Original Article

Analyzing the broadening scope of patentability in the advancing field of biotechnology

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ABSTRACT

The current U.S. patent system is considered to provide the broadest patent protection of all patent systems in existence, especially with respect to the biotechnology industry. Advances in science and technology have been key contributors to the growth and development of legislation controlling patent law. With these advancements have come vivid public debates on the morality of research with embryonic stem cells and the fusion of human and animal DNA to find cures for disease. Despite the rapid developments, the legislation controlling such research has been slow to progress. This paper will explore the legislative history surrounding biotechnology patents, focusing on the specific need for strong, adequate protection to promote the survival of the biotechnology industry.

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INTRODUCTION

Since its inception, the patent system of the United States has sought to protect inventions that are new and useful.[1] Advances in science and technology have been key contributors to the growth and development of legislation controlling patent law. The pharmaceutical industry has spurred important protections on intellectual property as research progresses in the quest to cure ailments and diseases to humans and animals alike. As the twenty first century approached, research in pharmaceutics progressed into new ground, expanding into biotechnology. Scientists began to apply newly discovered genetic techniques to researching cures for diseases and creating new gene therapy treatments for diseases such as Parkinson's and Multiple Sclerosis.[2] With these advancements have come vivid public debates on the morality of research with embryonic stem cells and the fusion of human and animal DNA to find cures for disease.[3] Many opponents argue that such inventions are against moral and ethical standards, that such experimentations should be ended, and a legislative line should be drawn to prevent the creation of "monsters" from human/animal DNA combinations.[3] Some opponents assert that as cloning techniques advance, Congress will need to address whether the results of such experiments are entitled to patent protection.[3]

Despite the rapid developments, the legislation controlling such research has been slow to progress.[3] The United States Patent and Trademark Office (USPTO) lacks the authority to create legislation concerning the limits or expanse of patentability.[3] The USPTO is ill-equipped to handle rejection of patent applications solely on the basis of morality or public perception.[3] In comparison, the European Patent Office (EPO) contains its own legislative powers and specific stance on patentability of biotechnology, making the EPO a stronger patent body than that of the United States.[4]

This paper will explore the legislative history surrounding biotechnology patents, focusing on the specific need for strong, adequate protection to promote the survival of the biotechnology industry. Attention will be given to: (1) the new pathway to market approval to follow-on biologics, (2) both regulatory and patent exclusivity periods and the issues surrounding classification of biotechnology inventions, (3) issues regarding biosimilar inventions and (4) moral concerns of those opposed to patentability for such inventions.

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THE FOUNDATION OF THE U. S. PATENT SYSTEM

Systems for granting exclusive control over the use of a particular invention can be traced through history.[1] The Statute of Monopolies, enacted by the English monarchy, granted a monopoly to the first inventor for up to fourteen years.[1] The standards laid out in the Statute of Monopolies carried over into the early history of the American colonies where each individual state granted patents according to state statutes.[1] The Founding Fathers consolidated the power to grant patents to the Federal government by providing in the Constitution that Congress would have the power to

> *…promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.*[5]

Congress first established a three-member board to examine patent applications, which was replaced three years later by the Patent Act of 1793, establishing a registration system maintained by the State Department.[1] Enforceability of such registered patents was left for the courts to determine.[1]

The Patent Act of 1836 established a system of formal examination and created a Patent Office within the State Department to handle patent applications.[1] This system remained virtually unchanged until the Patent Act of 1952, which established standards for determining whether an invention would be obvious to one of ordinary skill in the art and whether the invention is anticipated by comparison with prior art.[6] In 1982, President Reagan signed the Federal Courts Improvement Act, consolidating the jurisdiction of patents to the Federal Circuit.[1] Previously, disputes were heard either by the Court of Customs and Patent Appeals or by regional courts of appeals when the action was an infringement suit between private parties. Growing concerns over unmanageable caseload and inconsistent rulings among the courts prompted the consolidation.[7]

