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A Non-infringing Party Who Had Rejected a License Had Standing to Sue for Declaratory Judgment of Patent Invalidity

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On July 29, 2011, the Court of Appeals for Federal Circuit issued its much-anticipated decision in *Association of Molecular Pathology v. Myriad Genetics, Inc.*. Most of the publicity surrounding that decision naturally focused on the court's holdings on the patentability of isolated DNA molecules and various claims to testing methods. However, the court's resolution of the threshold issue of declaratory judgment jurisdiction also deserves attention. The panel unanimously found that one of the many plaintiffs -- a non-infringing party who had rejected a license more than ten years ago -- had standing to challenge the validity of Myriad's patents. *Slip. Op. at 8*. The panel's reasoning suggests that the result would have been the same if the plaintiff was a current licensee -- which has implications for all patent-holders.

Plaintiffs, an assortment of medical organizations, researchers, genetic counselors, and patients, sued the patent owner, Myriad, in the United States District Court for the Southern District of New York seeking a declaratory judgment that fifteen claims from seven patents were invalid because they covered subject matter not eligible to be patented. Myriad moved to dismiss the case, arguing that the Plaintiffs (none of whom were infringing the patents) lacked standing to sue. The district court disagreed, and the parties moved for summary judgment on the merits of the patentability challenge. The district court again held for Plaintiffs and Myriad appealed the decisions on standing and the merits. *Slip. Op. at 8-24*.

In analyzing the standing issue, the panel applied the totality of the circumstances test announced by the Supreme Court in *MedImmune v. Genentech* to ascertain whether (a) the Plaintiffs had alleged a real and immediate injury, that (b) was fairly traceable to Myriad's enforcement of its patents, and (c) would be likely to be redressed by a favorable decision. *Slip. Op. at 25*. In particular, the panel noted that *MedImmune* requires the Plaintiffs to allege (1) "an affirmative act by the patentee related to the enforcement of his patent rights;" and (2) "meaningful preparation to conduct potentially infringing activity." *Slip. Op. at 26*.

The first prong of that test (an affirmative act by the patentee) weeded out all but three of the plaintiffs -- Drs. Kazazian, Ganguly, and Ostrer -- who each ran a university laboratory and had received cease and desist letters from Myriad. Myriad had demanded royalty payments from the doctors in letters proposing a collaborative license. Although the letters were sent over ten years ago, the panel reasoned that neither the testing technology nor the parties' positions had changed in the interim. In further view of the patentee's enforcement of its patents against similarly situated parties, the panel concluded that these letters were the required affirmative acts. The panel further concluded that only Dr. Ostrer had met the second requirement of meaningful preparation, because he had both the resources and skill to do the allegedly infringing testing, and testified that he would immediately resume such testing if not for the threat of a lawsuit. *Slip. Op. at 30*. The other two doctors, by contrast, merely asserted they would "consider" resuming the testing -- an announcement of "'some day' intentions" which cannot establish standing. However, since one plaintiff had standing (and had pressed all of the claims), the panel moved on to decide the merits portion of the appeal. *Slip Op. p. 35*.

Although the Supreme Court liberalized standing for declaratory judgment claims in *MedImmune* to allow a paying licensee to sue the patentee on a contract theory, it did not address whether that paying licensee would have standing to sue directly for invalidity of the licensed patent claim(s). In the *Myriad* opinion, the panel interpreted *MedImmune* to permit a non-infringing party who rejected a license (becoming a customer instead of a competitor) to seek a declaratory judgment of invalidity, and the court's reasoning might well apply equally to current, paying licensees who become dissatisfied. While refusing to define the outer boundary of declaratory judgment standing, the Federal Circuit did emphasize that it would strictly apply the *MedImmune standard*, and that standing "will not

arise merely on the basis that a party learns of the existence of an adversely held patent, or even perceives that such a patent poses a risk of infringement." *Slip Op. at 28*. Even without further review from the *en banc* Federal Circuit or the Supreme Court, such scrutiny should offer a ray of hope to patent holders.