

The Logistics and Business Behind Gene Patenting



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WHEN A PATENT IS ISSUED FOR A NEW INVENTION, THE INVENTOR ESSENTIALLY RECEIVES A MONOPOLY OVER ITS USE FOR A CERTAIN AMOUNT OF TIME, SUCH THAT ALL WHO WISH TO USE THE INVENTION MAY BE CHARGED A FEE OR EVEN DENIED PERMISSION TO USE IT. ALTHOUGH THIS SEEMS APPROPRIATE AT FIRST, WHAT HAPPENS WHEN THE SCOPE OF PATENTS BROADEN TO INCLUDE PARTS OF THE HUMAN BODY? OVER THE PAST DECADES, PATENTS HAVE CLAIMED APPROXIMATELY ONE FIFTH OF THE ENTIRE HUMAN GENOME AND HAVE SPARKED CONSIDERABLE CONTROVERSY. THE FOLLOWING ARTICLE EXPLORES ARGUMENTS BOTH FOR AND AGAINST THE PATENTING OF GENES.

Based on a 2005 report, approximately 20% of the human genome has been claimed as intellectual property in the United States. This figure accounts for 4382 of the 23,688 genes in the National Centre for Biotechnology Information (NCBI) gene database.

Amongst the top ten gene patent owners, nine are based in the United States, including the University of California, Human Genome Sciences and Intycyte Genomics.

Many genes have been claimed in multiple patents. The BMP7 gene coding for an osteogenic factor and the CDKN2A tumour suppressor gene have been claimed in 20 patents.

- Jensen & Murray, 2005

INTRODUCTION TO GENE PATENTING

Since the 1980s, ownership of the human genome has increased. Entire genes, gene fragments, and even non-coding regions of the human genome have been patented (Nicol, 2005). According to patent laws, genes are patentable if they are: 1) appropriate subject matter, 2) novel, 3) non-obvious, and 4) have

demonstrable utility (Nicol, 2005).

Genes are appropriate for patenting because they are not a "product of nature". The genes are substantially different from their naturally occurring counterparts

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because they are purified, isolated, and lack intron sequences. The third requirement is fulfilled because patent laws do not differentiate between the complexity or simplicity of the method used to discover a gene (Bendekgey & Hamlet-Cox, 2002). The utility of a gene is determined in part by its function. The current method to determine a gene's function - through homology tests with sequenced genes - is only accurate 4

out of 5 times. However, this method is sufficient under current patent law (Grisham, 2000).

Thus, genomic companies, universities, or hospitals are able to patent genes, thereby excluding others from using them for approximately 20 years. During this time, marketing gene-derived products, charging licensing fees and collecting royalties from licensed users generate financial profit.

The majority of gene patents claim genes either as research tools or as diagnostic tools (Thomas et. al, 2002). Thus, the ethical issues of owning human DNA notwithstanding, many see gene patenting as not conducive and even restrictive for research and patient care. The following article examines arguments both for and against gene patenting with regard to these issues.

GENES AS RESEARCH TOOLS

The use of genes as research tools is the leading reason for filing a gene patent (Thomas et. al, 2002). Its repercussions have precipitated considerable debate regarding scientific research and development.

Points of Criticism

Research and development are inhibited because gene patents create the “anticommons” effect, where multiple patentees have the right to exclude others from research on a particular DNA sequence (Heller & Eisenberg, 1998). To this end, some genomic firms have patented thousands of Expressed Sequence Tags (ESTs) - short fragments of DNA useful for identifying genes within a chromosome. They have also privatized their EST databases, making them inaccessible to most academic institutions (Eisenberg, 2002). Given the competitive nature of research and development in genomics, this is evidence of the increasingly fragmented ownership of many patented genes. In this case, research and financial gain are limited to the patentee.

The anticommons effect also creates the problem of reach-through agreements, which complicates and raises the cost of research. Reach-through agreements are demands for royalties or licenses for future use of the patented gene. Mandatory royalty payments and possible future uncertainties are major deterrents for purchasing a license, thus limiting research on patented genes (Eisenberg, 2002). These disincentives are compounded when there are multiple patent holders on a single gene. According to one study, about a quarter of all patented genes have multiple rights holders (Eisenberg, 2002). The BRCA1 gene, which is linked to early onset breast cancer, is subject to 14 different patents held by 12 separate patentees (Eisenberg, 2002). Any research performed on genes with such fragmented ownership will incur hefty fees from “royalty stacking” – paying a gene’s multiple owners for use of the gene. Repercussions include a decreased incentive to verify and investigate new findings and extended applications.

Last, critics fear that gene patents break the longstanding traditions of open science. In the past, information has been disseminated to benefit other researchers. Patents, however, prohibit other researchers from accessing findings, creating an environment that is counter-productive to the advancement of science.

