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Life Sciences Law & Industry Report™

Patents

The Constitution allows ''Authors and Inventors the exclusive Right to their respective Writings and Discoveries.'' But the life sciences industry was shaken in 2012 when the Supreme Court in *Mayo v. Prometheus* found that patent claims for a discovery of a way to administer drugs were patent ineligible as reciting a law of nature—an exception to patent eligibility. Two recent court actions on medical discoveries are likely to change the life sciences patent landscape in a number of ways. Bloomberg BNA discussed this with notable life sciences patent attorneys.

Attorneys Disappointed, See Hope Concerning Medical Discovery Patents

The end result of two recent legal actions is that there are two different and distinct decisions in place from the Federal Circuit concerning the patenting of medical discoveries.

In one, *Sequenom, Inc. v. Ariosa, Inc.*, the Supreme Court's June 27 denial of review (certiorari) of the U.S. Court of Appeals for the Federal Circuit's invalidation of patent claims for a ''revolutionary'' medical discovery to help detect fetal abnormalities left the invalidation in place (10 LSLR 14, 7/8/16).

In the other, *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, the Federal Circuit July 5 found a non-detection medical discovery to be patent eligible (10 LSLR 14, 7/8/16).

Attorneys told Bloomberg BNA that, by leaving the Federal Circuit's invalidation of the Sequenom patent alone, the high court lost a ''perfect'' opportunity to provide clarification of its earlier decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (6 LSLR 404, 4/6/12).

Some saw the two Federal Circuit decisions as illustrative of the ''arbitrariness'' of the *Mayo* decision, while others applauded the appeals court for finding in *Rapid Litig. Mgmt. Ltd.* an offensive hole in the defensive wall that is *Mayo*. They suggested that *Rapid Litig. Mgmt. Ltd.* indicates that the law concerning medical discoveries is growing, although more slowly than many would like.

Examples of Arbitrariness? ''I am more than disappointed, and I think this is true for the majority of the IP community, in the Supreme Court's denial of cert in *Sequenom*,'' Teresa Stanek Rea, a partner in Crowell & Moring LLP's intellectual property (IP) group and former acting and deputy director of the Patent and Trademark Office, told Bloomberg BNA in a July 12 phone interview. ''Based on everything they've read, all the amicus briefs and articles from practitioners, I wish the justices could have been a little more open-minded and granted review.''

She added, ''I am afraid we may be going down the direction of not serving the IP community and also not serving society as a whole by not being able to provide the drugs and diagnostics methods people need. The Sequenom discovery was truly amazing and revolutionary, and the type of people who came up with that are the people we need to focus on so that they can focus on making life better for people who are ill.''

But Rea said she was proud of the Federal Circuit's ruling in *Rapid Litig. Mgmt. Ltd.* ''They looked at Section 101, trying to assume that the claims were patentable unless proven otherwise. The judges on the panel appear to be at least raising the question that if a claim

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changes lives, how can it not be eligible for a patent just because it obliquely touches on a product of nature or a natural phenomenon?''

However, while also happy about the results of the *Rapid Litig. Mgmt. Ltd.* ruling, Intellectual Property Consultant Robert A. Armitage, former senior vice president and general counsel for Eli Lilly and Co., emphasized the differing results between it and the *Sequenom* decision.

He told Bloomberg BNA in a July 12 e-mail, ''The two Federal Circuit decisions are stellar examples of the arbitrariness of the Supreme Court's patent-eligibility standard set out in *Mayo*. While the respective claims of the two patents both depended entirely on the laws or phenomena that operate in nature, both patents decisively limited what was actually claimed to real-world, technological applications of these laws or phenomena.''

Armitage added, ''It is impossible to see how any objective standard could have invalidated one patent's claims and sustained the other's.''

'Routine, Conventional Techniques.' The *Sequenom* litigation started when Ariosa Diagnostics Inc. of San Jose, Calif., and Natera Inc. of San Carlos, Calif., filed separate complaints seeking a declaration that their Harmony Test and Non-Invasive Paternity Test, respectively, didn't infringe any claims of the Sequenom patent. The patent described a method of detecting paternity-identifying DNA in a serum or plasma sample from a pregnant woman as an alternative to amniocentesis, which involves inserting a needle into a woman's abdomen.

On appeal, the reasoning of Federal Circuit's opinion was drawn almost completely from *Mayo*, in which the high court had found that claims for a ''administering'' and determining blood levels to detect diseases and conditions were patent ineligible as describing ''laws of nature,'' a court-established exception to patent eligibility in the court's interpretation of 35 U.S.C. § 101.

The two-part test the appeals court laid out in *Mayo* and clarified by the court in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (8 LSLR 605, 6/27/14) asks first if the claim is for a process, machine, manufacture or composition of matter; if so, in Step 2a, it asks if the claim is directed to a judicial exception to patent eligibility—laws of nature, abstract idea or natural phenomenon; and, if so, Step 2b asks if the claim recites additional elements that amount to something ''significantly more'' than the judicial exception.

Federal district courts have been applying the *Mayo*/*Alice* test to life sciences patents and invalidating claims at an ''alarming rate,'' attorneys have asserted (see 10 LSLR 13, 6/24/16).

