2017-2508

United States Court of Appeals for the Federal Circuit

ATHENA DIAGNOSTICS, INC., OXFORD UNIVERSITY INNOVATION LTD., MAX PLANCK GESELLSCHAFT ZUR FÖRDERUNG DER WISSENSCHAFTEN e.V.,

Plaintiffs-Appellants,

v.

MAYO COLLABORATIVE SERVICES, LLC, d/b/a MAYO MEDICAL LABORATORIES, MAYO CLINIC,

Defendants-Appellees.

Appeal from the United States District Court for the District of Massachusetts in Case No. 1:14-cv-40075-IT (Honorable Indira Talwani, Judge)

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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NOVEMBER 13, 2017

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

1. The full name of every party or *amicus curiae* represented by me is:

   Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization)

2. The name of the real parties in interest (if the party named in the caption is not the real party in interest) represented by me is:

   None.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are:

   None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this court are:

   Melissa A. Brand
   Hans Sauer
   Biotechnology Innovation Organization

   Brian P. Barrett
   Chair, BIO Amicus Committee
   Eli Lilly and Company

5. The title and number of any case know to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b).

   None.

Date: November 13, 2017

/s/ *Melissa A. Brand*
Counsel for Amicus Curiae BIO

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues of under $25 million.

BIO's members are concerned that, more than five years after the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), there continues to be unabated uncertainty about the patent-eligibility of many biotechnological inventions, with diagnostic and prognostic methods being particularly affected. The unstable state of patent-eligibility jurisprudence affects modern biotechnologies ranging from biomarker-assisted methods of drug treatment to companion diagnostic tests, fermentation products, industrial enzyme technology, and marker-assisted methods of plant breeding. As developers of, and investors in, such advanced technologies, BIO members have a strong interest in clear and predictable rules of patent-eligibility. *Amicus* BIO submits this brief in the hope that it will assist the court in the orderly development of the law in this important area. BIO has no direct stake in the result of this appeal

and takes no position on the ultimate validity of the patents at issue. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the *amicus curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member, and it is possible that individual members may have taken positions that are contrary to those expressed in this brief.

Pursuant to Federal Rule of Appellate Procedure 29(a), all parties have consented to BIO filing this brief.

ARGUMENT

A. This Court's Section 101 Precedent Should Be Applied Equally to Biotech Patents

In software cases, the Federal Circuit is increasingly applying a Step I analysis focusing on the invention's advance over the prior art: whether the claim offers a technical improvement over conventional prior art solutions; whether the claim improves the operation of previously-used methods, or similar articulations. This type of analysis is widely viewed as a positive development. As a result, it has been reported that big enterprise software companies no longer see a need for legislative intervention. *See, e.g.*, U.S. Patent & Trademark Office, Patent Eligible Subject Matter: Report on Views and Recommendations from the Public, at 39 (July 2017), https://cdn.patentlyo.com/media/2017/07/101-Report_FINAL1.pdf. But the courts

have not developed a corresponding approach for biotechnology patents. The instant appeal affords the opportunity to assess the applicability of the developments in software patent-eligibility cases to biotech patent cases and provide useful guidance to the district courts and biotech industry.

Post-*Alice*, a central issue in this Court's software patent-eligibility cases is whether the claims at issue focus on a specific means or method that improves a particular technology. For example, in *McRo, Inc. v. Bandai Namco Games America Inc.*, this Court held the claims at issue patent-eligible because they were directed to "a specific asserted improvement" in computer animation. 837 F.3d 1299, 1314 (Fed. Cir. 2016). In so concluding, the Court emphasized that there was no evidence of record that the claims simply automate a process previously used by those in this particular area of technology. *Id.* Similarly, in *Enfish, LLC v. Microsoft Corp.*, this Court rejected the argument that the disputed claims were simply directed to the concept of organizing information using a particular format, and concluded that the claims were patent-eligible because they were "directed to ***an improvement*** in the function of a computer." 822 F.3d 1327, 1337-38 (Fed. Cir. 2016) (emphasis added). Here too the Court noted that the solution recited in the claims at issue involved a "specific type" of structure "designed to improve" the function of the computer. *Id.* at 1339. This specific improvement to a particular technology-type analysis has assisted this Court in holding other software claims patent-eligible. *See, e.g.*, *DDR*

Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014) (holding claims directed to a solution that overcomes a problem specifically arising in the realm of computer networks patent-eligible); *Trading Techs. Int'l, Inc. v. CGW, Inc.*, 675 F. App'x 1001 (Fed. Cir. Jan. 18, 2017) (affirming patent-eligibility of claims directed to improving the accuracy of trader transactions and recognizing that "specific technologic modifications to solve a problem or improve the functioning of a known system generally produce patent-eligible subject matter").

