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## STUDY ON PATENTS IN GENOMICS AND HUMAN GENETICS

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### ABSTRACT

Genomics and human genetics are rapidly becoming attractive industries that also play an important role in advancing scientific knowledge. Increases in public and non-profit research funding, as well as commercial support for biotechnology and pharmaceutical R&D, contributed to the rise of these disciplines. The story's focus on DNA patents shows how the law has changed to accommodate (or ignore) developments in genomics. The traditional roles of patents, such as funding post-discovery clinical studies to evaluate safety and efficacy and encouraging investments in engineering and product development of things like equipment and therapeutic proteins, have been mostly fulfilled. Clinical genetic testing is accompanied by a number of patents on procedures and DNA sequences, although these provide less evidence of advantages and more evidence of challenges and barriers. This is mostly attributable to university exclusive licencing practises. Even while the law is shifting away from upholding the broadest and most disputed patent claims, the question of whether or not whole-genome sequencing infringes on existing patents remains unsettled.

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## 1. INTRODUCTION

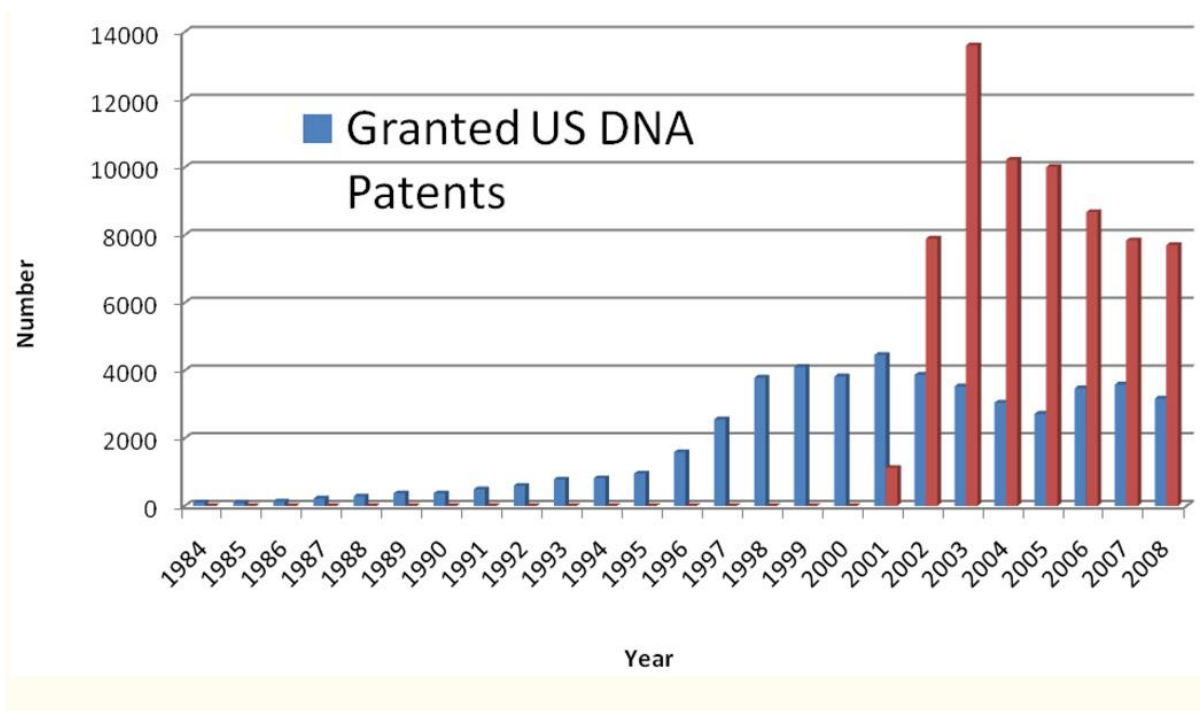
An individual, group, or company that can prove they were the first to identify a particular sequence of DNA (a gene) is awarded a gene patent by the government. The owner of a gene patent has the right to control all uses of the patented gene for 20 years from the patent's issue date. This includes commercial uses such as clinical genetic testing and non-commercial uses such as study. When a gene is patented, a company usually gains exclusive control over all genetic testing for the copyrighted gene.

The United States Supreme Court ruled in *Association for Molecular Pathology v. Myriad Genetics, Inc.* on June 13, 2013, that human genes are not copyrightable in the country since DNA is a "product of nature." The Court found that there is no property worth protecting when a gene is identified, and thus no basis for issuing patents. There were over 4,300 patents on human genes prior to this decision. The Supreme Court's ruling nullified the patents on those genes, opening them up for use in scientific study and commercial genetic testing.

