Morgan Lewis

ANNUAL 2019 DIGEST

2019 PTAB DIGEST:

THE LATEST TRENDS AND DEVELOPMENTS IN POST-GRANT PROCEEDINGS

CONTENTS

INTRODUCTION

As of 2019, post-grant proceedings have been in use for seven years. Designed as an alternative to district court litigation, post-grant proceedings have offered litigants a faster and more cost-effective forum for resolving patent validity disputes. In turn, the Patent Trial and Appeal Board (PTAB or Board) continues to be one of most popular venues for litigating patent disputes, with 1,464 petitions filed in FY19 alone.

Even with this foundation, post-grant proceedings continue to evolve—both procedurally and substantively—from year to year, and 2019 was no exception. In the last year alone, the trial practice guide was updated for the first time to provide guidance on a variety of issues, from motions to exclude to procedures for oral hearing before the Board; the claim construction standard at the PTAB was changed to the *Phillips* standard used in district courts and at the International Trade Commission, thereby creating a unified process across all potential forums; and the one-year time bar was expanded to apply even when a properly served infringement complaint is dismissed without prejudice, thus barring defendants from filing an inter partes review (IPR) petition after the one-year period has lapsed.

Amid these changes, Morgan Lewis has helped clients navigate each stage of post-grant proceedings. We have represented both patent owners and petitioners in post-grant proceedings at the US Patent and Trademark Office (USPTO). In fact, we handled the second-ever IPR proceeding argued in front of the USPTO. Routinely recognized by organizations such as *Juristat, Patexia*, and *Managing Intellectual Property*, the Morgan Lewis post-grant proceedings team consists of lawyers with patent litigation experience and technical knowledge spanning numerous disciplines. Several of our team members have been further recognized as leading IP professionals, key trailblazers, and some of the top industry-focused practitioners in the field.

Morgan Lewis stays focused on our clients' objectives and the need for regular and consistent communication in an ever-shifting legal landscape. As part of that effort, our PTAB working group compiles our annual *PTAB Digest* to help clients stay apprised of new developments in PTAB practice.

This year's *PTAB Digest* provides an overview of PTAB statistics, trends, and updates that impact strategies and business decisions for patent owners and petitioners alike. Please feel free to reach out to us if you have any comments, questions, or suggestions, or would like to hear more about our PTAB experience.

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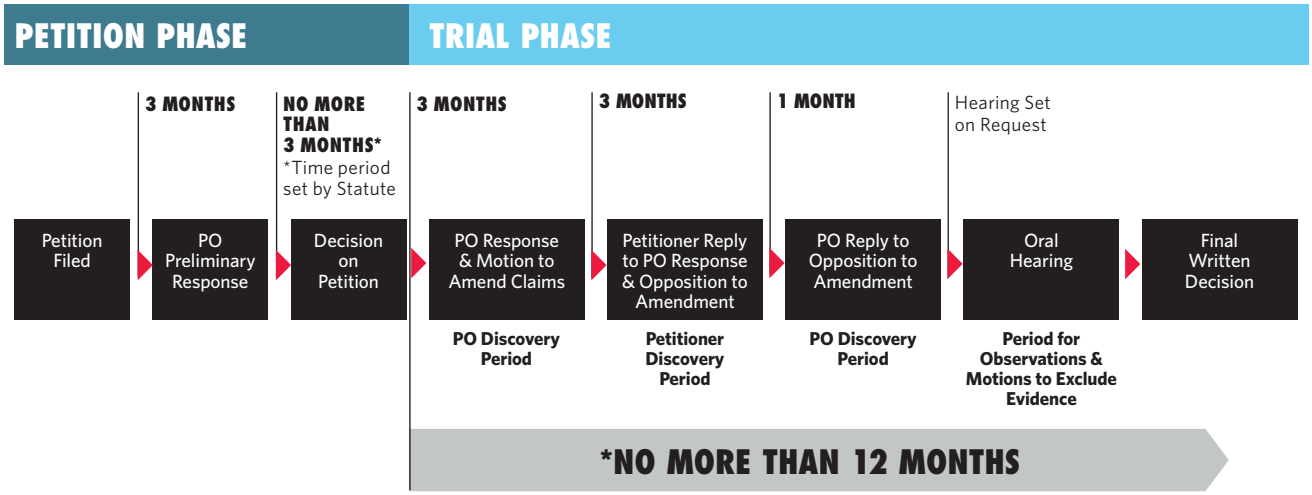
OVERVIEW OF POST-GRANT PROCEEDINGS

INTER PARTES REVIEW (IPR)

An inter partes review (IPR) is a trial proceeding before the US Patent Trial and Appeal Board (PTAB) for challenging the patentability of any subject matter claimed in an issued patent. Any party other than the patent owner can file an IPR petition. The only permissible grounds for challenging a patent in an IPR proceeding are anticipation and obviousness based on prior art patents or printed publications.

A challenger may initiate an IPR proceeding by an IPR petition to the PTAB asserting the unpatentability of one or more claims of a challenged patent.

TRIAL PROCEEDING TIMELINE



Source: USPTO

Within three months of the challenger's IPR petition submission, the patent owner may submit a preliminary response that may include a declaration from an expert. Upon review of the petition and the preliminary response, and within six months of the filing date the IPR petition was accorded, the PTAB will determine whether the challenger has established a reasonable likelihood that at least one claim is unpatentable.

If the PTAB institutes a trial, it will issue a scheduling order to generally complete the proceeding within 12 months of the institution date. The PTAB ultimately issues a final written decision on the patentability of the challenged claims. Either party can appeal the final decision to the US Court of Appeals for the Federal Circuit.

IPR provides several advantages to challengers as compared to litigation. An IPR proceeding is generally completed in 18 months or less from filing, whereas litigation on average takes at least two years to trial. In addition, the broadest claim construction standard and lower burden of proof for unpatentability are used in IPR proceedings versus litigation. These advantages lead to lower costs and a higher chance of success for challengers.

The downside of challenging patents via IPR is that if challengers do not prevail, they may be estopped from raising grounds that were raised or could have reasonably been raised in the IPR in subsequent proceedings before the US Patent and Trademark Office (USPTO), federal courts, and the US International Trade Commission.

IPR offers several benefits for challengers compared to other proceedings used to invalidate patents:

- IPR proceedings take less time than litigation to reach a final disposition, usually 18 months or less from filing the petition.
- IPR proceedings are substantially less expensive than litigation.
- IPR petitions may be filed at any time during the life of a patent, except for the nine months immediately following the issue date of a post–America Invents Act appeal.
- The petitioner may request a stay of any concurrent litigation in district court after filing an IPR petition.
- The standard of proof for invalidating a patent in an IPR proceeding is a "preponderance of the evidence" (~51%) rather than "clear and convincing evidence" (>70%), thereby allowing the challenger a greater likelihood of success.

IPR proceedings became available in 2013 with the enactment of the America Invents Act.

POST-GRANT REVIEW (PGR)

A post-grant review (PGR) is a trial proceeding conducted by the PTAB to determine the patentability of one or more claims of a patent that issued from an application filed after March 15, 2013.

The scope of challenges is much broader for PGRs compared to IPRs. In a PGR proceeding, the PTAB can institute trial on the basis of ineligible subject matter, lack of utility, lack of novelty, obviousness, lack of written description or enablement, and/or double patenting. Similar to an IPR proceeding, in a PGR proceeding claims in an unexpired patent are given their broadest reasonable interpretation, just as they are during prosecution before the USPTO.

Although PGR proceedings take place before the PTAB at the USPTO, they have some similarities to civil trials. In both IPRs and PGRs the parties can submit testimony in depositions and collect evidence.

To institute a PGR proceeding against a subject patent, a petitioner that has not previously filed a civil action challenging the validity of a claim of the subject patent must file a petition within nine months after patent issuance. Similar to an IPR, a PGR petitioner need not meet the standing requirements necessary for filing a declaratory judgment action in civil court, i.e., there is no requirement that there be an apprehension of suit. Also, IPR and PGR petitioners may not file their petitions anonymously.

In order to secure institution of a PGR, a petitioner must either

- show that it is more likely than not that at least one claim of the challenged patent is unpatentable, or
- raise a novel or unsettled legal question that is important to other patents or applications.

If the petition is granted, the PGR petitioner need only demonstrate the unpatentability of a challenged claim by a "preponderance of the evidence" rather than the "clear and convincing" standard used in civil court. A final determination by the PTAB will generally issue within one year of institution of the PGR (or 18 months from filing). Although PGR is used as an alternative to civil litigation, a petitioner should be wary of the estoppel effects of a PGR proceeding on subsequent litigation or other administrative proceedings (e.g., US International Trade Commission or USPTO actions). For example, if the PTAB issues a final written decision regarding the patentability of a claim, the petitioner(s) will be estopped from raising arguments in subsequent litigation or other administrative proceedings that were raised *or reasonably could have been raised* during the PGR.

PGR offers several benefits for a challenger compared to other proceedings used to invalidate a patent:

- PGR proceedings take less time than litigation to reach a final disposition—typically 18 months or less.
- PGR proceedings are a cost-effective alternative to litigation.
- The challenger's standard of proof for invalidating a patent is preponderance of the evidence rather than clear and convincing evidence, giving the challenger a greater likelihood of success.
- In addition to anticipation and obviousness based on printed publication or product prior art, a challenger may assert unpatentability of a patent on the basis of lack of enablement, lack of written description, and lack of patent-eligible subject matter (IPR proceedings allow only anticipation and obviousness challenges based on printed publications).

COVERED BUSINESS METHOD (CBM) PROCEEDINGS

Patents related to certain business methods may be challenged for patentability at the USPTO through a covered business method (CBM) review proceeding.

The transitional program for CBM patent reviews applies only to "covered business method patents," i.e., those patents that claim a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service. Claims for "technological inventions" are excluded from this definition. To be afforded review, the claims need to cover products and services that are financial in nature, while products and services that are only incidental to a financial activity likely will not be reviewed under CBM proceedings.