In life sciences cases, courts are not taking the same approach. Such decisions often fail to analyze how a claim provides a technological improvement to the way a diagnosis or other laboratory technique was performed prior to the claimed invention. For example, the invention in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* was undoubtedly a great improvement over preexisting methods for diagnosing fetal aneuploidies. Nonetheless, the Court dismissed Sequenom's argument that before the patent at issue, "no one was using the plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA," and instead simply concluded that the diagnostic claims were directed to matter that is naturally occurring. 788 F.3d 1371, 1376 & 1379 (Fed. Cir. 2015). Likewise, in the instant case, the district court failed to assess whether the asserted claims recited a technological improvement over prior methods of diagnosing Myasthenia Gravis (MG). Refusing to give weight to the claim limitations requiring use of a man-made molecule (^{125}I-MuSK) to form

a radiolabeled antibody-antigen complex never previously used in diagnosing MG (*see* U.S. Patent 7,267,820 at cl. 7-9), the court found that the gist of the claims was merely directed to the discovery that some patients with MG have MuSK autoantibodies in their bodies.

The district court's approach is unfortunately not uncommon. Courts in biotechnology cases appear to simplify or avoid the Step I analysis by analogizing the claims at issue to those in *Mayo*, *Myriad*, *Cleveland Clinic*, and *Merial*, without considering the technological contribution of each claim. But why do claims to improvements over conventional prior art solutions merit consideration in software cases but not in biotechnology cases? Whatever the reason, one gets a sense that there is an ongoing important patent-eligibility case law development that is leaving almost no trace in biotech cases. In the one biotech case where the Federal Circuit arguably took an approach consistent with software related 101 cases by asking whether the invention was "directed to" an improvement of preexisting conventional technology, *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016), it found patent-eligibility. Had this approach been applied in other biotech cases, one can surmise that more claims would have survived the *Mayo/Alice* test. Because the ability of biotech companies to innovate is highly dependent on secure and reliable patent laws, and many in the industry are currently drafting patent

applications, it is necessary for this Court to clarify how the software approach to patent-eligibility translates into biotech claims.

B. Courts Should Invoke a More Meaningful Inquiry into What Biotech Claims are "Directed to"

The case also illustrates a problem that often bites diagnostic claims even harder than other biotech claims. Diagnostic or screening claims seem particularly vulnerable to being ensnared under *Mayo* Step I because on their face they are often "directed to" something naturally-occurring, making it easy to look past the totality of reagents, instruments, and transformative steps used in the laboratory process. Yet for any given claim there are many ways of articulating what the claim is supposedly "directed to." How do courts choose between equally plausible narratives; and why do they so often choose the one interpretation that makes the claim fit Step I, and how do we know this is the most correct choice?

For example, in this case the court relied on the "stated purpose of the patent" to conclude that the claimed method is directed to diagnosing MG, which the court concluded is a patent-ineligible law of nature. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, No. 15cv40075, 2017 WL 3336275, at *4 (D. Mass. Aug. 4, 2017). The court reworded this "gist" of the claims in a few different ways: "the patent is directed at a method for the diagnosis of a disease," *id.* at *3, "Plaintiffs' method seeks to measure autoantibodies that have attached to a receptor protein, an interaction which is a [] natural process," *id.* at *4, "what is new and useful here is

the discovery that some patients with [MG] have MuSK autoantibodies in their bodily fluid," *id*. The only seeming justification the court provided for reaching its conclusion that the limitations pertaining to man-made complexes created in a laboratory (i.e., claims 7-9) had no weight in the "directed to" inquiry was that the patent is not a "composition patent" and that the claim purportedly "does not produce something useful beyond th[e] diagnosis." *Id*.at *3, *4. But there is no precedent for drawing a distinction between method claims and composition claims in this context. *See Alice Corp. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2360 (2014). And there is no rule that says that the primary use for an end product of a claimed invention is dispositive of patent-eligibility. If this were the case, then claims like those at issue in *McRo*—the end use of which was automating animation—likewise would have failed Step I.

