Comment 24 David Resnick

From: David Resnik [dresnik@brody.med.ecu.edu]
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To: mark.nagumo@uspto.gov
Subject: comments on revised utility guidelines

Dear Mr. Nagum:

Below are some comments on the PTO's utility guidelines. These comments are also the text of an editorial I am submitting for publication. Thanks for the opportunity to participate in the dialog.

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In a dramatic change in policy, The US Patent and Trademark Office (PTO) is planning to make it more difficult for researchers to obtain patents on genes and genome markers, such as expressed sequence tags (ESTs) and single polynucleotide polymorphisms (SNPs) [1]. The PTO has made this move, in part, in order to quell fears among scientists and clinicians that its policies could hamper the progress of science and medicine by allowing market forces to impede access to genetic data used in research and development (R&D). While many researchers have welcomed this change in policy, it will take more than new regulations to promote the optimal use of genetic data in science, medicine, and industry.

In reviewing patent applications on specific items (products, processes, or techniques), the PTO examines four criteria: ingenuity (the item is a human invention), originality (the item has not been previously patented or described in a public document), non-obviousness (the item is not obvious to a person trained in the relevant art), and usefulness (the item has some practical or scientific use) [2]. Since 1976, the PTO has awarded thousands of patents on the basis of these criteria, and last year it received nearly 3,000 patent applications for genes or genome markers [1].

To date, much of the backlash against gene patenting has focused on the first criteria, ingenuity. Many commentators and religious leaders have argued that genes are products of nature and therefore should not be patented [3],[4]. In response to these concerns, the PTO has ruled that genes are chemicals that can be isolated and purified. Although naturally occurring genes are a part of nature, modified or cloned genes are human inventions [2].

The latest controversy concerning gene patents involves interpretation of the "usefulness" criteria and the scope of patents. Many people in the research community are concerned that a loose interpretation of usefulness will allow individuals or corporations to patent genes or genome markers even when they do not know their specific functions in organisms. Others are concerned that a patent on a gene marker could give the patent holder control of the whole gene. If this type of patenting occurs, it could result in the under-utilization of genetic information due to multiple, overlapping patents, unreasonable licensing fees, the hoarding of genetic data, and "blocking" patents [5],[6],[7]. In addition, some scientists have complained that current policies award patents for very little work or effort [8].

To prevent these undesirable consequences, the PTO is planning to tighten the utility requirement for gene patents by requiring that applicants for gene patents to produce evidence that the DNA sequences they plan to patent have a utility that is specific, substantial, and credible [9]. This new policy is designed to prevent individuals or corporations from obtaining a patent on a gene when they have not identified any specific functions for the gene, but it would allow patents on genes or gene markers that are used in specific clinical or scientific applications, such as genetic diagnosis, drug development, or functional and comparative genomics. The PTO is also addressing concerns about the scope of patents. Under the new policy, a patent on single EST will not give the patent holder control of the whole gene [9].

Although some researchers are concerned that these new policies do not raise the gene patenting bar high enough, others have welcomed this change in PTO policy. So far industry representatives have not voiced strong objections to these new policies and some have said the changes will not affect their pending patents [1]. While there is nothing wrong with changing PTO policies in order promote scientific innovation and medical progress, more is needed than a change in PTO policy in order to deal with most of these perennial patenting issues.

Consider the problem of multiple, overlapping patents. The concern here is that gene patenting will allow many different companies to own patents with competing and overlaying claims. For instance, several different companies, agencies, or individuals might own patents on ESTs for the same gene. To use that gene in R&D, a researcher might have to negotiate licensing agreements with many different individuals, agencies, or corporations. This kind of administrative, financial, and legal nightmare would be a significant deterrent to genetic R&D [5].

The PTO's new policies address this problem but they do not solve it. If it is more difficult to obtain a patent, then there will be fewer patents and there will therefore be fewer overlapping patents. If EST patents do not give patent holders control of the whole gene, then EST patents will not overlap. However, no matter how difficult the government makes it to obtain a gene patent or how much the it narrows the scope of the patent, the possibility of multiple, overlapping patents will always exist. The problem arises because researchers often need to use thousands of different genes or gene markers in order in to conduct genetic R&D and many different parties may own patents on these items.

To prevent this problem from occurring, scientists, corporations, and government agencies must find ways of sharing genetic information for their mutual benefit. Since all individuals, agencies, and corporations may face this kind of problem in biotech R&D, they should realize that it is in their interests to develop cooperative arrangements in order to obtain access to genetic data and use genes in R&D [10]. Since a single patent infringement suite can cost both parties several million dollars, patent holders have strong economic reasons to avoid a patent "war." In fact, we are already seeing some signs of cooperation in genetic research. Many companies have developed reach through licensing agreements that provide downstream users with access to upstream research tools and data [5].