CBM proceedings are only available to persons who are accused of infringement of a covered business method patent. Generally, if a person is able to bring a declaratory judgment motion on a patent, he or she is eligible to file a CBM petition. However, a CBM petition cannot be filed if a PGR petition is available (i.e., within nine months after the issue date of a patent filed after March 15, 2013).

Similar to PGR proceedings, CBM proceedings may be used to challenge a claim of an issued patent on the grounds of utility, novelty, obviousness, written description, enablement, or double patenting.

Although CBM proceedings use many of the same standards and procedures as IPR and PGR proceedings, the estoppel provisions for CBM proceedings are different. Specifically, grounds that were not raised in a prior CBM proceeding but that reasonably could have been raised may still be raised in subsequent district court proceedings. However, like estoppel in a PGR proceeding, a challenger may not pursue subsequent actions in the USPTO based on any ground that was actually raised or reasonably could have been raised in the prior CBM proceeding.

The transitional program for CBM patent reviews is set to expire in September 2020.

EX PARTE REEXAMINATION

Ex parte reexamination may be requested by either a patent owner or a third party in order to challenge the novelty or nonobviousness of one or more claims in a patent. The scope of prior art submitted in support of the challenge is limited to printed publications and patents, while other types of prior art (such as product prior art) are inadmissible.

A request for ex parte reexamination can be filed at any time after a patent is granted and up to six years after it expires (a case-by-case determination may result in longer or shorter applicable time periods). A third party's involvement ceases after the party files the request. Upon review, the central reexamination unit of the USPTO will decide whether submitted prior art raises a substantial new question of patentability. Although ex parte reexaminations may take several years to conclude, there is no statutory time limit for the proceedings.

Ex parte reexamination provides several benefits for a third-party challenger compared to other proceedings used to invalidate a patent:

- Ex parte reexamination is a cost-effective alternative to litigation.
- The request can be submitted anonymously, e.g., the challenger may engage a third party for filing the request, thereby avoiding attention from the patent owner.
- The patentability threshold is lower than in court proceedings, increasing the likelihood of invalidating the challenged patent.
- Claims of the challenged patent are often narrowed, effectively removing an infringing article from the scope of the reexamined patent claims (amendment also has negative implications).
- Ex parte reexamination proceedings do not create legal estoppel.

Ex parte reexamination is not only available to challenge a patent; patent owners also may use the proceedings to test an issued patent. A patent owner looking to assert its patent, and therefore anticipating an invalidity challenge, may choose to initiate an ex parte reexamination before any litigation in order to resolve any anticipation or obviousness concerns about the patent. Having survived an ex parte reexamination, the patent then becomes more difficult to invalidate in a court proceeding on similar challenges.

DERIVATION PROCEEDINGS

A petitioner can use derivation proceedings to challenge the inventorship of an invention claimed in a published pending application or an issued patent. Only applications and patents having at least one claim with an effective filing date after March 15, 2013 are eligible for derivation proceedings. Derivation proceedings generally follow other PTAB trial procedures, such as an IPR or PGR, and may include limited discovery regarding issues specific to derivation.

A petitioner can use derivation proceedings to demonstrate that the filer of the patent "derived" the invention from the petitioner. Derivation proceedings are not designed to determine the "first to invent."

A petition requesting derivation proceedings must be filed within one year of publication of a pending application or one year of issuance of a patent, whichever is earlier, that claims the same or substantially the same invention as the invention in the petitioner's application. The petition must state with particularity the basis for finding that (a) an individual named in the earlier-filed application derived the invention from an individual named in the petition, and (b) the earlier application claiming the invention was filed without authorization.

A petition for derivation will be deemed insufficient unless it is supported by substantial evidence that includes at least one affidavit detailing corroborated communications of the invention to the first filer and a lack of authorization in filing the first application.

The PTAB may, in appropriate circumstances, correct the naming of an inventor in any application or patent at issue. In the alternative, the PTAB may refuse the claims of the earlier-filed application or cancel the claims of the involved patent. A decision adverse to the petitioner constitutes a final refusal of the petitioner's pending claims at issue.

Similar to patent interferences, and where applicable, derivation proceedings offer challengers a less costly opportunity to contest ownership of patented subject matter where the only alternative may be litigation.

PATENT INTERFERENCES

A patent interference is an inter partes proceeding to determine which party was the first to invent commonly claimed subject matter. An interference is also a viable procedure for challenging the validity of an issued patent or otherwise allowable claim(s) under virtually any theory of invalidity—provided that the challenged claims have an effective filing date of earlier than March 16, 2013. Applications with an effective filing date of March 16, 2013 or later are not subject to interference proceedings.

The only party that has standing to initiate or request an interference is an applicant with a pending patent application that contains allowable claims toward the same or substantially the same invention claimed in another pending application or unexpired patent. In addition, a patent examiner can initiate an interference proceeding sua sponte if the claims are otherwise allowable.

Once declared, the PTAB conducts the interference proceeding in two stages to determine which party was the first to invent the commonly claimed (i.e., interfering) subject matter. During the preliminary phase, each party can challenge the validity or patentability of the opponent's claims involved in the interference on almost any basis—including prior art, support, and derivation. This preliminary phase may also include limited discovery such as expert witness depositions. At the conclusion of the preliminary phase, the PTAB issues a decision on the validity or patentability of each challenged claim. If all of a party's involved claims are declared invalid or unpatentable, the interference is concluded with the surviving party being awarded priority of invention.

If each party has at least one claim that survives the preliminary phase, the PTAB conducts the priority phase to determine which party was the first to invent the commonly claimed subject matter. The priority phase also includes limited discovery—including expert witness depositions and the exchange of highly confidential documents such as invention records, internal communications, and inventor notebooks—for each party to establish its earliest possible dates of conception and/or reduction to practice.

Where applicable, patent interferences provide a substantial benefit for challenging ownership of a patent where the only alternative may be litigation.

PTAB SNAPSHOT

INVALIDITY RATE

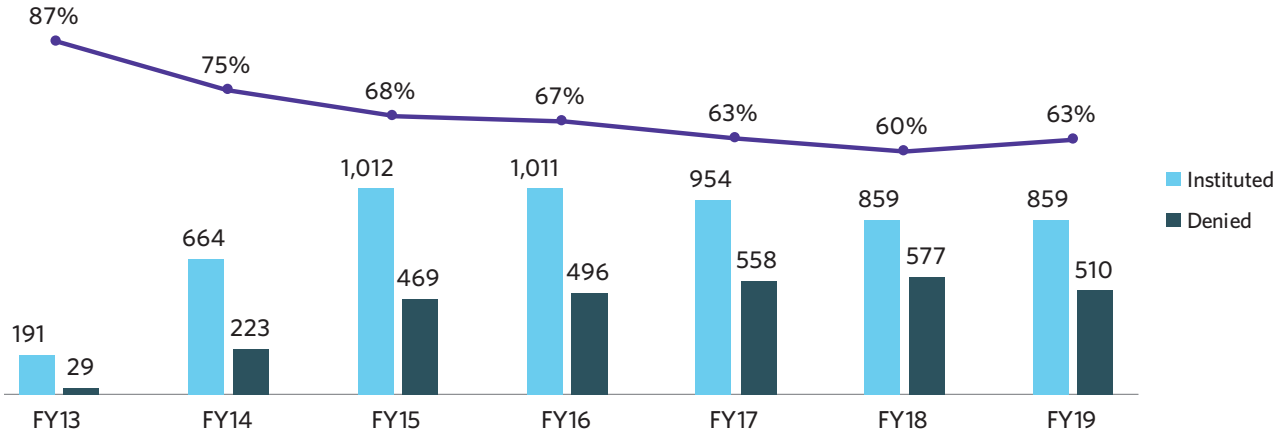
PTAB Institution Rate (Excluding rehearing requests)

PTAB Final Decisions invalidating all claims

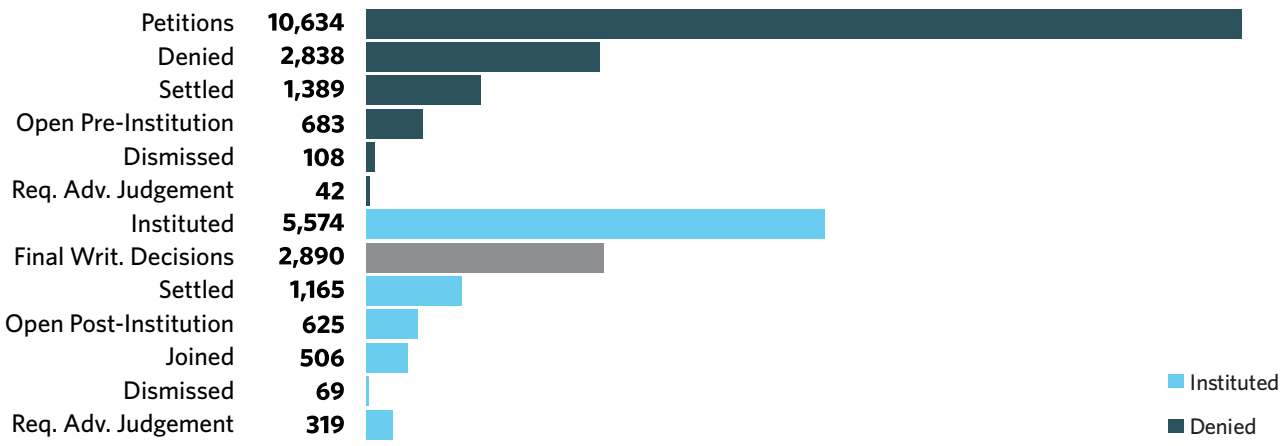
PTAB Final Decisions invalidating at least one claim

PTAB Final Decisions invalidating no claims

INSTITUTION RATES (OCT. 1, 2012–OCT. 31, 2019)



CASE DISPOSITION (OCT. 1, 2012–OCT. 31, 2019)



THE CHANGING LANDSCAPE OF PATENT DISPUTES

THE AMERICA INVENTS ACT (AIA) WENT INTO EFFECT IN SEPTEMBER 2012, PROVIDING ACCUSED PATENT INFRINGERS WITH NEW MECHANISMS TO CHALLENGE ISSUED PATENTS BEFORE THE PATENT TRIAL AND APPEAL BOARD (PTAB OR BOARD).

