Gene Patenting:
Do The Ends Justify The Means?

by
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INTRODUCTION

Over the course of the last decade, medical interest and research in the human genome has grown at an exponential rate. As a result, profit-seekers and scientists are turning to patent law to protect their financial and medical interests; recent recipients of patent protection include bacteria, a type of mouse, and even human genes. As these trends in medicine and intellectual property law develop, considerable debates are surging regarding the morality of awarding property rights in biological material, particularly human genes. While both sides of this debate present compelling arguments, if scientists and investors are expected to advance their innovative research, they must have some guarantee to protect their financial investment and scientific findings. Patents provide this guarantee.

Part One of this article describes the science behind gene patenting, examines the structure of the American patent system, and explains how human genes satisfy the legal requirements of patent law. Part Two presents the arguments of those who defend the practice of gene patenting, while Part Three answers the criticisms of those who morally oppose gene patenting on moral grounds. Finally, Part Four suggests changes to the American patent law system that would balance the interests of science and morality more effectively than the current system. Such changes include adding an experimentation exception to the current gene patenting regime, limiting the scope of genetic patents, and liberalizing the compulsory licensing system currently governing patents.

I. BASICS OF GENE SCIENCE AND THE AMERICAN PATENT SYSTEM

To understand the controversy surrounding gene patenting, one must possess a fundamental understanding of the patented items. The following discussion presents a brief explanation of genes, their uses, and the applicability of patent law to genetic research.

A. Genes, Gene Fragments and Proteins

The human body consists of proteins that serve a multitude of tasks, ranging from creating cellular structures to performing tasks necessary for cells to move and function throughout the body.¹ These proteins can form

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hair and fingernails or help in the digestive process, or, in the case of flawed proteins, can lead to debilitating diseases such as cystic fibrosis or cancer. Given this range of functions, these proteins remain important to medical researchers. The material that creates the proteins, however, is just as important as the proteins themselves.

A protein is created by the information contained in a strand of Deoxyribonucleic Acid ("DNA"), which is called a gene. Genes contain regions that indicate the beginning and end of the gene and portions that serve as the template for a particular protein. This genetic material is contained within chromosomes, which are larger, X-shaped structures that contain long, dense, coiled DNA. Numerous genes lie within each coiled chain of DNA and different gene fragments exist within each gene.

A gene fragment, as the name suggests, is a portion of a gene. These fragments, once identified, are useful in isolating full-length genes, finding regions on a DNA strand, and identifying patterns within genetic material. A gene fragment’s utility is limited to these three functions; its capacity to aid in isolating the full-length gene, however, gives the gene fragment a greater role in the overall scheme of scientific research. Full-length genes are functional units that can be tested and manipulated, unlike gene fragments, which have little use outside of isolating the parent gene. This distinction will become important when considering whether gene fragments alone should qualify as patentable. Now, with a basic understanding of gene fragments, the following sections discuss the legal basis, policy, and ethical issues that surround gene patenting.

B. American Patent Law and its Applicability to Genetic Material

Article I, Section 8 of the United States Constitution provides the legal framework for the American patent system. This provision rewards inventors for their innovation by granting a temporary monopoly on their inven-

Ms. Holman and Mr. Munzer, whose article forms the basis of this discussion of the basics of gene science.

2. *Id.* at 741-42.
3. *See id.* at 742.
4. *Id.*
5. *See id.* at 742-43.
6. *See id.*
7. *See id.* at 750.
8. *See id.* at 749.
9. *See id.* at 749.
11. *See* U.S. Const. art. I, § 8, cl. 8 (stating that “Congress shall have [the] Power . . . to promote the Progress of Science and Useful Arts, by securing for limited
tions in exchange for making their findings public.\textsuperscript{12} To receive patent protection, however, an invention must: (1) qualify as patentable subject matter; (2) be novel; (3) have utility; and (4) be non-obvious.\textsuperscript{13}

1. Subject Matter Patentability

The Patent and Trademark Office (“PTO”) issues several types of patents, such as “design,” “utility,” and “plant” patents.\textsuperscript{14} Patents in genes and genetic fragments fall under the category of utility patents, which covers such items as “machines, industrial processes, compositions of matter, and manufactured articles.”\textsuperscript{15} Regardless of which category an invention falls into, it must be a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” in order to be considered patentable subject matter.\textsuperscript{16} This general doctrine is limited by the fact that products of nature cannot qualify as patentable.\textsuperscript{17} Initially, this general explanation of what qualifies as patentable would indicate that genes and similar biological material would be precluded from patentability.