Other cooperative arrangements are also taking place. Recently, ten large pharmaceutical companies and a British charity have already reached an agreement to create free and open SNP archive [11]. This endeavor is not purely altruistic, since these companies are creating the public database in order to avoid purchasing multiple data collections from private firms. Maverick geneticist and president of Celera Genomics J. Craig Venter has promised to "give away" the DNA sequence of the human genome after his company finishes its sequencing project. Venter plans to make money from this endeavor by patenting genes and SNPs with therapeutic and diagnostic uses and by selling information services. Instead of hoarding data, his company plans to sell data at a

reasonable price. Other companies, such as Incyte Pharmaceuticals, are pursuing a similar strategy [12].

It should also be mentioned, of course, that private companies are not the only organizations interested in gene patenting. Publicly funded agencies, such as the National Institutes of Health (NIH), have also applied for patents on genes with specific diagnostic or therapeutic uses. However, these agencies treat genetic information as a public good and they intend to make genetic data free and open to the public [2]. Moreover, the publicly funded Human Genome Project (HGP) will provide researchers with a free and open genetic database. Since the HGP's database constitutes a form of public disclosure, it may undercut thousands of potential gene patents when completed.

The PTO's new rules also do not address the problem of excessive licensing fees. Some commentators have expressed the worry that licensing fees on upstream patented genes will be a significant economic deterrent to downstream genetic research.[5] For example, a company that owns patents on SNPs might charge a high fee every time a researcher wants to use them to develop a method of genetic diagnosis. Alternatively, the company might have a reasonable licensing fee but demand an unreasonable share of royalties. These high costs of using genetic information could adversely affect scientific innovation and medical diagnosis and therapy [6]. Clinicians have complained that Myriad Genetics is charging excessive licensing fees for use of BRCA1 and BRCA2 cancer genes in genetic research and diagnosis [8].

Market forces may solve the problem of excessive licensing fees. As long as the consumers of genetic information can choose the genes or gene markers that they wish to use, companies that charge excessive fees will lose business. If these companies want to turn a profit, they will lower their fees, and the market will set a reasonable price. However, there may be some genes or gene markers that are controlled by one company and are absolutely essential to research or therapy. Such a company, such as Myriad Genetics, would have a monopoly and would be impervious to market controls. When this situation arises, some regulation of the market may be required in order to set reasonable licensing fees [13].

Once again, the new rules do not address the problem of licensing fees directly. The possibility of unreasonable licensing fees will exist as long as companies have the power to evade market controls. To prevent this problem from occurring, the government may need to regulate the market to prevent monopolistic control of genetic information. Since the PTO does not have the authority control licensing fees, the Interstate Commerce Commission, the Federal Trade Commission, or Congress would need to address this issue.

Concerning "blocking" patents and the hoarding of genetic data, some commentators have worried that companies might develop gene patents in order to prevent other companies from using genetic information and to gain a competitive advantage. These companies would apply for patents with no intention of ever licensing their inventions or sharing data. This exclusionary practices, which occur in many industries, undermines the whole rationale for patent protection. One of the main reasons why the government grants patents is to encourage individuals and corporations to share their research findings and inventions.

Although some exclusionary patenting could occur in the context of genetic research, it is not likely to be widespread. Most companies who are patenting genes hope to make money from the genetic revolution; they have strong economic interests in developing their products in order to obtain licensing fees or to sell information services. Companies that use patents simply to prevent other competitors from using genes or gaining access to genetic information obtain no money from gene patenting. Thus, market forces could play a important role in curbing exclusionary practices.

Once again, this is an issue that the new PTO policies do not address directly. Companies will always be able to subvert the patent system in this manner, no matter how difficult the government makes it to obtain a patent or how much the government restricts the scope of patents. The key to preventing this problem is to provide companies with sufficient incentives to make their products available on the market. If the market fails to control these exclusionary practices, some additional regulations may be required in order to require patent holders to develop their products and make them available [7], [13].

Finally, the new polices do address the complaint that an individual or a company could obtain a patent with very little work or effort. By requiring patent applicants to demonstrate that a gene or gene marker has a utility that is specific, substantial, and credible, the PTO will encourage researchers to do more work in order to meet the utility requirement. However, it may still be relatively "easy" to demonstrate utility under these new rules, since routine searches for DNA homologies may provide sufficient proof of specific and substantial utility.

In any case, this complaint goes far beyond the current debate about gene patenting, since the patent system is designed to reward inventors for their ingenuity, not for their effort. Many people have work for years on inventions only to have someone else win the race for the patent. That's how the patent system works: to the victor go the spoils. One might argue that the entire system is unfair, of course, but this objection applies to all forms of patenting, not just to gene patenting.

In sum, while it may be a good idea to "raise the bar" on gene patents, this new PTO policy is little more than a temporary and limited solution to some of the difficult economic, legal, scientific, and medical issues relating to gene patents. To address these issues, biomedical researchers, government agencies, clinicians, and private corporations need to continue an open dialogue with each other and with the public. Hopefully, society will be able to develop an approach to gene patenting that encourages investment in genetic research but does not hamper progress in science and medicine [14]. The new PTO guidelines are a step in the right direction, but much more work still need to be done.

Notes and References

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