem_cells_diagram.png (Depicting a figure showing at what stage of development different types of stem cell can be formed).
A. Moore and its Progeny

Judicial decisions have had a significant impact on the ability of scientists to perform research. In Moore v. Regents of the University of California, the California Supreme Court held that organ donors have no property rights in cell lines derived from their organs. The majority premised its decision based on a desire to encourage research.

On October 5, 1975, John Moore visited the University of California at Los Angeles Medical Center after learning he had hairy-cell leukemia. He was hospitalized, and after the withdrawal of his blood, his physician and Defendant, Dr. Golde, learned that Moore’s “blood products and blood components were of great value in a number of commercial” applications. On October 8, 1976, Golde recommended that Moore’s spleen be removed to slow the progression of the disease.

Before the operation commenced, Golde and Dr. Quan, a researcher, agreed among themselves to take portions of the spleen and perform research on them. Neither relayed this intention to Moore, and Moore never granted permission for this use. Following the operation, Moore again traveled to the UCLA Medical Center several times for additional samples of his “blood, blood serum, skin, bone marrow aspirate, and sperm” over a period of seven years. The research activities on his spleen were concealed from him the entire time.

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26 Moore v. Regents of the Univ. of California, 793 P.2d 479 (Cal 1990), 51 Cal. 3d 120 (Cal. 1990).

27 Id. at 125.

28 Id. at 126.

29 Id.
Before August 1979, Golde established a cell line from Moore’s T-lymphocytes, and the Regents of the University of California subsequently applied for a patent on the cell line. Golde negotiated commercial development of the cell line and its derived products with Genetics Institute. Though it was difficult to measure the potential market of the cell line, estimates put the figure at around $3 billion.

In his complaint, Moore sought damages for the profits derived from the use of his cells to create a cell line without his consent. The court held that Moore had no property rights in his excised cells and, therefore, no rights to the profits made from cell line, and that the researchers had property rights in the derivatives of Moore’s cells. The court believed that the establishment of a duty to obtain consent for the use of human cells in research would hinder such research stating that “the impo[sition] of such a duty, which would affect medical research of importance to all of society, implicates policy concerns far removed from the traditional, two-party ownership disputes in which the law of conversion arose.” The court maintained that patents helped the dissemination of research and such dissemination occurs freely.

The award of property rights to the researchers authorized them to file and obtain the full benefits of patenting the cell line. By creating a bright-line division of property rights where donors have no property rights, the majority rationalized that multiple claims on property rights for cell lines would be reduced. The effect of this decision would, supposedly, reduce patent

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30 Id. at 127.
31 Id.
32 Id. (There are no published documents available that state the current actual value of the patent).
33 Id. at 154.
34 Id. at 163.
thickets, thus affording future researchers the opportunity to easier access to patented technologies. Conversely, if both the researchers and Moore had ownership, the scientists may have had to include Moore as an assignee of the patent, and subsequent researchers may have to obtain licensing rights from both. In another scenario, Moore would have received royalties from the cell line, which may have led to the patent owners charging higher licensing fees to subsequent researchers or the cell line becoming abandoned because of economic infeasibility. In either scenario, future researchers would have reduced access to patentable technologies.

Justice Mosk’s dissent, however, foreshadowed the new found hardship that occurs in conducting scientific research. He began with the one year novelty requirement of 35 U.S.C. § 102(b) for obtaining patents. Further, he explained that scientists are researchers and not professional negotiators. These scientists would try to recruit biotech and pharmaceutical companies to exploit the commercial potential of their discoveries instead of concentrating on making discoveries. Although this system of scientist and biotechnology company

35 See infra pp.27-28.

36 This would result from an award of property rights if Moore was successful in his claim of conversion of his excised cells.

37 Moore, however, would not be considered an inventor because he did not conceive or reduce the invention to practice. See 35 U.S.C. § 116 (2007) (“When an invention is made by two or more persons jointly, they shall apply for patent jointly…even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.”) with U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: Ownership of Human Tissues and Cells (1987) at 71 [hereinafter OTA Report] (“[T]he patient’s or research subject’s assertion that tissues have a value in research is not a conception unless there is recognition of a practical use for those tissues, or their derivatives, outside research.”).

38 See infra p.14.

39 Id. at 121.
collaboration was beginning to take place, Justice Mosk did not propose a solution for how researchers should remain researchers, as opposed to concentrate on commercializing their discoveries. Justice Mosk believed that this new method of conducting research would extend to public universities where secrecy, not collaboration, would consume the laboratory. Lastly, he believed that, more so than the novelty requirement, trade secret protection would hinder research. This is because trade secret protection, which commercial entities would negotiate from researchers, does not need to “meet the strict standards of patentability and the protection is both quickly acquired and unlimited in duration.” The majority brushed aside Justice Mosk’s concerns as baseless, more so relying upon the Office of Technology Assessment’s finding that distribution of biological materials are common between researchers and schools throughout the nation. The decision of the majority, however, has lead to much controversy among scientists and other critics because of reduced collaboration among the scientists and the high costs of obtaining a license for patented materials.