In 1980, however, the United States Supreme Court decided \textit{Diamond v. Chakrabarty}, which extended patent law to cover living things.\textsuperscript{18} \textit{Diamond} involved a patent application that claimed rights in a strain of bacteria that was genetically engineered to break down crude oil.\textsuperscript{19} The Patent Examiner and the Patent Office Board of Appeals denied the patent application, but the Court of Customs and Patent Appeals reversed this decision and the Supreme Court affirmed.\textsuperscript{20} The Supreme Court held that living organisms fall within the realm of patentable subject matter as long as they are “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity. . . .”\textsuperscript{21} Subsequent cases have extended the ruling in \textit{Diamond} to allow
patents to be granted for multi-cell organisms, such as animals.\textsuperscript{22} It seems that genes, which are naturally occurring, would not qualify as patentable subject matter even with these rulings in place.

Upon initial consideration, it appears that the identification of a gene is no more than the discovery of a naturally occurring object. The argument can be made that discovering a gene does not require the ingenuity involved in genetically creating bacteria. The fact remains, however, that the United States Court of Appeals for the Federal Circuit held in \textit{Amgen, Inc. v. Chughai Pharmaceutical Co., Ltd.} that “purified and isolated” gene sequences are different from those occurring in nature.\textsuperscript{23} The Court in \textit{Amgen} found that the ingenuity involved in isolating the useful portions and removing the extraneous portions of a gene created a new composition of matter, a composition that was sufficiently different from its naturally occurring counterpart to warrant patent protection.\textsuperscript{24} The following discussion concerning the novelty requirement of patent law will further develop this argument. Since a gene patent is really a patent on modified portions of DNA that are created through genetic engineering, granting such patents does seem acceptable.\textsuperscript{25}

\section{Novelty}

In order to protect against patenting something already in the public domain,\textsuperscript{26} patent law requires that an invention be an original innovation.\textsuperscript{27} This novelty requirement grants an inventor a limited monopoly only for the “development or revelation of something that is truly new.”\textsuperscript{28} There is a strong argument that non-naturally occurring organisms, which are clearly original, easily satisfy the novelty requirement.\textsuperscript{29} These non-naturally occurring organisms are the product of human ingenuity. With regard to genes, however, the analysis is not so straightforward. The genetic material involved in human gene patenting appears to be a product of nature. How,

\begin{itemize}
\item \textsuperscript{22} See generally Walter, \textit{supra} note 17 at 1033 (explaining the basics of patent law and its applicability to biotechnology).
\item \textsuperscript{24} See \textit{Amgen}, 927 F.2d at 1206-07.
\item \textsuperscript{25} See Looney, \textit{supra} note 23, at 253-55.
\item \textsuperscript{27} 35 U.S.C. § 102 (2000).
\item \textsuperscript{28} See Olson, \textit{supra} note 14, at 315.
\item \textsuperscript{29} See Diamond, 447 U.S. at 309-10.
\end{itemize}
then, can these genes qualify as novel? The answer to this novelty question mirrors the argument presented to justify genes as patentable material.

In their natural form, genes are not novel under any standard; once isolated and purified, however, these genes constitute creations that are easily distinguishable from their natural counterparts and are, therefore, “new.”

Genes “contain a great deal of extraneous information because they are comprised of sections that code for proteins as well as sections that do not. When scientists clone sequences, they isolate only the protein-coding portions, thus isolating and purifying the gene sequence.” This isolation creates the requisite novelty necessary to satisfy patent law.

