IP & TECHNOLOGY NEWSLETTER

WINTER RECAP 2020

IN THIS ISSUE

Edited by: Amanda Rosenfield Lippes and Erin S. Phillips

BOND
BSK.COM

PATENT PROSECUTION

Diagnosis vs. Treatment: When Does Patient Care Become Patentable?

By: Erin S. Phillips[1]

On January 13, 2020, the Supreme Court denied certiorari in two patent eligibility cases, signaling a clear distinction between the eligibility of diagnosis methods and treatment methods – or, perhaps more likely – volleying any 35 U.S.C. § 101 issues to Congress.

Methods for Disease Diagnosis

The Federal Circuit decided *Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC* in February 2019. 915 F.3d 743. Athena patented a method for diagnosing an autoimmune disease by detecting the binding of an autoantibody to a radioactively labeled, naturally-occurring protein. Athena brought suit against Mayo, alleging that Mayo practiced the patented diagnosis method with test kits. Mayo sought to invalidate Athena's claims as ineligible subject matter under 35 U.S.C. § 101. Specifically, Mayo argued that Athena's claims were directed to a natural law: the correlation between the presence of naturally-occurring autoantibodies and the disease.

Athena countered with the argument that the correlation was not previously known. Athena also argued that the claims were patent eligible for two reasons: (1) the protein triggering production of the autoantibody was a man-made molecule because it was radioactively labeled and (2) the method included additional steps such as introducing the man-made molecule to a patient sample and isolating complexes formed by the binding of the autoantibody and the man-made molecule. The Federal Circuit, in a 2-1 split panel, agreed with Mayo that Athena's claims were directed to a natural law and any additional method steps were standard or known techniques that did not amount to significantly more.

Following the decision, Athena petitioned the Federal Circuit for rehearing *en banc*. The Federal Circuit issued a *per curium* Order in July 2019, denying the petition in a 7-5 split and issuing eight separate opinions (four concurring and four dissenting). *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* 927 F.3d 1333. While the Federal Circuit agreed that diagnostic kits and techniques *should* be patent eligible subject matter, the opinions reflected a disagreement as to whether the court was required to invalidate Athena's claims under the current § 101 jurisprudence. The concurring opinions expressed belief that the current *Mayo/Alice* framework successfully invalidates overly broad claims; however, they found the framework hard to apply consistently. The dissenting opinions articulated concern that the current § 101 jurisprudence creates a per se rule that diagnostic kits and techniques are ineligible subject matter, citing the Federal Circuit's invalidation of every diagnostic claim that has come before it – eight separate cases.

The clear confusion in the *per curium* Order led most following the case to believe that it was ripe for review by the Supreme Court. Athena petitioned for certiorari, asking the Court to consider the question, "[w]hether a new and specific method of diagnosing a medical condition is patent-eligible subject matter, where the method detects a molecule never previously linked to the

1 Ms. Phillips is an Associate in Bond's IP & Technology Group, concentrating her practice on patents, trademarks, copyrights, and trade secrets. She is a registered patent attorney with experience prosecuting and enforcing patents related to medical devices, diagnostic equipment, and surgical procedures.

condition using novel man-made molecules and a series of specific chemical steps never previously performed." Petition for a Writ of Certiorari at i, *Athena v. Mayo,* No. 19-430 (Oct. 1, 2019). The Supreme Court denied certiorari.

Methods for Treating Diseases

Hikma Pharmaceuticals petitioned the Supreme Court to consider the question, "[w]hether methods of using drugs to treat medical conditions are patent-eligible processes under Section 101." Petition for a Writ of Certiorari at i, *Hikma Pharms. Int'l Ltd. v. Vanda Pharms. USA, Inc.,* No. 18-817 (Jan. 28, 2019). Vanda Pharmaceuticals patented a method for treating a patient suffering from schizophrenia. The method for treatment generally includes the steps of obtaining a sample from a patient, performing genotyping on the patient, and administering a specific dose of a drug product based on the results of the genotyping. Hikma sought to develop and sell a generic version of Vanda's drug product and Vanda filed suit against Hikma.