In *Sequenom*, the court said that the claims described a natural phenomenon and therefore failed Step 2a of *Mayo* because ''[t]he method therefore begins and ends with a natural phenomenon.'' In Step 2b, the amplifying and detecting steps to get from the starting natural phenomenon to the ending natural phenomenon, the court said, ''amount[] to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA [cell free DNA].''

Eligible 'But for' *Mayo*. The appeals court acknowledged the scientific value of the patentees' discovery. However, it said, ''even such valuable contributions can fall short of statutory subject matter, as it does here.''

In his concurrence, Judge Richard Linn distinguished the activities in *Sequenom*, where ''no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers,'' from those in *Mayo*, which covered ''the very steps that doctors were already doing—administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels.'' However, Linn said, ''the Supreme Court did not limit its ruling to those particular facts and circumstances.''

Linn added, ''But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.''

'Life Changing' But No Patent. The *Sequenom* ruling, which was issued the week before, dominated the discussions at the intellectual property sessions at the BIO International Convention in Philadelphia in June 2015. There, at a session at which Armitage was a speaker, participants called for Congress to rewrite Section 101 or for life sciences companies to de-emphasize patent protection for their inventions in favor of trade secret protection (9 LSLR 752, 6/26/15).

Attorneys at the convention told Bloomberg BNA how their families were personally affected by having an alternative to amniocentesis. ''It was revolutionary. It was life changing. And yet it couldn't keep a patent,'' one said.

''I am glad for future generations of women who will not have to endure such procedures thanks to scientific discoveries,'' Rea said.

''It is impossible to see how any objective standard could have invalidated one patent's claims and sustained the other's.''

ROBERT A. ARMITAGE, INTELLECTUAL PROPERTY CONSULTANT

The Federal Circuit denied Sequenom's motion for a rehearing or for an en banc (full court) hearing (9 LSLR 24, 12/11/15). Sequenom petitioned for certiorari to the Supreme Court, and 22 amici of the court filed briefs in support of the court reviewing the decision (10 LSLR 09, 4/29/16).

By the 2016 BIO International Convention in San Francisco, calls for change had softened as a result of

no positive action having been taken. At a session of that convention, Armitage warned that clarification from the Supreme Court could be a while in coming because the court was likely to call for the views of the solicitor general (CVSG) (10 LSLR 13, 6/24/16).

But the Supreme Court didn't issue a CVSG and denied certiorari without comment.

***Sequenom* Too Close to *Mayo*?** Antoinette Koski, an intellectual property and life sciences attorney at Foley & Lardner, Palo Alto, Calif., wrote in a July 12 e-mail to Bloomberg BNA, ''The denial of petitioner's request for review in *Sequenom* signals that the Federal Circuit's interpretation of the Supreme Court's *Mayo* ruling as it concerns claims solely directed to detecting natural phenomena, without more, is not so off the mark.''

Hans Sauer, deputy general counsel for intellectual property for the Biotechnology Innovation Organization (BIO) told Bloomberg BNA in a July 7 e-mail, ''The cert denial in *Sequenom* was an unqualified disappointment. The Federal Circuit had extended a tentative invitation to the Supreme Court to revisit the question; more than 20 amicus briefs were filed, and it is well known that the *Mayo-Alice* framework was and is causing a lot of confusion among judges, litigants, patent applicants and Patent and Trademark Office administrators.''

In response to the cert petition in *Impression Prods., Inc. v. Lexmark Int'l* (10 LSLR 04, 2/19/16) on the issue of patent exhaustion, Sauer said, ''where the government in fact had already expressed its views in the Federal Circuit, the Supreme Court had issued a CVSG just the week before. It's painful to see that they would order a CVSG in a case where the government's views are already well-known but not in a case where the government's views would be really new and informative. Taken together, one gets the sense that the Supreme Court genuinely doesn't care what the government thinks, or anyone else for that matter.''

Armitage told Bloomberg BNA, ''The *Sequenom* certiorari petition offered the Supreme Court the perfect vehicle to eliminate the problematic nature of this sort of patentability standard that can produce no predictable result when applied.''

More Useful Than Conventional Methods. The patent in *Rapid Litig. Mgmt. Ltd.*, issued to In Vitro Technologies Inc. and now assigned to Rapid Litigation Management Ltd., is related to hepatocytes, which are used to investigate how drugs under development might affect the liver. The claims address two problems in preserving hepatocytes—loss of viability after thawing a second time and difficulty pooling samples from multiple donors.

In reviewing the district court's ruling under the two-part *Mayo/Alice* test, the panel found that the method underlying BioreclamationIVT's LiverPool product claims a new and useful laboratory technique for preserving and pooling certain liver cells. It distinguished ineligible discoveries of ''observation and detection'' such as those in *Mayo* and *Sequenom* from eligible ''methods of producing things, or methods of treating disease.'' The appeals court vacated a district court judgment favoring alleged infringer Life Technologies Corp.

