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PRELIMINARY INJUNCTIONS POST-*MAYO* AND *MYRIAD*

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The Supreme Court has recently expressed increased interest in patent eligibility, or patentable subject matter, the doctrine that limits the types of inventions eligible for patenting. Its two decisions, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[1] in 2012, and *Association for Molecular Pathology v. Myriad Genetics, Inc.*,[2] in 2013, represented the first broad restrictions on patentable subject matter in over thirty years.[3] And later this term, the Court will decide yet another patent eligibility case: *Alice Corp. v. CLS Bank International*.[4] While the effects of the *Mayo* and *Myriad* decisions on patent law have been widely discussed, they have recently played a fascinating—and less explored—role in another area of law: preliminary injunctions. In several recent patent cases, the contours of *Mayo* and *Myriad* have driven district courts to deny preliminary injunctions on patent eligibility grounds. This has subtly altered the texture of the preliminary injunction standard in patent infringement disputes, causing district courts to place greater emphasis on difficult, scientifically complex questions of patent eligibility at nascent stages of litigation. While time—and appeals—will tell whether this change remains viable, this shift in the preliminary injunction standard provides a fascinating, practical case study as to one law: the law of unintended consequences.

MAYO AND *MYRIAD*

In *Mayo*, the asserted patents claimed a method for adjusting the dosage of thiopurine drugs—useful in treating gastrointestinal disease but sometimes toxic—based on specific concentrations of the drugs' metabolites in patients'

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1. 132 S. Ct. 1289 (2012).

2. 133 S. Ct. 2107 (2013).

3. In 2010, the Court decided another patentable subject matter case—*Bilski v. Kappos*, 130 S. Ct. 3218 (2010)—although the immediate effect of that decision has been unclear. *See generally* Mark A. Lemley et al., *Life After* Bilski, 63 STAN. L. REV. 1315 (2011) (discussing the uncertain future effect of *Bilski*). But prior to *Bilski*, the Supreme Court had not restricted patentable subject matter since *Parker v. Flook*, 437 U.S. 584 (1978), thirty-two years earlier.

4. 717 F.3d 1269 (Fed. Cir.), *cert. granted*, 134 S. Ct. 734 (2013) (No. 13-298).

blood.[5] The question presented to the Supreme Court was whether this insight—the specific correlation uncovered by researchers distinguishing therapeutic and toxic doses—"preempt[ed] all uses of the naturally occurring correlations" and therefore ran afoul of the Court's earlier patent eligibility jurisprudence.[6] While the Court could have decided the case narrowly, it invalidated the patents' claims on rather broad and cryptic terms: the claims failed to contain an "inventive concept";[7] they tread on "laws of nature";[8] and they were merely "well-understood, routine, conventional activity previously engaged in by researchers in the field."[9]

In *Myriad*, the asserted patents claimed two forms of DNA: human genes isolated, in toto, from the genome, called genomic DNA; and a selection of the functional, or protein-coding, part of those genes, called cDNA.[10] The question presented to the Supreme Court in *Myriad* was deceptively simple: "Are human genes patentable?"[11] Again, the Court could have disposed of the case on narrow, or at least coterminous, grounds. But the Court invalidated the patents' claims to genomic DNA on the theory that they were primarily "informational," while it upheld the patents' claims to cDNA as primarily "chemical."[12]

In many ways, these decisions have been difficult to interpret. First, the Court's failure to address *Mayo* in its *Myriad* decision highlights the "logical discontinuity" between the two decisions[13]: is a new chemical created using "well-understood, routine, conventional activity previously engaged in by researchers in the field" nonetheless patent eligible? Second, the decisions seem to join two previously distinct areas of patent ineligibility: "natural laws" and "products" on the one hand and "abstract ideas" on the other.[14] Third, patent eligibility's long-standing allowance of patents on "natural products" as long as they are "isolated and purified" from their surrounding environments now is in doubt.[15] Being forced to draw the difficult line between molecules that are pri-

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5. *See, e.g.*, U.S. Patent No. 6,355,623 col. 8 ll. 37-40 (filed Apr. 8, 1999).