Before the Federal Circuit, Hikma argued that Vanda's claims were essentially the same as the claims invalidated in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. 66 (2012). Rejecting Hikma's argument, the court held that *Mayo* claimed a diagnostic method based on "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.,* 887 F.3d 1117, 1280-1281 (citing *Mayo Collaborative Servs.,* 566 U.S. at 77). The Federal Circuit explained, "[a]lthough the representative claim in *Mayo* recited administering a thiopurine drug to a patient, the claim as a whole was not directed to the application of a drug to treat a particular disease." *Vanda Pharms. Inc.,* 887 F.3d at 1281. Thus, Vanda's claims describing the natural relationship between the drug product and the genotype only became patent eligible when the claims recited an application of the relationship (i.e., treating schizophrenia). Accordingly, the Federal Circuit upheld the validity of Vanda's treatment claims because they were "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." *Id.*

Claim Drafting and Eligibility Going Forward

Many view the *Athena* decision as a wholesale bar on patent eligibility for diagnostic claims. While this may appear to be true in view of *Athena*, there are a few exceptions. Diagnostic devices are still patent eligible if there are structural inventions, such as improvements in a lab-on-a-chip or point-of-care technologies, for example. Claims including nonroutine method steps and, in the best case, nonroutine methods steps which are taught away from in the prior art, can be patent eligible. *See Rapid Litig. Mgmt. v. CellzDirect, Inc.,* 827 F.3d 1042, 1048-1051 (holding a method for producing a preparation of a type of liver cell involving multiple freeze-thaw cycles not directed to a natural law because the prior art taught away from using *multiple* freeze-thaw cycles as compared to one free-thaw cycle).

The Federal Circuit distinguished *Athena* from *Vanda*, stating that "claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law" because it is not simply using a "well-known means of observing" a natural cause of an ailment. *Athena*, 915 F.3d at 753. Therefore, for eligible treatment method claims, the claims must not only recite administering a compound and observing its effects but also include the application (i.e., what it is treating). As evidence of this and in response to the *Vanda*

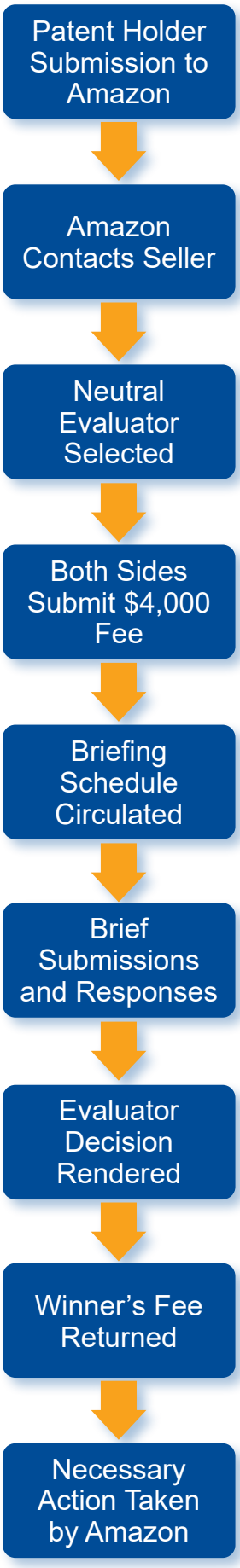
decision, the U.S. Patent and Trademark Office (USPTO) issued a memorandum in June 2018 discussing how the decision will affect the prosecution of future treatment method claims. The memorandum states that treatment claims *applying* natural relationships will be patent eligible under Step 2A of the USPTO's subject matter guidance (i.e., as not directed to a natural law). Thus, the USPTO will not require that a method for treatment "include nonroutine or unconventional steps" to be considered patent eligible under Step 2B.

Therefore, while most Federal Circuit judges may agree that the *Mayo/Alice* subject matter eligibility framework was not designed to create a distinction between methods for treatment and methods for diagnosis, the current application of § 101 jurisprudence has created one. Based on case law and guidance from the USPTO, it appears that most diagnostic method claims will require nonroutine and unconventional steps under Step 2B of the *Mayo/Alice* framework to become patent eligible while treatment method claims will not. With the certiorari denials this year, it appears we will have to wait for Congress to determine what innovations the patent system is aimed to protect.

PATENT INFRINGEMENT
Hope for Utility Patent Owners in Combating Infringement on Amazon

By: Zachary J. Dewey[2]

Amazon's new program called "Utility Patent Neutral Evaluation Procedure" promises to streamline resolution of infringement disputes by making the process timelier and less expensive than seeking a court order or an order from the International Trade Commission. However, the program is currently only available by invitation upon request.



Initial Application and Seller's Response

The evaluation process begins with the patent owner submitting basic information about itself, its patent, and *one* claim within a *single* U.S. utility patent that the owner asserts is being infringed by specific listings. Such listings are identified with an Amazon Standard Identification Number (ASIN), and the patent owner can only include multiple ASINs if the products thereunder are physically identical.