The *Athena* district court's analysis highlights the difficulties courts have faced in deciding to what biotechnology claims are directed. Taking Athena's claim 8 as an example, a court could determine that it is "directed to" any of the following:

- A method of diagnosing MG
- A method of diagnosing previously un-diagnosable patients having MG
- A method of forming a radiolabeled antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex
- A method of immunoprecipitating a radiolabeled antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex

Each of these is an equally plausible explanation of what claim 8 is "directed to," but that does not mean that selection of any one option is correct. *See, e.g.*,

CellzDirect, 827 F.3d at 1049 (explaining that just because "one way of describing the process is to describe the natural ability of the subject matter to *undergo* the process does not make the claim 'directed to' that natural ability"). This is not a trivial inquiry. The court's selection in this step can be crucial to the ability of a claim to survive a section 101 challenge. In the instant case, for example, the district court had a choice between two narratives: the claim is directed at "the creation of the 125I-MuSK-auto-antibody complex" or at "a method for the diagnosis of a disease." *Athena*, 2017 WL 3336275 at *3. A rational decision-maker could accept both statements as equally true: the asserted claims critically depend on the formation of the radiolabeled MuSK-antibody complex, which is the crucial step in the laboratory procedure – the "heart" of the claim, without which no result could be produced. Surely a decision-maker could conclude that this is what the claim is directed to. But of course it is equally true that the claim is directed to "a method of diagnosing MG." Forced to make an outcome-determinative choice between such equally valid propositions, courts have gone to great lengths to explain why their chosen option is right, without being able to explain why the rejected option is wrong. At bottom, the Step I inquiry thus relies heavily on the judge's intuition. It is, BIO submits, the most intuitive test in all of patent law, and this creates problems for appellate review as well as for the precedential value of such intuitive decision-making in subsequent cases.

Judge Linn made this point in his *Smart Sys. Innovations, LLC v. Chicago Transit Authority* dissent just recently, acknowledging that the Step I analysis often leads to arbitrary results and the improper striking down of meritorious claims. No. 2016-1233, 2017 WL 4654964, at *11 (Fed. Cir. Oct. 18, 2017). Judge Linn explained that despite the many section 101 decisions, there is no clear guidance as to how a court can reliably identify the "thrust" of the claims. *Id.* at *12. Despite five years of case law post-*Mayo*, it remains unclear where to "draw the line between properly determining what the claim is directed to and engaging in an overly reductionist exercise" to find the patent-ineligible concept underlying every claim. *Id.*at *11.

Biotech claims are almost certainly going to involve at least in part a natural law or natural phenomenon. Indeed, the Supreme Court acknowledged that ***all*** claims "at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. But the tendency in biotech cases is for courts at Step I to identify ***any*** law of nature or natural phenomena implicated by the claims, and then move to Step II without considering whether the claim in fact focuses on that law of nature or natural phenomenon. There is often no consideration of whether, for example, the claim depends on something more, like the "creation of a unique molecule." *See Ass'n for Molecular Pathology v. Myriad, Genetics, Inc.*, 133 S.Ct. 2107, 2118 (2013). Without addressing this issue, as Judge

Linn notes, the great uncertainty as to how courts should decide the "directed to" inquiry will remain a significant danger to "some of today's most important inventions" including "medical diagnostics." *Smart Sys.*, 2017 WL 4654964, at *11.

Moreover, this approach of automatically assuming Step I is met flies in the face of precedent acknowledging that diagnostic claims should not be per se patent-ineligible. In the series of Myriad cases, the Supreme Court and this Court both suggested that the patentee should be able to get some lesser claim scope. *See Myriad*, 133 S.Ct. at 2119-20; *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1349 (Fed. Cir. 2012) (*AMP II*) (Bryson, J., concurring in part, dissenting in part); *see also Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1288-89 (Dyk, J.) (concurring in denial of petition for rehearing en banc). But with courts striking down diagnostic patents without properly considering whether the claims are directed to innovative applications, it remains entirely unclear how a discoverer of a new genetic correlation or biomarker could procure any claim scope at all.