In 1999, the American Inventors Protection Act included among its provisions the protection of patent terms and mandatory publication of patent applications 18-months after filing.[8] The largest change to U.S. patent law came with the September 2011 enactment of The Leahy-Smith America Invents Act (AIA).[9] The AIA changed what qualifies as prior art under 35 U.S.C. § 102. The new language removes the twelve-month grace period within which an inventor must file an application after the publication or the grant of a patent on the invention in a foreign country.[10] Previously, only offers for sale or public use within the U.S. more than 1 year before filing would qualify as a bar.[11] As amended, the issuance of a patent, publication, offer for sale or public use of the invention anywhere in the world prior to the effective filing date of an application in the U.S. will qualify as prior art against the invention.[10] A limited grace period does remain however, with the requirement that disclosure to the public must be first by the inventor.[9] Perhaps the most notable change to the patent system is the transition from a first-to-invent system to a first-to-file system. The United States had the only system that granted a patent to the person who first invented; however, on March 16, 2013, the first-to-file provision of AIA will align U.S. practice with the rest of the world.[9]

PROTECTION GRANTED TO BIOTECHNOLOGY INVENTIONS

The first patents on biologic entities occurred in the 1980's, most notably with a patent granted that claimed a genetically engineered bacterium capable of breaking down multiple components of crude oil.[12,13] On certiorari, the Supreme Court determined that the applicant, Ananda Mohan Chakrabarty, was entitled to a patent for the bacterium, holding that the language of 35 U.S.C. § 101 "fairly embraces" a living organism made or modified by man.[12] This case established a pathway to exclusivity of biotechnology inventions, creating a foundation for research and development in an industry that is heavily reliant upon protection of intellectual property.[14] While the grant of patent protection for biotechnology inventions was an advancement for the industry, competition was still hindered, as those seeking to develop similar generic compounds (follow-on biologics or biosimilars) would face infringement actions from patent holders. Congress addressed the problem of generic competition in the pharmaceutical industry with the creation of the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.[1] The Hatch-Waxman Act created an abbreviated pathway for generic versions of brand drugs to get Food and Drug Administration (FDA) approval by permitting the use of brand clinical studies to show bioequivalency in the Abbreviated New Drug Application (ANDA) because the active ingredients are identical.[15] The Act eliminated infringement as a cause of action against a generic drug company for experimenting with a patented drug for the purpose of obtaining Food and Drug Administration (FDA) approval for the generic upon expiration of the patent.[1] A suit for infringement could be brought against the generic company, however, if the company applied for marketing approval by filing an Abbreviated New Drug Application (ANDA) with the FDA before the actual expiration of the patent. [16] The generic company

must therefore certify that there is no patent on the drug, the patent is expired, the testing does not infringe, or the patent is invalid, and that the generic will not go to market until the patent has expired.[16]

For the biotechnology industry, innovator biologics could obtain patent protection and approval from the FDA for clinical testing, obtained through a Biologics License Application (BLA), but no pathway similar to an ANDA pathway existed for follow-on biologics.[17] Although Hatch-Waxman did not benefit the biotechnology industry, it provided a template for legislators when creating an abbreviated version of a BLA.[18]

On June 28, 2012, the Supreme Court upheld the constitutionality of the Patient Protection and Affordable Care Act (PPACA), which contained the Biologics Price Competition and Innovation Act (BPCIA).[19] Similar to Hatch-Waxman, the BPCIA provided for an abbreviated pathway for follow-on biologics that can demonstrate high similarity or interchangeability with the patented brand product, referred to as the reference biologic product.[20] The Act also contains a provision for a 12-year exclusivity period to be granted to innovator biologics designed to prevent follow on biologics from infiltrating the market too soon, diminishing profits from reference products.[21] The exclusivity period exists independent of patent rights and is granted by the FDA upon BLA approval.[2, 20] During the exclusivity period, follow-on biologic competitors are prevented from applying for FDA approval and from using reference brand generated data for biosimilar studies.[20]

The exclusivity period has generated debate as to the actual intent of Congress and the meaning given by the FDA.[20] It has been asserted that the BPCIA provides for both a market exclusivity period and a data exclusivity period.[20] Contextually, market exclusivity is the FDA right granted to the innovator that prevents follow on biologics from applying for approval during the exclusivity period, and data exclusivity prevents the usage of innovator clinical studies to support follow-on biologic applications.[20] Opponents of a data exclusivity period assert that patent protection alone is sufficient to promote innovation in biotechnology.[2] However, the exclusivity period is not in addition to patent protection, but rather a parallel right that exists along side the issued patent.[2] Such an addition is needed to protect innovators from biosimilars that are altered enough to avoid infringement, but are similar enough to still take advantage of abbreviated approval.[2]