3. Utility

Going beyond the novelty requirement, utility in patent law requires nothing more of an innovation than to show usefulness. In most instances, establishing this standard can be quite easy, but such is not always the case in biotechnology. In cases in which the biotechnological material at issue cures disease or is used as a pharmaceutical product, it is easy to satisfy the utility standard; applicants for biotechnological patents, however, can rarely make these utility claims.

When genes or gene fragments are discovered, their specific purpose or possible use is not self-evident. In such cases one must, in order to demonstrate utility, show that the gene sequence can “function as different types of markers, probes, and primers for various genetic research.” If a gene or gene fragment can be used in one of these capacities, then utility has been established for purposes of patent law.

4. Non-Obviousness

The final factor a potentially patentable invention must satisfy is the non-obviousness requirement. Non-obviousness means that a person reasonably skilled in a particular area (e.g., genetic engineering), based on the knowledge in the area at the time, would not have foreseen the development of the invention in question. This final factor proves problematic in gene patenting cases because the discovery of new genes generally incorporates

30. See Walter, supra note 17, at 1037-38.
31. Id. at 1038.
33. See Walter, supra note 17, at 1038.
34. Id.
35. Id.
37. See id.
well-established scientific techniques. The patent inquiry does not focus solely on the identification of a new gene; rather, the analysis focuses on the newly-identified gene and the technique used to discover that gene. Thus, the “non-obviousness” of the specific gene in question may be defeated simply because the technique used to discover the gene has already been used.

The Federal Circuit temporarily solved the aforementioned problem by establishing that non-obviousness could be established for a specific gene despite the fact that the engineer isolated the gene through an already existing technique. The circuit court noted in In Re Deuel that “[a] general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search.” This decision permitted newly-identified genes to satisfy the non-obviousness requirement despite the fact that the process used to isolate the gene was obviously based on the knowledge in biotechnology at the time. A 1995 amendment to 35 USC § 103, however, now requires that both the process involved in gene isolation and the gene itself be non-obvious in order for patent protection to attach.

Given the above requirements of patent law, numerous biological “inventions,”—including human genes, can qualify for patent protection; beyond these black letter requirements, however, there are also ethical considerations. “Ethics ‘aspires to an ideal of optimum behavior and conduct.’ Law, in contrast, represents a ‘basic minimum standard of human behavior considered acceptable in society.’” The ethics of gene patenting are distinct from the law and therefore merit separate discussion. Since the legality of gene patenting has been established, the following discussion will address the ethical considerations of gene patenting.

The following sections may be viewed as somewhat of a cost/benefit analysis—that is, a balancing of the benefits of gene patents with the costs. The arguments will show that gene patenting—despite its current flaws—is a justifiable and necessary part of intellectual property law.

**II. Benefits of Gene Patenting**

In deciding whether to grant patents in human genes, one must ask if the ends produced by gene patenting justify the means. In short, they do. Genetic

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38. See Walter, supra note 17, at 1039.
39. See In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995).
40. Id. at 1558.
41. See Walter, supra note 17, at 1040.
42. Id.
43. Id.
44. Looney, supra note 23, at 247 (quoting John C. Fletcher & Dorothy C. Wertz, Ethics, Law, and Medical Genetics: After the Human Genome is Mapped, 39 Emory L.J. 747, 750 (1990)),
engineering currently produces pigs that manufacture human hemoglobin and mice that produce milk containing a protein used to dissolve blood clots.45 Biotechnology produces treatments designed to fight cancer, AIDS, diabetes and many other debilitating diseases.46 Clearly, gene patents provide the incentives necessary to take medicine and biotechnology to new heights, which will benefit all of humanity. These medical breakthroughs appear to justify gene patenting alone, but policy, efficiency, and fairness justifications support the practice as well.

