The Conundrum of Human Gene Patents

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Writer's Comment: This paper is the fortuitous culmination of my majors in English and Genetics. I wrote it while enrolled in Jean Thaiss's UWP 104B legal writing course, shortly after completing my Genetics major. The assignment essentially asked students to choose a thesis and present an argument written in the style of persuasive legal writing. Given my background, I chose to take on the maelstrom of technical and legal controversy which surrounds human gene patents. A great deal of effort went into providing the legal discussion with brief, but sufficient, explanations of the science involved. I also spent considerable time examining the record of legal disputes involving human gene patents which resulted in litigation. While this paper concludes by making a number of recommendations for improved gene patent regulation, it should be noted that because this paper was written for maximum persuasive effect, many of the recommendations are idealistic, and not necessarily intended to be practical. I'm extremely grateful to Professor Thaiss for her willingness to humor my enthusiasm for the subject, and for her guidance while researching case law.

—John W. Samples

Instructor's Comment: In my legal writing class, I asked each student to write an argument stating his or her informed opinion on a topic related to crime and punishment that our course work had revolved around for most of the term. Wes politely asked if he could choose his own topic. I was concerned he would have difficulty catching up, given the amount of preliminary work the rest of the class had already done on our collective topic. Wes doggedly pursued his topic of interest, however, often stopping by to inform me of his progress and consult me on his research and writing questions. I received a number of commendable papers on the California "three-strikes" penal law, the topic I had assigned the rest of the class, but Wes's paper ultimately stood out because it ventures into the frontiers of science as well as law.

—Jean Thaiss, University Writing Program

Introduction

To date, more than 4000 human gene patents have been filed and approved by the United States Patent and Trademark Office (USPTO).[1] Unfortunately, many of these human gene patents are woefully ambiguous because the USPTO has failed to employ a sufficient technical understanding of how the human genome works. These ambiguous human gene patents, and the intellectual property rights associated with them, have raised legal and public health issues with which existing intellectual property laws are incapable of coping. At the heart of this dilemma are antiquated intellectual property laws, and the USPTO's insufficient technical definition of "gene." Inadequate regulation is deterring investment in human gene discovery and making potentially revolutionary healthcare tools difficult to develop. Wide-sweeping reform of existing domestic and international intellectual property laws is urgently needed to ensure the viability of the biotechnology industry and to facilitate the development of treatments for diseases. A review of current USPTO guidelines and the technical details involved suggests that the legal and public health issues could be surmounted by establishing domestic and international institutions to ensure that human gene patents do not deter research or interfere with disease treatment.

Current USPTO Utility Guidelines

Contrary to popular belief, new substances discovered in nature are patentable.[2] Article 1, Section 8, Clause 8 of the Constitution of The United States explicitly grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[3] The USPTO has long held that this language, commonly known as the Patent Clause, implies that both inventions and discoveries, such as discoveries of human genes, are patentable.[4] In 1952 Congress refined intellectual property law by laying out statutory requirements for patentability in United States Code Title 35, Chapter 10 (35 U.S.C. § 100, *et seq.*). According to 35 U.S.C. § 101, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." Inventions or discoveries are patentable only if they

demonstrate "novelty, nonobviousness[,] usefulness, and [if] their patent disclosure [is] adequate."[5]

In 2001 the USPTO made a valiant effort to surmount the ambiguity of existing intellectual property laws by issuing new utility examination guidelines.[6] These guidelines attempted to discourage the frivolous submission of gene patents lacking clear practical uses by requiring all future gene patents to explicitly demonstrate "specific, substantial, and credible" utility.[7]

Though the USPTO is not allowed to create law beyond the limits of its mandate from Congress, it has arguably done so by incorporating several controversial and extremely technical standards in the new utility examination guidelines. The most significant guidelines are those which explicitly reject any notion that human genes should not be patentable. The USPTO guidelines explicitly state that a "gene is eligible for a patent as a composition of matter or as an article of manufacture."[8] The USPTO guidelines also state that the utility of a gene may depend on "the function of the encoded gene product" or the "specific and substantial utility" of the claimed DNA sequence itself.[9] This means that any nonobvious and novel DNA sequence which itself possesses a "specific, substantial, and credible" utility, or which encodes a nonobvious and novel product with "specific, substantial, and credible" utility can be patented.[10] Unfortunately, this understanding of a "gene" is based on outdated science that necessarily regards individual genes as discrete units in a huge library with each producing a single discrete product. In reality the human genome is like a complex network, filled with "genes" that "interact and overlap with one another and with other components in ways not yet fully understood."[11*]

[*]"Other components" includes factors which can influence gene expression, but which are not a direct character of DNA sequence. The addition of methyl groups to the backbone of DNA in a process known as methylation is a classic example. Methylation is epigenetic; methylation patterns can be inherited by daughter cells. Methylation acts to inactivate the expression of the methylated sequence.

Genes: A Technical Primer

Geneticists often joke that if one were to ask 100 biomedical researchers to define a "gene," one would receive 100 different responses. This is because there is no universally accepted, precise definition. The USPTO defines a gene as "an ordered sequence of DNA 'that encodes a specific functional product.'"[12] This technically antiquated definition clearly derives from classical genetics, which described a gene as a DNA sequence that "encodes a single [protein] product."[13] Modern molecular genetics has demonstrated that reality is much more complicated. To understand the multitude of ways in which DNA encodes functional products, it is necessary to understand the central dogma of biology. Simply put, the central dogma states that DNA is transcribed into mRNA, and the mRNA is then translated into protein (fig. 1).

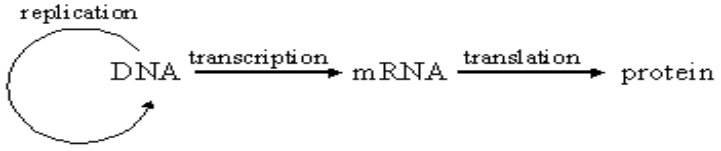

Figure 1: The Central Dogma of Biology
Michael J. Gregory, "Protein Synthesis: Transcription and Translation," Lecture, Clinton Community College (9 Sept 2007). <http://faculty.clintoncc.suny.edu/faculty/Michael.Gregory/files/Bio%20101/Bio 20101%20Lectures/Protein%20Synthesis/protein.htm>.

In the most basic sense, genes are simply groups of base pairs that act in concert to produce a protein. A gene that codes for a protein may contain non-protein-coding sequences, known as introns, which are spliced out from the mRNA before translation (fig. 2). Some introns may be regulatory sequences involved in transcription; some of them may be protein-coding portions of other genes. Distal regulatory sequences may also be involved. These may be located near the protein-coding region, many millions of base pairs away, or somewhere in between.*

There are two essential caveats which the USPTO definition of a gene and utility guidelines do not adequately address. The first is that a single gene or piece of DNA sequence may encode a large number of

*The human genome contains roughly 3 billion base pairs which encode 20,000–25,000 genes.

different functional products.* Regulatory sequences and other factors are able to produce a large number of alternative transcripts from a single gene by varying which portions of the DNA are transcribed and which portions of the primary mRNA transcript are spliced together into a mature mRNA transcript.† The second caveat is that genes overlap.[14] This means that the sequence of one gene could contain protein coding sequence which is essential for the final product of some other gene. Combined, these two caveats mean that individual genes, which encode a multitude of functional products, can be scattered throughout the genome.

