

## EXPERT ANALYSIS

### Sequenom, Alice and Mayo in 2016

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The year 2016 will be interesting for questions of subject matter eligibility. To close out 2015, the U.S. Court of Appeals for the Federal Circuit denied a petition to rehear the *Ariosa Diagnostics Inc. v. Sequenom Inc.* case en banc.<sup>1</sup>

The Federal Circuit's panel decision in *Sequenom* invalidated claims that were directed to detecting paternally inherited fetal DNA in a maternal blood sample and performing a prenatal diagnosis using the DNA. The claims were found invalid under 35 U.S.C.A. § 101 as not amounting to significantly more than a claim to a natural phenomenon.

Following the decision, defendant-appellant Sequenom filed a petition for rehearing by the Federal Circuit en banc. The Federal Circuit denied the request for rehearing, but in doing so openly expressed concern about the state of patent eligibility in a patent system that denies coverage to valuable innovations such as the one at issue in *Sequenom*.

Though he supported the denial, U.S. Circuit Judge Alan D. Lourie noted that "it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts."<sup>2</sup>

Going forward, this decision and the precedent it followed will have profound effects on digital health and diagnostic companies, which often innovate at the intersection of science and computer-implemented technology — two areas increasingly affected by subject matter eligibility concerns.

#### MAYO AND ALICE

First, in *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, the Supreme Court invalidated claims covering a method for optimizing therapeutic efficacy and reducing toxicity of a drug treatment.<sup>3</sup>

The invalidated claim described a process of administering a drug and determining the level of the drug in the subject's system, with particular levels indicating whether the amount of the drug needs to be increased or decreased.

In invalidating the claims, the Supreme Court set out a framework for identifying patent-eligible subject matter. First, a claim must be analyzed to determine if it is directed to a judicial exception, such as an abstract idea or law of nature. If the claim is directed toward a judicial exception, the court determines whether the balance of the claim adds significantly more than the judicial exception.

Two years after the ruling in *Mayo*, the Supreme Court decided *Alice Corp. Pty. Ltd. v. CLS Bank International*, which invalidated claims as being directed to an abstract idea without amounting to something significantly more.<sup>4</sup>

The invalidated claims involved mitigating settlement risk by using a computer system as a third-party intermediary between two parties exchanging financial obligations. The Supreme Court



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followed the *Mayo* framework and invalidated the claims. Further, the Supreme Court held that the addition of a generic computer to a claim does not amount to adding significantly more than an abstract idea.

Since *Mayo* and *Alice* were decided, numerous claims have been invalidated for being directed to patent-ineligible subject matter.<sup>5</sup> Given the precedent set by *Mayo* and *Alice* and the tone of the *Sequenom* decisions, it is likely that issues of subject matter eligibility will continue to be an evolving area of the law and cause uncertainty for patentees, entrepreneurs and innovators — especially those in the medical diagnostics space.

There are two primary areas of development to track:

- Further defining what an “abstract idea” is and how to identify a claim directed to an “abstract idea.”
- Further defining what will be sufficient to qualify as “something more” resulting in subject matter eligibility.

### AREA 1: FURTHER DEFINING AN ‘ABSTRACT IDEA’

The first step of the *Mayo/Alice* test is determining whether a claim is directed to a judicial exception, such as an abstract idea or a law of nature. This step must strike a careful balance. After all, in *Alice*, the Supreme Court cautioned that “at some level all inventions embody, use, reflect, rest upon or apply a law of nature, natural phenomenon, or abstract idea.”<sup>6</sup>

For a claim to be directed to an abstract idea, it must do more than merely “embody, use, reflect, rest upon, or apply” a judicial exception at some level. Otherwise, all patent claims would be directed to a judicial exception, rendering this step superfluous. The exact boundaries of this step are still being explored, but recent decisions have provided some clarity.

In view of the en banc denial, it appears that claims that “merely recite natural laws” meet the “directed to” portion of the test. Judge Lourie, however, cautioned that “appellants and amici have argued before us in briefs that a broad range of claims of this sort appear to be in serious jeopardy. ... It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.”<sup>7</sup>

A prevailing view is that “abstract ideas are essentially mental steps; they are not tangible even if they are written down or programmed into a physical machine.”<sup>8</sup> However, many computer programs can be simplified into pseudocode that can be considered a list of mental steps. Therefore, if a claim is directed to an abstract idea for reciting something that can be considered mental steps, then a broad swath of computer-implemented claims are automatically directed to an abstract idea.

