The *Myriad* Litigation & Patentability of Isolated DNA: One Year On

Jeremy J. Cobb, Esq.[1]

This article discusses recent trends in patent practice subsequent to the United States Supreme Court's June 2013 decision in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), relating to the patentability of isolated DNA pursuant to 35 U.S.C. § 101 (2012).[2]

THE *MYRIAD* DECISION

Myriad is an important case for, dare one say, myriad reasons. In an environment in which patents are routinely granted for molecules, the Court stepped in to draw the line at patenting of isolated DNA sequences. In customary analytical brevity, the Court incisively dispatched confusion, disagreement, and apparent complexity like so much clutter. It identified core issues and revisited first principals without undue explication. What took three opinions by a divided Federal Circuit panel took just one unanimous opinion (and an odd three-sentence concurring opinion) to explain. Of course, it is widely understood that the Court ruled against the patentability of isolated DNA sequences as products of nature—although the Court did not use that language in its holding—but in favor of the patentability of complementary DNA, cDNA. But in dicta, the Court also dealt a considerable blow to recognition of any *Chevron*-like deference to the Patent and Trademark Office's past patent practices (the Patent and Trademark Office had awarded the Myriad patents at issue, and Myriad urged the Court to uphold the patents, *inter alia*, on the basis of deference)—a teetering notion given that the Patent and Trademark Office had already taken to asking for judicial "guidance" in pending litigation[3]—in effect, an advisory opinion—and that the United States itself, in its amicus brief, argued in favor of invalidating the patents—a position militating against deference.

THE UPSHOT

In the wake of *Myriad*, the Patent and Trademark Office issued new guidelines.[4] Certainly it is in a difficult position because courts review patents de novo, and Patent and Trademark Office rulings are thus not dispositive. It must determine what it believes the law is and rule accordingly, but without final authority or even ex post judicial deference or a priori judicial guidance as to its determinations. This creates uncertainty among all patent participants:

---

[1] Mr. Cobb graduated from the University of Minnesota Law School in 2001, where he was an editor for the *Minnesota Journal of Law, Science & Technology* and named to the dean's list. He earned a bachelor of science in chemical engineering from the University of Michigan, Ann Arbor, *cum laude*, in 1995. He was a Regents-Alumni Scholar and earned Class Honors. A registered patent attorney admitted to practice before the United States Patent and Trademark Office, Mr. Cobb is patent counsel at Deep & Far, Attorneys at Law, in Taipei, Taiwan, and devotes a large portion of his practice to patents.

[2] Section 101 reads as follows: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

the patent bar, patentees, competitors of patentees, investors, litigants or potential litigants, and especially within the Patent and Trademark Office itself. As with *Myriad*, a court ruling can bring about sweeping changes in prosecution practice—what once was routinely patentable is no longer patentable. Thus, patent applicants are writing not just to the Patent and Trademark Office, but ultimately to a court, and sophisticated patent counsel should be mindful of that reality, taking care to make arguments, and to refrain from contrary admissions, during prosecution that will improve the odds of judicial approval. A patentee should not take positions during prosecution that may be inconsistent with positions it may take during subsequent litigation.

MYRIAD II

In the aftermath of its Supreme Court defeat, Myriad sought to enforce what remained of its patent rights. Along with other interested parties, it brought suit against a competitor in federal district court and sought a preliminary injunction enjoining defendant from infringing certain surviving patents. The Federal Circuit unanimously affirmed the district court's denial of Myriad's motion for a preliminary injunction, but went further, invalidating Myriad's asserted claims de novo. *Univ. of Utah Research v. Ambry Genetics Corp.*, Civ. Nos. 2014-1361, -1366 (Fed. Cir. Dec. 17, 2014). The court ruled that Myriad's claims directed to DNA primers were unpatentable because they were "structurally identical to the ends of DNA strands found in nature," *Univ. of Utah Research*, slip op. at 6, and, citing *Alice Corp. v. C.L.S. Bank Int'l*, 134 S.Ct. 2347 (2014), found its method claims similarly unpatentable as abstract ideas lacking any meaningful inventive step.

GOING FORWARD

The Myriad litigation and other cases make clear that the days of laissez-faire subject matter analysis are over, and we are in a new era in which section 101 is given significant weight, but Patent and Trademark Office past practice is given little weight. Thus, all patent participants are urged to exercise caution, and challengers may be emboldened to forge new business channels by seeking to invalidate competitors' patent rights in court. Facing this uncertainty, now, more than ever, attorneys who can exercise independent judgment and offer useful, competent counsel can provide their clients with the edge they need to survive.

---

[3] *In re* Comiskey, 554 F.3d 967, 973 (Fed. Cir. 2009).

[4] Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products, *United States Patent and Trademark Office* (Mar. 4, 2014) (available at http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf).