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SCOPE AND COST OF GENE PATENTING IN THE UNITED STATES

INTRODUCTION

Basic research into human genetics and genomics has revealed some useful discoveries about the link between genes and human health and disease. These discoveries have often lead to useful inventions for diagnostic and therapeutic tools – many of which public and private organizations have chosen to patent. However, because gene discovery has proven to be so potentially useful, many researchers and firms have rushed to patent genes before developing any useful invention, thus potentially preventing others from using that genetic knowledge in developing new, improved, or alternative diagnostics or therapies. Furthermore, even where useful inventions have led to patents, the breadth of these claims in the patent may preempt further study and invention based on that gene, potentially stifling new research into important human diseases. Since public money has funded a large part of the basic research leading to these patents, these assertions of ownership and exclusion are highly unjust.

In this report we aim to examine the scope of gene patenting in the U.S. Three important questions we address are:

(1) What is the scope of U.S. patents over human genes?

(2) How much public money has been invested in research ultimately leading to gene patents?

(3) Who holds these patents and how broad are they?

DISCUSSION

1. SCOPE

What constitutes a "gene patent" can sometimes be difficult to define. Nevertheless, the fraction of the human genome that is claimed in U.S.-issued patents is astounding. In one analysis of patents asserting a claim over human protein-encoding nucleotide sequence, Jensen and Murray found that, as of 2005:[1]

- Nearly 20% of human genes are explicitly claimed in U.S. patents
- This constitutes 4,382 of the 23,688 genes in the NCBI's gene database in 2005

[1] Kyle Jensen and Fiona Murray, Intellectual Property Landscape of the Human Genome, *Science* 310:239 (2005).

- These genes were claimed in 4,270 patents owned by over 115 different assignees

A more recent analysis that used a broader definition of "gene patents," Cook-Deegan and Heaney found that, as of April 2009, more than 50,000 U.S. patents had been entered into the DNA Patent Database at Georgetown University.[2] In fact, that same study suggested that by focusing their study solely on DNA sequence patents, Jensen and Murray vastly underestimated how much of our genome is patented. Furthermore, the most heavily patented genes are those dealing with serious human diseases, especially cancers – intensifying concerns about access to diagnostic and therapeutic technologies.[3] While the breadth of the patent – how much it claims to own, what it prevents others from using the genetic information for, etc. – is integral to assessing how these patents might stifle new research or hinder access to diagnostic and therapeutic tools, all indicators suggest that the scope of gene patents is broad and growing rapidly to cover many of the genes encoded in our DNA.

2. FUNDING

Much of the research, especially basic research, in the United States is funded at least in part by the federal government. The National Institutes of Health (NIH) is the primary federal funding agency for research into human health and disease. Much of this research is based on genetic and genomic studies, and therefore much of this investment has potentially contributed to currently patentable and patented discoveries.

Unfortunately, however, it is nearly impossible to actually determine what amount of public funding has led to gene patents. As Chandrasekharan *et al.* note:

> "Private sector genomics R&D interacts with publicly funded genomics research in highly complex ways that do not entirely comport with traditional frameworks of R&D that assume federal and non-profit funding for 'basic' research will produce knowledge that is applied downstream by private firms. Academic genomic research now entails the use of "research tools" purchased from private genomics firms, the majority of which were created after the HGP began."[4]

Nevertheless, some estimates and rough statistics indicate the high degree of the public investment into research leading to DNA patents. For example, a 1999 study of thirty-three gene patents directly relating to serious human diseases found that 67% had been directly funded, at least in part, by the U.S. government.[5] More recently, the NIH has begun tracking its spending on "genetics" and "genomics" across some of its constitutive agencies, with the former a broader category than the latter. While these moneys overlap, and while data is only available since 2003, some estimates of spending can be tracked. Analysis of these reports indicates that[6]:

- From 2003-2007, the NIH spent over $14 billion on genetics research

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[2] Robert Cook-Deegan and Christopher Heaney, Patents in Genomics and Human Genetics, *Annu. Rev. Genomics Hum. Genet.* 11:17.1 (2010).
[3] Jensen and Murray, *supra* note 1.
[4] Subhashini Chandrasekharan, Noah C. Perin, Ilse R. Wiechers, and Robert Cook-Deegan, Public-Private Interactions in Genomic Medicine: Research and Development, *Genomic and Personalized Medicine*, Ed. Willard & Ginsburg, Elsevier, Inc. (2009).
[5] Anna Schissel, Jon F. Merz and Mildred K. Cho, Survey Confirms Fears About Licensing of Genetic Tests, *Nature* 402:118 (1999).
[6] Jennifer Reineke Pohlhaus and Robert M. Cook-Deegan, Genomics Research: World Survey of Public Funding, *BMC Genomics* 9:472 (2008).