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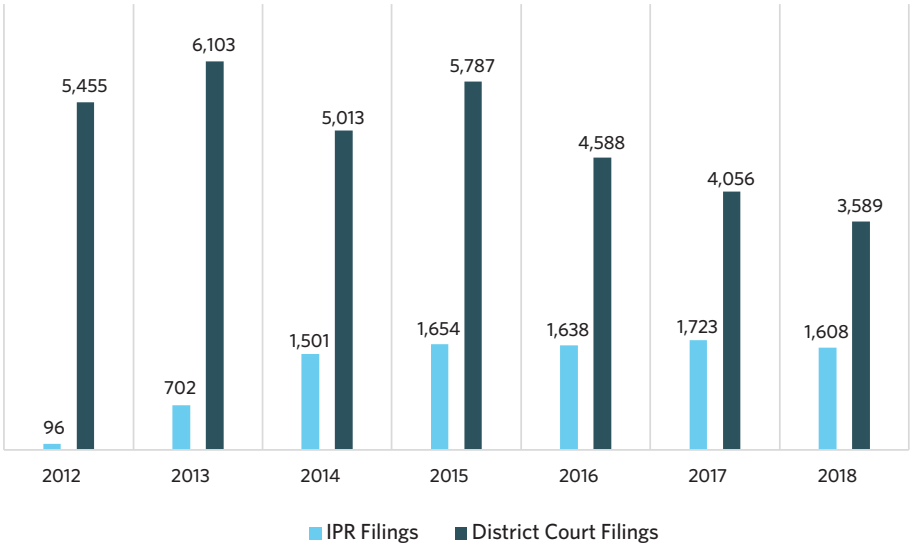
These mechanisms include inter partes review (IPR), post-grant review (PGR), and a transitional program for covered business method (CBM) patents. Certain benchmarks and tracking measures reveal several noteworthy trends, summarized below.[1]

IPR FILINGS REMAIN CONSISTENTLY HIGH

From the AIA's inception to 2019, the number of IPR petition filings has remained consistent after the initial surge from 2012 to 2014. Meanwhile, district court patent litigation has been steadily trending downward.



District court filings stayed on course for 2018 with the lowest number of new cases filed in the last six years: 3,589. Although there was a minor downturn from 2017 to 2018, the number of IPR filings has remained relatively consistent year to year, exceeding 1,600 IPR filings each year since 2015.

BIG TECH CONTINUES TO EMBRACE IPRS

With IPRs being a less expensive alternative to prolonged district court litigation, parties with the busiest patent litigation dockets often have busy IPR dockets. Indeed, IPRs offer defendants another avenue to invalidate asserted patents and potentially negotiate settlements.

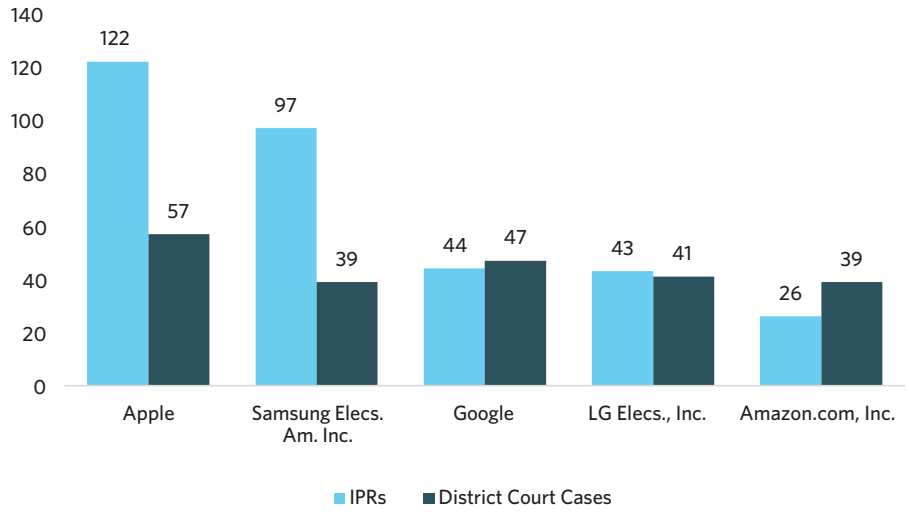
In 2018, Apple was a named defendant in the most district court patent cases (57), and Google came in second (47).[2] LG Electronics, Inc. (41), Amazon.com, Inc. (39), and Samsung Electronics America, Inc. (39) followed closely.[3] Each party was also in the top 10 PTAB petitioners for 2018 with 122, 97, 44, 43, and 26 petitions, respectively.[4]

[1] We compiled these statistics using Docket Navigator and Lex Machina. They should be treated as estimates throughout.

[2] Lex Machina Patent Litigation Report at Figure 10: Most Active Defendants in 2018 (Feb. 2019).

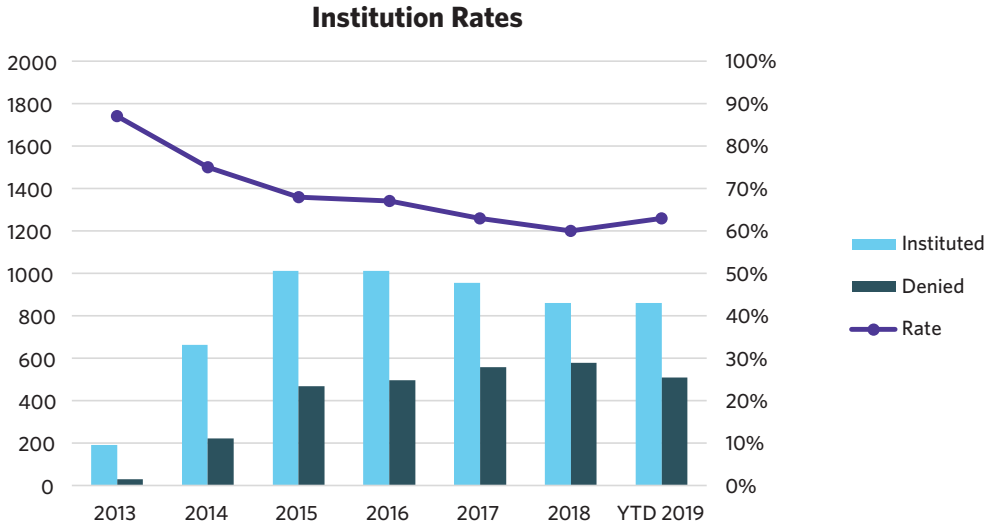
[3] *Id.*

[4] Docket Navigator, 2018 Year in Review: Patent Litigation Special Report at p. 49 (2018 PTAB Leaders by Number of Proceedings).



INSTITUTION RATES HAVE RISEN SLIGHTLY SINCE 2018

PTAB trial institution rates have progressively declined since 2013.[5] Factors that may have contributed to this gradual decline include (1) public or congressional pressure; (2) stricter standards for follow-on petitions and petitions that use the same art as in earlier proceedings; (3) an increase in challenges to robust, competitor patents; (4) the effects of the US Supreme Court's decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2019); (5) the PTAB's adoption of the *Phillips* claim construction standard; and (6) the PTAB's increased willingness to exercise its discretion.



Despite a slight uptick in institution rates from 2018 to 2019 (YTD), institution remains far from certain.[6] The PTAB's institution decision is "final and nonappealable."[7] Although a dissatisfied party may request a rehearing of an institution decision, the chances for success are drastically slim. For this reason, and if relevant and probative under Federal Rule of Evidence 403, a decision denying institution may be admissible in subsequent district court proceedings.[8]

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[5] Institution rates for each fiscal year are based on information available from the USPTO as of September 30, 2019, https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2019-09-30.pdf.

[6] YTD 2019 institution rate statistics are through September 30, 2019, per USPTO Trial Statistics, https://www.uspto.gov/sites/default/files/documents/Trial_Statistics_2019-09-30.pdf.

[7] 35 U.S.C. § 314(d).

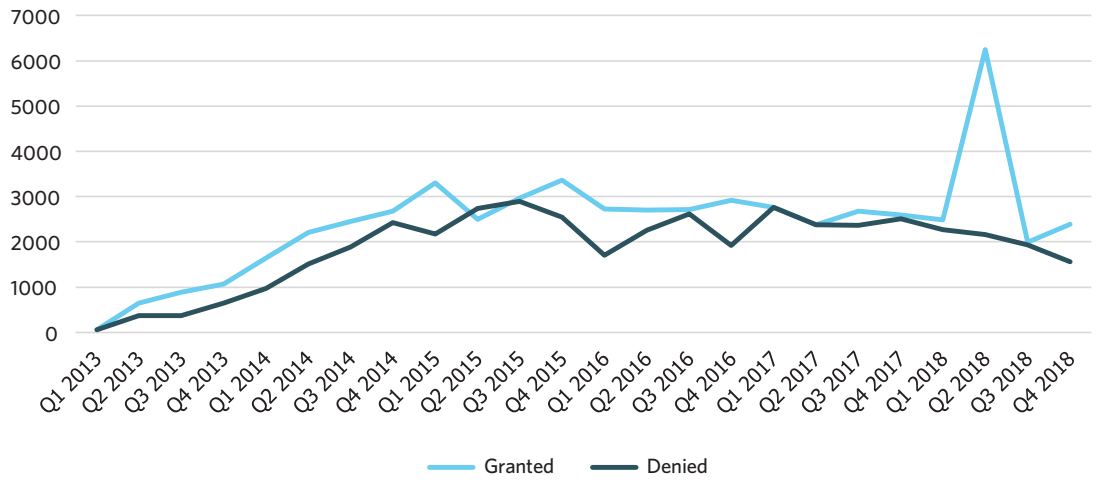
[8] *Compare, e.g., Interdigital Commc'ns Inc. v. Nokia Corp.*, No. CV 13-10-RGA, 2014 WL 8104167, at *1 (D. Del. Sept. 19, 2014) (excluding denial of petition because it is not a "decision on the merits" and is of "marginal relevance"), *with Universal Elecs., Inc. v. Universal Remote Control, Inc.*, 2014 WL 8096334, at *7 (C.D. Cal. 2014) (denying motion to exclude evidence of denied petition because "[a]ny potential confusion can be addressed by appropriate jury instructions on the standard of proof applicable to patent invalidity defenses and counterclaims").