State court decisions have shaped the avenues of research available to researchers because of the economic impact of these decisions. Moore v. Regents of the University of California has served as persuasive authority for many of the judicial decisions of other states. In Greenberg v. Miami Children’s Hospital Research Institute, a researcher collected tissue samples and information from the families of children who suffered from Canavan disease.

40 Id. at 123.

41 Id. at 122-123.

42 Moore, 51 Cal. 3d at 145 n.40 (citing OTA Report at p.53).

43 Moore, 51 Cal. 3d at 120.

The researcher subsequently found the gene responsible for the disease and patented the sequence. The families filed suit claiming a property interest in the donated tissue. Relying heavily on *Moore*, the court held that the researcher had a complete interest in the tissues and could patent the sequence.\(^{45}\)

In *Washington University v. Catalona*, Dr. Catalona, a Washington University researcher and “several other WU physicians” collected samples of “prostate tissue, blood, and DNA samples for prostate cancer research.”\(^{46}\) After difficulties with the University, he changed employers and solicited his previous patients for their samples. The Eight Circuit, relying on the caselaw analysis, policy considerations, and “implications of applicable federal and/or state laws dealing with biological materials”\(^{47}\) discussed in *Moore*, held that the patients had no property right to their donated samples, and thus, the University can obtain patents on discoveries made from the materials.\(^{48}\)

Though *Moore* represented the award of property rights for the creation of a cell line leading to patent rights, the repercussions of the decision reach all areas of research, including advancements in the field of embryonic stem cells. The previous discussion of cases suggests that *Moore* and its progeny have increased innovation in the biomedical field by eliminating property rights in the donees.\(^{49}\) The case, however, has actually hindered research by creating

\(^{45}\) *Id.* at 927.


\(^{47}\) *Id.* at 997.

\(^{48}\) *Id.* at 995.

\(^{49}\) See e.g., *Moore*, 793 P.2d at 479; *Greenberg*, 208 F. Supp. 2d at 918; *Catalona*, 437 F. Supp. 2d at 985. See also, *United States v. Arora*, 860 F. Supp. 1091 (D. Md. 1994) (holding a claim for conversion exists for established cell lines).
significant hurdles for downstream researchers by narrowly defining property rights in upstream research. From the current trends in scientific research, patients and researchers have painfully realized the warnings of Justice Mosk.

B. **Patents--Generally**

Patent law plays a pivotal role in a researcher’s pursuit of scientific advancement. Generally, biotechnological patents encompass gene patents, cell line patents, and process patents. Gene patents, cell line patents, and process patents exclude researchers from unlicensed use, but all differ in their effects. In essence, a patent is a grant from the government for an allowance of monopoly-like powers for a limited time in exchange for an addition to societal knowledge.\(^{50}\) The owner of a patent has an exclusive right against all unauthorized uses of the patented material and “may exclude the development of all subsequent, similar, non-identical, useful inventions.”\(^{51}\) Thus, a patent holder can prevent a scientist from using the patented material to do new research without a license. To qualify for a patent, the patented invention must have novelty and utility.\(^{52}\) Both these requirements, though necessary to obtain all patents, have hurt the volume and quality of scientific research.\(^{53}\)

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\(^{50}\) E.g., U.S. Const. art. I, § 8, cl. 8 (“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”); May Mowzoon, *Access Versus Incentive: Balancing Policies in Genetic Patents*, 35 *Ariz. St. L.J.* 1077, 1082 (2003).


\(^{53}\) *See infra* pp.14-16 and pp.19-20.
For the duration of the patent, patent holders seek to maximize their profit by charging monopoly prices far above the marginal cost of the technology.\textsuperscript{54} This differential will cause the exclusion of research where limited funds can only allow expenditures in an amount close to the cost of production.\textsuperscript{55} This situation creates a social harm because of a reduction of in-depth and valuable research. Thus, the true beneficiaries of scientific breakthroughs, patients, suffer because of a reduction in the number of therapeutic options available in all areas of medicine. Perhaps most disturbing to the public, a researcher who cannot obtain the proper licenses may complete research on the basis of incomplete information or abandon the research in favor of less promising undertakings with fewer licensing obstacles.\textsuperscript{56} On the other hand, in the case of a gene patent, a researcher who has licensed a gene sequence would not need to sequence the DNA fragment or perform other types of preliminary work before beginning research because this has already been completed upstream, ultimately leading to a possible cost-savings.

The novelty requisite of 35 U.S.C. § 102(b) requires that the invention not be “patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.”\textsuperscript{57} When a researcher makes a discovery that he eventually wants to patent, he can only disclose the discovery within one year of filing the patent, thus prolonging the secrecy of his discovery. The inventor may delay his filing in an effort to begin his twenty year patent term as late as possible and not publish his findings in a peer review journal. This practice reduces dissemination of


\textsuperscript{55} Id.

\textsuperscript{56} Michael A. Heller & Rebecca S. Eisenberg, \textit{Can patents deter innovation? The Anticommons in Biomedical Research}, 280 SCIENCE 698, 699 (May 1, 1998).

\textsuperscript{57} Depoorter, \textit{supra} note 51, at ¶76.
important discoveries in the field of stem cell research and fosters an environment of secrecy, which leads to less overall progression in the field.

