

United States

Gene patents under attack

Recently patent owners and applicants have run into stormy waters in the United States. *KSR v Teleflex* lowered the bar on finding obviousness, leading to a significant number of patents being invalidated and applications rejected on this ground. Business method patents were curtailed in 2009 by the new ‘machine-or-transformation’ test announced in *In re Bilski* and face additional uncertainty over the next year while the patent community waits to see how the Supreme Court rules on the appeal. Patent allowance rates in the United States are the lowest in decades (42 per cent for the first quarter of 2009). The perception of many in the patent community is that the US Patent and Trademark Office (USPTO) has become ‘anti-patent’. In fact, in August 2009 new USPTO Director David Kappos sent an internal email that appeared to focus on shifting examiners away from the mindset that “rejection equals quality”.

Against this background, it is no surprise that the public policy discussion concerning the ethical, legal and economic issues of gene patenting has made its way to court. On May 12 2009 the American Civil Liberties Union and the Public Patent Foundation, a not-for-profit organisation, took the lead in filing a lawsuit on behalf of numerous medical professionals and others in the US District Court for the Southern District of New York. The suit, *Association for Molecular Pathology v United States Patent and Trademark Office*, asserts that several patents on two human genes associated with breast and ovarian cancer (BRCA1 and BRCA2) are unconstitutional and invalid.

The plaintiffs include medical professionals, patients and an assortment of healthcare organisations, 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 include Myriad Genetics and the University of Utah Research Foundation, which

exclusively license or own the patents in question, and the USPTO itself. The circumstances indicate that the plaintiffs intend to pursue the case as an attack on gene patents in general, and that it may ultimately end up before the Supreme Court.

The BRCA patents

The plaintiffs have chosen a sympathetic vehicle to challenge the patentability of human genes. In the United States, more than 40,000 women a year die from breast cancer and about one in eight women will develop it at some point. Mutations in the BRCA1 and BRCA2 genes are associated with an increased risk of breast cancer, as well as ovarian cancer. Myriad Genetics owns the patents and is the only laboratory in the United States where diagnostic testing can be performed. The patents prevent others from testing these genes or developing alternative tests, which makes it impossible for women to use other tests or obtain an external second opinion regarding test results. Moreover, the tests are expensive – Myriad charges a relatively high rate (over \$3,000) for the tests, which places them out of the reach of many.

The plaintiffs include a number of sympathetic individuals, including patients and medical professionals. Based upon court pleadings, one patient was unable to obtain a second opinion on her test, while another could not get Medicaid to cover the cost of the test. Another patient submitted a blood sample to Myriad which her insurance company informed her it would cover, but Myriad allegedly would not accept that particular insurance coverage.

The suit attacks both the patentability of human genetic sequences and at least some form of diagnostic method claims. With regard to the first, it asserts 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 second, it asserts that claims for any

method of looking for naturally occurring mutations in human genes that fails to specify a particular method of analysis is invalid due to indefiniteness under 35 USC § 101, as well as being directed to an unpatentable abstract mental process.

Significant hurdles

The plaintiffs must overcome various significant hurdles. The first obstacle is procedural. None of the plaintiffs have themselves been sued for infringement by Myriad, although several assert that they have received cease-and-desist letters and have a reasonable fear of being sued. The case is a declaratory judgment action and thus the constitutional requirement of standing could lead to a dismissal of the case without a decision on the merits. In fact, the USPTO, Myriad Genetics and the University of Utah Research Foundation have filed motions to dismiss on a variety of issues, including standing. At the time of writing, those motions have not yet been resolved.

Second, there are nearly three decades of USPTO and court precedent, beginning in *Diamond v Chakrabarty* (1980), finding that genes are patentable subject matter. In *Chakrabarty* the Supreme Court held that a live, human-made micro-organism (a bacterium genetically engineered to break down crude oil) was patentable subject matter. Since that time, the USPTO and the courts have determined 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, patents have been allowed on a naturally occurring product that has been purified, isolated or otherwise altered. Accordingly, the USPTO has been granting patents for genes that have been isolated, purified or modified from their natural state.

The number of patents in the United States that cover genes is significant. The National Institute of Health has estimated that around 20 per cent of human genes are patented. These include genes that have been associated with forms of cancer, Alzheimer's and other diseases.