SAS HAS NOT MEANINGFULLY CHANGED INSTITUTION RATES

In *SAS Institute Inc. v. Iancu*, the US Supreme Court upheld the constitutionality of post-grant proceedings but brought the PTAB's practice of selective institution to an abrupt end.[9] Before the Supreme Court's decision in *SAS*, the PTAB would institute a proceeding on only those challenged claims for which the petition satisfied the threshold standard for instituting a proceeding, and issue a final written decision only on the instituted claims. Now, when the PTAB institutes a proceeding, it must decide the patentability of all claims originally challenged by the petitioner under 35 U.S.C. Section 318(a).[10] That is, "the PTAB will institute as to all claims or none."[11]

As shown below, there was a fleeting spike in the number of petitioned claims on which the PTAB instituted a proceeding following *SAS*. This may reflect the PTAB's decision to "issue an order supplementing the institution decision to institute on all challenges raised in the petition" for some "pending trials" at the time of the *SAS* decision "in which a panel ha[d] instituted trial only on some of the challenges raised in the petition (as opposed to all challenges raised in the petition)."[12] But, after the Q2 2018 spike, the quarterly institution rate returned to nearly the same as before *SAS*.

Number of Petitioned Claims Granted or Denied Institution



ADDITIONAL DISCOVERY

"Routine" discovery is allowed in all proceedings. This includes exhibits cited in papers or in testimony, cross-examination of testimonial witnesses, and "relevant information that is inconsistent with a position advanced" by a party to the proceeding.[13] Additional discovery may be available if the moving party shows that it is in the "interests of justice."[14] In *Garmin International, Inc. v. Cuozzo Speed Technologies, LLC*,[15] the Board set forth five factors that it will consider in determining whether additional discovery is in the "interests of justice":

1. More than a possibility and mere allegation
2. Litigation positions and underlying basis
3. Ability to generate equivalent information by other means
4. Easily understandable instructions
5. Requests are not overly burdensome to answer

[9] 138 S. Ct. 1348 (2018).

[10] *Id.* at 1354.

[11] USPTO, Guidance on the impact of SAS on AIA trial proceedings (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

[12] *Id.*

[13] *See* 37 C.F.R. § 42.51(b)(1).

[14] *Id.* § 42.51(b)(2).

[15] IPR2012-00001, 2013 WL 11311697, at *3-8 (PTAB Mar. 5, 2013) (citing Paper 20, 2-3).

The USPTO has explained that "[t]he list of factors set forth in Garmin is not exhaustive."[16]

The Board has been willing to grant additional discovery beyond the "routine" categories in some cases. The Board's decision in *Ventex Co., Ltd. v. Columbia Sportswear North America, Inc.*,[17] is one example. There, Columbia sought discovery of communications between Ventex and Ventex's customer, Seirus Innovative Accessories, Inc., about the IPR proceedings, the patent at issue, Columbia, and the litigation between Columbia and Seirus.[18] In particular, Columbia requested the supplier agreement between Seirus and Ventex to determine whether they were privies and whether Serius was a real party in interest.[19] According to Columbia, the Federal Circuit's decision in *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336 (Fed. Cir. 2018), and related cases "emphasize broader inquiries and scope of privity and real parties in interest under § 315(b) than the Board's prior precedent, which focused primarily on a Petitioner's 'control' of related litigation."[20] And the Federal Circuit issued its opinion *after* briefing in the proceeding closed and *after* the Board had denied Columbia's initial motion for discovery.[21]

The Board determined that the *Garmin* factors favored granting Columbia's request. First, the Board concluded that "[t]he supplier agreement standing alone tends to support Columbia's arguments to some extent, and therefore any communications regarding the subject of that agreement and the Seirus Litigation in general are potentially relevant in considering the privity inquiry."[22]

The third *Garmin* factor also favored granting Columbia's document requests and interrogatory request because "the Seirus Litigation did not provide an adequate basis to obtain the requested information, especially communications regarding this proceeding that may have occurred after discovery closed in the Seirus Litigation."[23] But the third factor did not weigh in favor of Columbia's deposition request because "[i]t is possible that the communications were so limited that documents themselves are adequate to reveal what is necessary, and that Columbia lacks an adequate basis to expect further useful information from the deposition."[24]

Finally, the fifth *Garmin* factor favored granting Columbia's document requests and interrogatory because, "[a]lthough Ventex may be correct that some of the requested communications may pertain to issues that are not relevant," the Board was "not persuaded that the production of the requested documents and communications that are in Ventex's control and responding to one interrogatory places an undue burden on Ventex without a more specific showing by Ventex."[25]

For these reasons,[26] the Board granted Columbia's motion for additional discovery for the document requests and interrogatory.[27] It permitted Columbia to request a conference with the Board "[i]f, after receipt of Ventex's documents and interrogatory response, Columbia view[ed] a deposition of a Ventex representative or a specific Ventex employee as warranted."[28]

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[16] Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 81 Fed. Reg. 18,750, 18,757 (Apr. 1, 2016).

[17] IPR2017-00789, Paper 72 (PTAB Sept. 27, 2018).

[18] *Id.* at 2-3.

[19] *Id.* at 3.

[20] *Id.*

[21] *Id.*

[22] *Id.* at 6.

[23] *Id.* at 7.

[24] *Id.*

[25] *Id.* at 8.

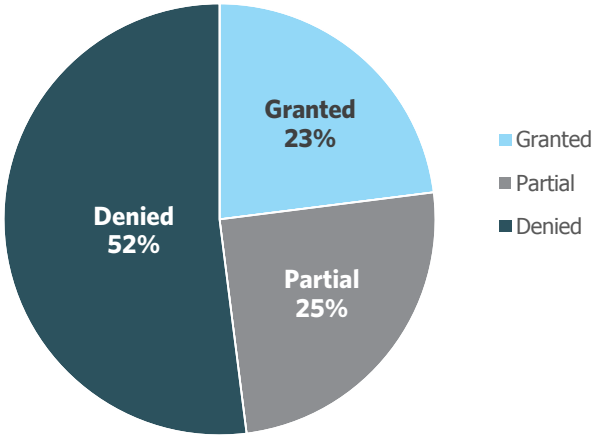
[26] Although the Board reached its decision "[b]ased on… [a] review of all of the [*Garmin*] factors" (*id.* at 8), the Board did not address the second or fourth factors.

[27] *Id.*

[28] *Id.*

As shown below, some type of additional discovery has been ordered in about half of the motions requesting it.

IPR Motions for Additional Discovery 2018



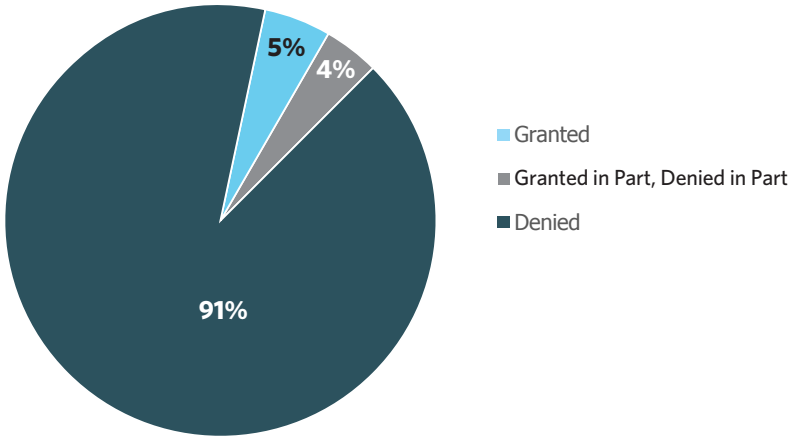
REQUESTS FOR REHEARING

The Board's decision whether to institute trial is "final and nonappealable."[29] After an unfavorable institution decision, a dissatisfied party seeking to upend the decision may file a request for rehearing.[30]

A request for rehearing is similar to a motion to reconsider in district courts in that no formal rehearing is conducted. Rather, the decision on the reconsideration itself is the "rehearing." The request must identify specifically all matters the party believes the Board misapprehended or overlooked, and the place where each matter was addressed previously.[31] A request for rehearing is not a chance to present new arguments or evidence that could have been presented in the petition.[32]

But requests for rehearing are rarely granted. To date, the PTAB has denied nearly all requests. This is particularly true for requests for rehearing of institution decisions, where the number of requests granted is in the single digits.

Requests for Rehearing Success Rate



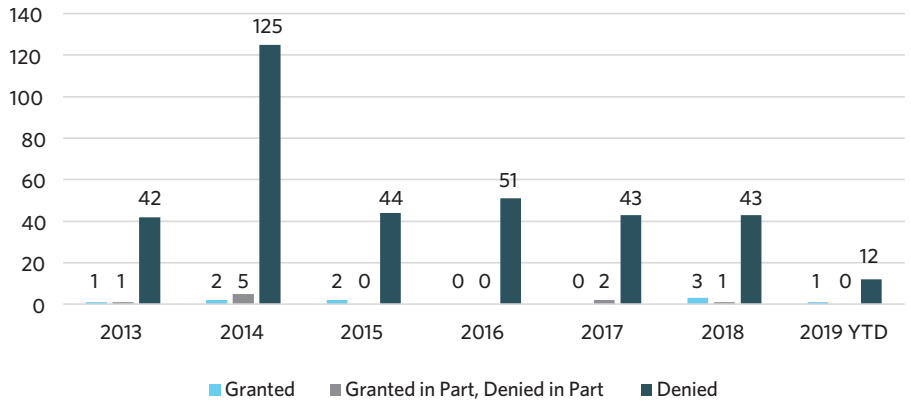
[29] 35 U.S.C. § 314(d); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139-41 (2016).

