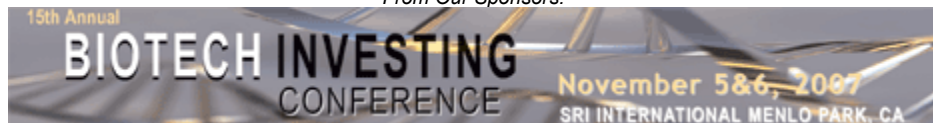


BIO WORLD® PERSPECTIVES

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Banning Gene Patents Can Bring Benefits

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The development of beneficial biotechnology products depends on a clear understanding of the underlying science. Similarly, the application of legal policies to biotechnology requires a clear understanding of the underlying law. Proponents of gene sequence patents often misinterpret law and policy which support the position that sequences should not be patentable and instead should be available to all researchers.

Incentives For Research?

A common argument is that without patents for genetic sequences, there would be no motivation or incentives to research. This is not the case. Scientists have long been searching for disease-causing genes and genetic mutations. When biologists began the Human Genome Project, they had no idea they would be able to patent genes. They were seeking academic advancement, Nobel Prizes and professional status.

Proponents of gene patents also say that the sequences of BRCA1 and BRCA2 would not have been identified without the lure of patent protection. However, in the early 1990s, an international consortium was sequencing BRCA1 in an effort to make the information publicly available to all researchers and drug developers. A University of Utah researcher split from the consortium and filed a patent on the sequence and mutations, claiming them as his own invention. His company, Myriad Genetics Inc., now charges women \$3,000 for the use of that sequence in diagnosis and is the exclusive provider of testing services in the U.S., a right afforded by the patent. No other provider can look at the sequence of the gene, even if that provider could offer a more efficient and comprehensive way of analyzing the breast cancer genes for mutations. (Studies have shown that the Myriad test actually misses 12 percent of the mutations in high risk patients. ¹)

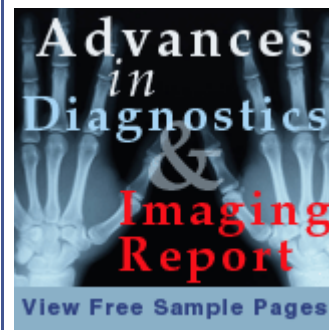
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Supreme Court Rulings

Another problematic argument that is made by proponents of gene patents is that U.S. Supreme Court precedent supports the issuance of patents for genetic sequences. To the contrary, in a series of cases over the past 150 years, the Supreme Court has held that one cannot patent products of nature, or materials isolated from products of nature, if those materials behave in the same way they would in nature. Gene patent proponents try to dilute that strong precedent by referring to the 1980 case *Diamond v. Chakrabarty*.² However, that case provides no basis for asserting that an isolated gene sequence is patentable; it involved a man-made (genetically engineered) bacterium, which the court carefully described as **not** naturally occurring. The court stated:

The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . . . Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."³

Some commentators take out of context a line from a 1952 Senate report (referred to in the *Chakrabarty* case) that said one could patent "[a]nything under the sun made by man." The report says that "[a] person may have 'invented' a **machine or manufacture**, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101, unless the conditions of the title are fulfilled."⁴ A gene sequence is not a machine or manufacture so it would not fall within this phrase. The sentence actually **limits** what can be patented, saying the patent holder must comply with Section 101, which the Supreme Court has held prohibits patents on products of nature and laws of nature.

USPTO Policy

Gene patent proponents also argue that because the U.S. Patent and Trademark Office (USPTO) has granted gene patents, those patents must be valid. However, the USPTO policy to grant patents for naturally occurring human nucleotide sequences, including full-length gene sequences, gene mutations and fragments of genetic material, was not made by Congress, and has not been upheld by the courts. The fact that the USPTO has adopted this policy does not mean that the policy correctly interprets the patent law as codified in the U.S. Code.

The USPTO, the courts and Congress all have active roles in assuring that the goals of the patent system are met and that the monopoly granted is not too broad. Often this means that the courts and Congress winnow back patents erroneously granted by the USPTO. In fact, almost half of all patents that are challenged are found invalid during litigation.⁵ In the past, the head of the USPTO has invalidated provisions of improperly granted patents, such as claims on certain computer programs. Congress also has created exceptions to patent law, for example, by exempting doctors from patent infringement liability if they use a patented medical or surgical procedure.⁶

Interpretation And Innovation

The Supreme Court recently has begun to review more patent cases and has indicated that, in a variety of fields, the USPTO and Federal Circuit have incorrectly interpreted patent law. In 2007, the Supreme Court issued a ruling that changed the way patent examiners determine whether a patent is obvious under 35 U.S.C. 103(a).⁷ Last year, Justices Stephen Breyer, John Paul Stevens and David Souter pointed out that not all patents encourage innovation. In particular, patents on products of nature



and laws of nature are improper. They stated that:

The justification for the principle does not lie in any claim that "laws of nature" are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than "promote the Progress of Science and useful Arts," the constitutional objective of patent and copyright protection.⁸

It is likely that if the Supreme Court were to directly address the issue of patents on genetic sequences based on the question of whether they are products of nature, it would declare specific claims of those patents invalid. It is only a matter of time before such a case reaches the U.S. Supreme Court.

Benefits To Both Public And Industry

Invalidate patents on gene sequences will be good for the public (who are, after all, the intended beneficiaries of patents). Patents are not needed for the discovery of genetic sequences. They often lead to increased costs for genetic testing and interfere with the development of superior technology.

In the end, a ban on patents on gene sequences, whether it comes from the U.S. Supreme Court or from Congress through a bill like HR 977, would not only comply with the legal underpinnings of patent law, but would also benefit industry and spur the development of technology. Increasingly, drug companies want to be able to use single nucleotide polymorphisms and sequences in drug target research without risking infringing dozens of patents. Companies that produce chips and systems for DNA testing oppose the patenting of genes because their technology — which makes it feasible to test for thousand of genes with a single chip — is not commercially viable if the royalty for use of each gene sequence is in the thousands of dollars. Thus, the law, the public and the market all have a reason to stand firm against gene patents.

Notes:

1. See Roxanne Khamsi, "U.S. tests may miss 'breast cancer genes,'" *New Scientist*, March 22, 2006.
2. 447 U.S. 303 (1980).
3. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), citing *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).
4. Senate Report No. 1979, 82d Cong., 2d Sess. (1952). [emphasis added]
5. John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 26 *The American Intellectual Property Law Association Quarterly Journal*, 185, 205-206 (1998) (46 percent of patents litigated to judgment on validity issues are held invalid).
6. 35 U.S.C § 287(c).
7. *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007).
8. *LabCorp v. Metabolite Laboratories, Inc.*, 126 S. Ct. 2921, 2922 (2006).

Editor's note: Readers may be interested in an earlier discussion on the patentability of genes, from the May 3 issue of BioWorld Perspectives - [click here to read that story.](#)