

“The Gene Patent Problem: Recommendations for Congress”

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The earliest Chinese medical textbooks stated, “The superior doctor prevents disease; mediocre doctors treated disease before it is evident; and inferior doctor treat full-blown disease,” (Cohen 338). Based on this idea, the current healthcare system can be classified as inferior. There is new hope, however, in genomics, which has mostly preventive medical applications. From personal genomic medicines to analysis of people’s simple nucleotide polymorphisms (SNPs), there are endless beneficial treatments and more are continually explored in scientific research. The promise of genomics has also garnered a capitalistic interest, as there are billions of dollars worth of business in this field. Indeed, the number of biotechnology companies has exploded in the last decade. Along with this boom, disputes over patent laws have risen quickly to the forefront. Debates over the patentability of genetically engineered organisms, SNPs and research methods erupted into lawsuits often appealed to the U.S. Supreme Court. This paper will not address the issue of whether gene patenting is ethical. It will instead address the problems of the current gene patent policy regarding scientific research and the healthcare industry. Specifically, whether gene patents impede scientific research for therapeutic purposes and what changes must be made to current patent policy.

Patent Types and Application to Genes

The U.S. Patent and Trademark Office (USPTO) allows people to patent machines, methods and composition of matter. The patents must also demonstrate utility (patent must be useful for something), nonobviousness (invention must require significant effort and not one that natural scientific progression will yield) and disclosure (invention has to be made known to

public). The machine patent was granted for new manufactured products like light bulbs, the methods patent was granted for new industrial methods like refining iron ore and the composition of matter patent was granted for newly synthesized chemical products like buckminster fullerene (Schacht 3).

With the advent of biotechnology, the issue of patenting biological objects arose with the landmark case of *Diamond v Chakrabarty* in 1982. Ananda Chakrabarty had genetically engineering a bacterium capable of metabolizing crude oil, which could be used to treat oil spills. He then filed for a patent with the U.S. Patent and Trademark Office, which rejected his patent based on the grounds that living organisms could not be patented (Pollack 2001). The Supreme Court ruled, however that “anything under the sun made by man,” can be patented (Burke 10). Since Chakrabarty had altered the organism from its naturally occurring state, he had “invented” a new organism that could not occur naturally and thus the machine patent was upheld for genetically engineered products. This provision has formed the basis for future legal disputes in gene patenting.

The first major court case regarding gene patenting was *Amgen v Chugai*. Amgen and Chugai both had patents for producing human erythropoietin. Amgen’s patent used recombinant technology while Chugai’s patent on the product was from natural sources. Amgen claimed its patent also extended to rights over the DNA code for erythropoietin and any cells that coded for the protein. The court ruled that Chugai’s patent was invalid due to a lack of evidence of its methods patent. However, it also ruled that Amgen could not claim the gene for erythropoietin because it had not described the sequence and chemical structure of the gene in its patent (Ladas and Parry). This case laid the groundwork for the current gene patent policy, which treats DNA as a chemical compound and allows anybody to patent genes and gene products as long as they have the gene sequence and purified and isolated the DNA fragment. In addition, the case also

showed that method patents could not be broadly applied to biotechnology as with industrial processes. Amgen's patent could not extend to cells making the protein, only the specific method of producing the erythropoietin.

Problems with Gene Patent Policy

There are several problems associated with current gene patent policy. Acknowledging the infinite problems associated with gene patent policy, the paper will focus on the problems associated with scientific research, namely academic research, and healthcare in the form of clinical trials.

The largest problem associated with current gene patent policy is hindering future scientific research. As stated previously, current patent policy allows anybody to patent genes, SNPs, express sequence tags (EST), gene products and any scientific process to obtain proteins. The problem with patenting any of these is that patent holders can prevent anyone from using these materials in any way. Companies like 23andMe could not analyze patented SNPs without licensing from the patent holder. Furthermore, this type of patenting can interfere with medical treatments of the future that rely on SNPs to help people undertake preventative measures to certain diseases (Barton 1341). Of all the patentable objects, SNPs are of most concern because they have the most lax patent policies among gene related products.

The effect of patents in academic research is a growing problem. Gene patent infringements have excluded researchers at academic institutions because most of the work is not for profit. In addition, patent holders at biotechnology firms have believed that such research can often times benefit themselves as more information is developed about the particular gene (Buckley 12). However, Stanford Law School Professor John Barton points out that the federal courts are challenging this long held assumption. In the case of *Embrex Inc v Service Engineering Corp*, the court ruled that there is no such exemption codified in law (Barton 1342).

Such a precedent will not cause companies to sue academic institutions, but may increase demands from patent holders for license fees, which will only burden researchers.

Another problem of patents in academic research is that it hinders the basic characteristics of research. Namely, scientific objectivity and peer review are undermined or eliminated with gene patents (Barton 2009). Scientific research has been described as a linear process where several different researchers can come up with the same results independently. This process is very important as researchers can undergo peer review, which involves verifying and duplicating results. Gene patent policies greatly hinder this process because anybody duplicating and verifying patented results is liable to an infringement lawsuit (Merz 7). Furthermore, gene patents have been criticized because there is a pressure to produce profitable results. The whole purpose of a patent is to allow the researcher to develop a marketable product out of the invention and thus, there is undue pressure for successful results to develop. Scientists are famous for noting that great discoveries are the result of thousands of failed experiments. In this light, gene patents can be described as undermining the spirit of scientific objectivity.

Perhaps the most underrated implication of gene patenting is the method patent. Original patent policy prohibited patenting laws of nature, scientific principles and business methods. The Court of Appeals for the Federal Circuit (CAFC), which provides legal rulings on patent disputes and policy, changed its policies during the information technology boom. Court decisions allowed business methods to be patented. In addition, the tangibility requirement for computer program patents was also eliminated, which allowed algorithms to be patentable (Barton 1343). Both of these rulings are fair and useful in enforcing patents for software and IT companies, but when applied to biotechnology companies create several disturbing consequences. According to Barton, these laws can allow people to patent statistical analysis techniques for evaluating clinical data, equations to predict enzyme levels in the body and any process of comparing two

gene sequences (Barton 1343). These implications would clearly harm biomedical research and bioinformatics.

Gene patenting has some implications in the healthcare industry. Biotechnology companies have increasingly developed more clinical trial products than the pharmaceutical industry. As a result, many patients are the beneficiaries to these treatments from biotechnology firms. Insurance coverage has long played an important role in these trials as some states like California ensure coverage for cancer therapy clinical trials. However, the problem becomes complicated when biotechnology companies offer clinical trials based on gene therapies from gene patents. The current laws would allow biotechnology companies to not refuse insurance coverage for their clinical trials. This potential problem will most definitely affect the healthcare of people who desperately need the cutting edge treatments offered by these clinical trials (Barton 2009).

Solutions

As one can see, the issue of gene patenting creates a large range of problems due to legal, economic and scientific implications. With respect to scientific research, it is crucial that gene patent policy be reformed from its current form to prevent the inevitable legal nightmare of future advances in genomics. This paper will make the following recommendations to Congress based on ideas from the National Research Council Report and John Barton's policy paper.

Without a question, the implications of gene patent policy for scientific research must be confronted first. The main question is how to deal with gene patents themselves. Gene patents should not be eliminated as some scientists have suggested because they have prompted Wall Street to invest billions of dollars into the biotechnology industry to develop new drugs that have greatly benefited society (Buckley 7). However, they also should not be allowed to be unregulated to the point that scientific research is hindered. The first aspect of the reform should

be to incorporate a scientific advisory board for the CAFC to help the U.S. Patent and Trademark Office make patent application decisions. This would help the courts make judicial decisions based on sound scientific insight and foresight to ensure that patent laws can stand the test of time. Furthermore, Congress should take the lead in proposing any kind of gene patent policy legislation rather than the Judiciary. The reason for this is that judicial actions apply to previous cases that may have had a different ruling while Congressional legislation applies to only current patents (Barton 1344). It would not be beneficial to the government to have thousands of previous lawsuits reopened and reargued. Instead, the reform should be targeted to the current patents.

Regarding SNPs, the reformed patent policy should prohibit SNP patenting. SNPs are valuable genetic tools for preventative medicine and companies that are utilizing SNPs should not be subject to licensing agreements, which would increase the costs. Furthermore, the exclusive patenting of SNPs would not provide any major benefit in developing new technologies other than monetary gain from licensing. Allowing SNPs to be in the public domain will ensure that innovation and research is directed at taking advantage and utilizing SNPs. In addition, this would stop the current practice of defensive patenting, where biotechnology companies rush to patent gene products without any thought to the use to prevent other companies from outpatenting them. On the issue of SNP usage, patents may be granted for microarrays and SNPs analysis. However, these patents would have to be very specific as to how they would use the SNPs.