6. Petition for Writ of Certiorari at i, *Mayo*, 132 S. Ct. 1289 (No. 10-1150), 2011 WL 992001.

7. *Mayo*, 132 S. Ct. at 1294 (internal quotation marks omitted).

8. *Id.* at 1298.

9. *Id.* at 1294.

10. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2111 (2013). cDNA is short for complementary DNA—complementary to messenger RNA, the sequence of an intermediate molecule in protein product. *Id.*

11. Petition for Writ of Certiorari at i, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2012 WL 4502947.

12. *Myriad*, 133 S. Ct. at 2118-19.

13. *See* Dan L. Burk, *The Curious Incident of the Supreme Court in* Myriad Genetics, 90 NOTRE DAME L. REV. (forthcoming 2014) (manuscript at 5), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2407094.

14. *See* John M. Golden, *Patentable Subject Matter and Institutional Choice*, 89 TEX. L. REV. 1041, 1078-79 (2011) (discussing the difficulties in separating these terms).

15. *See generally* Christopher Beauchamp, *Patenting Nature: A Problem of History*, 16 STAN. TECH. L. REV. 257, 300-06 (2013) (discussing the history of this exception).

marily "informational" and those that are primarily "chemical" further complicates this distinction. And fourth, the ultimate extent to which technologies constitute "well-understood, routine, conventional activity, previously engaged in by researchers in the field" is potentially troublesome.[16] Courts now face the unenviable task of harmonizing *Mayo* and *Myriad*.

THE PRELIMINARY INJUNCTION STANDARD

Patent holders, in seeking judgments that their adversaries' activities infringe their patents, typically ask courts not merely to award damages but to enjoin infringers from particular business activities.[17] Part and parcel of these requests are motions for preliminary injunctions—injunctions against the accused activity during the pendency of the lawsuit. In assessing preliminary injunctions, courts have used the traditional four-part test: whether the plaintiff has proved (1) a likelihood of success on the merits, (2) an irreparable injury, (3) that the balance of hardships falls in its favor, and (4) that the public interest counsels in favor of a preliminary injunction.[18] Because such requests come early in the litigation process—indeed, often in tandem with the complaint—courts must resolve these factors prior to having had an opportunity to issue substantive rulings with the aid of substantial discovery.

In the patent context, these factors are further given their own texture. The first prong, likelihood of success on the merits, maps to the ultimate questions of infringement and invalidity: whether the patent holder can prove infringement at trial, and whether the defendant can demonstrate that the patent is, for whatever reason, invalid. The second prong usually focuses on whether the patent holder would suffer "price erosion"—an irreversible drop in prices—if competitors enter the marketplace.[19] The third typically weighs the relative siz-

16. *See* Jacob S. Sherkow, *And How:* Mayo v. Prometheus *and the Method of Invention*, 122 YALE L.J. ONLINE 351, 351 (2013), http://www.yalelawjournal.org/pdf/1144_obtqyfxe.pdf.

17. Colleen V. Chien & Mark A. Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98 CORNELL L. REV. 1, 16 (2012) (estimating the injunction rate in infringement suits to be around seventy-five percent in district courts).

18. Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008).

19. The texture of this prong may soon change. In *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, Chief Justice John G. Roberts recently expressed the opinion that Teva was not entitled to a stay of the Federal Circuit's mandate invalidating some of its patents. The Chief Justice expressed skepticism that Teva would suffer "irreparable harm" if the mandate was not stayed because "should Teva prevail in this Court and its patent be held valid, Teva will be able to recover damages from respondents for past patent infringement," despite suffering from price erosion. Teva Pharm. USA, Inc. v. Sandoz, Inc., No. 13A1003 (13-854), 2014 WL 1516642 (U.S. Apr. 18, 2014) (Roberts, C.J., in chambers). How well the "irreparable harm" prong for stays of appellate mandates aligns with the "irreparable harm" prong of preliminary injunctions remains to be seen, but—as with *Mayo* and *Myriad*—the Court's words here may further alter district courts' interpretations of the standard in patent disputes.