The Supreme Court ruled that DNA sequences that have been altered by humans are not found in nature, justifying the patenting of DNA sequences generated in a laboratory. The Supreme Court has ruled that complementary DNA (cDNA) can be patented. The molecule messenger RNA, which provides the blueprint for protein synthesis, is used to create this synthetic DNA.

## 2. BACKGROUND

The 50,000th U.S. patent was granted by the USPTO in April 2009, and it may be found in Georgetown University's DNA Patent Database. DNA, RNA, nucleotide, plasmid, and other terms specific to nucleic acids are used in the patent claims. Because of the specific vocabulary associated with nucleic acid structures, patents that are both inspired and related to genetics and genomics may be easily traced. Patents are a measurable element of the tale of modern biotechnology's impact on the economy, and not just because of the inextricable bond between academia and industry. The first DNA patents were issued in the 1970s, but the number of patents issued exploded in the mid-1990s when molecular genetic techniques began producing patentable ideas. Example 1 in the Standard Format



**Figure 1** U.S. Patents: The Annual Distribution of DNA Patents and DNA Patent Applications, 1984–2008. The DNA Patent Database is an algorithmic resource for searching issued U.S. patents (since 1971) and published applications (since 2001) in genetics and genomics–related U.S. patent classes, as well as claims containing terms unique to nucleic acids, genetics, and genomics. DNA Patent Database is a source for the resulting patents. In 1984, for the first time, the DNA Patent Database lists more than a hundred granted patents.

### 2.1 WHAT IS A PATENT? WHO GRANTS A PATENT?

Legal protection against others producing, using, selling, importing, or offering to sell a patented innovation. The duty of protecting this right falls on the shoulders of national courts. If someone else copies, uses, or sells your invention without your permission, you can take legal action.

In response to patent applications, patent offices issue patents. While the procedures for obtaining a patent may vary, the requirements for doing so are generally the same across countries. The topic of an invention must be eligible for patenting. "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" is how the term is defined in the United States. For an invention to be granted a patent, it must also fulfil the following three requirements: (a) it must be novel; (b) it must be nonobvious; (c) it must be useful; (d) in Europe and most other countries, utility; (e) industrial use is legal in most countries. In addition, a patent needs to detail the invention sufficiently so that a "person having ordinary skill in the art" can make and utilise it without "undue experimentation." The patent will be invalid if it lacks sufficient "written description" and "enabling" language.

### 3. CONCERNS ABOUT DNA PATENTS INTERACT WITH POLITICAL AND SOCIAL ISSUES

When compared to other areas of R&D, human genetics and genomics stand out due to the unique nature of their end products and the widespread interest and concern among the scientific community about the ethics of research, its application, and the distribution of its advantages. Both the subjects and the targets of research have immediate implications for human life. Whose information, resources, and authority go into answering this question are all at play here. questions that are more tailored to the realm of genes than, example, the realm of computers or mobile phones. The values of equity and accessibility are important to the health care system.