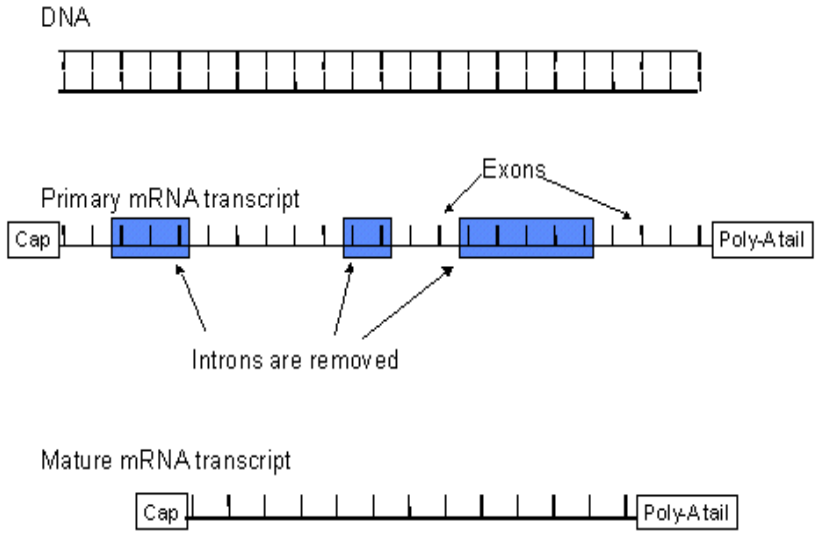

Figure 2: Intron excision
Michael J. Gregory, "Protein Synthesis: Transcription and Translation," Lecture, Clinton Community College (9 Sept 2007). <http://faculty.clintoncc.suny.edu/faculty/Michael.Gregory/files/Bio%20101/Bio 20101%20Lectures/Protein%20Synthesis/protein.htm>.

Legal Consequences and Solutions

To the USPTO's credit, the utility guidelines have done a great deal to improve the situation by reducing the number of patents that aim to simply lay claim to large swaths of DNA sequences now, and establish practical applications later.[15] Despite this improvement, current USPTO

*Alternative transcripts produced from a single gene are known as isoforms.

†Alternative splicing produces various combinations of exons from the same gene.

policy is still fatally flawed because it implicitly endorses the concept of one-gene–one-protein, and fails to accommodate the more accurate networked genome concept. As a result, there is very little reason for regulators and the biotechnology industry to consider the wide-sweeping effects of individual human gene patents on the networked genome. The USPTO's failure to sufficiently address these technical issues means that human gene patents are open to avenues of litigation which deter research and development investment and pose a public health risk.

A 1997 Federal Circuit Court ruling established that "an adequate written description of DNA requires a precise definition, such as by structure, formula, chemical name, or physical property."[16] The USPTO clarified the practical implications of the ruling by explaining that DNA sequence information is sufficient to describe the complete chemical structure of a gene.[17] This means that nearly every gene patent filed uses DNA sequence information to define the gene being patented. However, molecular genetics has made it clear that the sequence information of a gene does not necessarily correlate with a specific functional product, because numerous transcripts can be produced from a single piece of DNA sequence. Thus, DNA sequence alone is not sufficient to document the complete chemical structure of a distinct functional product. A single gene may yield a variety of very different specific, substantial, and creditable uses.[18] In fact, there is a real possibility that two separate entities may attempt to patent exactly the same gene for completely different purposes. Since genes overlap, it is also possible that two entities may attempt to patent overlapping genes for similar purposes. Nobody knows if infringement claims arising from these scenarios will be subject to dispute.[19] The law is relatively untested in this area, and the USPTOhas offered no guidance to quell the nightmares of the biotechnology industry.

The progress of science does not benefit from legal ambiguity.[20] The patent clause of the Constitution and USPTO aim to spur the advancement of science by granting temporarily exclusive rights to the commercial applications of discoveries developed through expensive research endeavors. However, because of the technical inadequacies of current policy, the USPTOhas created an intellectual property regulation climate which is completely contrary to the spirit of the patent clause found in the Constitution. Outright invalidating all 4000 existing human gene patents and banning any further human gene patents would ostensibly

resolve the issues arising from the USTPO's inadequate understanding of the human genome.[21] However, such an action would likely have a chilling effect on the biotechnology industry far worse than continuing in the current climate of ambiguity. Several private and public sector institutions, like the United Kingdom–based Wellcome Trust, are working to disclose the sequence of the human genome to the public commons. Once these genes are disclosed they become obvious, and thus nonpatentable. It appears that such disclosures can be used to destroy existing patent rights, as well as prevent future patents of the disclosed genes.[22] However, this method of human gene patent regulation does little to prevent the patenting of aberrant genes, such as those which are often associated with disease processes, as well as the patenting of downstream products which are modified as they become, or after they become, primary mRNA transcripts.[*] [23]

