View Online

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

February 2019

VISIT WEBSITE | CONTACT US | SUBSCRIBE | FORWARD TO A FRIEND

The *PTAB Strategies and Insights* newsletter provides timely updates and insights into how best to handle proceedings at the USPTO. It is designed to increase return on investment for all stakeholders looking at the entire patent life cycle in a global portfolio.

In addition to our newsletter articles this month, we direct your attention to the publication of our annual review of the top cases to reach the Federal Circuit from the PTAB. This is the third annual report on appeals from the PTAB to the Federal Circuit. A pdf of the full report can be downloaded from the Sterne Kessler Goldstein & Fox website here.

This month, we cover three topics:

- We are reprinting by permission an article by Rob Sterne addressing the challenges associated with subject matter eligibility stemming from the Federal Circuit's decision in *Athena Diagnostics v Mayo Collaborative Services*;
- We examine two Federal Circuit decisions allowing a single Petition Ground to include alternative invalidity theories; and
- We examine two new rulings on standing to appeal including one unique to joinder petitioners.

We welcome feedback and suggestions about this newsletter to ensure we are meeting the needs and expectations of our readers. So if you have topics you wish to see explored within an issue of the newsletter, please reach out to me.

IN THIS ISSUE

DOWNLOAD

To view our past issues, as well as other firm newsletters, please click here.

Thank you.

Best regards,
Jason

Editor & Author:

Jason D. Eisenberg
Director
jasone@sternekessler.com

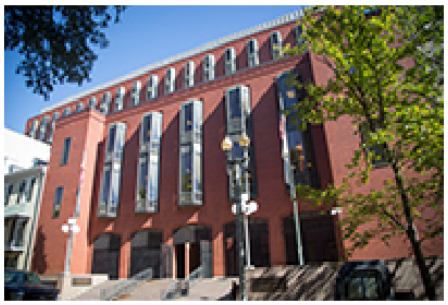
Author:

Robert Greene Sterne
Director
rsterne@sternekessler.com

Author:

Trent W. Merrell
Associate
tmerrell@sternekessler.com

FOCUS2019 #6 - IMPORTANT SCIENTIFIC DISCOVERY DOES NOT GUARANTEE U.S. PATENT ELIGIBILITY



By: Robert Greene Sterne

A method of diagnosing neurological disorders invented by researchers at Oxford University and the Max-Planck Society was found patent ineligible by the Federal Circuit in the case *Athena Diagnostics, Inc. v. Mayo Collaborative Services (2017-2508)* on February 6. This is a troubling decision for innovators in medical diagnostics because it demonstrates in stark relief the impact of the Supreme Court's 2012 diagnostic eligibility decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and its 2014 two-step patent eligibility decision in *Alice Corp. v. CLS Bank International*.

Read More

WITH THE RIGHT LANGUAGE, FEDERAL CIRCUIT FINDS ALTERNATIVE INVALIDITY THEORIES OK EVEN WITHIN A SINGLE GROUND

By: Trent W. Merrell and Jason D. Eisenberg

In a precedential decision Realtime (page 8-9) and a follow-on non-precedential decision Polygroup (page 15), two Federal Circuit panels (with Dyk on each) appear to hold that a single two-reference obviousness Ground, when articulated correctly, can be two Grounds -- alternative single-reference and two-reference Grounds. Here, each petition included the

general statements: (A) Ref 1 teaches all the claim features but (B) if Ref 1 lacks feature X, then Ref 2 teaches the feature. The Federal Circuit held they will read this part of the petition as asserting both (A) a one-reference Ground, and if that reference lacks feature X then (B) a two-reference obviousness Ground. This appears to be true even if the statement of the grounds lacks an articulation of this alternative theory of invalidity.

Read More

FEDERAL CIRCUIT ISSUES FURTHER GUIDANCE ON AIA PROCEEDING STANDING TO APPEAL

By: Jason D. Eisenberg

Joinder Petitioners Have Standing To Appeal

In *Mylan v. Research Corporation Tech (RCT)*, the Patent Owner, who won at the PTAB, argued that time barred joinder petitioners (Mylan, Breckenridge and Alembic - Appellants) could not appeal if the non-time barred petitioner (Argentum) could not appeal because Appellants were not within the zone of interest under 35 USC 319. The Federal Circuit disagreed, allowed the appeal, and affirmed the Patent Owner's win at the PTAB.

Read More

View Online

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

February 2019

VISIT WEBSITE | CONTACT US | SUBSCRIBE | FORWARD TO A FRIEND

FOCUS2019 #6 - IMPORTANT SCIENTIFIC DISCOVERY DOES NOT GUARANTEE U.S. PATENT ELIGIBILITY

This article is a reprint of Robert G. Sterne's weekly newsletter, dated February 13, 2019. Rob Sterne produces a private newsletter, distributed to an invited list of recipients. This article is reprinted by permission. For information about obtaining an invitation to Rob Sterne's weekly newsletter, please email Bonnie Wertz with a request to be added to the list.