es of the parties. And the fourth, at least historically, centered on the "strong public interest in upholding a patentee's exclusive rights."[20]

These factors—combined with a legal presumption of patent validity—typically tipped in favor of the patent holder, long making preliminary injunctions a "potent weapon in patent litigation."[21] Famously, in *Hybritech, Inc. v. Abbott Laboratories*, the district court granted a preliminary injunction to prevent the sale of Abbott's antibody assays despite expressing doubt over every one of the four prongs.[22] At the time, however—over twenty years before the Supreme Court's foray into patent eligibility—there was little doubt that Hybritech's inventions, or any inventions like them, were patentable subject matter. Times have changed.

ARIA AND *AMBRY*

Mayo and *Myriad*'s lack of clarity, combined with their broad, sweeping statements about the doctrine of patent eligibility, have added a particular wrinkle to requests for preliminary injunctions: despite patents' presumption of validity, courts appear to have become more emboldened to deny preliminary injunctions on the grounds that the asserted patents are likely to be invalid for lack of patentable subject matter. That is, it seems that courts have begun to use the vagaries of *Mayo* and *Myriad* as a way to deny—and subtly alter the standards for—preliminary injunctions. Two recent district court cases, *Aria Diagnostics, Inc. v. Sequenom, Inc.*[23] and *In re* BRCA1- *and* BRCA2-*Based Hereditary Cancer Test Patent Litigation* (*Ambry*),[24] demonstrate this development.

A. Aria

In *Aria*, the asserted patent claimed a method of detecting certain fetal genetic abnormalities, such as Down syndrome, using a simple, noninvasive blood test of the pregnant mother.[25] The heart of the invention focused on the insight that some of the carrying mother's blood would likely contain some of

20. *See In re BRCA1-* and *BRCA2-*Based Hereditary Cancer Test Patent Litig. (*Ambry*), No. 2:14-MD-2510, 2014 WL 931057, at *56 (D. Utah Mar. 10, 2014).

21. James J. Foster, *The Preliminary Injunction—A "New" and Potent Weapon in Patent Litigation*, 68 J. PAT. & TRADEMARK OFF. SOC'Y 281, 281 (1986) (capitalization altered); *see* M.A. Cunningham, *Preliminary Injunctive Relief in Patent Litigation*, 35 IDEA 213, 231 (1995) (assessing the preliminary injunction grant rate in patent cases to be sixty-one percent between October 1, 1982, and December 31, 1993).

22. No. CV 86-7461/AK (PX), 1987 WL 123997 (C.D. Cal. July 14, 1987), *aff'd*, 849 F.2d 1446 (Fed. Cir. 1988).

23. No. C 11-06391 SI, 2012 WL 2599340, at *1 (N.D. Cal. July 5, 2012), *vacated*, 726 F.3d 1296 (Fed. Cir. 2013).

24. 2014 WL 931057, at *1-2.

25. U.S. Patent No. 6,258,540 col. 23 ll. 61-68 (filed Mar. 4, 1998).

the fetus's DNA, known as cell-free fetal DNA, or cffDNA.[26] On Sequenom's request for a preliminary injunction, the district court considered whether "the discovery that fetal DNA is detectable in maternal [blood] . . . is an unpatentable natural phenomenon under *Mayo*."[27]

Prior to *Mayo*, this analysis—at least in the context of requests for preliminary injunctions—would have strongly favored Sequenom, the patent holder. Patents are entitled to a presumption of validity, which can only be undone by "clear and convincing" evidence—a difficult burden prior to the Supreme Court's decision in *Mayo*.[28] Furthermore, the burden of proof regarding invalidity rests on the accused infringer.[29]