The hierarchy of claims in this case is illustrative: the claims proceed from a broad disembodied base claim (diagnose MG by detecting autoantibodies to MuSK) to particular detection methods (immunoprecipitation of auto-anti-MuSK-antibodies complexed to I-125-labeled MuSK substrate). Thus, while claim 1 (which was not asserted in this action), claims a broad method of diagnosis, claims 8 and 9 involve

specific and narrow techniques that require the creation of particular man-made molecules to improve prior art diagnostic techniques. Surely there can be no preemption concern with such targeted claims. And it is hard to see how such claims are not the types of "new applications of knowledge" that the Supreme Court indicated are patent-eligible in *Myriad*. Yet the district court here relegated the specific radiolabeling and immunoprecipitation limitations in claims 8 and 9 to the Step II inquiry, assessing whether they were routine and conventional. Had the court properly considered each of claims 8 and 9 as a whole, the court could have determined that these claims are not "directed to" patent-ineligible concepts, but instead are directed to specific applications of knowledge that improve a particular technology.

That these claims use a non-naturally-occurring "transformed" radiolabeled substrate (itself presumably patent-eligible) is important. In *AMP II*, this Court upheld a similar screening method claim using a transformed substrate. This part of the decision was never overruled or revisited.[1] In the relevant portion of *AMP II*, the method claim at issue (claim 20) comprised the steps of (1) growing host cells transformed with an altered gene, (2) determining the growth of cells with or without

[1] *See Myriad*, 133 S.Ct. at 2113 n.2 (noting the claims that were the subject of the Supreme Court's *Myriad* decision).

a potential therapeutic drug, and (3) comparing the growth rates of the cells. The panel unanimously agreed that

> Claim 20 thus recites a screening method premised on the use of "transformed" host cells. Those cells, like the patent-eligible cells in Chakrabarty, are not naturally occurring. Rather, they are derived by altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility. *See* '282 patent col.27 ll.28-33. The claim thus includes more than the abstract mental step of looking at two numbers and "comparing" two host cells' growth rates.

AMP II, 689 F.3d at 1336. The court explained that "once one has determined that a claimed composition of matter is patent-eligible subject matter" the use of known laboratory techniques does not render the claim patent-ineligible. *Id.* "The transformed, man-made nature of the underlying subject matter in claim 20 makes the claim patent-eligible." *Id.*

There is no reason to assume that this portion of *AMP II* is no longer valid precedent. But if it is, then guidance from this Court would be helpful as to how technological improvements in the diagnostics space can possibly receive patent protection. Surely it cannot be that to receive a claim, the patentee must invent a new reagent or laboratory equipment. Innovators in the software space do not have to create two inventions to get a single patent claim, and there is no reason to require it of innovators in the biotech arena. The value of diagnostic innovation is undeniable, and clarity as to how inventors in this space can protect their inventions is critical to continue incentivizing their advances.

C. Guidance Is Necessary Regarding the Inventive Concept Inquiry and Other Sections of the Patent Statute

The district court's difficulty in considering the relevance of the radioimmunoprecipitation assay steps to patent-eligibility carries through to its Step II analysis. Rather than addressing whether the combination of steps and reagents was routine and conventional, the court pointed to the specification and said that if the combination were not routine and conventional then the claims would lack written description and would be non-enabled. This is an unprecedented conflation of distinct patent law doctrines.

Using section 112 as a whipsaw to render claims patent-ineligible puts the patentee in an untenable position that flouts the legal standards applied in patent litigation. The district court effectively gave the patentee a choice: accept that your immunoprecipitation and iodination limitations are routine and conventional, or prove that your claims are enabled and have adequate written description. The court did not even require the defendant to establish any sort of failure under section 112. But it is well-established that the burden of proving lack of written description or non-enablement is always on the party alleging invalidity. *See Microsoft Corp. v. i4i Ltd.*, 564 U.S. 91, 100 (2011). Not only does the court's approach violate the tenet that patents are presumed valid, *id.*, but it ignores the fact that at the motion to dismiss stage, the facts must be construed in the light most favorable to plaintiff, *Ocasio-Hernández v. Fortuño-Burset*, 640 F.3d 1, 7 (1st Cir. 2011). Moreover,

because of the fact-intensive nature and complexities of these section 112 doctrines, it is virtually unheard of for such questions to be addressed at the motion to dismiss stage. Given these facts, it is difficult to understand how the district court could have properly concluded that in order for a patentee to demonstrate non-conventionality, the patentee must additionally prove written description and enablement.