By: Robert Greene Sterne

A method of diagnosing neurological disorders invented by researchers at Oxford University and the Max-Planck Society was found patent ineligible by the Federal Circuit in the case *Athena Diagnostics, Inc. v. Mayo Collaborative Services (2017-2508)* on February 6. This is a troubling decision for innovators in medical diagnostics because it demonstrates in stark relief the impact of the Supreme Court's 2012 diagnostic eligibility decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and its 2014 two-step patent eligibility decision in *Alice Corp. v. CLS Bank International*.

The patent owners asserted U.S. Patent No. 7,267,820 in the US District Court in Massachusetts, one of the leading medical innovation centers in the U.S. At the beginning of the case, the defendant filed a motion to have the case dismissed for failure to state a claim. The invention focused on diagnosing *myasthenia gravis* ("MG"), a neurological disorder where patients experience muscle weakness and symptoms including drooping eyelids, double vision, and slurred speech. The court determined that the claims focused on the interaction of 125I-labeled MuSK with MuSK autoantibodies in bodily fluid, an interaction which occurs naturally. Applying the *Mayo* and *Alice* tests, the court concluded that the claims were directed to a law of nature and that the recited diagnostic steps involved only standard techniques in the art. As such, the claims were found to be patent ineligible – despite the importance of the discovery and its medical significance – and the court dismissed the case.

A panel of Judges Newman, Lourie, and Stoll heard arguments at the Federal Circuit. Each was an expert patent attorney before being elevated to the bench, so the patent owners could not have had a more sympathetic panel. It is worth listening to the October 4, 2018 Federal Circuit oral argument to get a full appreciation of the judges' concerns about the patent eligibility issue before them.

Judge Lourie: So how does one protect the discovery of the relationship between the MuSK antibody complex and the disease other than with a Nobel Prize?

Counsel for Mayo: The relationship your Honor is not protectable. That's the answer. If they want to have a claim to their special method of iodination they are free to try to get one, and if there is something special about iodinating or something special that requires human intervention in doing this test they can go get a claim to that and try to articulate it. But what the law prevents, as it currently stands, is a claim that is directed to a natural law that uses conventional steps to elucidate or observe, if you will, that natural law. That is what this claim absolutely does.

(Link to Oral Recording: Excerpt from 19:04 to 19:58)

Clearly U.S. patent law does not reward enforceable patents only to those inventions receiving a Nobel Prize. Judge Newman follows Judge Lourie's question with ones involving the public policy of encouraging investment in diagnostic methods through patent protection.

The panel split 2:1 with Judges Lourie and Stoll finding the claims patent ineligible and Judge Newman writing a strong dissent in favor of patent eligibility. This decision extends the Federal Circuit diagnostic invention holdings of ineligibility of *Ariosa Diagnostics, Inc. v. Sequenom, Inc*. and *Cleveland Clinic Found. V. True Health Diagnostics LLC*.

There was significant *amicus* interest in this case**.** Some of the Federal Circuit judges seem frustrated with this harsh treatment of diagnostic innovation, but the court appears hamstrung and powerless to do anything differently because of the recent Supreme Court decisions. The biotech industry is particularly harmed and biotech interests may seek legislation from the U.S. Congress to change the law. But there are powerful economic interests that want to preserve this new legal regime who undoubtedly will lobby extensively against such legislation.

The U.S. appears to be more restrictive than other industrial market concerning patent eligibility for medical diagnostics. Based on anecdotal evidence, this has already resulted in lack of investment in the U.S. for some very promising technology. Moreover, investment is clearly moving to those jurisdictions where there is better patent eligibility protection. This does not bode well for the U.S. medical innovation community, which includes some of the most prominent academic institutions and teaching hospitals in the world. With declining U.S. investment in basic research, this undoubtedly will result in less U.S. innovation.

From a patent protection point of view, patent drafters must be vigilant in tracking this developing law to optimize the chances of success on the patent eligibility issue. The '820 patent was drafted prior to the *Mayo* decision and statements made in the patent specification later undermined patent eligibility. The claims were broad and care should be taken to avoid broader scope than is necessary for infringement protection. The use of declarations during patent prosecution should be considered. And the court complaint should include support for patent eligibility. All of this is good lawyering under the present circumstances, but in the long run something needs to be done to encourage U.S. investment in this critical technology for the future of mankind.

My partners Pauline M. Pelletier and Jeremiah B. Frueauf have published an excellent client

alert on this case that warrants your attention. As always, all errors in this newsletter are mine alone.

Best regards,
Rob Sterne

This e-newsletter is for educational purposes only and does not constitute legal advice. The views expressed are those of the author(s) and do not necessarily reflect those of Sterne Kessler Goldstein & Fox PLLC or any other organization or individual.

Technical Minds. Legal Muscle.