On the issue of research tools and methods, these should also not be patentable. As discussed before, methods patents can allow people to patent any piece of information used to analyze biological functions, which provide no benefit other than financial gain for the patent holder. Furthermore, it is important to note that the theory behind method patents was established

for computer software, so that people could not merely use the software's algorithm on paper. The spirit of the law was not intended to extend to biological systems. As a result, method patents of any kind regarding biological systems must be prohibited (Barton 2009). Furthermore, this recommendation has a sound basis in jurisprudence. The Patent Act of 1952 prohibits the patenting of abstract ideas, which would include laboratory methods and protocols (Affymetrix 5).

The most difficult portion of the proposed reform is regarding academic use of gene patents for research purposes. Some experts like Ted Buckley favor the current system of patent holders allowing research as long as there is no commercial benefit. This practice can no longer exist due in part to new legal interpretations and the increasing trend of academic institutions licensing inventions. As stated before, the idea that researchers from academic institutions can freely infringe on gene patent laws is being challenged. For this reason, it is no longer appropriate to dodge the issue. Biotechnology companies cannot afford to tangle with academic institutions because the two are necessary to further biological research. Gene patents time limits should be evaluated as a case per case basis such, which would ensure that patent holders are motivated to try to utilize patents effectively for innovation rather than to stop others from innovating. This would mean that patent applicants be very specific as to what they intend to accomplish with the patented gene. The proposed CAFC scientific advisory board would then suggest the appropriate time, which can be as little as five years to the maximum twenty years. Furthermore, gene patents should come with a forced license provision. This would allow anybody to use the gene for meaningful scientific research for a reasonable licensing fee. The NIH advisory board would be responsible for approving these licensing based on the criteria that they are simply used for academic research. This provision would create an organized system for using patented genes in academia. Clearly, there will still be problems associated with this

policy. Researchers could conceivably develop a commercial application of the patented gene, which some argue may be unfair to the patent holder, especially if the patent holder was pursuing a similar line of research. To remedy such problems, the patent policy can hold a provision that for a period of time, the patent would remain exclusive and up to the discretion of the patent holder for licensing issues. This would give the patent holder a sufficient time to develop his or her ideas stemming from the patent. Finally, this policy also partially solves the problem of peer review as after the five-year period, anyone can use the patented gene. While this is not a complete solution, it is important to remember no single policy plan can solve every problem associated with gene patenting.

Collaboration is an important aspect of scientific research. Given the broad scope and limitless potential of genomics research, a collaborative genomic partnership is also recommended. This would mean that the USPTO's genomic patenting office would collaborate with the European and Japanese counterparts (Barton 1345). This would ensure that patented genes and technologies are shared by these nations undergoing advanced genomics research. This idea would ensure that intellectual property of genes extends beyond the U.S. border and also will serve an important role in furthering innovation. It further promotes more peer review and possibly unites the European, Japanese and American scientific communities.

The final portion of the new policy would address the question of healthcare. Patent holders would have the right to reject health care coverage for clinical trials involving the patented gene. However, the limited patent time limit ensures that patents lasting five years would most likely expire before the clinical trials would commence. This ensures that the firms cannot reject health insurance for clinical trials. Some critics might argue that when the patent expires, other firms would try to compete to develop the clinical trials. However, the patent holder would have an advantage in the extra development time and any new firms would be

hesitant to try to invest so much money into a project that may not be completed before the patent holder. For the patents that are still valid at the times of clinical trials, there should be a provision that patent holders cannot reject health insurance if the insurance company covers the clinical trial. This ensures that patients receive the proper healthcare.

Conclusion

The scientific research and clinical trial problems stemming from gene patent policy must be resolved. Biotechnology is the fastest growing industry in America and allowing the legal status quo will simply not suffice. Within the scope of this paper, the recommendations suggested are appropriate. The CAFC scientific advisory board should evaluate all patents related to biological systems, time limits must be granted as a case-by-case basis, method patents must be denied for any kind of biological research, SNP patents must be denied and all clinical trials using patented genes must be covered by health insurance. These recommendations must be taken seriously by Congress and state legislatures to ensure that the United States has the legal standards necessary to allow scientific progress and innovation that has been the hallmark of this great nation.

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