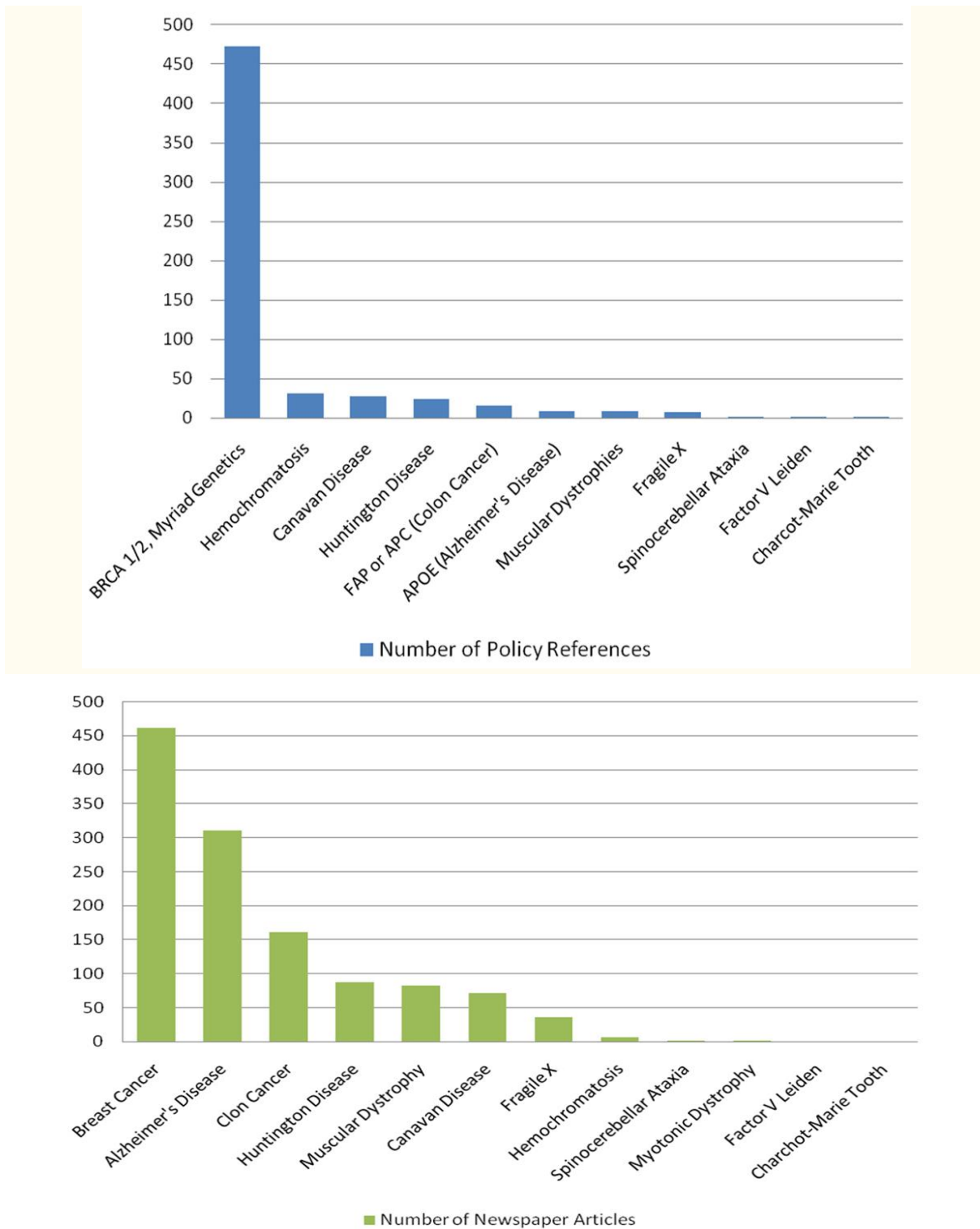
Who gets to say what's best for humanity when it comes to how we use modified living forms? This concern was first voiced by the heads of the three main American religious groups in a letter to President Jimmy Carter sent shortly after the 1980 Supreme Court decision *Diamond v. Chakrabarty*, which legalised patents on living creatures. Who will regulate genetic research, the outcomes of which could have far-reaching consequences for human survival? Who stands to gain, and who stands to lose (whether directly or indirectly)?

These aren't your run-of-the-mill inquiries. These issues pertain to our morality, ethics, and faith. The sanctity of human life and each person's inherent value are fundamental themes.

U.S. Catholic Conference; Randall C., National Council of Churches; Benjamin Mandelbaum, Synagogue Council of America; Thomas Kelly, National Council of Churches) on the Supreme Court's decision to allow patents on new forms of life. calls into question the original intent of patent laws, which were written for a different purpose. Exchange of messages with Jimmy Carter.

#### 3.1 MEDIA ATTENTION AND POLICY REPORTS

A lot of people have strong feelings about patenting genes and genomes. A media content analysis of gene patent arguments in English language newspapers (Figure 2a) revealed that patents on the BRCA1 and BRCA2 genes, which are linked to inherited risk of breast and ovarian cancer, were the most prevalent. The media response in the United States has been particularly critical, despite the fact that the patent holder, Myriad Genetics, is headquartered there. Wherever Myriad threatened patent enforcement — Australia, the UK, or Canada — the press was adverse.



**Figure 2** Newspaper articles and policy reports often make mention of genetic disorders, genes, and the debates surrounding them. Newspaper and policy report mentions of gene patents in the English language, categorised by gene and by firm. Caulfield and coworkers looked through Australian, Canadian, British, and American English-language media for coverage of gene patents from 1994 to 2006. Newspapers were analysed for the frequency with which they covered stories about diseases, genes, and controversial topics. b) In a

separate piece, Caulfield and coworkers looked through policy reports written in English about gene patenting from 2002–2006, specifically for mentions of individual patents and companies. Indicated are the total numbers of occurrences (excluding synonyms) of specific patents and companies among the aforementioned reports.