[30] 37 C.F.R. § 42.71.

[31] *Id.* § 42.71(d).

[32] *Foursquare Labs, Inc. v. Silver St. Intellectual Techs.*, Inc., IPR2014-00159, 2014 WL 3945911, at *4 (PTAB Aug. 1, 2014).

Success of Requests for Rehearing: Decisions on Institution



One possible reason for the nominal success rate is the movant's high burden. The movant must show that "the Board misapprehended or overlooked" matters in its previous ruling.[33] Still, a request for rehearing may be a party's best or only option after receiving an unfavorable decision.

TIME TO MILESTONES

An AIA trial is statutorily required to be completed within one year of its institution.[34] As shown below, the PTAB generally adheres to the representative timeline first provided in the 2012 trial guide.[35] But deviations may occur. For example, the one-year time limit may be extended up to six months for good cause or adjusted for joinder of multiple proceedings.[36]

	Includes Institution Decision (From Petition Filing Date)	Final Written Decision (From Petition Filing Date)
Minimum	3.2 months	1 year, 1.3 months
Median	6.2 months	1 year, 6.1 months
Maximum	7.8 months	1 year, 10.8 months
Average	6.2 months	1 year, 5.9 months

MOTION TO AMEND CLAIMS

Unlike district court litigation, post-grant proceedings before the PTAB afford patent owners the opportunity to amend any challenged patent claims under 35 U.S.C. § 316(d). By filing a motion to amend during the pendency of a proceeding, patent owners may persuade the Board to either (1) cancel any challenged claims or (2) replace any challenged claims with substituted claims. Though intended to provide patent owners with a level playing field, the PTAB has rarely granted PGR in the past, largely due to previously imposing on patent owners the burden of proving that the amending claims are patentable over the prior art.

[33] 37 C.F.R. § 42.71(d).

[34] 37 C.F.R. §§ 42.100(c), 42.200(c), 42.300(c).

[35] 77 Fed. Reg. at 48,757.

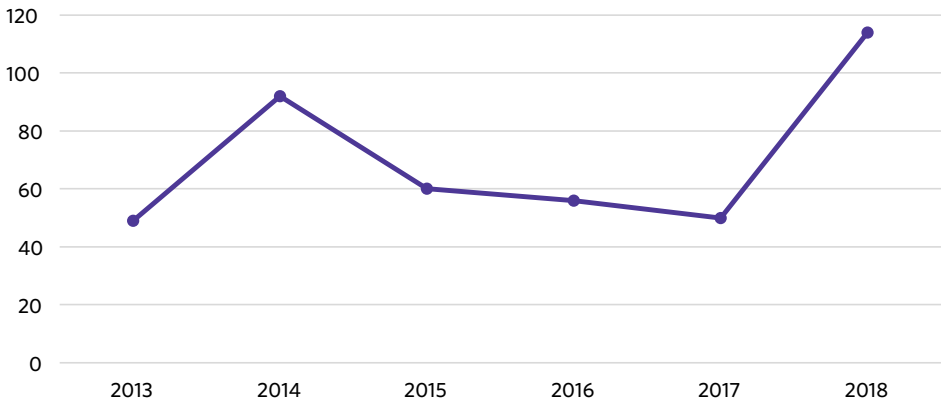
[36] 37 C.F.R. §§ 42.100(c), 42.200(c), 42.300(c).

That all changed in 2017 when the US Court of Appeals for the Federal Circuit in *Aqua Products, Inc. v. Matal*[37] held that patent owners no longer bear the burden of demonstrating the patentability of the proposed claim amendments. With a decision including five separate opinions, the court concluded that "(1) the PTO has not adopted a rule placing the burden of persuasion with respect to the patentability of amended claims on the patent owner that is entitled to deference; and (2) in the absence of anything that might be entitled to deference, the PTO may not place that burden on the patentee."[38]

Following the Federal Circuit's decision, the USPTO issued a memorandum titled "Guidance on Motions to Amend in view of *Aqua Products*."[39] The memorandum states that "if a patent owner files a motion to amend (or has one pending) and that motion meets the requirements of 35 U.S.C. § 316(d)..., the Board will proceed to determine whether the substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by the petitioner."[40]

Sensing a turn in the tide, patent owners have begun filing motions to amend at unprecedented rates. The number of motions to amend filed in fiscal year 2018 (114) is more than that filed in any other fiscal year, and is more than double the number of motions to amend filed in each of fiscal year 2017 (50) and fiscal year 2016 (56).[41]

Motions to Amend (Substitute or Cancel) Filed by Year



The dramatic uptick in filing rates suggests that patentees are laying odds that the PTAB will more readily permit claims amendments. But their bets may not be paying off just yet. As shown in the two charts below, the success rate for motions to amend has not changed.

[37] 872 F.3d 1290 (Fed. Cir. 2017).

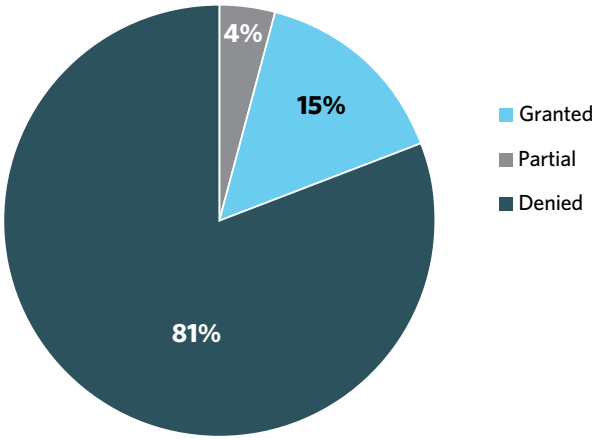
[38] *Id.* at 1327.

[39] *See* Memorandum from David P. Ruschke, Chief Administrative Patent Judge, to PTAB (Nov. 21, 2017), https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf?utm_campaign=subscriptioncenter&utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=.

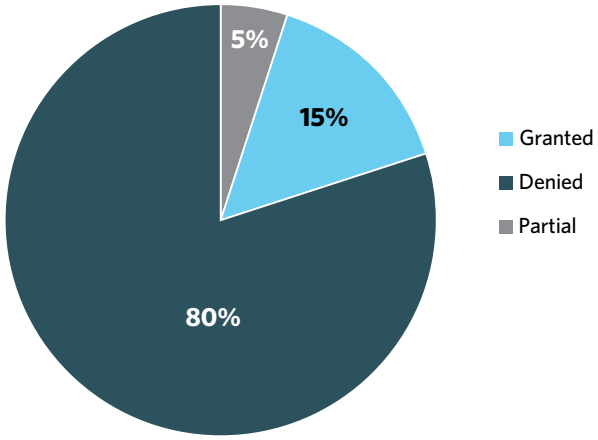
[40] *Id.*

[41] Patent Trial and Appeal Board Motion to Amend Study, Installment 5: Update through September 30, 2018, https://www.uspto.gov/sites/default/files/documents/ptab_%20mta_study_%28installment_5_-_%20update_through_fy2018%29.pdf.

Motion to Amend: Substitute Claims (Pre-*Aqua* Products)



Motion to Amend: Substitute Claims (Post-*Aqua* Products)



CONCLUSION

Since first going into effect more than seven years ago, IPR proceedings remain an important cog in the US patent system. Scrutinizing statistics from those seven years are an important tool in guiding strategy for patent owners and petitioners alike.

We continually build upon this knowledge of IPR proceedings to offer focused services and achieve positive outcomes for our clients. Having represented clients in approximately 195 PTAB trials, our team has a proven record of success. For trials in which the PTAB has issued a final written decision, we have an 82% rate of receiving whole or partial wins when representing petitioners, and a 65% success rate when representing patent owners.

For these successes and others, we have received numerous accolades, including the following:

- **Recognized, IP Stars**, PTAB Litigation, United States, *Managing Intellectual Property* (2017–2019)
- **Recommended, Intellectual Property, Patents:** Prosecution (including Re-Examination and Post-Grant Proceedings), *The Legal 500 US* (2019)
- **Top 20 PTAB Law Firms**, based on number of proceedings, *Docket Navigator* (2018)
- **Top 25 Most Active Law Firms** Representing Petitioners, IPR Intelligence Report, *Patexia* (2018)

TRIAL PROCEDURE

FEDERAL CIRCUIT LIFTS BAR ON JUDICIAL REVIEW OF PTAB TIME-BAR DETERMINATIONS

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The Federal Circuit recently reversed course and expanded judicial review of PTAB institution decisions to include time-bar determinations, potentially clearing a path for petitioners and patent owners to appeal other threshold determinations.

The US Court of Appeals for the Federal Circuit sitting en banc recently revisited whether the bar on judicial review of institution decisions by the Patent Trial and Appeal Board (PTAB or the Board) applies to time-bar determinations. Overruling a prior panel decision answering in the affirmative, on January 8 the full Federal Circuit held that the PTAB's time-bar determinations are in fact appealable. The ruling provides dissatisfied litigants with new ammunition for challenging institution decisions, and potentially opens the door to appeals on other threshold determinations that do not reach the merits of the inter partes review (IPR) petition.