In 2006, a survey by David Blumenthal of the Harvard Institute of Health Policy found that forty-four percent of geneticists and thirty-two percent of other life scientists at the 100 most research-intensive universities in the United States reported that they had withheld data with sixteen percent of geneticists withholding information in their manuscripts to protect their lead, twelve percent to protect trade secrets, six percent to allow time for patents, and two percent to protect commercial value. The survey also found that “one of every five professors in the life sciences had delayed publication of research results for at least half a year in order to protect financial interests. Those scientists who directly engaged in the commercialization of their research were three times more likely to delay publication and twice as likely to refuse to share information than those doing basic work.” Another survey found that forty-nine percent of doctoral and post-doctoral students believed that their rates of discovery were negatively impacted by withholding of information.” Thus, the statutory bar of prior art under § 102 and a patent applicant’s desire to avoid this restriction directly reduces access to important information by other researchers.

1. Gene Patents


59 *Id.*

A gene patent claims and provides rights to a specific sequence of DNA. This requires an identification of a novel genetic sequence as well as an explanation of the product and how the product functions in nature through a specification. A specification provides a written description enabling one skilled in the field of art to use the sequence for its stated purpose. In practice, however, the function of the product is often unknown for known sequences. Furthermore, these patents often define the utility of the sequence as providing scientific probes to assist in locating a gene, to facilitate isolating another expressed sequence tag, or to help map a chromosome, yet only knowing a sequence is required to create probes, find ESTs, or map chromosomes. Thus, the disclosure required to obtain a gene patent is illusory because private rights of exclusion are established for mere information rather than a concrete output of the information, such as a known protein.

61 35 U.S.C. § 112 (2007) (The specification is part of a patent application, which “contain[s] a written description of the invention, and of the manner and process of making and using it… [and] shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”).


63 Id.

64 Expressed sequence tags (ESTs) are cDNA (complementary deoxyribonucleic acid) strands of approximately 500-800 nucleotides. They are made by creating mRNA (the genetic material transcribed from DNA, which a cell then uses to translate to amino acids) sequences and synthesizing a complementary strand of DNA. Scientists can then use this cDNA to discover genes and gene sequences.

65 Human Genome Project Information, supra note 62.

66 Telephone Interview with Rachel Laing, supra note 7.

67 Depoorter, supra note 51, at ¶125.
The impact of these patents is two-fold: 1) property rights, and therefore a large portion of profits derived from downstream research, are awarded for minimal research compared to the more complicated and intensive discovery and functional analysis of a product; and 2) the discovery of sequences becomes more valuable, thus more prevalent, than downstream research, which can provide a therapeutic product, leading to a diversion of resources from functional product research. In a sense, these patents discourage scientists from applied research.

Gene patents negatively affect researchers because the researchers involved in downstream research on a gene sequence must license the patented sequences used to create drugs or gene therapies. Downstream research is more important as far as directly benefiting patients and more difficult. Finding a sequence requires much less work than the resulting downstream research derived from a gene sequence because sequencing the entire genome has already occurred, and new, high-speed sequencers can quickly determine the sequence of a gene.

The negative implications of patents are not limited to research but to diagnostic testing as well. Healthcare providers and their patients suffer because diagnosticians must pay expensive licensing fees for diagnostic tests, which use patented gene sequences, limiting

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68 Upstream tools refer to discoveries leading to further discoveries and include PCR, SCNT, and high-throughput sequencing. Downstream research utilizes upstream tools to create downstream discoveries.

available screening options. For instance, Myriad Genetics holds patents on BRCA1 and BRAC2, both breast cancer gene markers, and charges $3,000 per test as a licensing fee. Use of this diagnostic test without licensing, according to Myriad Genetics, constitutes an infringement of its patent. This restriction burdens the public in two ways: 1) research using the breast cancer markers, which requires licensing of the patent, becomes more difficult because of the prohibitive cost, thus reducing emergence of better quality tests, and 2) the use of this test to detect and prevent breast cancer becomes limited to the insured and affluent. Thus, patent owners can monopolize markets by forbidding entities from using patented materials and hinder collaboration among researchers. In both cases, the difficulties are not abstract. First, researchers must make a conscious decision to pursue research only when the monetary benefit of their success multiplied by their probability of success exceeds the cost of licensing. For instance, Myriad Genetics, “refuses to allow [its] patent[s] on [BRCA1 and BRCA2] to be licensed for prenatal testing for genetic markers.”

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In response to these licensing fees, the European patent office revoked the patent, and the Canadian government decided to test without paying for the patent. In another example, a survey completed in 2003 of diagnostic laboratories found that twenty-five percent had stopped performing any clinical test or service, and fifty-three percent had stopped research efforts because of a patent or license.

The utility requirement of 35 U.S.C. § 112 necessitates that an invention have usefulness and be described in the specification in order to be eligible for a patent. A gene patent does not have the traditional utility of other types of patents because it may list only a sequence of base pairs of DNA. Though a person applying for a patent must discover this sequence, the sequence itself need not have any actual use. A researcher then must use the sequence, for instance, a breast cancer gene marker, to create a new method of detection of breast cancer. Thus, a minor

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78 35 U.S.C. § 112 (2007) (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”).