A. Policy Justification for Gene Patenting

Patents serve the purpose of encouraging the “Progress of Science and the useful Arts”47 and, from this perspective, patents are quite effective. Patents encourage ingenuity, which results “in an increase in the general knowledge base and creates useful products for the public’s benefit.”48 This is especially true in the context of biotechnology, a field to which patents contribute amazing developments.

Medical research, specifically research relating to the human gene, is expensive and requires the support of substantial financial contributions from companies and individual investors.49 Typically, capital markets raise this money and investments exist only if the prospect of large profits looms on the horizon.50 Companies owning gene patents have the potential for large profits since the patents provide exclusive rights; not surprisingly, investors are attracted to such companies with these exclusive rights.51 Patents on genes are rewards for the investor’s risk and the researcher’s hard work; therefore, if we do not allow patents on genes, we severely compromise the efficiency of biotech research.52 Without gene patents, researchers would be required to resort to protections under trade secret law, or to similar protective techniques, to prevent the disclosure of their discoveries.53 As a result, a great deal of research in the area would be duplicated, and a

46. Id.
47. U.S CONST. art. I, § 8, cl. 8.
49. See Justin Gillis, Gene Research Success Spurs Profit Debate, WASH. POST A1 (December 30, 2000).
50. See id.
52. See Looney, supra note 23 at 242-43.
53. See id. at 244-45.
great deal of time and money would be wasted.\textsuperscript{54} In addition, the public disclosure of discoveries that occurs under a patent regime would go unrealized since inventors cannot publicly disclose their inventions when relying on trade secret protections.\textsuperscript{55} Rather, investors must conceal their invention in order to maintain a monopoly. Thus, without gene patents, research and science would lead to a most inefficient and unethical result.

It is certainly the case that an intellectual property system that allows for gene patents limits the ability of scientists to conduct research. Gene patents vest a right to use—or not use—a patent; patent protection, therefore, includes the right to exclude others from using the patented material or process. In essence, once a patent approval takes place, the patent precludes others from using the invention. In the context of genes, scientists who do not hold genetic patents cannot conduct research involving the patented genetic material; the alternative, though, is the deprivation of any incentive to be the first to purify and isolate genes. This is, in essence, a classic free-rider problem. Without patent protection, the first researcher to isolate a gene absorbs all of the costs, while the benefits extend to everyone, assuming disclosure of the isolation takes place. Alternatively, an inventor may attempt to avoid the misappropriation of the fruits of his hard work by simply avoiding public disclosure. These types of results are a greater evil than the research restrictions that are present in the current patent system.

\textbf{B. Results of Genetic Engineering}

Gene patenting promotes advancements in medicine and genetic engineering that justify the practice of granting such patents. In the pharmaceutical industry, goats have been genetically altered to produce milk containing a drug used to treat cystic fibrosis, and sheep have been genetically altered to produce a protein used to treat emphysema.\textsuperscript{56} It is possible that in the near future animals will be genetically engineered to produce insulin, growth hormones, and drugs designed to treat heart attacks and strokes.\textsuperscript{57} The quality of these genetically engineered products is higher than that of synthetic products, and scientists can produce them without harm to the animals involved.\textsuperscript{58} In addition, gene patenting has led to achievements such as isolating the mutant gene that causes Canavan disease, which is a dangerous ailment that prevents children from developing normally.\textsuperscript{59} Thus, one can see the tremendous potential health benefits associated with isolating and patenting genes.

\begin{footnotesize}
\textsuperscript{54} See id. at 242-43.
\textsuperscript{55} See id. at 244-45.
\textsuperscript{56} Walter, supra note 17, at 1032.
\textsuperscript{57} Id.
\textsuperscript{58} See id.
\textsuperscript{59} See Gillis, supra note 49.
\end{footnotesize}
In the food and agriculture industries, genetic engineering may lead to higher quality food for humans by creating animals “that are “better able to resist disease”.”60 Researchers have been successful in creating larger and leaner fish, rabbits, and sheep than could be produced naturally.61 The concept of producing higher quality animals is not new.62 In fact, farmers have been selectively breeding animals for generations to achieve the ends that genetic engineering is now achieving.63 Furthermore, genetic engineering avoids many of the problems that have traditionally been associated with selective breeding practices.64

The present and possible future results of genetic engineering will benefit the human race; therefore, we need to assure the protection of genetic engineering so that these advancements will continue. Thus far, gene patenting appears to make legal and ethical sense but, as in most debates, strong arguments exist on both sides of the issue. The following discussion presents opposing arguments to gene patenting and attempts to illustrate that, despite these arguments, ethics and good public policy support gene patenting.