Such automatic classification would ignore the difference between functioning software and computer programs expressed as pseudocode on paper or in someone’s head. As explained by U.S. District Judge Mariana R. Pfaelzer of the Central District of California:

Many inventions could be theorized with pencil and paper, but pencil and paper can rarely produce the actual effect of the invention. Likewise, with regard to software, a human could spend months or years writing on paper the 1s and 0s comprising a computer program and applying the same algorithms as the program. At the end of the effort, he would be left with a lot of paper that obviously would not produce the same result as the software.<sup>9</sup>

Given that judicial exceptions, such as abstract ideas and natural laws, are a part of all inventions at some level, this first step of the *Mayo* test will continue to snare many patents. Questions regarding the precise definition of an “abstract idea” will likely continue, and with the concerns expressed by judges on the Federal Circuit and elsewhere it can be expected that more will be written on the subject.

## AREA 2: FURTHER DEFINING ‘SOMETHING MORE’

At the second step of *Mayo/Alice* test, courts “must examine the elements of the claim to determine whether it contains an ‘inventive concept’ sufficient to ‘transform’ the claimed abstract idea into a patent-eligible application.”<sup>10</sup> As with the first step, the boundaries of this step have been explored in recent decisions.

The inventive concept in *Sequenom* resulted in a new and groundbreaking fetal diagnostic test. However, the Federal Circuit did not find that result enough to transform the claimed invention to patent-eligible subject matter. Instead, the *Sequenom* panel decision held that the claims recited routine and conventional steps and that “appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept.”<sup>11</sup>

Just what amounts to “routine and conventional” is unclear. The use of “routine and conventional” appears to set a lower standard than what is required by 35 U.S.C.A. § 102 for novelty and 35 U.S.C.A. § 103 for non-obviousness. It appears that something can be known and obvious in the art without being routine and conventional. However, unlike novelty and non-obviousness, which have been explored by years of judicial decisions, there are many questions that still are unanswered about when technology becomes “routine and conventional.”

For example, because most computer programs build upon well-known libraries and patterns of code, those abstract ideas will likely be implemented using conventional techniques, which may make it difficult for some software to amount to more than an abstract idea.

Some on the Federal Circuit expressed concerns that such a use of the “inventive concept” test would have significant effects on life science industries. For example, U.S. Circuit Judge Timothy B. Dyk stated in the en banc denial that:

*Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself. This is especially true in the life sciences, where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems. I worry that method claims that apply newly discovered natural laws and phenomena in somewhat conventional ways are screened out by the *Mayo* test.<sup>12</sup>

As U.S. Circuit Judge Richard Linn said in his concurrence in the *Sequenom* panel decision, “[t]his case represents the consequence — perhaps unintended — of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.”<sup>13</sup>

With life science and software inventions continuing to be before the Federal Circuit, federal district courts and Patent Trial and Appeals Boards, tensions between the “something more” test and meritorious inventions will likely continue in 2016.

## MORE AREAS OF SUBJECT MATTER ELIGIBILITY TO WATCH

While developments relating to the steps of the *Mayo/Alice* test are important, they are not the only trends to watch for in 2016. As issues of subject matter eligibility continue to be explored, there are several additional areas of potential development to watch. These include:

### ***Patent application publications in view of Alice and Mayo***

Patent applications are generally published 18 months after filing, which makes them and their associated papers publicly available. *Mayo* was decided in March 2012, and *Alice* was decided in June 2014. This means that in 2016, applications drafted in view of *Alice* will begin to publish and applications drafted in view of *Mayo* may begin to receive their first office actions. These public documents will provide a good resource for patent practitioners when drafting their own applications and responses to office actions.

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### More non-publication requests

An applicant may request that a patent application not publish. This prevents the application and its papers from being made publicly available until the application issues as a patent. Some of the subject matter that is hardest hit by the recent Section 101 precedent may be the kind of subject matter that can be protected as a trade secret. There may be an increase in non-publication requests as practitioners preserve the option to pursue trade secret protection if an application’s claims appear stuck after a few office actions.