Once again, the BRCA patent controversy was the most prominent topic of discussion among the 18 foreign policy publications analysed by Caulfield et al. (Figure 2b). France and Belgium both established laws in response to the BRCA dilemma, while Ontario commissioned a report on the Myriad Genetics controversy in 2002. The case study by Gold & Carbone demonstrates how simmering anxiety about gene patenting erupted into open controversy, and how that in turn led to the willful and strategic disregard of Myriad's patents. The National Health Service in the United Kingdom was Myriad's most promising market at the time, and Shobita Parthasarathy paints a similar picture of opposition there. Class action litigation against Myriad and its co-defendants was initiated in May 2009 by a coalition of medical organisations and individual plaintiffs coordinated by the American Civil Liberties Union.

#### 4. THE EMERGENCE OF GENOMIC PATENTS

##### **Genetics and Genomics: Born into Biotechnology**

The promise of money and employment from biotechnology developed in tandem with the popularity of molecular biology research throughout the 1980s. There was a bundle including molecular genetics, biotechnology, and hopes for economic growth. In this context, the study of human genetics and genomics rose to prominence. When it comes to the conceptual and scientific significance, as well as the evident and foreseeable practical impact, and frequently commercial worth, of research, there is a lot of room in Pasteur's Quadrant for the study of human genetics and genomics.

##### **June 1980: *Diamond v. Chakrabarty***

In June 1980, by a vote of 5 to 4, the United States Supreme Court handed down its ruling in *Diamond v. Chakrabarty*. Because General Electric's claimed innovation was microbes genetically modified to degrade petrochemicals and produce oil spills, the USPTO rejected the company's patent application. The Supreme Court of the United States has ruled that this is patentable technology. There was extensive public discussion about recombinant DNA and the possible biohazards of introducing human gene splicing at the time this case was settled, when gene cloning successes were proving the promise of biotechnology.

The Supreme Court's decision was read to suggest that items and organisms developed in this way were patentable, even though Chakrabarty's modified *Pseudomonas* bacterium did not incorporate recombinant DNA. Those with a financial interest in the emerging biotechnology "industry"—including universities, pharmaceutical companies, and biotech

startups—argued in favour of extending patent protection to encompass Chakrabarty's bacterium. Patents on insulin and growth hormone were among the earliest to be filed, and assessments of patents on underlying techniques like Cohen–Boyer cloning and Axel co transformation were already underway.

The events of October 14, 1980, mark a turning point in the development of recombinant DNA, DNA sequencing, and industrial biotechnology. The Nobel Prize in Medicine or Physiology was shared by Paul Berg, Walter Gilbert, and Frederick Sanger for their work on recombinant DNA. Herb Boyer and Robert Swanson, two venture capitalists, established Genentech. DNA cloning was first developed in Boyer's lab at UC San Francisco. Boyer, a member of the team getting ready for Genentech's first public offering (IPO), remembers the San Francisco Chronicle from that day, saying, "...the headline was 'Genentech Jolts Wall Street' and underneath is a photo of Paul Berg, 'Berg Wins Nobel Prize.'" A Nobel-worthy narrative of business plotting and scientific discovery has been brought together in the current era of molecular genetics.

#### **DNA Patents before Chakrabarty**

In the final three claims of the invention detailed in U.S. Patent 3,615,654, RNA is specifically mentioned as a means by which liquid ammonia can alter the protein and nucleic acid composition of cells. Similarly, the majority of the earliest DNA patents dealt with dietary or pharmacological methods of treating cells. Only a small fraction of the 159 nucleic acid-related patents issued between 1971 and 1980 made use of molecular biology approaches. However, a handful of these foreshadowed the flood of molecular biology-based DNA patents that would follow. In 1973, for example, Purdue University's Peter Gilham and Herbert Weith were awarded a patent for what was effectively a method for DNA sequencing. Inducible interferon nucleic acids were patented by Johns Hopkins University in 1977. But these patents did not spark a discussion about biotech patents in the public sphere. By the end of 1980, everything had shifted.

#### **Conclusion**

First, this article might conclude that there are legitimate grounds for scepticism and criticism of the patent system, but that the systemic issues that have been widely predicted have not yet materialised. Those that do appear have more to do with business and competitive issues than patents. There are others who are beginning to see the value in patents, but there is still a prevalent culture of intervention, moderation in policy suggestions, and exemptions for research. There is little evidence that adopting research exemption will address the so-called existing anti-commons problem or limited access difficulties, especially with regards to DNA testing. And any changes must be tested against the foundation that patents offer for advancing and disseminating research technology.

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