79 See supra p.16 for the United States Patent and Trademark Office requirements to obtain a gene patent.
amount of work, such as discovering the sequence, results in patent rights. Meanwhile a more significant portion of work, such as long-term downstream research on a sequence in order to create a new method of detection of breast cancer, can only occur if a scientist acquires a license. Thus, researchers feel compelled to patent sequences instead of focusing research on useful products. This situation results in an inefficient allocation of resources, which limits our technological progression in stem cell research.

This is not to say that gene patents have no positive effects. They can stimulate growth in the biomedical field by incentivizing research through the award of exclusionary rights. This allows upstream research, leading to a patented gene, to potentially pay for itself and produce a profit. For instance, to obtain approval from the FDA for its breast cancer tests, Myriad Genetics invested considerable amounts of money in clinical testing and quality control to create a marketable product. Otherwise, investors would have little incentive to invest capital to promote further biomedical research. Further, downstream researchers do not directly bear the

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80 Caulfield, supra note 69.


82 Heller & Eisenberg, supra note 56, at 698; Proponents of gene patents argue that gene patents should be treated like pharmaceutical patents in terms of owners receiving compensation for upstream research. One should note, however, molecular biologists began identifying genes long before the patent office made clear that genes could be patented. Additionally, unlike pharmaceuticals, gene sequencing requires no expensive clinical trials and after identification of a gene sequence, in some cases, clinical testing can begin almost immediately. See Andrews, supra note 81, for further discussion on the costs of upstream research of gene patents.

83 David B. Resnik, Are DNA Patents Bad for Medicine?, 65 Health Pol’y 181, 190 (2003). But see Andrews, supra note 81, at 77, stating that “the FDA does not regulate the clinical services of genetic tests” and Myriad Genetics only had to pay for approval for sale of its genetic diagnostic tests.

84 Lila Feisee & Brian Stanton, Are Biotechnology Patents Important?, PTO PULSE (Mar. 2000), available at
costs of sequencing, whether through the investment of sequencers or failures arising from sequencing,\(^85\) and have a direct base from which to begin research.\(^86\) Also, patents can encourage dissemination of information through disclosure from filings.\(^87\)

In addition, the economic gains realized from the patents will generate a source of tax revenue for the government through the profits realized from such patents.\(^88\) Moreover, a commentator suggested that the licensing fees charged by private organizations remain sensitive to the free market dynamics of supply and demand.\(^89\) Thus, if consumers do not pay Myriad’s prices for its breast cancer tests, Myriad will be forced to lower its prices.\(^90\)

Nevertheless, this form of incentive based research does not reward useful breakthroughs because scientists will stop their efforts after the discovery of one sequence to move to another instead of exploring each sequence in depth. Perhaps the most disturbing aspect of gene patents is the source of funding from which the sequences are discovered. Unlike pharmaceuticals, which use money for research primarily through private funds, the discovery of genes has consumed $1.8 billion of taxpayer money—alone in the year 2000.\(^91\) Even then, private

\(^85\) Cf. Pogge, supra note 54.

\(^86\) Depoorter, supra note 51, at ¶37.

\(^87\) Heller & Eisenberg, supra note 56, at 698.

\(^88\) Id. at 189.

\(^89\) Id. at 193.

\(^90\) Id.

companies still utilize sequence data from publicly funded projects to patent their discoveries.\textsuperscript{92} Though the \textit{Moore} Court based its decision on promoting research, its decision has helped foster a system that encourages the discovery of sequences not viable products directly beneficial to mankind.

2. \textbf{Cell Line Patents}

The United States Supreme Court interpreted patentability to extend to man-made, genetically engineered bacteria in \textit{Diamond v Chakrabarty}\textsuperscript{93} and the United States Court of Appeals for the Federal Circuit extended this holding to include purified and isolated DNA sequences in \textit{Amgen, Inc. v Chugai Pharmaceutical Co., Ltd.}\textsuperscript{94} In response to these and other court decisions, the United States Patent and Trademark Office determined that purified and isolated stem cell lines were patentable subject-matter under 35 U.S.C. § 101.\textsuperscript{95}

Patenting of cell lines prevents researchers from taking full advantage of all available resources when they are unable to pay licensing fees. Additionally, working with embryonic stem cell lines magnifies the problem of high licensing costs because of federal policy limiting

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\textsuperscript{94} \textit{Amgen, Inc. v. Chugai Pharm. Co., Ltd.}, 927 F.2d 1200, 18 USPQ2d 1016 (Fed.Cir.1991).

\textsuperscript{95} Statement of Q. Todd Dickinson, Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee, available at \url{http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/stemcell.pdf}.
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their use. Research on only twenty-one embryonic stem cell lines are eligible for federal funds. This exclusivity allows the patent owners to charge exorbitant licensing rates for using these cell lines.

Patenting cell lines has beneficial effects as well. In contrast to sequencing a gene, creating a cell line requires considerably more research and development, and patent rights help offset this cost and reward the innovation. Like gene patents, cell line patents also encourage investment in the patent holder and arguably increase economic efficiency through privatization. In addition, these patents can encourage dissemination of information as well through disclosures from patent filings.