But *Mayo*'s elusive language regarding which inventions constitute unpatentable "natural phenomena" through "well-understood, routine, conventional activity" provided Aria—and a skeptical district court—with at least a "substantial question" as to the validity of Sequenom's patent. A method for analyzing cffDNA, while clearly not an "abstract idea" under the Supreme Court's pre-*Mayo* jurisprudence, now potentially fell within the realm of patent-ineligible "natural phenomena." And the procedures used to quantify cffDNA—revolutionary from a market perspective[30]—could, in some sense, be considered no more than a creative application of "standard" (i.e., "well-understood, routine, conventional") techniques in molecular biology.[31] These arguments—almost certainly losers prior to *Mayo*—led the district court to ultimately deny Sequenom's request for a preliminary injunction because "Sequenom ha[d] not put forward substantial evidence that the steps described in the specification [were] 'sufficient to ensure that the patent in practice amount[ed] to significantly more than a patent upon the natural law itself.'"[32]

This concern with whether there exists "substantial evidence" to overcome the practice of a "natural law," however, marks a subtle shift in preliminary injunction jurisprudence. Accurately assessing questions of patent eligibility requires more than rote legal conclusions. As the Federal Circuit recently declared, conclusions concerning patent eligibility are "rife with underlying factual issues"[33]—complex, sophisticated factual issues difficult to determine at nascent stages of litigation. Whether cffDNA constitutes a natural phenomenon under *Mayo* implicates scientific, technological, and even philosophical inquiries poorly positioned for resolution on requests for preliminary injunc-

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26. *Aria*, 2012 WL 2599340, at *2.

27. *Id*. at *11 (citation omitted).

28. Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2242 (2011).

29. *Id*. at 2245.

30. *See Aria*, 2012 WL 2599340, at *3 (listing the potential market for cffDNA analysis as 750,000 patients).

31. *See id*. at *12 ("However, the steps Sequenom used to enable their method claims in light of the cell-free DNA discovery—namely fractionation (separating blood into cells and plasma), amplification, and detection—are described as 'standard' in the patent itself.").

32. *Id*.

33. Ultramercial, Inc. v. Hulu, LLC, 722 F.3d 1335, 1339 (Fed. Cir. 2013).

tions.[34] And whether anything constitutes "well-understood, routine, conventional" techniques likely requires on-the-ground analysis of scientific practice, better analyzed after substantial discovery.[35] By placing its focus on the first preliminary injunction prong—likelihood of success on the merits—the district court subtly moved the preliminary injunction standard from the preliminary to the permanent, from a rudimentary calculus of harms to one fully engaged with scientific fact.

B. Ambry

In *Ambry*, a suit brought by Myriad after the fallout from its earlier Supreme Court loss, the district court employed a similar analysis. Almost immediately after the Court's decision, several competitors, including Ambry Genetics, boldly announced that they were planning to directly compete with Myriad by offering *BRCA1* and *BRCA2* sequencing services to detect breast cancer risk.[36] Myriad subsequently brought suit against several companies on its remaining patent claims—including those expressly found to be patent eligible by the Supreme Court—and asked the district court to enter a preliminary injunction against Ambry.[37]

Although this factual and procedural posture makes it difficult, if not impossible, to conceive of *Ambry* in the absence of *Myriad*, two facets of the *Myriad* decision appeared to strongly support Myriad's request for a preliminary injunction. First, the Supreme Court had specifically declared that Myriad's cDNA claims were eligible for patent protection. Second, Myriad's remaining claims were still afforded the same presumptions of validity given to any issued claims: they could only be invalidated by a showing of "clear and convincing" evidence. Neither facet strongly suggested that Ambry would have likely succeeded on the merits. Nonetheless, the district court fully engaged the parties on the technological issues surrounding patent ineligibility, receiving thousands of pages of scientific material, presiding over a two-day "technology tutorial," and crafting a 106-page opinion, the bulk of which detailed the parties' scientific arguments.[38]

Ultimately, it was those scientific arguments that formed the backbone of the court's denial of Myriad's request for a preliminary injunction. The *Ambry* court declared that Myriad's synthetic DNA patents were likely invalid because, according to the *Myriad* decision itself, the claimed synthetic DNA se-

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34. *See* Jacob S. Sherkow, *The Natural Complexity of Patent Eligibility*, 99 IOWA L. REV. 1137, 1139 (2014).

