

Myriad Gene Patent Litigation Goes Down Under

by John Conley

On Tuesday, June 9, 2010, several plaintiffs, including a breast cancer patient and a cancer advocacy group, [sued in a Sydney, Australia federal court to invalidate Myriad Genetics' patents](#) on the breast cancer susceptibility genes BRCA-1 and 2. According to published reports and comments by Australian patent law experts, the suit substantially tracks the [much-publicized one filed in New York by the American Civil Liberties Union](#). In particular, this suit is also [a frontal attack](#) on the Myriad patents, seeking a judgment that genes in isolation from the body are products of nature and thus not patentable inventions.

The factual background in Australia seems a bit different. Myriad has granted an exclusive license to perform BRCA gene tests to a Melbourne company called [Genetic Technologies Limited](#), which is a co-defendant in the case. But GTL has been reported to have “gifted” its patent rights to health care institutions, and not to charge royalties. Nonetheless, the plaintiffs’ lawyers have expressed concern about the possibility of GTL exploiting their monopoly as in the U.S., where the tests cost over \$3,000. They note that on two earlier occasions GTL sent letters to hospitals telling them to stop testing. A number of Australian sources have also worried aloud about the implications of the patents for medical research.

In a technical sense, the case will have no direct effects outside of Australia. The general principle of international patent law is “non-extraterritoriality”—a jaw-breaker that means simply that a patent is enforceable only within the boundaries of the country that issues it. So even if the Australian courts ultimately invalidate the Myriad patents, that will not affect their status anywhere else. Plaintiffs who want to challenge the patents will have to do so country-by-country.

But as is so often the case with legal issues (fortunately for lawyers, and unfortunately for their clients), the situation is more complicated on a practical level. First, there is a partial exception to the country-by-country rule: the [European Patent Office](#) in Munich. There is still no such thing as a true “European patent” (the European Union has been working on it for years), but the EPO will examine applications under a single standard for patentability (established by a treaty called the [European Patent Convention](#)) and issue what it calls a “bundle” of national patents. That is, you can designate the countries in which you want your patent to be effective—say the U.K., France, and Germany—and the EPO can issue you a bundle containing a British, a French, and a German patent. Although you have to go to the individual countries to sue infringers, some challenges to the patent can be brought in the EPO. The Myriad patents have a long and complex history in the EPO, [with the net result that they have a narrower scope than in the U.S.](#)

A second point is that the Australian court system is well-regarded throughout the world, so a decision against the patents there could influence courts facing the same issue elsewhere—even though it wouldn’t bind them. Even the U.S. Supreme Court, which has long paid little or no attention to foreign precedent, has been citing foreign legal authorities more frequently in recent years.

The final point relates to the potential business strategy of competitors of companies like Myriad. Assume that a U.S. company wants to include genes patented by others (Myriad or someone else) in a broad-based diagnostic testing program. One approach would be to seek a license from the patent-holder. But there is an alternative: do the testing in a country that doesn’t recognize the patent. U.S. patent law (like that of almost every country) forbids [making, using, or selling the patented invention within the U.S.](#) There are some circumstances in which U.S. law can reach foreign activities (such as when the infringer sells parts of the invention from the U.S. to be assembled abroad), but under the present state of the law it would probably not be infringement to test patented genes abroad and send the results back to the U.S. The more countries that invalidate the patent, the more places there are to execute this strategy.

So the new Australian case will be, at a minimum, a chance for that country to engage in a public debate over the wisdom and legality of patenting genes—which is exactly what is happening in the United States as a result of the ACLU litigation. But in the long term it could serve to undercut the practical value of gene patents everywhere.