III. ARGUMENTS OPPOSING GENE PATENTING

Generally speaking, those who oppose granting patents on genes oppose them for ethical and not for social, political, or economic reasons. Clearly, gene patenting provides economic incentives to medical researchers, just as the policy behind patents intended. But a financial incentive alone, many argue, cannot justify sanctioning an arguably unethical practice. Ethics is an essential consideration in any scientific endeavor,65 and as science moves to new heights, so too have the ethical questions surrounding many of the scientific practices, including gene patenting.

A. Universal Heritage Argument

A preliminary question concerning the ethics of gene patenting is whether it is “ethical to patent segments of the human genome when these segments are inherent to each individual’s personal identity and common to all humanity.”66 Many argue that it is inappropriate to grant a patent on something that is, as French Minister for Research and Technology Hubert

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60. Walter, supra note 17, at 1033.
61. Id.
62. Id.
63. Id.
64. Id.
65. Looney, supra note 23, at 236.
66. Lacy, supra note 48, at 798.
Curien put it, “part of our universal heritage.” The universal heritage theory emphasizes preserving resources for future generations and dismisses the “economic benefits” argument, which is offered in support of gene patents. The supporters of the universal heritage theory might concede, for example, that private ownership of the moon may have some economic benefits, but would argue that such ownership is not allowable because the moon cannot belong to any one individual. Similarly, these universal heritage theorists argue that genes are the product of millions of years of evolution and thus are the property of all of mankind, not any one individual. As a result, those who advance the universal heritage theory claim that the information contained within genetic material cannot become intellectual property.

The universal heritage ethical argument is incomplete. As previously discussed, a gene patent covers something different from that which occurs in nature. Gene patents are not mere discoveries. Even if they were, however, it is incorrect to argue against their ownership. The ingenuity and effort expended in isolating or genetically engineering genes are enough to warrant the granting of ownership rights. The granting of patents occurs when something new is added to the public’s knowledge base, not when something is taken out of the public domain. As a result, the universal heritage theory fails to adequately establish a basis for finding gene patents unethical.

B. Distributive Justice

The principle of distributive justice, which addresses the “‘just distribution in society structured by various moral, legal, and cultural rules and principles that form the terms of cooperation for that society, that is, the implicit and explicit terms under which individuals are obligated to cooperate,’” joins the universal heritage theory in opposing gene patenting. The concern under this principle is the “correct distribution of burdens and benefits in society,” which does not appear to be in agreement with gene patenting.

The distributive justice argument incorrectly claims that the practice of gene patenting vests the benefits of biotech research in a small number of

67. Id. (quoting Hubert Curien, The Human Genome Project and Patents, 254 SCIENCE 1710, 1710 (1991)).
69. See id at 249-50.
70. Id.
71. See Lacy, supra note 48, at 797-98.
72. Id. at 801 (quoting Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 67, 258 (3d ed. 1989)).
73. Id.
countries, while denying these benefits to less-developed countries.\textsuperscript{74} Certainly, small segments of the population should not monopolize the benefits of genetic research, but gene patenting does not contribute to such a monopoly. In fact, exactly the opposite is true. Gene patenting facilitates scientific research by providing the incentives necessary to yield the benefits of genetic research. Furthermore, gene patenting does not restrict the benefits of biotech research to the few, but rather offers genetic researchers economic benefits in exchange for the public disclosure of their inventions. Therefore, under the principle of distributive justice, gene patenting is a correct result. Under an intellectual property regime that allows gene patenting, researchers and their investors reap the monetary rewards of genetic research, and the patent discloses medical advances to the public.\textsuperscript{75} Thus, the public gains the benefits of the newly acquired scientific knowledge and the researcher receives a reward for his effort.\textsuperscript{76} The resulting benefits and rewards are consistent not only with the ethical principle of distributive justice, but also with principles of fairness.\textsuperscript{77}

