PUBLICATION

Human Gene Patents Ruled Invalid

Authors: W. Edward Ramage
March 31, 2010

On Monday, March 29, 2010, the United States District Court for the Southern District of New York issued its opinion invalidating several patents with claims covering genes associated with breast cancer. In a thorough 156-page analysis, Judge Robert Sweet relied on U.S. Supreme Court precedent to determine that the purification of a natural product, without more, could not transform it into patentable subject matter. Since the isolated DNA being claimed was not "markedly different" from native DNA, the patent claims were held to be invalid. This decision, if upheld by the Federal Circuit Court of Appeals or the U.S. Supreme Court, will prevent the U.S. Patent and Trademark Office from issuing similar "gene patents" in the future, and will potentially invalidate similar claims in many existing patents.

Background

The decision in *Association for Molecular Pathology, et al. v. United States Patent and Trademark Office, et al*., No. 09-Civ-4515 (S.D.N.Y.) granted the plaintiffs' motion for summary judgment seeking to invalidate the patents in question. The American Civil Liberties Union and the Public Patent Foundation, a not-for-profit organization, took the lead in filing the lawsuit on behalf of numerous medical professionals and others asserting that several patents on two human genes (BRCA1 and BRCA2) associated with breast and ovarian cancer are unconstitutional and invalid. Named plaintiffs include medical professionals, patents, and an assortment of health care organizations, including the Association for Molecular Pathology, the American College of Medical Genetics, the American Society for Clinical Pathology, the College of American Pathologists, Breast Cancer Action, and the Boston Women's Health Book Collective. The defendants are Myriad Genetics and the University of Utah Research Foundation (UURF), who own or control the patents in question, and the United States Patent and Trademark Office (USPTO) itself.

The patents covering the BRCA1 and BRCA2 genes are not unusual or unique. The USPTO takes the position that genes are chemical compounds, albeit complex ones, and thus qualify for potential patenting as compositions of matter. And while a naturally occurring product as it exists in nature cannot be patented, the USPTO has allowed patents on naturally occurring products that have been purified, isolated, or otherwise altered. As a result, the number of patents in the United States that cover "isolated" or "purified" genes is significant. The National Institute of Health has estimated that around 20% of human genes are patented. These include genes that have been associated with forms of cancer, Alzheimer's, and other diseases. The case was clearly intended to be an attack on this practice.

There are seven patents at issue, with a variety of claims directed to the BRCA1 and BRCA2 genes and certain related methods. Myriad, through ownership, part-ownership, or licensing, holds and controls rights under all seven of the patents. Myriad is the only laboratory in the United States where commercial diagnostic testing can be performed. The patents prevent others from testing these genes or developing alternative tests, which makes it practically impossible for women to use other tests or get an outside second opinion about test results.

The suit attacked both the patentability of human genetic sequences, and at least some form of diagnostic method claims. The patents do not contain claims directed to methods of sequencing genes, and the suit does not attack the patentability of any such techniques.

In a motion for summary judgment, the plaintiffs asserted that the BRCA1 and BRCA2 genes, and their naturally-occurring mutations, are natural phenomena, products of nature, and manifestations of laws of nature, and thus are not patentable subject matter under 35 USC § 101. With regard to the patentability of diagnostic methods, they asserted that claims for any method of looking for naturally-occurring mutations in human genes that does not specify any particular method of analysis is invalid due to indefiniteness, as well as being directed to an unpatentable abstract mental process. Myriad had countered with a cross-motion for summary judgment seeking a declaration that the patent claims were valid. The decision on Monday granted the plaintiffs' motion and denied the defense's cross-motion on validity. (The USPTO's motion for summary judgment on the constitutional issues was granted under the doctrine of constitutional avoidance, which states that courts should not reach unnecessary constitutional questions.)

Gene Patents Invalid as Product of Nature

With regard to the gene claims, the district court started with Section 101 of the Patent Act, which provides that an inventor can obtain a patent for any new and useful process, machine, manufacture, or composition of matter. These broad classifications are not unlimited, however, as the Supreme Court has recognized three categories of unpatentable subject matter: laws or products of nature, physical phenomena, and abstract ideas. While isolated human genes or DNA fall within the general category of composition of matter, the critical point is whether they would be excluded from patentability as products of nature.

Relying on several Supreme Court decisions, the court determined that the appropriate test was whether the invention had "markedly different characteristics" from the natural product (i.e. had a new or distinctive form, quality, or property). Mere purification of a natural material would not make the purified product patentable unless it resulted in properties and characteristics that were different in kind from those of the known product rather than in degree. Using this test, the court then examined the isolated DNA as claimed in the patents, and held that it was not markedly different from native DNA as it exists in nature, and thus was unpatentable.

Method Claims Invalid Under *In re Bilski*

The court then addressed the method or process claims. There were several variations. One claim was for the process of analyzing a BRCA sequence and noting whether or not a naturally-occurring mutation exists. Other claims were directed toward comparing two gene sequences to see if any differences exist. Another claim was directed to comparing the growth rates of cells in the presence or absence of a potential cancer therapeutic.

The court applied the "machine-or-transformation" test from *In re Bilski* to each, and easily determined that the "analysis" and "comparison" method claims did not satisfy either part of the test. The machine-or-transformation test states that a claimed process must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing. The method claims in question were not tied to a particular machine or apparatus, and did not involve any transformation.

It should be noted, however, that the *In re Bilski* case has been appealed to the Supreme Court, and a decision is expected within the next few months. Based on comments by several justices during oral argument, it appears likely that the Supreme Court will uphold the rejection of the *Bilski* method claims, although perhaps using a different rationale or test. Thus, while the rejection of the BRCA method claims in this case may be based on a test that soon may be moot, it is unlikely that the claims would survive whatever test or analysis replaces it.

Impact

This is only Round 1 of the fight. The case undoubtedly will be appealed to the Federal Circuit Court of Appeals, and the losing side there is likely to seek review by the Supreme Court. Given the Supreme Court's recent interest in the area of patentable subject matter (as evidenced by *In re Bilski*), the odds are good that the issue of gene patentability will ultimately be resolved in that arena.

If the decision is upheld on appeal, the USPTO already has indicated that it would conform its patent examination policies to avoid issuing patents directed to isolated DNA, which would prevent applicants from obtaining such patents in the future. Applicants would still be able to get patents directed to genetic material, but would have to show that their claimed invention had "markedly different characteristics" from native DNA. In anticipation of this, applicants with currently pending applications should examine their current claims and consider adding claims to inventions with "markedly different characteristics", if possible. If the decision is upheld, then the chances of having at least some of the claims survive are greatly improved.

A final decision upholding this analysis also would adversely impact a significant number of "gene patents" that have already been issued. However, as there is great variation in the style and scope of claims, not all claims directed to genetic material will be invalid. Thus, it is possible that only some of the claims in a particular patent may be invalid. Each patent claim would have to be analyzed individually to determine whether it was directed to patentable subject matter.

For more information or assistance, please contact your Baker Donelson attorney or any of the attorneys in Baker Donelson's Intellectual Property group.