Should Genes be Patentable?

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Introduction

This article explores the complicated topic of gene patentability within patent law. Over the past couple of decades, patent law has undergone notable changes, particularly concerning human life patents. A key moment was the 2013 Supreme Court case, *Molecular Pathology v. Myriad Genetics, Inc.*, where the Court limited the patentability of genes. More recently, the Patent Eligibility Restoration Act of 2023 was introduced in Congress. This Bill seeks to broaden what can be patented, including genes. Despite the various ethical, legal, and economic concerns gene patenting raises, this article focuses on the legal and economic arguments, putting aside moral and ethical considerations.

Understanding Patent Rights

A patent grants an inventor exclusive rights for a limited time to their invention. This right enables the patent holder to prevent others from commercially using the invention.[1] For instance, an inventor of a pharmaceutical drug can secure a patent to prohibit other manufacturers from producing and selling the drug for a limited time, typically 20 years.

The Evolution of Patent Laws: Human Life & DNA Patents

Under US patent law, human life is not eligible for patenting. Despite this, until 2013, the US Patent and Trademark Office granted numerous patents for DNA and RNA molecules.[2] Then in 2013, *Molecular Pathology v. Myriad Genetics, Inc.*, reached the Supreme Court, centering on the BRCA1 and BRCA2 genes (linked to preventing hereditary breast and ovarian cancer).[3] Myriad Genetics aimed to identify the location of the BRCA1 and BRCA2 genes on human DNA to develop a test to identify individuals at an increased risk of developing cancer.[4] Myriad Genetics was the first to locate and patent these genes.[5] The Supreme Court, however, ruled Myriad Genetics' covered ineligible subject matter, stating that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated."[6]

The Patent Eligibility Restoration Act of 2023: A New Chapter

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[1] Sirpa Soini et al., *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 Eur. J. Hum. Genet. S10, S10-S50 (2008), https://www.nature.com/articles/ejhg200837.
[2] *See* Subhashini Chandrasekharan & Robert Cook-Deegan, *Gene Patents and Personalized Medicine – What Lies Ahead?*, 1 Genome Med. 92 (2009), https://genomemedicine.biomedcentral.com/articles/10.1186/gm92.
[3] Emily Morris, *A Response to 'Another Legislative Attempt to Revive Gene Patenting'*, Harvard Law (Aug. 26, 2022), https://blog.petrieflom.law.harvard.edu/2022/08/26/a-response-to-another-legislative-attempt-to-revive-gene-patenting/.
[4] *Id*.
[5] *See id*.
[6] *See id*.

On June 22, 2023, US Senators Thom Tillis (R-NC) and Chris Coons (D-DE) introduced the Patent Eligibility Restoration Act of 2023.[7] This bill aims to broaden patent eligibility across various fields, including medical diagnostics and biotechnology.[8] Its primary goal is to remove judicial exceptions to patent eligibility and to establish clear criteria for determining what can be patented.[9] Notably, the bill proposes making genes patentable.

Debating Gene Patentability:

(A) Arguments Against Gene Patentability

Opponents of gene patentability, particularly concerning the Patent Eligibility Restoration Act of 2023, argue that gene patents are more detrimental than beneficial. They contend that such patents hinder access to genetic tests, as evidenced by the reduced availability of testing for diseases like hereditary hemochromatosis, Canavan's disease, and breast cancer.[10] Supporting this view, a U.S. survey showed that 25% of genetic testing clinics stopped offering tests due to existing patents.[11]

Critics also maintain that gene patents create market monopolies, limiting the number of providers for patented tests[12] and impede on the development of alternative testing methods. Such monopolization can potentially raise patient costs;[13] for instance, Myriad Genetics charged over $3,000.00 for testing the presence of the BRCA1 and BRCA2 genes.[14]

Furthermore, opponents assert that patents obstruct research and development. David Koepsell, a Professor at Delft University of Technology, notes that patents hinder scientific research by preventing the replication of genes for study.[15] Some studies corroborate this, showing that patents adversely affect the ability of clinical laboratories to develop genetic tests and conduct research.[16]

The final argument raised by opponents is that patents should protect inventions, not discoveries.[17] While it is acceptable to patent technologies like rapid-sequencing, they argue that genes, being natural discoveries rather than inventions, should not be patentable.