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

February 2019

WITH THE RIGHT LANGUAGE, FEDERAL CIRCUIT FINDS ALTERNATIVE INVALIDITY THEORIES OK EVEN WITHIN A SINGLE GROUND

By: Trent W. Merrell and Jason D. Eisenberg

In a precedential decision Realtime (page 8-9) and a follow-on non-precedential decision Polygroup (page 15), two Federal Circuit panels (with Dyk on each) appear to hold that a single two-reference obviousness Ground, when articulated correctly, can be two Grounds -- alternative single-reference and two-reference Grounds. Here, each petition included the general statements: (A) Ref 1 teaches all the claim features but (B) if Ref 1 lacks feature X, then Ref 2 teaches the feature. The Federal Circuit held they will read this part of the petition as asserting both (A) a one-reference Ground, and if that reference lacks feature X then (B) a two-reference obviousness Ground. This appears to be true even if the statement of the grounds lacks an articulation of this alternative theory of invalidity.

Since 2012 many Patent Owners have argued, and the PTAB has generally agreed, for a petition to comply with the statute and rules each ground must be listed in the statement of grounds and separately argued within the petition. Without the statement of grounds explicitly stating that the Petitioner is arguing two grounds, and a separation of grounds within the arguments section, Patent Owners have argued neither they nor the Board can properly evaluate, and respond to, the merits in the petition.

On the other hand, there are many instances where petitioners may believe that a main reference actually teaches all the features of a claim under their proffered meaning of a controversial claim term, but a secondary reference may be needed, in the event that the Board disagrees with their proposed claim construction(s). Or, there are also cases where, although the main references at least suggest a teaching, a secondary reference explicitly teaches the claim term and fills any potential gaps in the main reference. In both cases, petitioners may now feel more encouraged that they can meet the statute and rules using the language found in

the *Realtime* and *Polygroup* petitions.

In the end, Patent Owner challenges of this alleged posturing by a Petitioner may be weakened by these Federal Circuit decisions. For now, however, the Rules still require petitioners to "identify the specific statutory grounds on which the challenge to the claim is based and the patents or printed publications relied upon for each ground." 37 C.F.R. § 42.104(b)(4). But, there must still be a line between (a) cases where petitioners articulate the alternative-ground language of *Realtime* and *Polygroup* and (b) cases where petitioners fail to clearly articulate the grounds and require the Board to play archeologist with the record.

Only time will tell if the PTAB changes its current position and whether Patent Owners can use a different line of attack in this situation to show the petition is deficient warranting denial.

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

February 2019

FEDERAL CIRCUIT ISSUES FURTHER GUIDANCE ON AIA PROCEEDING STANDING TO APPEAL

By: Jason D. Eisenberg

Joinder Petitioners Have Standing To Appeal

In *Mylan v. Research Corporation Tech (RCT)*, the Patent Owner, who won at the PTAB, argued that time barred joinder petitioners (Mylan, Breckenridge and Alembic - Appellants) could not appeal if the non-time barred petitioner (Argentum) could not appeal because Appellants were not within the zone of interest under 35 USC 319. The Federal Circuit disagreed, allowed the appeal, and affirmed the Patent Owner's win at the PTAB.

The Court needed to determine whether Congress authorized appeal for joinder petitioners when the first petitioner (Argentum) had no right to appeal. The Court found Section 315 contemplates joined petitioners as "parties." The Court then noted Section 319 provides that "[a] party dissatisfied with the final written decision" of the Board "may appeal the decision pursuant to sections 141 through 144. Any party to the inter partes review shall have the right to be a party to the appeal." And the Court found party should mean the same thing between Sections 315 and 319. Further, the Court found that despite Appellants being subordinate to Argentum during the PTAB trial based on their joinder status, that did not diminish their ability to be full appellants. Finally, Appellants appeal was not an improper end around the time bar rules.

Generic That Ends Activities Ends Standing to Appeal

In *Momenta v. Bristol Myers Squibb*, the Federal Circuit found no standing. The Court reiterated that although an AIA proceeding does not require case or controversy standing to file agency proceeding, those factors were still required for appeal. Here, Momenta, a generic, has ceased all infringing activity – development of a Orencia® biosimilar -before the end of their IPR trial, although to that point it had spent millions of dollars. And Momenta was subject to all

petitioner estoppels for having brought the IPR proceeding. Further, Momenta argued it might receive a royalty from another generic, Mylan. Despite these facts, the Court relied on *Consumer Watchdog, RPX v ChanBaond, JTEKT v GKN, DuPont v Synvina,* along with several Supreme Court standing decisions(*Lujan, Summers v Earth Island, Cuozzo, etc.)*, to find no standing and mootness of the appeal because there was no actual case or controversy without any real potential for injury or injury in fact to Momenta. The etsoppel provisions and weak potential for future royalties failed to supersede the fact that there was no longer a thread of infringement since Momenta ceased all activities directed toward this biosimilar.

Technical Minds. Legal Muscle.