Concerns over the ability to show bioequivalence between follow on biologics and reference products have led some to assert that the FDA should consider follow-on biologic applications as BLAs.[20,22] Presently, a follow-on biologic will be found to be "biosimilar" or have "biosimilarity" if it is highly similar to the reference product and no differences relating to safety, purity, and potency exist.[18] Biosimilars are "considered to have a new active ingredient compared to the reference product."[18] For a follow on biologic to be considered "interchangeable" with the reference product it must be both biosimilar and produce the "same" clinical results as the reference in any patent.[18] The interchangeable status also means the active ingredient is the same as that of the reference product.[18]

Some suggest that because current technology cannot accurately determine if innovator and competitor products are bioequavalents similar enough to merit a biosimilar application, consideration as a new BLA protects innovator interests as well as those of companies developing follow-on biologics.[20] It has been asserted that under BPCIA standards for determining biosimilarity, a follow-on biologic may be similar enough to the reference product to be approved as biosimilar, "but different enough under intellectual property law to avoid infringing issued patents" protection.[23] This potential loophole in the legislation could act as a disincentive to innovation, as the protection afforded the innovator can easily be designed around, allowing the biosimilar to take advantage of the innovator market and prior research without infringing on the innovator patent.[23]

With the existence of a follow-on biologic that is biosimilar, containing an active ingredient different from that of the reference product, but still restricted by the FDA to the biosimilar pathway for market approval rather than that of a BLA, the question that emerges is how to deal with these biosimilar compounds with new active ingredients under patent law.

THE LAW AFTER MYRIAD GENETICS

In a highly contested decision, the Association for Molecular Pathology v. USPTO and Myriad Genetics, Inc., the Court of Appeals for the Federal Circuit reversed a District Court finding that isolated DNA sequences were not patentable subject matter.[24] The plaintiffs asserted that Myriad held seven patents containing composition and method claims directed to non-patentable subject matter relating to human genetics.[24] Initially, the District Court found the claims to contain non-patentable subject matter because the claimed isolated DNA contained the same sequences as natural DNA, making it a product of nature unfit for patent protection under 35 U.S.C. § 101.[25] The appellate court, however, found isolated DNA underwent a human modification, a structural transformation, which produced a sequence that does not naturally exist.[24] Judge Lourie found that the distinct nature of isolated DNA determines patent eligibility, not the informational content or biological function.[24] Concerning the method claims on appeal, the court held Myriad's

method of screening cancer treatments by analyzing cell growth rates contained a transformative step eligible for patent protection.[24] The court then affirmed the lower courts holding that claims "comparing" or "analyzing" DNA sequences were directed to patent ineligible subject matter because they were abstract ideas.[24]

Even though issues concerning isolated DNA had been litigated, the decision as to whether isolated DNA was patent eligible subject matter remained undecided until Myriad. In re Kubin, for example, held claims to methods for the coding of polynucleotides of proteins that had previously been identified were not patentable because they were obvious to try, but never addressed whether the actual sequences were patentable.[26] A legal determination that isolated DNA is patentable subject matter is therefore significant to continued innovation for an industry that deals primarily with living organisms.

While the Myriad decision brought relief to the biotechnology industry, opponents argued that mere isolation does not significantly change DNA and maintain that decision negatively impacts those seeking to conduct research on patent protected isolated DNA. [27,28] One opponent of the Myriad decision offers an alternative to the biological or chemical review of isolated DNA.[27] Rather, it is proposed that the biology and chemistry both should be considered when determining patentability.[27] A "totality-of-the-circumstances" approach is suggested, whereby examination of both structure and content of DNA determines patentability of isolated sequences.[27] It is asserted that to ignore "either the structure or the information undermines the importance of these fundamental structures" and that under a "totality-of-the-circumstances" approach isolated DNA is not patentable.[27] This conclusion is based on the "relatively insignificant" structural change between isolated DNA and natural DNA, as both contain identical information.[27]