BACKGROUND

When Congress passed the Leahy-Smith America Invents Act (AIA) in 2011, it intended for post-grant proceedings, including IPR, to be quick and cost-effective alternatives to district court litigation for challenging the patentability of issued patent claims.[1] To that end, Section 314 of Title 35 limits the judicial review of the Board's institution decision by providing that "[t]he determination by the Director whether to institute an inter partes review *under this section* shall be final and nonappealable."[2] The US Supreme Court made clear in *Cuozzo* that Section 314(d) bars judicial review of institution decisions concerning compliance with Section 312(a)(3)—i.e., whether the petition identified with sufficient particularity "each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim."[3] The *Cuozzo* court, however, expressly declined to "decide the precise effect of § 314(d) on appeals that implicate constitutional questions, *that depend on other less closely related statutes*, or that present other questions of interpretation that reach, in terms of scope and impact, well beyond '*this section*.'"[4]

[1] H.R. Rep. No. 112-98, pt. 1, at 48 (2001); 157 Cong. Rec. 2,710 (2011) (statement of Sen. Grassley).

[2] The director has delegated the authority to institute IPR to the PTAB. 37 C.F.R. §§ 42.4(a), 42.108.

[3] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139-42 (2016).

[4] *Id.* at 2141 (emphasis added).

The time-bar provision, Section 315(b) of the AIA, requires the Board to deny institution of an IPR even if the petition otherwise complies with Section 312(a)(3). The provision provides that "[a]n inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privity of the petitioner is served with a complaint alleging infringement of the patent." This one-year time bar does not apply to requests for joinder under Section 315(c).

Prior to *Cuozzo*, a Federal Circuit panel determined for the first time whether Section 314(d) precludes judicial review of Section 315(b) time-bar determinations.5 There, the patent owner appealed a final written decision canceling certain patent claims through IPR, arguing that the Board overstepped its statutory authority by instituting IPR on a petition that was time-barred under Section 315(b).[6] The Federal Circuit panel rejected this argument, holding that "35 U.S.C. § 314(d) prohibits this court from reviewing the Board's determination to initiate IPR proceedings based on [the patent owner's] assessment of the time bar of § 315(b), even if such assessment is reconsidered during the merits phase of proceedings and restated as part of the final written decision."[7] According to the panel, the Board's misinterpretation of Section 315(b) does not constitute ultra vires agency action that might otherwise support judicial review.[8] The panel concluded that it was barred from reviewing Section 315(b) decisions and dismissed the case for lack of personal jurisdiction.

THE DECISION

In 2013, Broadcom Corporation (Broadcom) filed three separate IPR petitions challenging three patents owned by Wi-Fi One, LLC (Wi-Fi), all of which had been asserted in 2010 in the Eastern District of Texas against multiple defendants, but never against Broadcom itself. In response to Broadcom's petitions, Wi-Fi argued that the Board was prohibited from instituting review on any of the three petitions because Broadcom was in privity with the Eastern District of Texas defendants, and as such, the IPR petitions were time-barred under Section 315(b).

The Board disagreed and instituted IPR on the challenged claims, and issued final written decisions finding the challenged claims unpatentable. In those decisions, the Board determined that Wi-Fi had not shown that Broadcom was in privity with the defendants in the Eastern District of Texas litigation, and, therefore, the IPR petitions were not time-barred under Section 315(b).[9]

Wi-Fi appealed the final written decisions, arguing, among other things, that the Board's time-bar determinations should be reversed. After a panel of the Federal Circuit rejected Wi-Fi's arguments, finding the Section 315(b) time-bar rulings nonappealable, Wi-Fi petitioned for rehearing en banc, and the Federal Circuit granted its petition.

The en banc panel began by finding no "specific legislative history that clearly and convincingly indicates congressional intent to bar judicial review of § 315(b) time-bar determinations."10 Turning next to the statutory language, the Federal Circuit found that Section 315(b) controls the Board's authority to institute IPR, and as such, is "unrelated" to the noninitiation and preliminary-only merits determinations because it "does not go to the merits of the petition."[11]

> The time-bar decision is nowhere referred to in § 314(a). Additionally, the time bar is not focused on the particular claims, whereas § 314(a)'s threshold determination is; the time bar involves only the time of service of a complaint alleging infringement "of the patent." Nothing in § 315(b) sets up a two-stage process for addressing the time bar: the time-bar determination may be decided fully and finally at the institution stage.[12]

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5 803 F.3d 652, 658 (Fed. Cir. 2015).

6 *Id.* at 653.

7 *Id.* at 658.

8 *Id.* at 658-59.

9 *Broadcom Corp. v. Wi-Fi One, LLC,* No. IPR2013-00601, 2015 WL 1263008, at *4-5 (PTAB Mar. 6, 2015); *Broadcom Corp. v. Wi-Fi One, LLC,* No. IPR2013-00602, 2015 WL 1263009, at *4 (PTAB Mar. 6, 2015); *Broadcom Corp. v. Wi-Fi One, LLC,* No. IPR2013-00636, 2015 WL 1263010, at *4 (PTAB Mar. 6, 2015).

10 *Wi-Fi One, LLC v. Broadcom Corp.*, No. 15-1944, slip op. at 15.

11 *Id.* at 17.

12 *Id.*

Simply put, the time-bar determination "has nothing to do with the patentability merits or discretion not to institute."[13] The Federal Circuit further distinguished Section 315 as "a condition precedent to the Director's authority to act" that "sets limits on the Director's statutory authority to institute," which "is precisely the type of issue that courts have historically reviewed."[14]

For these reasons, the Federal Circuit held that "the statutory scheme as a whole demonstrates that § 315 is not 'closely related' to the institution decision addressed in § 314(a), and is therefore not subject to § 314(d)'s bar on judicial review."[15] The court remanded for the panel to consider in the first instance the merits of Wi-Fi's time-bar appeal.

FUTURE IMPLICATIONS

The Federal Circuit's decision in *Wi-Fi* clears the way for more PTAB appeals, allowing patent owners and petitioners to immediately appeal time-bar determinations made by the PTAB at the institution stage. Although the en banc panel declined to decide "whether all disputes arising from §§ 311-314 are final and non-appealable,"[16] the decision signals a raised scrutiny of the PTAB's institution decisions.

By carving out an avenue for appealing an institution decision, which was strictly limited in the past, the *Wi-Fi* court's ruling suggests that the court may in the future permit appeals on other threshold determinations that do not reach the merits of the IPR petition. Such determinations may include whether a petitioner has fulfilled the AIA's requirement of naming all of the interested parties to a petition or is barred by estoppel from filing the petition.

[13] *Id.*

[14] *Id.* at 20.

[15] *Id.*

[16] *Id.* at 21.

PTAB DECLINES TO VACATE FINAL WRITTEN DECISION IN INTER PARTES REVIEW DESPITE SETTLEMENT

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Settling an inter partes review after a final written decision by the Patent Trial and Appeal Board may not result in the PTAB vacating the decision.

In *Dish Network LLC v. TQ Beta, LLC*, the Patent Trial and Appeal Board (PTAB) recently denied a patent owner's request to vacate a final written decision that was pending on appeal to the US Court of Appeals for the Federal Circuit when the parties settled their dispute involving the patent subject to the inter partes review (IPR).[1]

The PTAB held that although the statutes and regulations governing IPRs encourage settlements, it would be against the public interest to vacate the final written decision simply because the parties have settled once a decision has been issued finding claims to be unpatentable on the merits.[2]

The PTAB entered a final written decision entering adverse judgment against the patent owner as to three claims.[3] The patent owner appealed to the US Court of Appeals for the Federal Circuit.[4] Prior to receiving a decision on appeal, the parties settled their dispute over the patent subject to the IPR.[5] The patent owner then filed an unopposed motion asking the court to dismiss the appeal and remand the case to the PTAB so that it may file a motion to vacate the final written decision.[6] The court granted the motion but noted it took no position on the motion to vacate.[7]

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1 Case IPR2015-01756, Paper 39 (PTAB April 12, 2018).

2 Slip op. at 6-7.

3 Slip op. at 2.

4 *Id.*

5 *Id.*

6 *Id.*

7 *Id.*

The patent owner argued that vacating the final written decision is appropriate because the law and sound policy favor and encourage settlements.[8] If the PTAB does not vacate the final written decision, the patent owner argued, there would be no incentive for parties to settle their disputes after a final written decision has been entered because the parties would be forced to go through the full appeal.[9] The PTAB disagreed and noted that Congress set forth the dual policy goals of encouraging settlement, and cancelling claims that have been shown to be unpatentable on the merits during the course of such review.[10] The PTAB, citing 37 CFR 42.74(a), noted that it has the authority to independently determine questions of patentability, even after parties have settled, in order to promote the public policy favoring the cancellation of any claim that has been shown to be unpatentable on the merits, thereby promoting the integrity of the patent system.[11]

[8] *Id.* at 3.

[9] *Id.*

[10] *Id.* at 4.

[11] *Id.* at 5.

PTAB'S TRIAL PRACTICE GUIDE UPDATE: IMPLICATIONS FOR PARTIES MOVING FORWARD

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The first update to the Patent Trial and Appeal Board Trial Practice Guide includes guidance that will benefit both petitioners and patent owners, from updates regarding expert testimony and motions to exclude and to strike, to procedures for oral hearing before the Board, among other changes.

Since its publication six years ago, the America Invents Act (AIA) Trial Practice Guide (the Practice Guide or Guide) has remained unchanged. On August 10, 2018, the US Patent and Trademark Office (USPTO or the Office) released its first update to the Guide. The updates address six general areas: (1) expert testimony; (2) factors in the determination of whether to institute a trial; (3) sur-replies to principal briefs as a matter of right; (4) the distinction between motions to exclude and motions to strike, and the proper use of each; (5) procedures for oral hearing before the Patent Trial and Appeal Board (PTAB or the Board); and (6) prehearing conferences.[1] Summaries of this guidance are provided below, along with suggested practice pointers for both petitioners and patent owners.