### More declarations

During prosecution, a response to an office action may include evidence submitted by way of a declaration or affidavit. However, it appears that declarations and affidavits are not often used when responding to office actions that reject claims for subject matter ineligibility. Indeed, during the question-and-answer segment of the U.S. Patent and Trademark Office’s Jan. 21, 2015, forum on subject matter eligibility, Greg Vidovich, a group director of PTO work groups examining e-commerce technology, mentioned that he “actually expected more affidavits” regarding subject matter eligibility.<sup>14</sup> He said, “We haven’t seen many declarations. ... I don’t know the exact number but it’s been very, very low at this point.” As practitioners continue to look for ways to overcome subject matter eligibility rejections, 2016 may see an increased use of declarations or affidavits.

### More Jepson-type claims

Jepson-type claims are claims that follow a claiming strategy in which the scope of prior art is described and an improvement over the prior art is claimed.<sup>15</sup> In denying the rehearing of *Sequenom* en banc, Judge Lourie said, “The claim to this invention ... might have been better drafted as a so-called Jepson claim.”<sup>16</sup> While patent practitioners often shy away from Jepson-type claims because of the risk of mischaracterizing the prior art, the challenges posed by the recent cases on Section 101 and the suggestion by Judge Lourie may inspire a resurgence of this technique.

## CONCLUSION

Patentees and technology companies continue to labor under significant uncertainty regarding the validity of existing patents and the eligibility of future innovations for patent protection. As more patents are challenged, and as the PTO continues to develop its review process with respect to new applications, further clarity is likely to emerge on what innovations, or aspects of innovations, are able to pass muster as subject matter eligible.

## NOTES

<sup>1</sup> *Ariosa Diagnostics Inc. v. Sequenom Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *reh’g denied*, 809 F.3d 1282 (Fed. Cir. 2015), *petition for cert. filed*, No. 15-1182 (U.S. Mar. 21, 2016).

<sup>2</sup> *Ariosa Diagnostics*, 809 F.3d at 1287 (Lourie, J., concurring).

<sup>3</sup> 132 S. Ct. 1289 (2012).

<sup>4</sup> 134 S. Ct. 2347 (2014).

<sup>5</sup> See, e.g., July 2015 Update Appendix 3: Subject Matter Eligibility Court Decisions (a collection of court decisions relating to subject matter eligibility that is maintained by the PTO), available at <http://1.usa.gov/1qUZR2X>.

<sup>6</sup> *Alice*, 134 S. Ct. at 2354 (quoting *Mayo*, 132 S. Ct. at 1293).

<sup>7</sup> *Ariosa Diagnostics*, 809 F.3d at 1285 (Lourie, J., concurring).

<sup>8</sup> *Id.*

<sup>9</sup> *Cal. Inst. of Tech. v. Hughes Commc’ns Inc.*, 59 F. Supp. 3d 974, 994 (C.D. Cal. 2014) (explaining further that “[c]ourts should not view software as abstract simply because it exists in an intangible form. It is as fruitless to say that a human could use pencil and paper to perform the same calculations as a computer, as it is to say that a human could use pencil and paper to write down the chemical structure of a DNA

strand. In either case, any effort on the part of a human will only be a symbolic representation. The effort will not produce the same effect as executing a computer program or isolating a DNA strand.”).

<sup>10</sup> *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1298).

<sup>11</sup> *Ariosa Diagnostics*, 788 F.3d at 1378.

<sup>12</sup> *Ariosa Diagnostics*, 809 F.3d at 1289.

<sup>13</sup> *Ariosa Diagnostics*, 788 F.3d at 1380.

<sup>14</sup> See Subject Matter Eligibility Forum – Part 3, at 51:05, available at <http://livestream.com/uspto/SubjectMatterForum2015>; but see Order on Motion to Strike, *Genband US LLC v. Metaswitch Networks Corp.*, Case No. 2:14-cv-33-JRG-RSP, at \*6 (E.D. Tex. Jan. 8, 2016) (noting that “to the extent expert testimony is helpful when deciding a question of law such as subject matter eligibility, its utility is limited to supplying background facts about the nature of the art and the patents”).

<sup>15</sup> Manual of Patent Examining Procedure § 2129(III) (describing Jepson claims (citing 37 C.F.R. § 1.75(e))).

<sup>16</sup> *Ariosa Diagnostics*, 809 F.3d at 1286.



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