The district court's approach also ignores the important distinctions between these doctrines. Whether the written description requirement is met requires an analysis of whether a person of ordinary skill in the art would have understood from the specification that the applicant possessed what it is that he claimed to have invented. *Ariad Pharm., Inc. v. Eli Lilly*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). An assessment of enablement requires an analysis of whether a person of ordinary skill in the art could have made and used the claimed invention. This inquiry is almost always informed by a fact-intensive assessment of the so-called *Wands* factors after a challenger has come forward with evidence that experimentation would be required to practice the claimed invention.[2] *Alcon Research Ltd. v. Barr*

[2] The court also erred in assuming that the supposed absence of a detailed disclosure of the complexity associated with the iodination and immunoprecipitation steps necessary renders the claims non-enabled. This Court has explained that a claim does not lack enablement where some experimentation is needed, so long as the experimentation required to practice to invention is not unduly extensive. *PPG Indus., Inc. v. Guardian Indust. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996). Thus, the district court was not correct to conclude that the absence of a detailed how-to necessarily means that the claim steps are routine and conventional.

Labs., Inc., 745 F.3d 1180, 1190 (Fed. Cir. 2014). Step II of the *Mayo*/*Alice* test asks whether the limitations are "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Alice*, 134 S.Ct. at 2355 (quoting *Mayo*, 566 U.S. at 72-73). To collapse these distinct inquiries into effectively two sides of the same coin is a dangerous oversimplification of each. It suggests that the requisite "inventive concept" must reside in claim elements whose practice is so extraordinarily difficult that ordinary artisans at the time could not have practiced them without undue experimentation, and that the inventor could not have had possession of them.

Taking just Step II and enablement as an example, the district court appears to assume that the inquiry into what is routine and conventional is the same as whether undue experimentation is required to practice. But undue experimentation is a fact specific eight-factor analysis (*In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)) whereas Step II is an amorphous search for "something more" in the claims. Moreover, accepting the district court's approach would be inconsistent with this Court's ruling in *Ariad* that written description and enablement are two separate doctrines. 598 F.3d at 1344. Surely if a court must analyze the written description and enablement requirements separately, a court cannot equate the inquiry under Step II with both of the separate inquiries for written description and enablement.

The numerous other differences between these section 112 requirements and the Step II analysis further counsel against tying them all together. For example, written description and enablement are viewed from the perspective of an ordinary skilled artisan; Step II is seemingly conducted from the viewpoint of the factfinder.[3] Courts assessing written description and enablement must engage in fact finding and such findings are owed deference on appeal; district courts appear to conduct the Step II inquiry without any formal fact finding. Written description and enablement are almost always assessed after claim construction whereas courts have been permitted to invalidate claims under section 101 without claim construction (as was the case in the instant action). Written description and enablement are statutory requirements for patentability; whether limitations recite more than routine or conventional activity is one part of a two-step test developed in the common law. Expert testimony is widely used to assess written description and enablement; courts frequently conduct the Step II inquiry without the aid of expert opinion.

Under the district court's logic, it can reject a patentee's argument about one issue by presuming that the argument would invalidate the patent on two unrelated grounds without having to perform the required legal analysis for those doctrines.

[3] It is not clear that this is how Step II should be conducted, but given that this Court has stated that a district court may find claims patent-ineligible at the motion to dismiss stage, which is typically before a finding of the applicable standard for a person of ordinary skill in the art, it appears that the Step II analysis need not be viewed from the perspective of the ordinarily skilled artisan.

And despite the presumption of validity, apparently, it is the patentee's burden to prove the validity of its claims. That is not logical, but it is dangerous. Without guidance from this Court, there is a significant threat that other district courts could use this logic to easily dismiss a patentee's Step II arguments based on some supposed relationship to other unproven grounds of invalidity. To the extent that there is a relationship between Step II and section 112, clarification would be helpful to innovators seeking patent protection.

CONCLUSION

For these reasons, BIO respectfully requests that the Court address these issues and provide guidance as to the application of the developments in section 101 jurisprudence to patented biotechnology innovations.

Respectfully submitted,

Date: November 13, 2017 /s/ *Melissa A. Brand*

Counsel for Amicus Curiae BIO

United States Court of Appeals
for the Federal Circuit

ATHENA DIAGNOSTICS, INC., ET AL. v. MAYO COLLABORATIVE SERVICES, LLC, ET AL., No. **2017-2508**

CERTIFICATE OF SERVICE

I, Melissa Pickett, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Amicus Curiae, BIOTECHNOLOGY INNOVATION ORGANIZATION to print this document. I am an employee of Counsel Press.

On **November 13, 2017**, Counsel for *Amicus Curiae* has authorized me to electronically file the foregoing **THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS AMICUS CURIAE IN SUPPORT OF NEITHER PARTY** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

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