3. Process Patents

For advancements to occur, scientists must utilize powerful tools such as PCR and SCNT to provide them with new avenues of potential discovery. They must, however, consider the implications of using these patented tools. If their research uses these tools, scientists will have to license them from the patent holder and subject their discoveries to reach-through royalty

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97 See supra p.17.

98 Heller & Eisenberg, supra note 56, at 699.

99 Id. at 698.

100 Cf. Charlotte H. Harrison, Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue, 28 AM. J. L. & MED. 77 at 86-87 (2002) (noting that efficiencies of private entities may be higher than public entities, however, this difference can be accounted for by their differing strategic and policy goals).

101 Heller & Eisenberg, supra note 56, at 699.
clauses. And with new developments emerging through patents, access to these technologies must increase as well. This situation significantly impacts a researcher’s decision to pursue a certain line of work.

Wisconsin Alumni Research Foundation (“WARF”) holds three broad process patents, which essentially give it control of embryonic stem cell research in the United States. These patents claim the extraction of cells from embryos. Thus, when an American researcher uses embryonic stem cells in any way, he or she must pay a licensing fee to WARF. These licensing fees can amount to $250,000, in addition to annual maintenance fees of $40,000. Moreover, licensing negotiations over such “technologies and materials can be long and complicated, imposing delays and administrative burdens on research.” Further, when an

102 See infra pp.25-26.

103 This is in addition to the 5 patents it holds on embryonic stem cell lines.


106 David Walberg, “Was stem-cell advance ‘obvious’?”, THE WISCONSIN STATE JOURNAL, October 15, 2006, available at http://www.tmcnet.com/usubmit/2006/10/15/1982334.htm; Somers, supra note 103 (“WARF also agreed to make it easy for nonprofit research labs to obtain and use the cells. Originally, WARF charged research institutes $5,000, but that fee recently was reduced to $500. However, if the research leads to a discovery that could be patented and then licensed to other scientists, the foundation wants those licensees to pay it [sic] too”).

107 See supra note 104.

108 GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES, supra note 73, at 18.
entity combines technology under several different patents, the licensing fees of these several patents stack. This translates into exorbitant costs and fees for a scientist to even begin conducting research. Though WARF claims that it charges reduced prices for universities, WARF subjects the universities to a “reach-through royalty clause[s]”. In this situation, when one of WARF’s patents is used to develop a tool, the tool becomes subject to royalties.

WARF is not the only entity that makes use of these royalty agreements. Cetus Corporation proposed using royalty agreements on use of PCR, but after Hoffman-La Roche acquired the rights to PCR, it did not include royalty obligations in its licensing agreements. Also, DuPont Corporation’s licenses to use oncomouse and cre-lox technologies required royalty obligations. Reach-through royalty clauses present a problem in that a patent-holder will have a right to any downstream research, thereby reducing the financial viability of any commercial product—and more-so when multiple licenses are required. Though the majority in Moore sought to curtail the predicament of multiple licenses by denying Moore property rights, permitting research entities to fully control these same intellectual property rights has nonetheless allowed these entities independently to create requirements detrimental to the speedy progression of technology in the field.

109 See supra note 104.

110 See supra note 104.

111 Cetus to Exact Royalties from PCR Sales; Probe Absolves Convicted Rapist, 8 BIOTECHNOLOGY NEWSWATCH 7 (Sep. 5, 1988).


But patent licensing in upstream tools\textsuperscript{114} in areas such as recombinant DNA techniques may enable researchers to justify undertaking of riskier research because of reduced costs in research and development of the necessary upstream tools.\textsuperscript{115} Additionally, as in the case of PCR, licensing agreements without royalty clauses can increase the upfront costs of licensing by shifting the projected value of the royalty clause to the upfront price.

C. Negative Effects Compound

The implications of patents and licensing compound when dealing with several entities or entities with several patents of the same type. Commentators have coined the term “tragedy of the anticommons” in which “people underuse scarce resources because too many owners can block each other.”\textsuperscript{116} This is opposed to the traditional “tragedy of the commons” model in which people overuse freely available resources. Under the commons theory, people overuse shared resources because no one has a right to exclude another. In the past, the federal government “sponsored premature ‘upstream’ research and encouraged broad dissemination of results in the public domain [and] [u]npatented biomedical discoveries were freely incorporated in ‘downstream’ products for diagnosing and treating disease.”\textsuperscript{117} Consequently, after a shift in government policy\textsuperscript{118} and subsequent increase of biomedical patents, too many intellectual

\textsuperscript{114} Upstream tools refer to discoveries leading to further discoveries and include PCR, SCNT, and high-throughput sequencing. Downstream research utilizes upstream tools to create downstream discoveries.

\textsuperscript{115} Heller & Eisenberg, supra note 56, at 699.


\textsuperscript{117} Id.

\textsuperscript{118} 35 U.S.C. § 200 (2007) (“It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or
property owners now have the right to exclude others from a scarce resource. As a result, we see the emergence of patent thickets.