(B) Counterarguments Supporting Gene Patents

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[7] Patent Eligibility Restoration Act of 2023, S.2140, 118th Cong. (2023).
[8] *See id*.
[9] *See id*.
[10] Chandrasekharan *supra* note 2.
[11] *See* Soini *supra* note 1.
[12] *See* Chandrasekharan *supra* note 2.
[13] *See* Soini *supra* note 1.
[14] *See* Morris *supra* note 3.
[15] *See* Lindsey Wagner, Human Genes Should Not Be Patented, UVA Lawyer (2009), https://www.law.virginia.edu/static/uvalawyer/html/alumni/uvalawyer/spr09/humangenes.htm.
[16] *See* Soini *supra* note 1.
[17] *See* Wagner *supra* note 15.

While opponents criticize gene patents, evidence of their impact is mixed. Numerous articles indicate a lack of sufficient empirical data on the effects of genetic patents.[18] Moreover, a study by Duke University highlighted the difficulty in substantiating claims that patents significantly limit clinical and patient access to genetic testing.[19]

Contrary to the belief that patents make healthcare unaffordable, their impact on pricing is variable. Research led by Robert Cook-Deegan and his colleagues at Duke University indicated that BRCA1 and BRCA2 patents did not consistently affect the prices of diagnostic tests.[20] For instance, after the *Myriad* case, the cost of testing the BRCA1 and BRCA2 genes varied from $200 to $5,000, primarily affected by factors like insurance coverage and testing methods.[21]

Regarding research and development, studies by Bhavan Sampat and Heidi L. Williams suggest gene patents have minimal effect on subsequent innovation and are preferable to trade secrecy.[22] They argue that patents promote disclosure, making information about genes more available.[23]

The Patent Eligibility Restoration Act is Necessary

The Patent Eligibility Restoration Act of 2023 marks a significant legislative step towards expanding patent eligibility by removing judicial exceptions.[24] This Act plays a key role in encouraging investment in the field of genetics, particularly in genetic testing, by biotechnology firms. These firms often encounter significant risks and incur high costs during their research phases. For instance, developing new pharmaceutical and biological technologies, including genetic tests, can cost more than $1 billion.[25] However, many of these costly projects do not result in successful or commercially viable inventions, highlighting the importance of patents in providing financial incentives that justify such substantial investments. A case in point is Myriad Genetics, which made substantial investments in identifying the BRCA1 and BRCA2 genes.[26] In cases like these, patent-driven incentives are vital to justify and sustain the high level of investment required.

Patents also play a crucial role in enabling companies to secure private funding for their research and development activities in pharmaceutical and biological innovations. A study by David Taylor showed that decreased patentability after the *Myriad* case led to a reduction in research and development investment.[27] The potential for financial gain through new genetic

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[18] *See* Soini *supra* note 1.
[19] *See* Chandrasekharan *supra* note 2.
[20] *See* Morris *supra* note 3.
[21] *Id*.
[22] *See id*.
[23] *Id*.
[24] *See* Patent Eligibility Restoration Act of 2023, S.2140, 118th Cong. (2023).
[25] *See* Morris *supra* note 3.
[26] *See id*.
[27] *See id*.

testing capabilities is a key motivator for companies to undertake high-risk gene development and research.[28]

Additionally, the Patent Eligibility Restoration Act of 2023 seeks to strengthen the patent system and improve transparency by mandating public disclosure of inventions and their patent details.[29] This transparency facilitates access for other researchers to build upon existing work.

Lastly, without an expansion of patent eligibility in the U.S., there is a concern that innovators may relocate their research to regions where genomic DNA and proteins are patentable, like the European Union, Australia, and Japan.[30] Such a move could significantly shift biotechnological innovation outside of the U.S.

Conclusion: The Future of Biotechnology & Patent Law

In conclusion, supporting the Patent Eligibility Restoration Act of 2023 and the patentability of genetic testing represents a forward-thinking approach to innovation in biotechnology. This stance recognizes the critical role of patents in driving research and development, particularly in the high-risk, high-cost domain of genetic research. By allowing patents for genetic testing, the Act incentivizes investment and discovery, ensuring that the pioneering efforts of firms and researchers are adequately rewarded and protected. This not only catalyzes further advancements in healthcare, but also promotes a competitive, yet collaborative scientific environment where discoveries are shared and built upon. The Act, by broadening patent eligibility, will usher in a new era of medical breakthroughs and technological advancements, ultimately contributing to the betterment of global healthcare and the enrichment of human knowledge.

[28] *See* Soini *supra* note 1.
[29] *See* Morris *supra* note 3.
[30] *Id*.