- Over the same time period, a survey of agencies across the federal government reveal that the U.S. spent over $4 billion on the narrow category of "genomics" research, which is more likely to culminate in gene patents
  - This averages to approximately $3.5 per capita each year
  - These funds are in addition to the $2.7 billion expended by the NIH on the Human Genome Project

It remains true that not all genetics or genomics research leads to a patent. But most research directly leading to a patent rests on basic discoveries made in academic and government laboratories using technologies and techniques originally invented with public funds. While not absolute figures, these numbers do indicate a massive investment on the part of U.S. taxpayers into genetics research, a large part of which has led to privately-held patents that threaten our access to new diagnostics and therapies for life-threatening diseases.

3. OWNERSHIP and BREADTH

Depending on the definition of "gene patent" we use, we will find different actors holding these IP rights. Generally, these stakeholders include agribusiness and chemical companies, the U.S. government, public and private universities, pharmaceutical firms, biotechnology firms, firms created to exploit genomic technologies, instrumentation and DNA chip firms, academic research institutes, and hospitals with research units.[7] According to one study from 2005, 63% of gene patents were assigned to private firms, as compared to 28% that were assigned to "public" organizations, including governments, schools, universities, research institutions, and hospitals.[8]

Furthermore, many of the genes studied were concentrated in the hands of a small number of large actors. For example, Incyte Pharmaceuticals' patent rights covered almost half of genes patented by 2005.[9] A different research study looking at private firms' genetic IP rights found that the top ten genomics firms held nearly 60% of the total U.S. patents and 64% of DNA patents as of 2006.[10] Many of these patents are also exclusive – 3,000 of the 4,000+ patented genes studied by Jensen and Murray were controlled by a single IP rights holder.[11] While these concerns are partially ameliorated by the high percentage of DNA patents held by research and academic institutions, which is far higher than that of patents generally[12], this is still concerning in light of many universities' inability to license patents broadly. An analysis in 1999 suggested that most if not all licenses granted by universities were in fact exclusive, and "are, to various degrees, restricting the performance of testing services by other laboratories."[13]

Jensen and Murray also found that many human genes had multiple patents claiming them.[14] Importantly, many of these heavily patented genes tended to have relevance to human health and disease. For

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[7] Cook-Deegan and Heaney, *supra* note 2.
[8] Jensen and Murray, *supra* note 1.
[9] *Id*.
[10] Chandrasekharan, *et al.*, *supra* note 4. These firms included Incyte (561 patents), Human Genome Sciences (390), Millenium Pharmaceuticals (302), Affimetrix (247), Applera (182), Gen-Probe (180), ZymoGenetics (151), Invitrogen (139), Sirna Therapeutics (121) and Strategene (94).
[11] Jensen and Murray, *supra* note 1.
[12] Cook-Deegan and Heaney, *supra* note 2.
[13] Schissel, *et al.*, *supra* note 5.
[14] Jensen and Murray, *supra* note 1.

example, of the 291 cancer genes reviewed, 131 were patented–significantly more than would be expected for a random sample of genes.[15]

Finally, an analysis by law students and scientists of a narrow range of DNA patents granted over human disease-related genes reveals that many, if not most, patents are problematic even under current U.S. patent law.[16] Authors locate this problem with the U.S. patent examiners, suggesting they do not have the right technical backgrounds, training, financial incentives or adequate time too fully assess the patentability of the claimed material.[17]

CONCLUSION

While studies are limited, available data demonstrates that patents over human genes cover a large proportion of the human genome. More importantly, these patents are concentrated around genes intimately linked to serious human diseases and are largely held by a small set of stakeholders. U.S. taxpayers have poured a huge sum – upwards of $4 billion a year in federal funding alone – into research that has potentially contributed to privately-held ownership of human genetic material. When exclusive ownership of human DNA has the potential to limit the public's access to vital diagnostic and therapeutic tools for combating serious diseases and cancers, these trends are unacceptable. CRG urges policymakers to limit the IP rights granted over human genes in order to ensure that the discoveries and therapies resulting from publicly funded research benefit the public itself.

[15] *Id.*
[16] Jordan Paradise, Lori Andrews, and Timothy Holbrook, Patents on Human Genes: An Analysis of Scope and Claims, *Science* 307:1566 (2005).
[17] *Id.*