Patent thickets occur when multiple licenses are required from different patent owners. Carl Shapiro, an economist, commented that when there exist multiple monopolists controlling various components of a product, the price of the resulting product is higher than if a single firm controlled all the inputs. For instance, if we hypothesize a scenario in which a researcher wants to create a fully functioning human liver and requires scientific techniques, cell lines, and gene sequences from twenty different entities, he must individually negotiate a license from each of the entities. Further, a large-scale empirical study showed that gene patent thickets reduce the dissemination of knowledge and use by a decline of forward citation as the number of times development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.”).

patented is increased.\textsuperscript{120} Considering that many genes with several overlapping patents have commercial applications, this finding is quite alarming.\textsuperscript{121}

Further compounding this problem, disputes may arise over the proper ownership of a patent, forcing a researcher to make a either a calculated guess as to the true owner or to forgo the research project altogether. For instance, in the case of Severe Acute Respiratory Syndrome ("SARS"), manufacturers delayed their decision to invest in producing a vaccine because of simultaneous patent claims on the SARS gene.\textsuperscript{122} This left manufactures unable to determine "the future cost of licensing the patent rights [and] whether all necessary patents [would] be available for licensing."\textsuperscript{123} Meanwhile, SARS affected twenty-nine countries with an eleven percent death rate.\textsuperscript{124} In this instance, a dramatic illustration of the worst fears of critics of gene

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\item \textit{Id.} These include CDKN2A, a gene mutation causing malignant melanoma and pancreatic cancer (20 times), BRCA1, which is responsible for early onset of breast cancer, (14 times); and LEPR, a leptin receptor important for circulating signals for the regulation of body weight (12 times).

\item Michael Crichton, \textit{Addressing Congressional Aides on what is wrong with patenting genes} (Sep. 2006).


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In essence, research has taken a back seat to commercialization of useful scientific information, a situation one cannot believe that the *Moore* Court envisioned with its decision.

**D. Trade Secrets**

More-so restrictive than the novelty requirement, as Justice Mosk described, trade secret provisions limit collaboration among researchers. Because of the commercialization of academic research, contractual restrictions to disclosure have evolved. These provisions can last indefinitely, comparatively much longer than the prior art bar or a twenty year patent term. Further, entities can more easily acquire these restrictions than patents. And with these contractual restrictions, no disclosure to the public occurs, of either general advancements or of similar disclosures required for a patent, so the public as a whole does not benefit from increased knowledge in the field.

**E. Executive and Legislative Hurdles**

In the case of cell lines derived from embryonic stem cells, another problem occurs resembling a monopoly. In a radio address by President Bush in 2001, he authorized use of federal funds only on limited pre-existing embryonic stem cells. Of the twenty-one pre-

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125 Michael Crichton, Addressing Congressional Aides on what is wrong with patenting genes (Sep. 2006); see generally *Michael Crichton: The Official Site*, [http://www.crichton-official.com/aboutmichaelcrichton-biography.html](http://www.crichton-official.com/aboutmichaelcrichton-biography.html) (last visited Jan. 15, 2009) (“graduating summa cum laude from Harvard College, received his MD from Harvard Medical School, and was a postdoctoral fellow at the Salk Institute for Biological Studies, researching public policy with Jacob Bronowski. He taught courses in anthropology at Cambridge University and writing at MIT.”).


existing embryonic stem cell lines that were eligible for federal funding, the Wisconsin Alumni Research Foundation (“WARF”) owns patents on five of them, and five other entities own the other sixteen. As discussed above, WARF’s approach to controlling its patents has reduced technological advancements. Even putting aside this problem, such a small number of embryonic stem cell lines available for federal funding, relative to other types of stem cells, limits viable avenues of research, especially when considering that these stem cell lines were established by in vitro techniques, making them incredibly susceptible to mutations.

Although the Moore patent was closely related to a foreseeable commercial product because it was of a cell line, the National Institutes of Health, in 1991, “pointed the way toward patenting anonymous gene fragments with its notorious patent applications on expressed sequence tags” nearly unrelated to a foreseeable commercial product. This behavior paved the way for different entities to file patents on “newly indentified DNA sequences, including gene fragments, before identifying a corresponding gene, protein, biological function, or potential

List” hyperlink; then follow “Stem cell research, Crawford, TX—953” hyperlink) (This was not a numbered Executive Order, and, therefore, part of the Public Papers of the Presidents of the United States).

128 National Institutes of Health: Eligibility Criteria for NIH Funding of Human Embryonic Stem Cell Research, http://stemcells.nih.gov/staticresources/research/registry/PDFs/EligibilityCriteria.pdf (last visited Jan. 15, 2009) (The eligibility criteria required that prior to President Bush’s announcement “the derivation process had already been initiated and the embryo from which the stem cell line was derived no longer had the possibility of development as a human being.” Additionally, “the stem cells must have been derived from an embryo that was created for reproductive purposes, the embryo was no longer needed for these purposes, informed consent must have been obtained for the donation of the embryo, [and] no financial inducements were provided for donation of the embryo.”).

129 See supra pp.24-25.

130 Heller & Eisenberg, supra note 56, at 699.

131 Id.
commercial product.\textsuperscript{132} Awarding patent rights for these types of discoveries magnifies the negative impact of Moore.