In an effort to improve regulation of all human gene patents, a regulatory body which combines sufficient legal and scientific knowledge is needed to surmount the existing conundrum established. Such an entity would be charged with resolving human gene patent–related intellectual property disputes; establishing federal laws to minimize human gene patent intellectual property transfer costs; and in cases of extreme public health crisis, advising the legislative and executive branches on temporary policies to resolve the crisis and serve the immediate public interest exclusively. Such an institution might be modeled after existing administrative law review boards found throughout various federal agencies, such as the five-member National Transportation and Safety Board, which reviews decisions handed down by the Federal Aviation Administration. In the case of a USPTO human gene patent review board, a seven-member panel could be composed of two scientists from the Centers for Disease Control (CDC), two scientists from the National Institutes of Health (NIH), and three legal experts from the USPTO. Decisions from such a board could be appealed directly to the United States Court of Appeals, and then to the United Sates Supreme Court, should the board fail to resolve the issue.

Given that the authority of such a board would be functionally equivalent to that of a United States district court, its rulings on disputes

[*]Such exploitation of the "nonobviousness" requirement would also likely fail to render "other components" that are not DNA sequence–based, like methylation, unpatentable.

would create law by establishing precedents. By ensuring that human gene patent disputes will be resolved by a technically informed board, this procedure could mitigate the ambiguity of current USPTO policy which deters research investment by the biotechnology industry. Using a technically competent board to manage human gene patent technology transfer costs at a federal level will ensure that human gene research does not become cost-prohibitive for institutions in the United States. Finally, the duty of advising the legislative and executive branches in the event of a public health crisis will help to ensure that much-needed disease therapies that are dependent on patented human genes will be accessible to everyone.

Public Health Consequences and Solutions

Domestic concerns aside, the USPTO's decision to allow human gene patents while ignoring molecular biology's model of the networked genome may have disastrous consequence for public health on an international scale. Already, some potentially lifesaving biomedical assays are exorbitantly expensive for many, because human gene patent owners can charge whatever they want for their intellectual property. [24] For example, a test for the mutated genes which can cause breast cancer could cost as little as $1,000, but because of licensing fees and royalties, this test currently costs $3,000 in countries which honor U.S. patent rights.[*] [25]

The consequences of the USPTO policies which allow isolated human genes to be patented, and allow patent owners to restrict the use of their human genes in biomedical assays, will only get worse as the cost of individual whole genome sequencing plummets. Preventative treatment of genetically identified risk factors could completely revolutionize health care the world over. Instead of treating disease symptoms, people could preempt the occurrence of genetically-based disease with frequent screening and lifestyle adjustments. Traditional medicine that depends on the regular consumption of pharmaceuticals could become a thing of the past. Improvements in sequencing technology and economies of scale will reduce the cost of whole genome sequencing to $1000 per person within the next ten years. However, if human gene patent owners demand exorbitant fees for the use of their intellectual property, as they have with breast cancer genes, the $1000 human genome could poten-

[*] These genes are often referred to as the BRCA genes.

tially cost $50 million.* This is ridiculous considering that human gene patents could not exist were it not for the DNA inside each cell of every human being.

The USPTO's inept technical standards take a frightening turn towards science fiction in light of the recent SARS epidemic. When SARS appeared in China in 2002, the world acted quickly to sequence the virus's DNA in an effort to facilitate the expedient development of a vaccine and assay for screening.[26] However, many researchers were hesitant to make the SARS genome sequence public, because of gene patent concerns.[27] Ultimately Hong Kong University, a Canadian public health agency, and the U.S. Centers for Disease Control filed gene patents.[28] Ostensibly, these patents were filed to protect the public interest and prevent profit-motivated SARS gene patents.[29] However, the World Health Organization (WHO) has since expressed concern that these patents will hinder the eventual development of products such as vaccines.