PUBLIC PERCEPTION OF BROADENING THE SCOPE OF PATENTABLE BIOTECHNOLOGY

United States

In addition to legislative concerns, the biotechnology industry is host to a plethora of social concerns. It has been asserted that the USPTO has no authority to prevent the approval of morally questionable inventions and that the "moral utility" doctrine must be strengthened into a cognizable law granting the authority to the USPTO to deny applications on a moral or ethical basis.[3] It has also asserted that the utility requirement is too easily satisfied because any invention that claims to have a beneficial legal application can satisfy utility.[3] It is also noted that the United States has no judicially identified standards to guide decisions on morally questionable inventions, in contrast to other patent bodies in foreign countries.[29] It is believed that Congress is likely to have an increase in the number of challenges to biotechnology patents from advocacy groups that question the role of the public in science and technology.[4]

Much of the controversy surrounding biotechnology patents comes from debates on genetically engineered organisms and animal-human hybrid organisms, known as chimeras.[3] Activists argue that there should be limits on what is patentable and that ethical and moral considerations should be a vital part of the patent consideration process.[4] The USPTO has long held the position, as stated in the legislative history of the Patent Act of 1952, that "anything under the sun that is made by man" is patentable as evidentiary support that Congress intended a wide scope for patentability.[3, 12] On this basis, the USPTO has granted patents for organisms and technologies that could lead to cures for a host of ailments and diseases.[3]

It has also been argued that although federal funding is not available for genetic research on cloning, federal patent protection is, in effect, indirect research funding, as it provides an incentive for private investors to fund such research.[3] Proponents of this theory argue that a patent on this technology is government encouragement for such research because it provides

> *incentives for parties to undertake expensive and risky research…[and] induce upfront funding of projects with the expectation that monopoly profits can be generated over the long term.*[3]

The "patent first, ask questions later" approach suggests that the patents issued can go against the values of a significant part of society and cause a public outcry over the legislation that would allow for such approval.[3] It has been asserted that the decision in Chakrabarty replaced a system controlled by a judicially created moral utility doctrine with the patent first system.[3] The U.S. system, however, is based on an approach that is meant to provide access and benefits for all citizens, not just those with inventions that are publically accepted as moral.[4]

Opponents of broadening the scope of biotechnology patent protection also argue that biotechnology generates many morally questionable inventions for which patents have already been granted.[3] Such inventions include isolated genes, sequenced DNA, embryonic stem cell research, genetically modified transgenic animals, and animal cloning methods.[3] Some objections stem from concern that the inventions will lead to the mixing of human and animal DNA, creating "monsters" that

degrade human dignity and eventually lead to ownership of humans.[3]

In order to provoke Congressional debate on drawing a moral line regarding controversial biotechnology inventions, activist Jeremy Rifkin, assisted by cellular biologist Stuart Newman, filed a patent application for human/ animal chimera in 1997.[4] The USPTO denied the application citing the Thirteenth Amendment, forbidding slavery and ownership of human beings, and the moral utility doctrine, which it interpreted to exclude inventions that are "injurious to the well being, good policy, or good morals of society."[4] Upon receiving the chimera application, the USPTO issued a statement that inventions encompassing human/ non-human chimeras could not be patented if they failed to meet the public policy and morality aspects of the utility requirement.[30] However, the USPTO has acknowledged that is has no authority to deny a patent on a morality or public policy basis.[3]

Whether the USPTO can use the Thirteenth Amendment as a basis for rejecting a human/ animal chimeras indicates that the chimera would be human enough to merit protection from slavery has not yet been determined.[3] With respect to chimera research, it has been posited that although current stem cell research uses embryonic cells from embryos up to two weeks old, research could benefit from the use of more developed fetuses.[3] For research on early stage embryos, however, the ruling in Roe v. Wade, which found embryos are not entitled to constitutional protection as "persons," would preclude a patent rejection under the Thirteenth Amendment.[3] Thus the courts are to determine whether patent rights granted for human DNA conferred ownership akin to slavery and if such inventions were human enough to be entitled to constitutional protection against such ownership.[3] Even with the rejection of the Rifkin's application, the USPTO remained without a legal basis for rejecting similar applications, however, a provision in the AIA provides "no patent may issue on a claim directly to or encompassing a human organism."[29,31] The impact of this provision on biotechnology patents in biotechnology remains to be seen.[32]