Once the accused seller has received the information, they have three weeks to either agree to participate in the evaluation or have the accused listings removed from Amazon's marketplace. If the seller agrees to participate, they must then provide Amazon with certain basic information.

Evaluator and Associated Fee

Amazon then uses the parties' submissions to select an appropriate Neutral Patent Evaluator from a list of attorneys experienced in U.S. patent disputes, presumably based on the technology at issue. Once the evaluator is selected, each party receives instructions on how to wire $4,000 to the evaluator to cover the associated fees. If the patent owner does not

2 Mr. Dewey is an Associate in Bond's Business & Transactions and Mergers & Acquisitions Groups, and previously worked in the Technology Transfer Office at the University at Buffalo.

submit the fee within two weeks, no evaluation will occur, and any seller fee submitted will be returned. If the accused seller does not submit the fee, the evaluator notifies Amazon which will then remove the accused listing belonging to that seller. The winner is refunded its fee at the end of the evaluation. The fee exists only to cover the evaluator's time and is not an Amazon revenue-generating mechanism.[3]

Let's Be Brief!

Once the evaluator receives the fees, it sets a schedule for briefing patent invalidity and infringement. Typically, the patent owner has 21 days to submit its opening brief, the seller has 14 days to file a response, and then the patent owner has 7 days to submit a reply, if they choose.

The patent owner is limited to 20 pages total for both its opening brief and reply, and the accused seller is limited to 15 pages for its response. No discovery is allowed and there is no formal evaluator hearing.

Additionally, the seller is limited to *three* arguments in its response:

1. the accused products do not infringe;
2. the asserted patent has already been declared invalid or unenforceable by a court of competent jurisdiction; and/or,
3. that the accused (or physically identical) products were on sale one year or more before the asserted patent's earliest effective filing date.

All of these arguments are able to be independently verified based on credible evidence.

The Decision

Based on the submissions, and within 14 days from the patent owner's reply brief, the evaluator issues a yes/no decision as to whether the patent owner is likely to prove infringement with respect to the accused product(s). If the patent owner wins, the evaluator will not provide any reasoning for its decision and Amazon will remove the listing(s) within 10 business days of receiving the decision. If the seller wins, the evaluator will provide a brief explanation as to why it found the patent owner not likely to prove infringement and Amazon will not remove the accused product(s).

There is no appeal or reconsideration process. However, Amazon will honor a subsequent district court, ITC, or USPTO order on the patent owner's behalf that is contrary to the evaluator's decision. Likewise, in order to be reinstated on Amazon, any accused seller can obtain a judgment or order in litigation that an accused product does not infringe or that the asserted patent is invalid or unenforceable. That accused seller may then submit it to Amazon, and Amazon *may* allow relisting of the accused product.

Settlement Mechanism and Continuing Infringement

It should be noted that after the accused seller has submitted their response, but before the patent owner submits their reply, the parties can settle their dispute and the evaluator will then terminate the evaluation. The evaluator can retain up to $1,000 to cover their efforts, equally divided from the parties' payments when settlement occurs, and the remainder will be refunded to each respective party.

In addition to providing a streamlined mechanism for the initial dispute, where victory can be obtained without a previous order from a court of competent jurisdiction, the evaluator's decision can subsequently be used by the patent owner. This includes for purposes of reporting infringement to Amazon using its existing reporting procedures, just as they would have used a court or ITC order to have listings for infringing products removed both currently existing and in the future.

3 Multiple accused sellers must each pay $4,000; if the patent owner prevails, the evaluator keeps a combined pro-rated $4,000 and the remainder is donated to the Amazon Smile charity of the patent owner's choosing.

TRADEMARKS
Beware Common Trademark Scams

By: Dr. Blaine T. Bettinger[4]

Trademarks are one of the most valuable assets a person or company can possess. Obtaining a federal registration for a trademark provides strong protection for that asset. To obtain this strong federal protection, trademark owners must file and prosecute a trademark application with the United States Patent and Trademark Office (USPTO).

Unfortunately, scammers and unethical private companies recognize this need and exploit it by offering trademark owners expensive services that are either unnecessary or non-existent. Already prolific, these scams are on the rise as it becomes easier to digitally glean information about trademark applicants from public databases.

Within days of filing a trademark application, the application is listed in the federal trademark database along with the information provided by the applicant including the mark and the name and address of the trademark owner, as shown in the accompanying image below.