The WHO is right to be concerned. It is essential that the world address the consequences of human gene patents on an international scale. When it became apparent that the human genome would eventually be sequenced in the late 1980s, the Human Genome Organisation (HUGO) was founded to coordinate international research efforts.[30] HUGO later participated in the Human Genome Project (HGP), which began in the United States, in 1990, by most accounts. Today HUGO consists of 23 member countries, including the United States, and it has been designated by the United Nations (U.N.) as the agency through which international human gene–related technology transfer should be facilitated.[31] While HUGO is well versed in the science necessary to facilitate such technology transfers at reasonable costs, in an effort to foster human genome research the world over, its ability to resolve international intellectual property disputes is questionable. HUGO would be well advised to partner with an international dispute resolution agency, such as the International Courts of Justice (IJC), which is the judicial arm of the U.N.

In 2002 the IJC established a special seven-member chamber for hearing concerns related exclusively to the environment, given the recent increase in international legal disputes related to environmental policies. A similar chamber, dedicated to the international legal concerns arising

*25,000 genes in the human genome, multiplied by $2000 worth of royalties each (according to the current BRCA model), equals $50,000,000.

from human genome–related intellectual property disputes, could be established. Members of HUGO, charged with analyzing the technical and scientific concerns of such disputes might hold three of the seats, while the other four could be held by traditional IJC judges, charged with understanding and applying relevant international law. Such an unconventional chamber of the IJC would ensure that international law would be correctly applied to human gene patent–related disputes, and it would give HUGO claws with which to enforce its technology transfer policies. Such a chamber could also be called upon to advise the U.N. in the event of international health crises concerning patented human gene–derived therapies, in order to help facilitate the delivery of emergency health care in a fashion which would not have a chilling effect on the global biotechnology industry's willingness to invest in research.

Conclusion

Our understanding of the human genome will undoubtedly evolve as science marches on. It is imperative that we do not hinder this development by resigning ourselves to poorly administered regulation based on antiquated science. Instead, the United States, and the world, must develop powerful regulatory institutions that are capable of evolving along with the advancement of science. The USPTO's failure to accommodate the networked genome model along with the recent findings of molecular biology has already had some negative effects on human gene research. However, it is not too late to change course and employ the concept of intellectual property, as it relates to human genes, as the Patent Clause intended.

Glossary

Assay: A method for determining the presence of a compound; in this case, variations of patented human genes.

Base pairs: The two complementary molecules that hold together the two strands of DNA through weak chemical bonds. There are four flavors of base pairs: adenine, thymine, cytosine, and guanine. The sequence of the four base pairs in a given stretch of DNA encodes the information necessary to produce a protein.

Coding region: The regions which are not spliced out, which encode for some functional final product.

Disease: Any abnormal condition of the body, caused by an array of things, including pathogens, aging, and genetic composition.

Functional Product: Anything derived from DNA which interacts with, or helps to form the human body. Proteins are one good example.

Intron: An mRNA sequence which is spliced out after transcription but before translation. Technically speaking, an intron is an intron because it is spliced out, not because of the DNA sequence from which it derives. The coding regions which remain are called exons.

Molecular Genetics: The name given to the study of the molecular structure and function of genes.

Protein: Large complex molecules that perform a wide variety of functions essential for life.

Regulatory sequence: A sequence of DNA which increases, decreases, initiates, or completely blocks the transcription of other DNA sequences. Regulatory sequences are often affected by systemic factors, like hormones.

SARS: Severe Acute Reparatory Syndrome. SARS is a virus. Though not technically alive, viruses contain genetic information, such as DNA, to facilitate their replication.

Translation: The process by which information transferred from DNA by RNA is translated into an amino acid chain, which eventually becomes a protein or some other functional product.

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U.S. Const Art I, § 8, cl 8.

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[5]Ibid.

[6]Ibid.

[7]"Gene Patent Guidelines"

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