The Federal Circuit concluded that the patent's claims survived the test under Step 2a of *Mayo/Alice*. The district court had ruled that the ineligible law of nature here was the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles. But the end result for these patent claims, the court wrote, is a method of preserving cells, in claim 1, with the additional method of pooling hepatocytes, in claim 5.

Finally, the court indicated that the claims would have passed the two-part *Mayo/Alice* test even if they had proceeded to Step 2b of the test. The repetition of the freezing and thawing steps was ''far from routine and conventional'' and the combination of steps made the claims, the court said.

Good News for Non-Detection Discoveries. Andrew J. Pincus of Mayer Brown LLP, Washington, who represented Rapid Litigation Management, told Bloomberg BNA in a July 7 phone interview, ''The court found that the claims were for creating a new substance and rejected the district court's theory that if your claim depends on an operation of natural law then it's likely invalid. This was one of the first cases to recognize the importance of Step 2b for looking to see if the claims represent something new, looking to see if they're turning old things into new things.''

Armitage said, ''With the Supreme Court's decision to pass on the *Sequenom* petition, [Chief] Judge [Sharon] Prost's decision in *Rapid Litig. Mgmt.* is very encouraging. If the lower courts must apply a standard that is no better than arbitrary, then fulfilling the constitutional purpose of the patent system to promote progress in the useful arts is far better accomplished by recognizing that methods such as those for performing a prenatal diagnoses, and those for preserving multicryopreserved hepatocytes, are not directed to laws and phenomena because they are self-evidently directed to practically useful and inventive applications of the laws and phenomena on which they are grounded.''

BIO's Sauer told Bloomberg BNA, ''Maybe decisions like *Rapid Litig. Mgmt.* are a sign that the Federal Circuit has given up hoping for more input from the high court and has recognized that they have to work with Supreme Court rulings without further help from above. We think the *Rapid Litig. Mgmt.* opinion is encouraging for biotech, diagnostic and otherwise. For more than two years the lower courts, perplexed as they may have been, applied the *Mayo/Alice* framework in a literal, even abject, manner. There was not much development of this new area of patent law. In this and other recent opinions, we may now be seeing the beginnings of more meaningful development, where the Federal Circuit is building on the Supreme Court cases with additional substance and analysis.''

Crowell & Moring's Rea said, ''I am proud of the Federal Circuit for the way it approached the case and handled it. It would be quicker—and some courts have been doing this—to take the easy way out and say a claim isn't patent eligible under Section 101 and not proceed through Section 102 to see if the claim is novel, Section 103 to see if it's not obvious and Section 112 to see if it has a written description and is enabled. Really, the last thing an analysis of a claim should consider, after having been through all the other sections, is, does it cover subject matter that is not patent eligible?''

Pincus said that the decision ''is very significant news for the life sciences industry because it shows that the law is going to develop in this area and that there are limits on Section 101 invalidations.''

The decision is also ''helpful because it explains how *Mayo* works once you get outside of the detection area,'' Pincus said.

Is *Rapid* Helpful to Detection Claims? Asked whether the *Rapid Litig. Mgmt. Ltd.* decision could be of any help to owners and applicants of diagnostic method detection patents, Pincus said that they might look to the issue of preemption.

In most Section 101 cases, a patent owner will argue that its specific application of the natural phenomenon, law of nature or abstract idea merits patent eligibility because it doesn't preempt all commercially viable uses of the phenomenon. In *Mayo*, the Supreme Court's discussion of the issue was thought to be ambiguous and the *Sequenom* panel dealt with the issue in passing, saying, ''While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. [Where] a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.''

But in *Rapid Litig. Mgmt. Ltd.*, Pincus said, the Federal Circuit panel directly addressed the issue of preemption, quoting the *Sequenom* opinion by saying, ''[W]hile pre-emption is not the test for determining patent-eligibility, it is certainly the 'concern that undergirds [Section] 101 jurisprudence,' '' quoting *Alice*. ''Here, while not resting our opinion on them, we note the district court's findings that the patent 'does not lock up the natural law in its entirety' and that 'LTC has already managed to engineer around the patent.' These findings accord with our conclusion that the patent is not 'directed to' a patent-ineligible building block of human ingenuity.''

Pincus said, ''So it becomes an issue of how much of the field remains open. If your claim is in the detection area and it allows for discovery of other methods by others, you may be in a better position than otherwise.''

Rea said, ''Detection patent applicants should see if their claims can fit into the fact pattern of those in *Rapid Litig. Mgmt.* and, if they do, proceed accordingly.''

Let All Sections Work Together. Armitage emphasized the importance, which he said the *Rapid Litig. Mgmt. Ltd.* opinion also indicated, of all of the different sections of the patent law having their separate functions rather than too much emphasis being put on Section 101.

''As Judge [Pauline] Newman [of the Federal Circuit] concisely noted in dissent in the [June 27] *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC* appeal , 'If the claims are unpatentable, any issue of abstractness, however defined, is mooted. And if the subject matter is patentable, it is not an abstract idea.'' Hopefully, as the lower courts more carefully examine claims in patents, the purposeless invalidation of claims such as was done in *Sequenom* will give way more reflective analyses such as those of Judges Prost and Newman,'' Armitage said.

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