Through executive orders and legislation, the federal government has modified its stance on embryonic stem cell research in the last two decades. In 1980, Congress began to encourage universities and other institutions to patent discoveries in an effort to increase innovation.\textsuperscript{133} Cases like Moore helped promote this initiative by seeking to reduce property claims.\textsuperscript{134} This led to less research on sequences with promising results because of excessive licensing fees and royalties created through these patents.\textsuperscript{135} Thus, fewer viable products and uses for the patented materials result because researchers often cannot afford such fees. This leads to an inefficient use of resources—significant delays in researching occur due to high costs. Simultaneously, research moves toward un-patented sequences, which may have less promising results.

In 1995, Congress passed the Dickey Amendment to prohibit federal funds for research where human embryos are made or destroyed.\textsuperscript{136} Though Congress undoubtedly wants the public to pursue research, it made a policy decision to limit research where an embryo is harmed. In 1999, however, the National Institutes of Health, part of the executive branch, determined that embryonic stem cells do not fall under the category of human embryos by the statutory definition

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\item\textsuperscript{132} Id.
\item\textsuperscript{133} 35 U.S.C. § 200 (2007).
\item\textsuperscript{135} Heller & Eisenberg, supra note 56, at 699.
\item\textsuperscript{136} Public Law 106-554, § 510.
\end{enumerate}
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of the Dickey Amendment. In an important policy shift, however, President Bush used an Executive Order in 2001 limiting the use of federal funds to pre-existing embryonic stem cell lines. In 2005, perhaps a reflection in a change in public policy, the House and Senate voted to pass the Stem Cell Research Enhancement Act to allow federal funds for research of embryonic stem cells. President Bush, however, vetoed the bill. Then, in 2007, by executive order, President Bush expanded use of federal funds for pluripotent cells but left his previous limitation for embryonic stem cells intact.

IV. Recent Changes in Policy

To facilitate reaping the benefits of biotechnology as quickly as possible, access to patented processes and patented materials must increase. A number of factors can help to explain why changes in patent policy have not occurred. First, the representation of upstream commercial interests in the United States Patent and Trademark Office has not been counter-balanced by those with interests in expanding research avenues or increasing patient care. Further, legal challenges have produced inconsistent judgments, and these uncertain legal challenges present difficulty for small companies and academic institutions with limited funds.


138 Address to the Nation on Stem Cell Research From Crawford, Texas, 2 PUB. PAPERS 953 (Aug. 9, 2001).


141 Martin Bobrow & Sandy Thomas, Patents in a Genetic Age, 409 NATURE 763 (Feb. 15 2001).

142 Id.
In addition, submitting to an expensive licensing deal will likely cost less than the potential costs associated with litigation. Finally, dramatic changes to patent law may significantly disrupt the economic viability of patent holders. As a result, changes in policy for these types of patents remain stagnant.

Contrary to the federal government, state governments have largely supported embryonic stem cell research. Undeterred by lack of federal funding, California voters approved Proposition 71 in 2004, making embryonic stem cell research a constitutional right and providing $3 billion in research funding. Aside from California, New Jersey expressly supports “research involving the derivation and use of human embryonic stem cells” for embryonic stem cell research, Maryland has provided money for embryonic stem cell research, and Massachusetts passed legislation allowing embryonic stem cell research. Further, the former Governor of Illinois signed an executive order authorizing $10 million for stem cell research.

143 Id.; Nicholas Thompson, Gene Blues, Wash. Monthly, Apr. 2001 (citing the legal battle between Elan, a pharmaceutical company, and the prestigious Mayo Clinic over the clinic's Alzheimer's research with Elan's patented human genes as well as the University of Rochester's lawsuit against Pharmacia over a gene crucial to a painkiller, Celebrex, and Amgen's victory over Transkaryotic Therapies for attempting to create a competitor to Amgen's anemia-fighting drug Epogen), available at http://www.washingtonmonthly.com/features/2001/0104.thompson.html; Marcia Barinaga, Genentech, UC Settle Suit for $200 Million, 286 SCIENCE 1655 (1999).

144 C.A. Const. art. 35, §§ 1-7.


Unlike WARF, some non-profit patent holding entities, such as Stanford University and the University of California, more strongly believe in promoting research. They have licensed their patents for recombinant DNA processes more cheaply to biotech companies, for $10,000 plus royalties, and at no cost for universities and non-profit organizations. This model of behavior allows both the patent holder to recoup its costs for its initial research and allows innovation to benefit patients at a cost-savings.

On March 9, 2009, President Obama, through an Executive Order, revoked former President Bush’s Executive Order, and expanded the use of federal funds to embryonic stem cell research. His order required that the Secretary of Human Health and Services issue new NIH guidelines to determine eligibility criteria for federal funding. As a result of this Executive Order, the monopolistic character of embryonic stem cell lines should be reduced and research should increase. At best, though, embryonic stem cell line patents will still have the negative

149 One should note that WARF is a non-profit organization, like Stanford University and the University of California, yet its actions resemble those of a private entity.