Europe

The European Patent Office (EPO) was created by the European Patent Convention (EPC) in 1973 as an effort to create a uniform patent system in Europe.[1] The EPO has a judicial process for dealing with disputes and substantive rule-making authority.[4] This system also has a more focused approach for handling issues of morality and public perception through a morality based eligibility bar.[3] The European system also affords individual Member States the ability to consider morality of inventions when determining patent eligibility.[33] Article 53 of the European Patent Convention states the exceptions to patentability, providing:

> *European patents shall not be granted in respect of:*
> *(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality;*
> *(b) plant or animal varieties or essentially biological processes for the production of plants or animals;*
> *(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body*[34]

The European Parliament further elaborated on the concept of "*ordre public*" with Biotech Directive 98/44/EC, which stated that certain processes, including cloning of humans, use of human embryos for industrial and commercial purposes, and modification of the human genetic identity, should not be patented for ethical and moral reasons.[35] However, the directive provided that, although human genes are not patentable, a technical process leading to the discovery and isolation of a sequence may be patentable.[35] In addition, the Directive instructed patent officials to consult the European Union (EU) ethics panel on questions concerning patent applications.[35]

The Biotech Directive, in addition to the "*ordre public*" has been used to raise morality objections to patents on DNA sequences.[36] The common argument is that the grant of patent protection over a sequence of DNA is a grant over a piece of human life.[36] This patenting life argument is akin to the Thirteenth Amendment argument offered by the USPTO for biotechnology patents on genetic inventions as both use the premise that patents on cloning and sequences of human DNA violates morality and leads to human ownership.

Although similar arguments against biotechnology patents are presented in both Europe and the United States, the European system is better equipped to deal with the concerns of the public. Articles 99 of the EPC provides that "[w]ithin nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European patent office of opposition to that patent."[34] Article 100 provides grounds for opposition being that the subject matter is not patentable.[34]

While the U.S. system is without any such provisions for opponents of morally controversial patents, it is also without legislative power to deny such technologies

if they meet the patentability requirements.[3] In addition, U.S. courts are without a basis for reading moral limitations on current patent provisions.[3] The result is that only Congress has Constitutional authority to enact a legislative solution for morality issues facing the USPTO and to provide the language for the judiciary to interpret.[3]

CONCLUSIONS

The current U.S. patent system is considered to provide the broadest patent protection of all patent systems in existence, especially with respect to the biotechnology industry.[36] Accordingly, the public debate to narrow the scope of patent protection rages on within the country, as opponents of genetic research continue to assert morality at the expense of treatments to deadly diseases. As science advances, the biotechnology industry will only continue to grow as new discoveries illuminate the path to finding cures to diseases and prolonging health. Undoubtedly, millions will view this endeavor as enormously rewarding, just as millions may view the advancements as abhorrent, immoral, and unethical.

While the European Patent Office provides a model for the USPTO to copy, that system is not without its flaws.[33] With the enactment of the AIA and the first-to-file system, the U.S. steps closer to the European system and joins a practice that has been the standard in the rest of the patent world.[9] Arguably, having a system of patent approval identical to that of the EPO would provide inventors with the broadest range of global patent protection. However, as stances on patent protection are so rigidly delineated, the creation of such a uniform system is not readily foreseeable.

After the recent court decision in Myriad and the enactment of BPCIA, the standard for what gene sequences may be patented and the commercial exclusivity available for biotechnology inventions has been drastically altered, making patents on biotechnology inventions more difficult to obtain.[21,25,37] Although this appears to be a new hurdle, it perhaps is just a reminder that simply attempting to obtain patent protection on routine biotechnology will be unsuccessful and that the innovation that led to the creation of a biotechnology industry is to be modeled if protection is to be obtained.[38]

Biotechnology will continue to flourish and genetic advances will be made, despite morality and ethical arguments. Congress must find a legislative neutral ground if the rate of progress is to continue at the current pace to the benefit of society.

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