Myriad **Mysteries**

Thomas G. Field, Jr.

Professor Field finds the *Myriad* opinions to pose compelling questions.

In May 2009, the American Civil Liberties Foundation filed an action said to be "unique in the identity of the parties, the scope and significance of the issues presented, and the consequences of the remedy sought." Ass'n Molecular Pathology v. U.S. PTO, 669 F.Supp.2d 365, 368, 370 (S.D.N.Y. 2009) (Myriad I). The suit sought a declaration of invalidity for several claims in seven patents held or controlled by Myriad Genetics. *Id.* at 376-77. The Foundation also challenged the constitutionality of PTO grants on First Amendment and other grounds. *Id.* at 376.

The following November, the court denied motions to dismiss. *Id.* at 398. In April 2010, it addressed the merits. 702 F.Supp.2d 181 (S.D.N.Y. 2010) (Myriad II). All challenged claims were invalidated for covering nonpatentable subject matter. *Id.* at 220-232 and 232-37 (composition and method respectively). Having resolved the case on the basis of § 101, the court chose not to address constitutional issues and dismissed the PTO. *Id.* at 238.

The Federal Circuit ruled on the appeal last July. 2011 WL 3211513 (Myriad III). It unanimously affirmed "the district court's decision to exercise declaratory judgment jurisdiction." *Id.* at *1. It also unanimously agreed that all but one set of method claims cover patentable subject matter. *Id.* at * 22. Judge Moore concurred in reversing the district court's rulings on composition claims. *Id.* at 24. With regard to most of the latter, however, Judge Bryson dissented. *Id.* at 37.

Twenty-eight appellate briefs were filed by or on behalf of a host of amici, including the federal government, a diverse assortment of associations, universities, professors and individuals. There is no mystery about the source of interest: "Mutations in [two BRCA] genes correlate with an increased risk of breast and ovarian cancer… up to an 85% cumulative risk of breast cancer, as well as up to a 50% cumulative risk of ovarian cancer. …. The women with inherited BRCA1 mutations have a 40-52% cumulative risk of ovarian cancer by [age 70]. For women with inherited BRCA2 mutations, the risk is approximately 15-25%. Male carriers of mutations are also at an increased risk for breast and prostate cancer." *Myriad II,* 702 F.Supp.2d at 203 (citations omitted).

Tests identifying such mutations are important to assessing prevention and treatment options. Despite Myriad's efforts as the sole U.S. provider to make BRCA tests available to all, those tests are beyond the financial reach of some, including a few named as plaintiffs. *Id.* The opinion also points out that Myriad's charge is $3000 per test; triple that of a nonlicensee in Ontario. *Id.* It further notes that Myriad's 2008 revenue was $222 million, compared to $32 million in costs. *Id.* One mystery is how such facts bear on patent-eligible subject matter.

Further, in a vein potentially more relevant to validity, the opinion flags the involvement of others in the search for the BRCA genes. Indeed, it relates, "the consensus among the scientific community is that another research group "was the first to sequence the BRCA2 gene." *Id.* at 202. Continuing, the opinion states, "The isolation of the BRCA1/2 genes required considerable effort… as well as ingenuity…. However, the process and techniques used were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach." *Id.* at 202-03.

None of the preceding facts bears on patentable subject matter. Yet it would not be surprising if a notion that Myriad reaps more than it sowed nevertheless influenced resolution of that question.

Significance of the issues, coupled with plausible justifications derived from legal uncertainty is apt to have deterred the Federal Circuit from simply finding lack of standing, but the panel could identify only one qualified plaintiff. *Myriad III* at *12-13. Even so, Myriad's attorneys now claim that he has become incapable of infringement. AIPLA Report 2011. How that will play out remains to be seen.

Moreover, Myriad claimed "that other unchallenged claims to BRCA probes and primers will still prevent [any party] from engaging in BRCA sequencing." *Id.* at *13. Still, "Myriad has failed to direct us to any specific unchallenged claim that will have that effect. And Plaintiffs' counsel stated at oral argument that his clients can sequence the BRCA genes without using BRCA probes and primers." *Id.* The mystery here, of course, is why Myriad, if given an opportunity, didn't make a better record.

As noted above, Judge Moore concurred. Expressing reservations about claims to isolated genes, she urges patent-eligibility because the PTO has allowed them, firms have made investments believing that they fall within the ambit of patentable subject matter and Congress seems to have acquiesced. *Id.* at *35-36. To the extent that Federal Circuit opinions since Diamond v. Chakrabarty, 447 U.S. 303 (1980), not to mention Judge Rich's opinion affirmed there (In re Bergy, 596 F.2d 952 (CCPA 1979)), support patentability of isolated genetic material, judges and justices should think hard about the economic implications of finding such claims invalid solely on the basis of subject matter.

Judge Bryson's dissent centers on novelty; he would find DNA patent-eligible only if it has not been isolated from nature. *Id.* at *43. He nevertheless objects to claims to otherwise-qualifying short sequences, observing, "Myriad could easily have claimed more narrowly to achieve the utility it attaches to [such] segments." *Id.* Moreover, he finds another claim of that type "breathtakingly broad" but regards it as "likely to be invalid on other grounds, and thus a ruling as to patent-eligibility… may be superfluous." *Id.* at *43, 44.

The last quoted passage, however, seems remarkably apt to all challenged composition claims. Constrained by precedent, lower courts must labor to avoid superfluity. The Supreme Court, absent claims to reliance of the sort flagged by Judge Moore, need not. That Court could avoid continued pursuit of answers to intractable questions by abandoning the notion that composition claims, barring explicit congressional exclusion, may be challenged solely on the basis of subject matter. The biggest mystery, amply highlighted by most of 137 pages of *Myriad* opinions and hundreds more pages of briefs already generated, is why that wasn't accomplished long ago.