C. Religious Objections to Gene Patenting

Those opposed to gene patenting on religious grounds claim that genetic engineering is tantamount to “playing God”\textsuperscript{78} and that such genetic manipulation enters an area of life that God rules and that humans should not enter.\textsuperscript{79} These opponents of genetic engineering believe that there is a clear line between God’s role and the role of humans.\textsuperscript{80}

Some would argue that, as human knowledge increases, the area within human control begins to intrude upon God’s territory.\textsuperscript{81} Religious objectors view genetic engineering practices as narrowing the gap between human power and the power of God.\textsuperscript{82} These individuals see humans as “stewards who conserve and protect what God has created.”\textsuperscript{83} As such, humans are to protect God’s creations by respecting the “design of creation and the limits which God has placed on both the orders of biological nature and human

\begin{itemize}
  \item \textsuperscript{74} See id. at 802.
  \item \textsuperscript{75} See id.
  \item \textsuperscript{76} See id.
  \item \textsuperscript{77} See id. at 802-03.
  \item \textsuperscript{78} See Walter, supra note 17, at 1044.
  \item \textsuperscript{80} Id.
  \item \textsuperscript{81} See id.
  \item \textsuperscript{82} Id.
  \item \textsuperscript{83} Id. at 779.
\end{itemize}
society.”84 Despite the dissonance between the aforementioned religious argument and science, it is possible to reconcile genetic engineering with religious teachings.

God created humans in his image and, in the Book of Genesis, directed humans “to be fertile and multiply, to fill the Earth and subdue it. This dominion over all living things has been taken as a mandate to use the Earth as we see fit.”85 Humans, specifically in the area of medicine, have taken this command to heart and have worked to advance our society. No area of our lives is immune from the effects of technology or from the genius humans have used to advance our race. Genetic engineering encouraged by the use of gene patents is merely a means of advancing medicine for the betterment of the human race. God gave humans dominion over the Earth and the ability to think and act with free will; in this context, it is clear that by attempting to better ourselves we are merely using God’s gifts as best we can, not trying to make ourselves more Godly through the use of gene patenting.

D. Commodification of the Genetic Material

Other opponents of gene patenting base their objections on the argument that patents in biotechnology are essentially the issuance of property rights in life. The argument also states that, as such, life is reduced to a commodity that is no different from a car or some other inanimate object.86 This objection, however, is misguided due to a misunderstanding of intellectual property law and is ethically inapplicable to gene patents.

First, the concept that biotechnological patents grant ownership rights in life is misguided because patent ownership is more of a legal fiction than an assignment of property rights. Patent protection merely vests a temporary monopoly in a person who creates an invention. In the context of gene patenting, this means that the fruits of the inventor’s labor go to him; nevertheless, as discussed earlier, the invention is dispersed throughout the public domain. Therefore, the gene is not “owned” by its inventor, nor are the benefits of the invention vested only in the inventor.

Even if ownership of a gene patent translated into ownership of the actual gene, it would not necessarily be immoral. Perhaps the argument that patents reduce life to a commodity has some moral resonance in the context of patents in living creatures, but no such argument can be advanced when dealing with genes. Genes have no autonomy rights in and of themselves. As a result, genes do not have the same types of rights that living creatures in general may have. Therefore, gene patents do not undermine the concepts of autonomy and ethics that may arise with regard to patenting animals and other living creatures. Nor do gene patents cheapen life, but rather provide no more than economic incentives to conduct research. These patents exist to

84. Id.
85. See Churchill, supra note 51, at 178 (citing GENESIS ch. 1, v. 28).
86. See Walter, supra note 17, at 1044-45.
serve an ethical purpose (i.e., find cures for human diseases) and should not be overanalyzed in order to justify the argument that they are immoral with regard to ownership rights.

Secondly, the belief that there are things that people cannot sell or even insert into a market setting is also misguided. Proponents of this argument believe that it is ethically repugnant to award property rights in genetic material. Just as we are not allowed to sell our children or our organs, proponents argue, we should not allow others to sell and manipulate our genetic material for profit: “[O]ne may not purport to sell what cannot be sold, for in the very process of sale that which is purportedly sold is transformed and its value is destroyed or diminished.”87 The problem with this argument, however, is that the law and public morality draw a distinction between the sale of organs and the like and the sale of other bodily materials such as bone marrow and blood.88 Due to the recognition of the universal value of blood, for example, society allows a market to exist for this bodily fluid.89 “Therefore, society and public morality have consented to market some genetic material, such as blood and other bodily fluids.

I would submit that genes are on the scale of blood and bone marrow, not organs and children, and are therefore worthy of being placed in a market system. In fact, genes are almost indistinguishable from blood in their characteristics. Genetic material, like blood, can be isolated from renewable bodily fluids, and its extraction is no more intrusive than the donating of blood. As such, if society, the law, and supporters of the commodification argument are willing to allow blood, semen, and bone marrow to be part of the market system, then no compelling argument can exclude genes. The newness of gene patents and an ignorance of the benefits of this practice in a market system have led to its opposition.

Although each ethical argument presented contains flaws, the arguments are strong nonetheless and can be obstacles to researchers and investors advancing in biotechnology and medicine with gene patents. Thus, the current American patent system may fail to adequately balance research incentives with ethics. This being the case, we could possibly eliminate much of the ethical debate surrounding gene patenting by adopting certain changes to the current American intellectual property regime. These changes might improve the balance between the incentives behind gene patenting and the ethical and policy concerns surrounding the practice.


88. Id at 29.

89. Id.
IV. SUGGESTED CHANGES TO THE CURRENT AMERICAN PATENT SYSTEM

A. Experimentation exception

Although patents may make sense in protecting a patent holder’s commercial interest, they may not be, at least in their current form, the best method of ensuring that medical technology moves forward at its fastest pace. Patents do create incentives for scientists to conduct important research and do ensure that the products of the research are then placed in the public domain, but they also limit how other scientists may use this information. Adding an exemption from patent infringement for scientists conducting pure research, however, is a way to alleviate this restriction on the patented information.90

An exemption of this sort would protect a patent holder from having the patent infringed in a commercial setting while still allowing medical research to proceed.91 In addition, this type of exemption is consistent with the patent system’s goal of promoting innovation and advancement in the arts and sciences. This proposed exemption would affect the public interest at large and might eliminate some of the ethical objections to gene patenting. Moreover, the exemption would allow access to once-restricted patented materials, thereby diluting opponents’ arguments regarding limiting medical research.

B. Limiting Scope of Genetic Patents

In addition to the experimentation exception, limiting the scope of genetic patents would reduce the danger of monopolies in gene patenting. Currently, one can patent gene fragments so long as they can serve as markers or probes;92 this is problematic, though, because it precludes others from patenting the full gene sequence once it is isolated.93 Furthermore, as previously discussed, it is the complete gene that possesses the real utility or novelty. Thus, legislators should adopt definitions for novelty and utility of gene patents to include only true medical and scientific uses, rather than uses as probes or markers. Although this adjustment may preclude the person who first discovers a gene fragment from obtaining patent rights, it will ensure that patented genes truly possess some practical use. Limiting the scope of gene patents will motivate scientists and researchers to find beneficial uses for their genetic inventions, rather than rushing to isolate and purify gene fragments in order to get patent rights without knowing if the fragment has any medical worth or scientific purpose.

