

Myriad, Prometheus Pushing Life Sciences Cos. To Licensing

By Erin Coe

Law360, San Diego (June 03, 2014, 4:40 PM ET) -- The U.S. Supreme Court's decisions in *Association for Molecular Pathology v. Myriad Genetics* last year and *Mayo v. Prometheus* in 2012 found life sciences patents invalid for claiming laws of nature, rulings that lawyers say have driven life sciences companies to shift from litigation to focus directly on licensing and to try circumventing the decisions by changing how they apply for patents.

In June 2013, the high court held that Myriad's patents on isolated DNA associated with an increased risk of breast cancer covered a law of nature that can't be patented under Section 101 of the Patent Act. Myriad simply uncovered the precise location and genetic sequence of two genes without creating or altering any of the genetic information in the genes, the court found.

The ruling followed its March 2012 decision invalidating Prometheus' blood testing method patents, which transformed blood taken from the body to determine the proper dosage of thiopurine drugs to treat autoimmune diseases, because processes merely reciting laws of nature were unpatentable.

The decisions have rocked the life sciences industry, with the Myriad decision invalidating an estimated 8,000 composition-of-matter patents covering isolated genomic DNA, and with the Prometheus opinion calling into question the validity of a wide array of medical and life sciences patents, especially those directed to drug screening, drug mechanisms of action or diagnostic or treatment methods, according to Kenneth Weatherwax, founding partner of Goldberg Lowenstein & Weatherwax LLP.

As a result, many companies holding these types of life sciences patents have become more reluctant to enforce them in court and instead are actively seeking ways to license the patents, particularly because while the court may have placed a cloud over their validity in the U.S., they remain enforceable abroad, according to lawyers.

"Companies are less confident they can enforce these life sciences patents in litigation, which is why they are going directly to licensing and offering discounted rates from what they would have offered previously," Weatherwax said. "The decisions have eroded the value of their patent portfolios."

While the Supreme Court decisions have undercut life sciences companies' patent rights, they have given more leverage to potential licensees in negotiations over life sciences patent portfolios, according to Jeffrey Mann, head of Morgan Lewis & Bockius LLP's San Francisco intellectual property practice.

"Innovators in this area are seeing a significant diminishment in their rights and ability to protect their

inventions in the U.S., but for innovators that need a license to some sort of platform technology, they are seeing things potentially open up and become more free because the rights of the owners of the platform technology in the U.S. have, at best, become clouded, and at worst, become invalid and unenforceable," he said.

When asking a competitor to take a license to a portfolio with patents that are likely invalid in the U.S., patent holders are trying to center the discussions on the fact that the patents are valid in key markets abroad, like Europe and Asia, according to Mann, who has represented both licensors and potential licensees in negotiations. But making this proposition isn't easy, and licensors are still grappling with the best ways to value such a deal, he said.

"It's a bit awkward telling a potential licensor, 'We don't think the patents are valid in the U.S., but we sure would like to be partners with you outside the U.S.' because it doesn't set up terribly good feelings at the outset," he said. "I'm in negotiations on a few matters right now, and it's still a difficult discussion on which to get clarity."

Mann said he has seen licensees of life science patent portfolios discuss licensing deals where the upfront payment, running royalty rate, minimum royalty rate or a combination of all three is discounted by between 15 to 50 percent from the original asking price, but the discount often depends on other relevant business factors, such as the licensor's experience with the technology or its access to a sales force or distribution network.

Patent holders also are trying to use different license structures to sweeten deals involving life science patent portfolios, such as proposing a low asking price for U.S. patent rights with some sort of bonus the licensee must pay if a court finds the U.S. claims are valid or requiring full value for the U.S. rights, but allowing the licensee to get a partial refund if the patents are invalidated, according to Mann. In addition, some patent owners are going into negotiations after acquiring an opinion of counsel that states its life sciences patents are valid under the high court rulings.

"These are some of the structures we have been discussing with clients to try to deal with the uncertainty by using rational business sense," he said.

The Supreme Court decisions also have had a major impact on the viability of early-stage companies and university spin-outs, according to Steve Lendaris, a partner at Baker Botts LLP. These companies tend to focus on discoveries involving the relationship between genes and certain diseases, while more mature businesses devote resources to researching the applications of the discoveries.

"The challenge for early-stage companies is getting patents through the U.S. Patent and Trademark Office, which has become more conservative in issuing patents in the life sciences space," he said. "It's also challenging for these companies to get money from an investor to get going. In order to do a spin-out, universities generally need to get one or more investors involved, and that's usually predicated on having patents, but nowadays, they are having a harder time attracting the types of patent investors that they were used to seeing."

The obstacles facing early-stage companies end up affecting larger biotechnology and pharmaceutical companies because without the constant growth of entities at the most basic level, it can be tougher for them to find candidate products to build their drug pipeline, he said.

Companies also have started altering their prosecution strategies on life science patent applications

before the USPTO, according to lawyers.

The agency issued guidelines to its examiners in March, giving them detailed examples on how to determine if patent claims are “significantly different” from a natural material, law or phenomenon in light of the Myriad and Prometheus rulings. In April, it said it was already updating its guidelines after receiving comments that voiced concerns with its strict view of the decisions that struck down patents on human DNA.

To get around the Myriad decision, companies have been seeking to cover method and apparatus claims, rather than the composition-of-matter claims that were invalidated by the Supreme Court, according to Weatherwax.

“Myriad may also encourage genome alteration to increase patent eligibility, since the court suggests that genetically modified biologics are patentable,” he said.

However, he noted that genome alteration would be an ironic result, considering that the challengers of the patents in Myriad were activists who were opposed to commercial genetic experimentation.

To circumvent the Prometheus ruling, companies are considering narrowing the scope of the claims to focus on the parts of an invention that are clearly different from a law of nature, according to James Mullen III, managing partner of Morrison & Foerster LLP’s San Diego office.

For instance, if a company tries to claim a diagnostic method that measures a certain protein level in patients’ blood to determine if they might go bald, and the USPTO rejects the attempt to claim a correlation between a high level of the protein and baldness, the applicant could argue that the act of measuring the protein and correlating its level in the blood with baldness is not a law of nature, but an arbitrary discovery deserving of patent protection.

“One could argue that measuring is an inventive act that is done by a human and doesn’t occur in nature,” he said. “If a patent applicant has a more focused application of the technology, it will have a better chance of convincing the USPTO to grant its claims.”

After the Prometheus decision, life scientists are trying to not simply claim the detection of a novel correlation, but to add the step of treatment, such as with a nonspecific drug class, dependent on the outcome of the novel correlation, according to Weatherwax.

“The idea is that if the correlation is new, a treatment based on the correlation is not conventional, and therefore confers patent eligibility under [Prometheus],” he said.

--Editing by Jeremy Barker.