REPLIES AND SUR-REPLIES

The Board continues to grapple with the US Supreme Court's recent holding in *SAS Institute, Inc. v. Iancu*: Once a petition is instituted, a petitioner "is entitled to a final written decision addressing all of the claims it has challenged."[2] The Board sees "significant additional work for a given instituted inter partes review" due to *SAS*, which recently has led to a proposed increase in AIA trial filing fees.[3]

The original Practice Guide stated that a "reply may only respond to arguments raised in the corresponding opposition" (e.g., patent owner's response).[4] Now, the updates permit petitioners' reply briefs to address issues discussed in the institution decision.[5] Given that the Board may institute trial on both stronger and weaker grounds in the same petition per *SAS*, parties are advised to carefully review and respond to Board commentary on the less meritorious grounds in institution decisions.

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1 USPTO, Board Trial Practice Guide August 2018 Update, https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/ptab-trial-practice-guide-august-2018 (notice published on Aug. 13, 2018 at Fed. Reg. Vol. 83, No. 156, 39989).

2 138 S. Ct. 1348, 1359 (2018).

3 Letter from Director Iancu to Patent Public Advisory Committee, https://www.uspto.gov/sites/default/files/documents/Letter_from_the_Director_to_PPAC.pdf (announcing "roughly 25 percent" increase in AIA trial fees "due to a variety of factors, including the Supreme Court decision in *SAS Institute Inc. v. Iancu*").

4 77 Fed Reg 157, 48767; *see also* 37 CFR 42.23(b).

5 *Id.* at 14.

Of particular importance is the Board's announcement that "[s]ur-replies to principal briefs (i.e., to a reply to a patent owner response or to a reply to an opposition to a motion to amend) normally will be authorized by the scheduling order entered at institution."[6] In other words, sur-replies, which the Board once rarely authorized upon motion, are now authorized as a matter of course in scheduling orders.[7] As such, patent owners, and no longer petitioners, get the final word on whether the petitioner has met its burden to show that the challenged claims are unpatentable. Patent owners can respond to arguments made in reply briefs, comment on reply declaration testimony, point to cross-examination testimony, and address the institution decision if necessary to respond to the petitioner's reply—essentially replacing the previous practice of filing observations on cross-examination testimony.

CONSIDERING NONEXCLUSIVE FACTORS IN DETERMINING INSTITUTION

As a further response to the *SAS* decision, the Board now invites parties to address specific factors that weigh in favor of or against the director exercising discretion to deny a petition under Sections 314(a), 324(a), and 325(d) of the Guide.

For Sections 314(a) and 324(a), the Practice Guide notes that the director's discretion must "consider the effect of any such regulation [under this section] on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter" (as specified in Sections 316(b) and 326(b)). For follow-on petitions, the updated Practice Guide indicates that factors articulated in the *General Plastics case*[8] help the Board to weigh these statutory considerations. But, the updated Practice Guide also notes that the factors articulated in *General Plastics*, and the considerations under Sections 316(b) and 326(b), also apply outside of the follow-on petition context.

Specifically, the Practice Guide highlights that "[t]here may be other reasons besides the 'follow-on' petition context where the 'effect… on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings,' *favors denying a petition even though some claims meet the threshold standards for institution under 35 U.S.C. §§ 314(a), 324(a)*."[9] For example, the Board highlights a decision denying institution under Section 314(a) where, "due to petitioner's delay, the Board likely would not have been able to rule on patentability until after the district court trial date."[10] The Board's examples also note that "parties may wish to address in their submissions whether any other such reasons exist in their case that may give rise to additional factors that may bear on the Board's discretionary decision to institute or not institute, and whether and how such factors should be considered along with the *General Plastics* factors."[11]

In the Section 325(d) context, "the Board considers whether the same or substantially the same prior art or arguments were presented previously." For this evaluation, the Practice Guide directs practitioners to the nonexclusive factors set forth in *Becton Dickinson* and reiterates that the "efficient administration of the Office" will be considered.[12]

This update may serve as a warning for petitioners to choose grounds wisely; a single, strong ground among several other weak grounds may not be sufficient for the Board to institute trial on a petition. Petitioners should consider explaining why each of the discretionary factors in *General Plastics* and *Becton Dickinson*, as applicable, weighs in favor of institution.

Patent owners should consider addressing the considerations under Sections 316(b) and 326(b), including the *General Plastics* factors, in their preliminary responses. If a petition raises prior art or arguments that the Office previously considered (e.g., during examination, ex parte reexamination), patent owners should analyze the *Becton Dickinson* factors[13] and explain why the "efficient administration of the Office" warrants against devoting more resources to recycled art and/or arguments.

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[6] *Id.*

[7] See USPTO, Trial Practice Guide Update, https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf at App'x A (Aug. 2018).

[8] *Gen. Plastics Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16-17 (PTAB Sept. 6, 2017) (precedential).

[9] USPTO, Trial Practice Guide Update, https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf at 10 (Aug. 2018) (quoting 35 U.S.C. § 316(b) (emphasis added) (citation omitted)).

[10] *See NetApp, Inc. v. Realtime Data LLC*, Case IPR2017-01195, slip op. at 12-13 (PTAB Oct. 12, 2017) (Paper 9).

[11] *Id.* at 11.

[12] IPR2017-01586, Paper 8 at 17-18 (Board Dec. 15, 2017) (informative).

[13] *See Becton Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (informative).

PREHEARING CONFERENCES

Practitioners may now use a new "prehearing conference" procedure to address issues best resolved prior to the oral hearing.[14] For example, during a prehearing conference, the Board may take up motions to strike, motions to exclude, or unresolved issues about demonstratives.[15] Either party may request a prehearing conference no later than three business days before the oral hearing, but the Board prefers a joint request listing the issues.[16] Patent owners and petitioners alike should consider using prehearing conferences to strategically consolidate prehearing issues.

OTHER CHANGES

Use of Expert Testimony. According to the Practice Guide, an expert need not qualify as a person of ordinary skill in the art to be an expert under Federal Rule of Evidence 702.[17] The Practice Guide's example is an expert that lacks an advanced degree in a particular field but otherwise provides testimony that is helpful to the Board and has experience amounting to "sufficient qualification in the pertinent art."[18] This guidance is unlikely to change current practice where the Board almost never disqualifies experts, and instead assigns the appropriate weight to expert testimony.

Motions to Exclude Versus Motions to Strike. The Practice Guide specifically addresses motions to exclude and motions to strike in an effort to guide practitioners who often conflate the two procedural mechanisms. A motion to exclude should only "explain why the evidence is not admissible (e.g., relevance or hearsay)"; it should not be used to argue the evidence's weight or sufficiency.[19] In contrast, a motion to strike, which the Board must first authorize, may be appropriate where a brief raises new issues or otherwise exceeds its proper scope by, for example, presenting new evidence.[20] Consistent with practice, however, the Practice Guide warns that a motion to strike is an "exceptional remedy that the Board expects will be granted rarely."[21]

Oral Hearing: Live Testimony and Sur-rebuttal. For oral hearings, a petitioner is not permitted to reserve more than 50% of its time for rebuttal absent special circumstances, and patent owners may receive a brief sur-rebuttal upon request.[22] This appears to be an attempt by the Board to prohibit petitioners from declining to present their case in chief, instead reserving 90% or more of their time for rebuttal alone.

Though rarely seen, the Board continues to permit presentation of live testimony at the oral hearing.[23] The Board considers the propriety of live testimony on a case-by-case basis, and the Practice Guide notes that the Board is more likely to grant a request where credibility is best evaluated by assessing the witness's demeanor in person.[24]

Length and Word Count. Aside from the categories enumerated in the USPTO's overview, the Practice Guide reminds practitioners that "less is more." An increased number of arguments, grounds, or hearing demonstratives means an increased likelihood of distraction from stronger arguments and, in fact, "can otherwise cause meritorious issues to be missed or discounted."[25] As to word count, the Board references decisions that approve parties' reliance on word-processor word-count tools.[26] But the Practice Guide warns against couching words in images, abusing spaces between words, and using excessive abbreviations, and also urges parties to "raise the [word count] issue with the Board promptly after discovering the issue" if the party feels that "it would suffer undue prejudice from an opposing party's word count limit violation or abuse."[27]

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[14] *Id.* at 19.

[15] *Id.* at 19-20.

[16] *Id.* at 19.

[17] USPTO, Trial Practice Guide Update, https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf at 2-3 (Aug. 2018).

[18] *Id.* at 3.

[19] *Id.* at 16.

[20] *Id.* at 17-18.

[21] *Id.* at 18.

[22] *Id.* at 20.

[23] *Id.* at 22-23.

[24] *Id.*

[25] *Id.* at 7.

[26] *Id.*

[27] *Id.* at 7-8.

TAKEAWAYS

In sum, the first update to the PTAB's Practice Guide includes guidance from which both petitioners and patent owners will benefit. From automatic sur-replies to prehearing conferences, all parties will need to develop best practices for taking advantage of these new procedures. Expect more updates to follow, as the PTAB intends to update the Practice Guide on a "section-by-section, rolling basis."[28]

[28] *Id.* at 2.

MANDAMUS NOT AVAILABLE TO SECURE APPELLATE REVIEW OF PTAB INSTITUTION DECISIONS

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The US Court of Appeals for the Federal Circuit in In re: Power Integrations, Inc. holds that mandamus actions are not available to allow a "disappointed petitioner [to] by-pass the statutory bar on appellate review simply by directing its challenge to asserted procedural irregularities rather than to the substance of the non-institution ruling."