Points of Approval

Some believe that gene patents may promote innovation. Patents constitute the right to exclude other parties from benefiting financially from the invention or discovery made, thereby granting the patentee market exclusivity. This is an incentive for innovation and discovery. In fact, the rapid growth of the American biotechnology industry in the 1980s and 1990s is attributed to the incentive patents provided for research (Klein, 2007). Without the security of patent

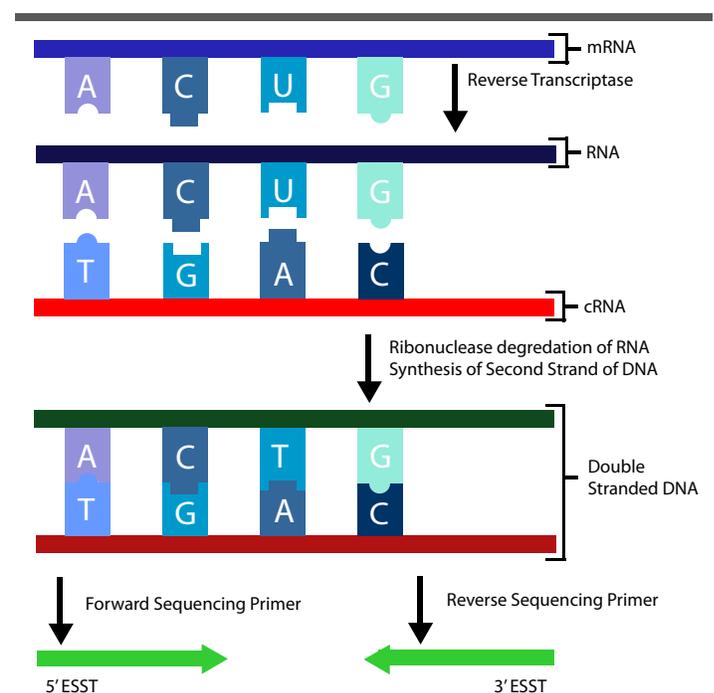
protection, investors will not be willing to provide research firms with necessary funding. This particular outcome would slow the development of gene research tools to the detriment of the greater scientific community (Bendekgey & Hamlet-Cox, 2002).

Second, proponents of gene patenting believe that patent laws should not discriminate against certain types of inventions. As long as an invention satisfies all patent criteria, it should be patentable. It is not the patenting of genes that creates problems for research, but rather the misuse of patent rights. One suggested method for addressing this problem is to rescind or amend the Bayh-Dole Act (Bendekgey & Hamlet-Cox, 2002). This law allows universities to patent inventions funded by federal research grants; however, they are not exclusively in the business of making profit off scientific developments. Hence, universities should provide non-exclusive patents.

The strongest argument may be that there is a lack of evidence that patenting genes inhibits research progress (Bendekgey & Hamlet-Cox, 2002). Many of the arguments against patenting genes are speculative. Without concrete evidence that gene patents are counter-productive for research, gene patents should continue to be granted.

PATENTING GENES AS DIAGNOSTIC TOOLS

Genes with diagnostic utility are the second most common type of patented genes (Thomas et al, 2002). This raises



Test requiring expressed sequence tags (production shown above) may potentially be abandoned by laboratories due to patent disputes.

separate and distinct issues compared to those raised by patenting genes as research tools.

Points of Criticism

Patents on genes as diagnostic tools grant the patentee a monopoly over all methods of testing for a specific disease. This hinders the functioning of clinical laboratories, which are faced with a limited number of options. They would have to acquire a license and pay any up-front fees and royalties that the license entails. Royalties can range from \$2 to \$20 per test (Merz & Cho, 2005). This can increase the cost of

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testing services preventing some patients from accessing potentially vital information. Another option for clinical laboratories is to send samples off to commercial laboratories owned by patentees and their specified licensees for testing. Pathologists are thereby prevented from performing tests themselves (Leonard, 2002). This severely limits their ability to treat patients, remain updated in current advances, and train residents and fellows (Merz & Cho, 2005). A third option for clinical laboratories is to avoid testing on patented genes by developing in-house tests for different mutations of a disease gene. These tests run the risk of increasing costs and errors (Merz et al, 2002). The final option would be to simply stop offering tests. For example, 30% of surveyed laboratories in the US stopped performing tests for haemochromatosis because of patents (Merz et. al, 2002). This compromises health care quality by reducing patient access to testing services.

Points of Approval

Proponents of gene patenting feel that patents promote disclosure and dissemination of findings in a way that provides the patentee a degree of security. Gene patents also provide security for investors. Without gene patents, there is a lack of monetary support from investors for research that may be considered risky (Bendekgey & Hamlet-Cox, 2002).

Similar to genes patented as research tools, there is little evidence that genes patented for diagnostic use have

compromised healthcare quality. Mertz and Cho (2005) indicate that labs have stopped offering testing services because of patent disputes, but do not provide concrete evidence that this is widespread and pervasive.

Finally, it is easy for patents to be considered negative on the basis of figures and prices. However, it is important to consider gene patents in the context of a profit-centered healthcare system, such as that in the United States (Merz & Cho, 2005). The ability to secure profit in addition to remunerating the cost of research and development is what spurs innovation.

FUTURE DIRECTIONS

Despite the strong arguments for and against gene patenting, it has become a legal reality in many countries, including Canada. What remains is for the legal system and health care industry to adapt to this circumstance. The courts must determine the validity of gene patentees' claims so that they do not have negative consequences. The health care industry would also need to implement policies to maximize the benefits provided by gene patenting and consider the well-being of patients. 

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