This free digital information is then easily scraped and used by scammers to target trademark owners.

Targeting of trademark owners by these scammers has always been accomplished via the mail. The scammer typically creates a company that has official-looking words such as “Trademark,” “Patent,” or “United States” to give the appearance that the company is either the USPTO or affiliated with the USPTO. The letter will contain information about the trademark application (which is easily obtainable from the database) and owner, and it will offer services that require a fee. The letter may even cite real due dates or sections of the U.S. Trademark Act to further bolster the appearance of validity.

Typically, the offered service is either worthless or requires a fee far greater than is necessary to perform a legitimate service. Trademark owners expecting to hear from the USPTO about their application are often unprepared for these convincing scam mailings. The exorbitant fees are often paid in the mistaken belief that they are required for a federal trademark application or registration.

4 Dr. Bettinger is Senior Counsel in Bond’s IP & Technology Group. His practice focuses on IP and technology matters, including patents, trademarks, copyrights and trade secrets.

Word Mark	**PODCAST**
Goods and Services	IC 041. US 100 101 107. G & S: Entertainment services, namely, providing podcasts. FIRST USE: 20190101
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	10,000,001
Filing Date	September 17, 2019
Current Basis	1A
Original Filing Basis	1A
Published for Opposition	February 1, 2019
Owner	(APPLICANT) LAST NAME, FIRST NAME, INDIVIDUAL UNITED STATES, Street Address, City, State, Zip"
Disclaimer	NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "PODCAST" APART FROM THE MARK AS SHOWN
Type of Mark	SERVICE MARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

Although the letter may sometimes contain fine print indicating that it is not an invoice or that the service is optional, the fine print is easily missed by a busy trademark owner.

If a trademark owner is working with an attorney to file an application, the USPTO will send all correspondence directly to the attorney. Unfortunately, this doesn't prevent scammers from sending mailings to the trademark owner. But, the attorney will keep the applicant apprised of all official communications, fees, and due dates. Trademark owners can thus rest easy knowing that the attorney is monitoring the case and can ignore these third-party mailings or send them to the attorney for review.

How Can You Avoid Being Scammed?

- Review all correspondence carefully! Official correspondence will come from the "United States Patent and Trademark Office" in Alexandria, Virginia, with zip code 22313.
- Know ahead of time exactly what fees and services are necessary to obtain a federal trademark registration.
- Work with an attorney to file your trademark application.

If you're working with an attorney to file a trademark application, contact that attorney immediately if you receive a letter from anyone other than that attorney about your trademark. Never contact or send money to a third-party organization about a trademark application without first contacting your attorney. For more information about trademark applications or trademark scams, contact us.

TRADEMARKS

New Trademark Filing Rules: What You Need To Know

By: Amanda Rosenfield Lippes[5]

As of February 15, 2020, all documents electronically filed with the U.S. Trademark Office (USPTO) must include an email address for the applicant or registrant. This applies to any new trademark applications, any filings to prosecute an existing application, and any filings to maintain a registered mark.

A separate email address for the applicant or registrant is required even if the applicant or registrant is represented by an attorney and the email address cannot be identical to the listed primary correspondence email address of the attorney.

Even for in-house counsel and attorneys representing themselves, two separate email address are still required: one for the owner and another for the attorney and they cannot be identical.

Note, when this rule was initially launched, the email address provided by the applicant or registrant was viewable in the filed document in the TSDR documents tab. As a result, scammers could scrape this additional information to target trademark owners with solicitations. On April 24, 2020, the USPTO announced it is now masking the email addresses provided with "XXXX" in the owner email address field to address these concerns. This masking has been applied even to those filings that occurred between February 15, 2020 and April 24, 2020. Thus, while trademark owners should expect to receive solicitations from scammers in the mail, they should not expect to receive solicitations via email.

What to do?

To comply with this requirement, trademark applicants and registrants can choose to use

5 Ms. Lippes is a Senior Associate in Bond's IP & Technology Group.

an already-existing email address they check regularly. Alternatively, applicants and registrants can choose to create a new email address specifically for the purpose of corresponding with the USPTO. For example, an applicant or registrant can create a new email address, such as, trademarks@yourdomainname.com. For applicants and registrants that are represented by an attorney, the USPTO will correspond only with the attorney of record regarding the trademark application or registration so this new email address will only be used in case the applicant or registrant is no longer represented by counsel.