90. See Olsen, supra note 14, at 332.
91. See id.
92. See id.
93. See id.
Alternatively, those who discover a gene fragment whose only known use is as a marker or probe should receive only limited protection. By doing this, legislators could prevent patent holders from gaining a monopoly on a full gene sequence when only a fragment has been isolated and when this fragment has no known medical use.

C. Compulsory Licensing

Compulsory licensing, another suggestion for the current American patent system, grows out of the almost complete control held by the person, or entity, with patent rights over an invention. Under the American patent system, a patent holder has the right to “exclude others from making, using, offering for sale, or selling the invention...” This right creates not only rewards for ingenuity, but also the possibility of abuse. Abuses may arise from antitrust violations, illegal tying arrangements, or other activities that undermine the purpose of the patent system. Adding to this potential for abuse, the American patent system does not require that a patent holder make use of his invention, thereby allowing a patent holder to just “sit-on” his invention.

The American patent regime addresses these problems, at least in a limited fashion, with compulsory licenses. These compulsory licenses come into play when a patent holder fails to use his patent, thereby allowing a third party to apply for a license on the unused patented invention. Granting compulsory licenses may undermine the economic incentives inherent in the United States’ intellectual property system. Compulsory licenses, however, allow the public to obtain the patented invention at the market price, rather than at the monopolistic price, which would be the prevailing price if these types of licenses were not granted. Although this is true, the fact remains that the purpose of the patent system is to reward ingenuity and progress in the arts and sciences, not to stifle progress with a monopoly on an invention.

94. Id.
95. Id.
98. See Gormley, supra note 96, at 134.
99. Id.
100. Id. at 134-35.
101. Id. at 135.
102. Id. at 136.
103. See id.
whose inventor does not plan to use or allow anyone else to use the invention. Clearly, not all patentees adhere to this noble purpose; therefore, compulsory licenses help maintain the balance between rewarding researchers and making scientific progress on behalf of society.

Ultimately the patent system should lead to inventions that benefit all of mankind. In cases in which an inventor tries to limit the societal benefits of his invention, compulsory licenses should be granted. In fact, in the case of gene patenting, compulsory licenses should be granted more liberally or perhaps in every case. The most effective method of finding the potential benefits hidden in genes may be to grant compulsory licenses to each applicant.

Making compulsory licenses a more prominent part of patent law may seem contrary to the general purpose of patents, but it is important to note that when the government grants a compulsory license, the inventor receives royalties from the person or entity that obtains the compulsory license. These licenses do not take an inventor’s monopoly away; instead, they serve to further the public good while providing the inventor with monetary benefits, which are the driving force behind inventors seeking patent protection for their creations.

Whether or not lawmakers adopt the aforementioned proposed changes to the American patent system, it is clear that some changes should take place to balance ethical concerns about gene patenting more effectively with the policy rationales behind them. With or without changes to the current patent system, gene patenting has had tremendous effects on science and medicine, effects that justify its very existence. Legislators should not leave well enough alone but should, taking into consideration all the relevant legal, policy and ethical concerns, strive to create the most ideal patent system.

**Conclusion**

The United States Supreme Court has held that human genes meet all of the requirements of patentability, as defined by the United States Code. Furthermore, gene patents have served their purpose by providing economic incentives that have led to remarkable scientific developments in the field of biotechnology. Finally, this article has demonstrated that, although ethical concerns do surround the patenting of human genes, the results and counter ethical arguments in favor of gene patenting must prevail so that the use of those patents supports society’s struggle to bring human suffering and disease to an end.

Justice and fairness allow people to reap the fruits of their labor, and economics gives people an incentive to follow a certain course of action. Gene patenting provides economic incentives and a just reward for the labors of scientists and the monetary sacrifices of investors. Within this realm of practice reside significant ethical questions, but when analyzed closely, one can see that the incredible public benefit and rewards from gene patenting are

104. *Id.* at 138.
often consistent with these ethical principles. In addition, the proposed changes to the American patent system would help alleviate this tension between scientific advances and ethics. And finally, after observing the moral debates, the societal benefit, and the medical advancements of gene patenting, one can argue that the ends do indeed justify the means.