The plaintiffs' attack on this practice is straightforward. The Supreme Court has not considered the patentability of human genes *per se*, and they argue that, in fact, its precedents support the conclusion that genes, and natural mutations of genes, are not patentable subject matter, even when isolated or removed from the human body. They point to several Supreme Court decisions from as early as 1874 establishing that merely extracting, purifying or changing a natural product does not render that product patentable, unless a

fundamentally new product is created. Thus, simply removing a gene from the human body or purifying it does not render it potentially patentable. In addition, they note that *Chakrabarty* correctly recognised the patentability of a genetically engineered bacterium with markedly different characteristics from any found in nature, and thus does not support the patentability of genes *per se*.

The plaintiffs may have more success with their attacks on the diagnostic method claims, particularly those that appear to be based on making correlations (eg, making a correlation between any alteration in the BRCA2 sequence and a predisposition for breast cancer). Several recent court decisions indicate that methods which are based on correlations or comparisons, or on simple human thought, are not patentable or can be attacked on similar grounds. For example, in *In re Fisher* (2005) the US Court of Appeals for the Federal Circuit rejected claims to expressed sequence tags (gene fragments) based on lack of enablement and utility. In December 2008 the Federal Circuit in *Classen v Biogen* cited *In re Bilski* in summarily invalidating patent claims involving the correlation between vaccination schedules and the incidence of immune mediated disorders. More recently, Justice Breyer of the Supreme Court articulated his concern about 'thought' claims in his dissenting opinion in *Laboratory Corp v Metabolite Labs* (2006), where the petition for *certiorari* was dismissed as improvidently granted because the issue of patentability had not been raised by the petitioner at an earlier stage. Justice Breyer noted that even when a claim in issue was framed as a process with discrete testing and correlating steps, the process simply "instructs the user to (1) obtain test results and (2) think about them". These cases, among others, signal that patenting certain types of genetic diagnostic method and test in the United States may be more difficult in the future.

Motion for summary judgment

Since the *Association for Molecular Pathology Case* was filed in May 2009 it has not languished. In addition to the motions to dismiss filed by the USPTO, Myriad and the University of Utah Research Foundation, the plaintiffs launched a counterattack in August 2009 by moving for summary judgment on the critical issues. The motion argues that human genetic sequences and the scientific enquiry of looking at a gene or comparing two genes constitute natural phenomena, laws of nature and abstract ideas, and thus are not patentable. It adds an interesting twist by further asserting that the claims are unconstitutional under the First Amendment, as the patents directly limit the free expression of thought and

knowledge. Finally, the plaintiffs argue that the patent claims are invalid under Article 1, Section 8, Clause 8 of the Constitution (the IP clause) because they retard and impede, rather than advance, the progress of knowledge.

A number of *amicus* briefs in support of the plaintiffs' motion have been filed. Support has come from the American Medical Association, the American Society of Human Genetics, the American College of Obstetricians and Gynecologists, the American College of Embryology, the Medical Society of the State of New York, the March of Dimes Foundations and the National Women's Health Network, among others.

At the time of writing, the defendants had not yet had the opportunity to file a response to the motion for summary judgment. Supporters of the patentability of genes are also expected to weigh in with their own *amicus* briefs. A hearing on the motions to dismiss was held on September 30 2009 and a ruling will already have been made by the time of publication. While the plaintiffs are unlikely to prevail at this stage, the case will undoubtedly be taken on appeal to the Federal Circuit, with an eye on ultimate resolution by the Supreme Court. Thus, the case has the potential to

impact on the biotechnology industry substantially by invalidating many existing patents.

Beyond that, however, the case is likely to bring additional publicity and awareness to the rather esoteric issue of gene patentability. Gene patenting is also subject to attack through legislative action. In February 2007 a bill entitled the Genomic Research and Accessibility Act was introduced that would end the patenting of any portion of the human genome. However, it would not affect already issued patents. While that bill has not advanced, it or others like it could simply be waiting for the right push. And that push may come from the *Association for Molecular Pathology Case*. Even if the case ultimately fails, it has been suggested that it can be used by opponents of gene patenting to create or emphasise a negative image of biotechnology companies as money-hungry monopolists using the patent system to reap a profit from the common man or woman, and potentially even exclude them from medical care. This form of attack may be particularly dangerous for the biotechnology industry, given the current movement in Congress towards healthcare access and reform and the focus on the reduction of medical costs.



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