152 Id.

153 It is important to note that the Executive Order does not legalize embryonic stem cell research, an area of much moral disagreement. The states retain sovereignty by individually deciding whether to allow certain cloning techniques, thus preserving interstate diversity. Several states specifically ban embryonic stem cell research. For more information on legality of embryonic stem cell research by state, see State Embryonic and Fetal Research Laws, http://www.ncsl.org/programs/health/genetics/embfet.htm (last modified Jan. 2008).
characteristics of other cell line patents. As a result, this Executive Order will not remove all the roadblocks researchers face to increase scientific progress.

V. Proposed Modifications of Policy

The Moore Court rendered its decision by considering both the value of property rights and the promotion of valuable research. Though this decision may have had good intentions, and even made a positive impact when initially made, the decision no longer serves the function that the respective justices intended. Patent holders have ignored the policy considerations that the court discussed and have generally reduced collaboration and information sharing of discoveries between researchers. This reduction has effectively slowed innovation in biotechnology through increased costs of research, increased costs of already developed diagnostic tests, and a diversion of resources to discovery of sequences instead of more useful techniques. Because of the widespread adoption of the decision, states other than California have experienced the same slowdowns. At this point, overturning Moore and its progeny would not reverse the effects of the decision because of subsequently created policies; a broader and stronger approach is required.

We can, however, take several different steps, aside from overturning Moore and its progeny, to increase research. First, the boldest stance Congress can take would be to forbid or curtail the use of gene patents. This prohibition can range from prohibiting patents on any genetic material and only granting patents on processes such as PCR and SCNT, purified proteins, and/or non-naturally occurring proteins, all of which are useful techniques or products.\(^{154}\) Similar laws have been successful in Japan,\(^{155}\) where its biotechnological sector

remains strong,\textsuperscript{156} as well as other countries in the European Union.\textsuperscript{157} Such a proposal, however, raises a host of questions and implicitly asserts that the courts cannot adequately address the problem through a different interpretation of patent law. As of yet, however, the courts have not remedied the dilemma sufficiently, and, further, Congress may be better equipped to make such substantive changes in law and policy. First, what would happen to already granted patents? Second, how would this effect the financial outlook of patent holding entities and would they “move” their patent rights to other countries with patent protection? With these complications aside, this approach may still prove ineffective, however, because private entities would still create contracts protecting such trade secrets and/or block publication of their research.

Second, requiring mandatory licensing of intellectual property at capped prices could reduce costs for new research, as some developing nations have done with HIV.\textsuperscript{158} Mandatory licensing could cause a reduction in patenting upstream research for both new technologies and genes. This action would allow competitors to cheaply produce patented products, thereby reducing upstream research because of the discouragement of discovery and innovation for


\textsuperscript{156} Andrews, \textit{supra} note 81, at 86.

\textsuperscript{157} Eisenberg, \textit{supra} note 2, at 1018-19, n.6 (noting that “Germany, France, the United Kingdom, Italy, the Netherlands, Belgium, Luxembourg, Ireland, Greece and Spain have either amended their national patent laws to conform with Article 31 (b) of the Community Patent Convention or have legislation pending to achieve this effect.”).

upstream entities. With the advent of high-throughput sequencing, though, discovery of new genes would still grow.

Another proposition would create an exemption to patent infringement for researchers at non-profit institutions. Such a plan would allow private entities to remain commercially competitive by licensing their intellectual property rights to other private entities, yet permit non-profit institutions the freedom to access important techniques and data in order complete expensive, but necessary testing and studies. This policy would essentially establish a median between eliminating biotechnology patents altogether and the current restrictiveness of patents. Thus, viability of private companies would be preserved to a greater extent compared with elimination of the patents, thereby retaining private innovation and discovery and allowing growth in research in the public domain. To further enhance this proposition, private companies could create patent pools where these companies would essentially buy into a large pool of different biotechnology patents, much like in other industries where tremendous growth has resulted. This would allow cost-spreading among the different companies and allow much greater access to a variety of different technologies and genes.

Research derived from embryonic stem cells presents a compelling situation because of President Bush’s Executive Order, which allowed use of federal funds for only twenty-one embryonic stem cell lines. This Executive Order presented two problems for researchers who wanted to receive federal funds: 1) research would be restricted to only these cell lines, thereby limiting avenues of discovery, and 2) owners of the embryonic stem cell lines held an essential monopoly whereby they could not only charge high licensing fees but also insist on reach-

\footnote{159 See generally Shapiro, supra note 119, at 119.}

\footnote{160 Address to the Nation on Stem Cell Research from Crawford, Texas, 2 PUB. PAPERS 953 (Aug. 9, 2001).}
through royalty clauses. A seemingly facile solution would authorize researchers to use a greater variety of embryonic stem cell lines. However, this would constitute a considerable policy shift because of the ethical considerations raised by destroying embryos. Yet, President Obama’s reversal of President Bush’s Executive Order seems to do just this.161 Scientists will now have greater access to different cell lines and will likely enjoy lower costs because of a newly created, free-market of cell lines.

In conclusion, if we seek the incredible benefits that we can gain from embryonic stem cells and technologies in the biomedical field as quickly as possible, a conscious public policy shift must be made to stop deterring innovation in the field by increasing discoveries and reducing the costs of research.