35. *See* Sherkow, *supra* note 16, at 356-57.

36. *See Ambry*, No. 2:14-MD-2510, 2014 WL 931057, at *1 (D. Utah Mar. 10, 2014).

37. *Id.*

38. *Id.* at *1-30.

quences were not "distinct from the DNA from which it was derived"[39]—a conclusion based in part on the court's own analysis of the genetic sequences at issue.[40] Further, the court declared that Myriad's claims directed to methods of using its synthetic DNA were also likely invalid because, under *Mayo*, those methods failed to contain an "inventive concept" according to the court's recitation of the state of the art in molecular biology as it existed twenty years prior (when Myriad had filed for its patent).[41]

Like the court's analysis in *Aria*, this nuanced, scholarly focus on how *Mayo* and *Myriad* apply to truly difficult questions of molecular biology subtly shifts the preliminary injunction analysis from the passing to the painstaking. The court's thorough analysis of the complementarity of genetic sequences and the history of molecular biology, and its valiant attempt to harmonize the Supreme Court's disparate patentable subject matter jurisprudence, belongs—if it belongs anywhere—on papers for summary judgment, after the parties have thoroughly engaged in discovery, narrowed the issues in dispute, and had time to prepare expert rebuttal reports.

THE FUTURE OF PRELIMINARY INJUNCTIONS

Mayo and *Myriad*, as seen through *Aria* and *Ambry*, provide some insight into the future of preliminary injunctions. In patent cases, it seems clear that courts will increasingly engage in substantive issues of patent eligibility on requests for preliminary injunctions—and in doing so, increasingly deny them on the grounds that the asserted patents are ineligible for protection. While judges may feel that *Mayo* and *Myriad* give them broad leeway for such denials, the opinions' cryptic language and legal nuances make preliminary injunctions a poor forum for such deliberation. Patent holders, when requesting preliminary injunctions, should now be prepared to make full-throated defenses of their inventions' eligibility.

Relatedly, *Aria* and *Ambry* also seem to show that district courts now appear more willing to imbue the latter three preliminary injunction factors with their result in the first. In the *Ambry* case, for example, the district court's analysis of the public interest factor—historically pro-patentee—presumed the negative utility of Myriad's patents: they "hindered rather than promoted innovation," "distort[ed] rather than serve[d] the patent system[]," and utilized "a commercial path that turns much of our patent system policy on its head."[42] This all but suggests that the court's thorough analysis as to whether Myriad was likely to succeed on the merits simply became a mandate for the remaining parcels of equity. While it is true that the first prong, likelihood of success on

39. *Id*. at *44 (quoting Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119 (2013)) (internal quotation marks omitted).

40. *Id*. at *46.

41. *Id*. at *49-54.

42. *Id*. at *57.

the merits, is the most important preliminary injunction factor, it is still but one factor of four. The preliminary injunction standard should be an independent, holistic balancing of each. Where the likelihood-of-success question is close or exceedingly difficult—as it doubtless will be in many patent disputes after *Mayo* and *Myriad*—that should counsel courts to pay *more*, and more serious, attention to the remaining factors, not *less*.

More broadly, this subtle shift in preliminary injunctions paints an interesting picture of some of the unintended effects of Supreme Court jurisprudence. *Mayo* and *Myriad* were not decisions of clarity—nor were they meant to be—but they were necessary attempts to prune a thorny and wild area of patent law. The opinions, if anything, counsel a careful deliberation of technology and law, with an implicit understanding that such analyses were difficult. But these cautions have taken on a character of their own in the rapidly moving, partially blind atmosphere of preliminary injunctions. This is all a greater lesson that an appellate court's desire for care can be a trial court's command to haste.