Undeterred by the Supreme Court, Myriad Starts Suing

by John Conley

As soon as the Supreme Court issued its decision in *AMP v. Myriad Genetics*, Myriad issued public statements saying that it had many surviving patents that would perpetuate its BRCA testing monopoly. We may now find out if that's true.

On, July 9 and July 10, 2013, Myriad Genetics filed patent infringement suits against, respectively, Ambry Genetics [pdf] and Gene by Gene [pdf]. Both are relatively small players, and Gene by Gene is better known for ancestry testing. Both suits were filed in Myriad's home court, the U.S. District Court for the District of Utah. Because of their nationwide marketing efforts, Myriad probably won't have a problem asserting jurisdiction over these defendants in Utah. In both cases, Myriad has asked for a preliminary injunction, meaning a pre-trial order that infringement is probably taking place and the defendant must stop what it's doing pending final resolution at trial. On the fastest possible track, a ruling on that PI is probably months away, and a trial a year or more, and a final resolution after appeal a matter of several years.

Both Ambry and Gene by Gene announced BRCA 1 and 2 tests almost immediately after the Supreme Court's decision. The complaints against the two companies are very similar, with slight differences in the patent claims that Myriad is asserting. Myriad has not, of course, sued on the gDNA claims that the Supreme Court threw out, nor on the method claims that were invalidated by the Federal Circuit in the part of the case that the Supreme Court did not review. Instead, Myriad alleges that the defendants' tests will infringe a number of other claims in ten different patents that cover, among other things, cDNA (in stretches as short as 15 nucleotides), primers, and methods for screening mutations and evaluating or diagnosing patients. They are clearly everything-but-the-kitchen-sink complaints. Nonetheless, many of the allegations seem plausible in the limited sense that the claims asserted appear to cover (or "read on," in patent jargon) what the defendants are probably doing or planning to do.

The first question that occurs to me is why these two companies chose to jump right into the market. They had to be aware that Myriad has other patents that would likely read on their testing activities. That leaves three hypotheses: (1) They didn't believe Myriad would sue. (2) They thought that if they showed some willingness to fight, Myriad would back down and settle (that is, license its patents) on acceptable terms. (So far, Ambry has issued a statement promising that it will defend the case "vigorously," but I haven't seen anything from Gene by Gene.) (3) They think that Myriad's patents are vulnerable and are prepared to spend a lot of money to prove that, or otherwise win the case.

Hypothesis (1) is obviously out. (2) and (3) are related: defendants, especially small ones, usually get good settlements only after they make a convincing showing that they will fight and might win—and they rarely can get to that point without spending a lot money in litigation. More on that possibility below.

That leads to the next question: why did Myriad sue these companies? The obvious answer is to tell the market—loudly—that it's not ready to concede its patent-based monopoly on BRCA testing. These two companies, since they made splashy entries moments after the Supreme Court ruled, and might be vulnerable to a war of attrition, presented themselves as ideal targets. They might not present effective defenses, or might cave quickly on terms favorable to Myriad.

What's the downside for Myriad? One issue is the PR hit it will probably take—evil monopolist and all that. But after the Supreme Court case, how much worse could the PR be? Is it bad PR that will hurt the company financially?

The real danger is that many of these patent claims *are* vulnerable, and might be invalidated if either case proceeds to its conclusion. Most would probably survive patentable subject matter scrutiny (the issue in the Supreme Court case), though some might not, including the short cDNA sequences and some of the method claims. But even those that survive the subject matter test would still have to satisfy the more demanding novelty and nonobviousness standards, and many of them might not.

But the bottom line for Myriad was probably that it thought that had no choice but to sue. Myriad had already seen that competitors were acting as if they now could ignore its patents. Its confident, if not bellicose, post-Supreme Court statements had accomplished nothing. The only escalation available was infringement litigation. Faced with a choice between putting its patents at risk by suing and having them ignored, it probably seemed an easy call: use 'em or lose 'em.

It's not clear how it will play out, in either the short or long term. In deciding on the PI the court will first have to assess Myriad's "probability of success on the merits"—that is, whether it would be likely to win at trial. This would have to include a preliminary assessment of the likely validity of the patents. Even if the court were to find for Myriad on probability of success, it would still have to "balance the equities" before enjoining (prohibiting) the defendants' activities before trial. This means weighing the effect on Myriad of denying the injunction against the effect on the defendant of granting it, all the while factoring in the public interest (think needy patients). It's not hard to see that balancing test going against Myriad.

At this very early stage, it appears that a PI might be a tough—but not impossible—sell for Myriad. Beyond that, it's far too early even to speculate, especially since we don't know if the defendants will be willing or able to maintain an all-out defense for the duration.