To make sure applicants and registrants are aware of any official communications received from the USPTO at this new email address, an automatic forwarding rule can be created. This automatic forwarding rule can be set up to identify all communications received from an email address ending in "@USPTO.gov" and forward all such emails to one or more other email addresses.

All official correspondence regarding a trademark application or registration will come from the "United States Patent and Trademark Office" in Alexandria, Virginia, with zip code 22313 by mail. All official emails will come from the domain "@USPTO.gov." If an applicant or registrant receives any notice regarding their application or registration and is asked to provide payment to an address that does not belong to the USPTO do not pay it and send it to your attorney for proper verification.

NEWS & HIGHLIGHTS

COVID-19 and the USPTO: What to Know

By: Erin S. Phillips[6]

With the passing of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the USPTO announced extensions of certain patent and trademark-related deadlines on March 31, 2020 and April 28, 2020.

Prior to March 31st, the USPTO announced both the closing of its offices and its position that the effects of COVID-19 qualify as an "extraordinary situation" under 37 C.F.R. § 1.183 and 37 C.F.R. § 2.146. With this qualification, the USPTO waived certain requirements, such as the fee to revive abandoned trademark and patent applications, the fee to reinstate canceled/expired trademark registrations, and the requirement for original handwritten signatures on certain correspondence and for certain payments with the USPTO.

Under the CARES Act, the USPTO provided a 30-day extension of time for certain Patent- and PTAB-related deadlines and certain Trademark and TTAB-related deadlines. If an eligible document or fee was due between (and including) March 27, 2020 and April 30, 2020, the filing is considered timely if made within 30 days of the original due date, provided that the filing is accompanied by a statement that the delay in filing or payment is due to the COVID-19 outbreak (e.g., through office closures, cash flow interruptions, inaccessibility of files, personal or family illness, and travel delays). Certain time extensions only apply to small and micro entities, such as 30-day extensions for maintenance fee payments.

On April 28, 2020, the USPTO further extended the time to file eligible patent and trademark-related documents and to pay certain required fees, which otherwise would have been due between March 27 and May 31, to June 1, 2020.

As the COVID-19 situation continues to evolve, the USPTO may choose to extend relief under the CARES Act. If you believe that you are in need of relief for patent and trademark matters, please contact us.

6 *See* note 1.

BOND CONTACTS
INTELLECTUAL PROPERTY & TECHNOLOGY

Chair

George R. McGuire.....315.218.8515
gmcguire@bsk.com

Co-Deputy Chairs

David L. Nocilly.....315.218.8530
dnocilly@bsk.com

Jeremy P. Oczek.....716.416.7037
jpoczek@bsk.com

Attorneys

Jeffrey F. Allen.....585.362.4709
jeffreyallen@bsk.com

Mitchell J. Banas, Jr......716.416.7010
mbanas@bsk.com

Blaine T. Bettinger, Ph.D......315.218.8291
bbettinger@bsk.com

Daniel R. Carosa.....716.416.7116
dcarosa@bsk.com

Jessica L. Copeland.....716.416.7034
jcopeland@bsk.com

James D. Dati.....239.659.3845
jdati@bsk.com

Jonathan B. Fellows.....315.218.8120
jfellows@bsk.com

Suzanne O. Galbato.....315.218.8370
sgalbato@bsk.com

Brian J. Gerling.....315.218.8229
bgerling@bsk.com

Jonathan L. Gray.....315.218.8621
jgray@bsk.com

Amanda Rosenfield Lippes....716.416.7059
alippes@bsk.com

Lacey C. Miller.....315.218.8371
lmiller@bsk.com

Joseph M. Noto.....585.362.4704
jnoto@bsk.com

Louis Orbach.....315.218.8633
lorbach@bsk.com

Erin S. Phillips.....315.218.8511
ephillips@bsk.com

Sharon M. Porcellio.....716.416.7044
sporcellio@bsk.com

Jeffrey B. Powers.....585.362.4863
jpowers@bsk.com

Fred J.M. Price.....315.218.8130
fjprice@bsk.com

Charles C. Swanekamp.....716.416.7055
cswanekamp@bsk.com

Corey J. Zorsch.....716.416.7045
czorsch@bsk.com

Paralegals

Karen Meskos.....315.218.8266
kmeskos@bsk.com

Ann R. Miller.....315.218.8523
amiller@bsk.com

Christina L. Yaple.....716.416.7028
cyaple@bsk.com

Technical Advisor

Michael G. Bayne, Ph.D......315.218.8524
mbayne@bsk.com

BOND SCHOENECK & KING ATTORNEYS