In the recent case of *In re: Power Integrations, Inc.*, a rebuffed petitioner, Power Integrations, Inc. (Power), asked the Federal Circuit to review a decision by the Patent Trial and Appeal Board (PTAB or Board) denying institution of Inter Partes Review (IPR) proceedings.[1] The U.S. Supreme Court, however, in *Cuozzo Speed Technologies, LLC v. Lee* (*Cuozzo*) already foreclosed appellate review of run-of-the-mill PTAB institution decisions. Attempting to circumvent *Cuozzo*'s mandates, Power argued that a writ of mandamus should issue, because the Board had **violated procedural rights** guaranteed by the Administrative Procedure Act (APA).[2] Essentially, Power argued that the Board "did not provide an adequate explanation for its non-institution decisions."[3]

The Federal Circuit cited the Board's "four decisions, each from 15 to 20 pages long, supplemented by four substantive decisions on rehearing" and found "no merit" to Power's arguments.[4] The Federal Circuit also emphasized that "[a] **disappointed petitioner cannot by-pass the statutory bar on appellate review simply by directing its challenge to asserted procedural irregularities rather than to the substance of the non-institution ruling**."[5]

While handily dismissing Power's arguments, the Federal Circuit left disappointed petitioners with a glimmer of hope in obtaining appellate review of PTAB institution decisions: "This is not to say that mandamus will never lie in response to action by the agency relating to the noninstitution of inter partes review. The circumstances described by the Supreme Court in *Cuozzo* as illustrations of issues for which an appeal might be justified (e.g., constitutional issues, issues involving questions outside the scope of section 314(d), and actions by the agency beyond its statutory limits) would be potential candidates for mandamus review as well."[6]

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1 *In re: Power Integrations, Inc.*, Case Nos. 2018-144, 2018-145, 2018-146, and 2018-147 (Fed. Cir. 2018), available here: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/18-144.Motion_Panel_Opinion.8-16-2018.pdf.

2 *Id.* at 6-7.

3 *Id.* at 7.

4 *Id.*

5 *Id.* at 9-10.

6 *Id.* at 10 (citing *Cuozzo* and also identifying "'shenanigans' on the part of the Board" as potentially "justify[ing] appellate review or review by mandamus") (internal citations omitted)

PRACTICE POINTERS FOR PATENT OWNERS

The underlying factual background of this case involved the PTAB's finding that Power had not met its burden to show that its asserted non-patent literature references qualified as printed publications under 35 USC §§ 102 and 311(b).7 These deficiencies were pointed out to the Board in each of the patent owner's preliminary responses.[8]

This factual background serves as a reminder to patent owners of the value in taking the time to very carefully evaluate the petitioner's evidence and point out all holes at the preliminary response stage. These are powerful arguments, allowing patent owners to secure institution denials that will not face appellate review.[9]

If a petition includes a first ground that is subject to an authentication challenge and a second ground that is not susceptible to such a challenge, patent owners might weigh the benefits of statutorily disclaiming enough claims to render the second ground moot. This strategy could allow patent owners to get rid of a petition pre-institution, thus allowing their case to return to district court.

One drawback to raising these authentication issues at the pre-institution stage is that petitioners are not subject to the estoppel effects of §§ 315(e) and 325(e). As such, in certain instances, patent owners might occasionally consider waiving their preliminary responses if the petitioner has not properly authenticated a reference. The Board may *sua sponte* identify the authentication issue, but, if they do not, and the case proceeds to a final written decision, then the estoppel will apply (instead of possibly allowing the petitioner to fix the authentication issues before re-litigating the issue in district court or in a follow-on petition).[10]

PRACTICE POINTERS FOR PETITIONERS

Given the factual background discussed above, petitioners will be well-served to remember that the petition is the one and only place to make your invalidity case, and to support that case with strong evidence. When relying on non-patent literature documents, take care to ensure that you provide sufficient evidence to establish that a reference qualifies as a printed publication.

For publications available through a library, consider declarations from librarians explaining intake procedures and how long after intake the publications would have been available to members of the public.[11] Consider also pointing out corroborating evidence that provides other indicia of public availability, such as checkout cards, library stamps, any mentions of republishing rights, etc..[12] For publications that were distributed at meetings or conferences, consider submitting declarations to establish all of the relevant public-dissemination factors. These factors were recently examined and summarized by the Federal Circuit in its *Medtronic, Inc. v. Barry* decision: "... [1] the size and nature of the meetings and whether they are open to people interested in the subject matter of the material disclosed...[2] whether there is an expectation of confidentiality between the distributor and the recipients of the materials..."[13]

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7 *Id*. at 2-4.

8 *See Power Integrations, Inc. v. Semiconductor Components Industries, LLC*, Case No. IPR2017-01903, Paper 6 (arguing, as sole argument in preliminary response, that petitioner did not meet its burden to show that a reference qualified as a printed publication); *Power Integrations, Inc. v. Semiconductor Components Industries, LLC*, Case No. IPR2017-01904, Paper 6 (same); *Power Integrations, Inc. v. Semiconductor Components Industries, LLC*, Case No. IPR2017-01944, Paper 6 (same); and *Power Integrations, Inc. v. Semiconductor Components Industries, LLC*, Case No. IPR2017-01975, Paper 6 (same).

9 Even if the petitioner tries to fix evidentiary problems in a follow-on petition, patent owners will have arguments for denial under 35 USC § 325(d). *See Gen. Plastics Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16-17 (PTAB Sept. 6, 2017) (precedential).

10 There are arguments under § 325(d) that follow-on petitions attempting to fix evidentiary issues (which could have been addressed in the initial petition) should be denied. *Supra* fn. 8.

11 *See, e.g., Palo Alto Networks, Inc. and Symantec Corp. v. Finjan, Inc.*, Case No. IPR2015-01979, Paper 62 at 20-29 (PTAB March 15, 2017) (crediting testimony from a librarian in finding that a reference qualified as a printed publication).

12 *See, e.g., id.*at 24-26 (identifying a dated stamp of the cover page of a reference, a copyright page providing for "limited rights to copy and 'republish', and statements "indicating that copies of the periodical were available from [a publisher] without restriction," among others, as providing "indicia of circulation to the public" and "indicia of publication").

13 *Medtronic, Inc. v. Barry*, Case Nos. 2017-1169 and 2017-1170 (Fed. Cir. 2018) (vacating Board findings on whether certain references qualified as printed publications and remanding for consideration of all relevant public-dissemination factors), available here: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1169.Opinion.6-8-2018.1.pdf.

Submitting sufficient evidence to at least secure institution is key for petitioners, as the Federal Circuit can review and reverse Board findings regarding printed publications after a final written decision has issued.[14]

Petitioners may also consider asking the Board for permission to submit a reply brief to the patent owner's preliminary response, especially if there are any misstatements or new developments regarding the relevant legal standards used to establish what qualifies as a printed publication.[15]

[14] *See GoPro, Inc. v. Contour IP Holding LLC*, Case Nos. 2017-1894 and 2017-1936 (Fed. Cir. 2018) (reversing Board finding that a reference distributed at a trade show did not qualify as a printed publication), available here: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1894.Opinion.7-27-2018.pdf.

[15] *See generally Roquette Freres, S.A., v. Tate & Lyle Ingredients Americas LLC*, Case Nos. IPR2017-01506 and IPR2017-01507, Paper 11 (PTAB October 4, 2017) (granting petitioner's request to reply to patent owner's preliminary response to address a Board decision that had been partially reversed one day before the petition was filed).

FEDERAL CIRCUIT: ESTOPPEL APPLIES EVEN IF INFRINGEMENT COMPLAINT IS DISMISSED WITHOUT PREJUDICE

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The US Court of Appeals for the Federal Circuit recently held en banc that the one-year time bar under 35 USC § 315(b) applies even when a properly served infringement complaint is dismissed without prejudice, thus barring the defendant from filing an inter partes review petition after the one-year period elapses.

The US Court of Appeals for the Federal Circuit issued its *Click-to-Call* panel decision on August 16, with an en banc footnote addressing whether the one-year estoppel clock under 35 USC § 315(b) applies when a properly served infringement complaint is dismissed without prejudice.[1] Before *Click-to-Call*, the US Patent Trial and Appeal Board (PTAB) had interpreted Section 315(b) to mean that "the dismissal of the infringement suit [by plaintiff] nullifies the effect of the service of the complaint and, as a consequence, does not bar [the defendant] from pursuing an inter partes review of [the asserted patent]."[2]

The en banc court rejected the PTAB's interpretation of Section 315(b), holding that Section 315(b)'s time bar applies when "an IPR petitioner was served with a complaint for patent infringement more than one year before filing its petition, but the district court action in which the petitioner was so served was voluntarily dismissed without prejudice."[3] Relying heavily on Section 315(b)'s language "served with a complaint," the *Click-to-Call* panel reasoned that "[Section] 315(b)'s time bar is implicated once a party receives notice through official delivery of a complaint in a civil action, *irrespective of subsequent events*."[4]

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1 *Click-to-Call Tech., LP v. Ingenio, Inc.*, http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/15-1242.Opinion.8-16-2018.pdf, Case No. 2015-1242 slip op. (Fed. Cir. Aug. 16, 2018) (en banc note 3).

2 *Id.* at 7.

3 *Id.* at 10 n.3 (en banc).

4 *Id.* at 13 (emphasis added).

Judges Dyk and Lourie dissented.[5] Relying on Section 315(b)'s language, background, and purpose, the dissent concluded that the Section 315(b) time bar "should not apply when the underlying complaint alleging infringement has been voluntarily dismissed without prejudice."[6] The dissent also cautioned that the court's contrary holding could permit patent owners to "manipulate the filing of infringement actions" by filing an infringement complaint, serving it, dismissing the suit, and then refiling the complaint once the one-year estoppel clock has elapsed.[7]

PRACTICE POINTER

When served with an infringement complaint, a defendant should be cognizant that its one-year bar to file an inter partes review petition has begun, regardless of the disposition of the complaint.

[5] *Id.* (Dyk, J., dissenting).

[6] *Id.* at 12-13.

[7] *Id.* at 12.

STANDARDIZED: USPTO ADOPTS FEDERAL COURT PHILLIPS CLAIM CONSTRUCTION STANDARD AT PTAB

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In a final rule package recently published by the US Patent and Trademark Office, the agency conformed the standard for construing unexpired claims under certain Patent Trial and Appeal Board proceedings to the *Phillips* standard used in district courts and at the International Trade Commission, creating a unified process across all potential forums.

After November 13, 2018, it will no longer be a viable option for accused infringers to take the common approach of offering slightly differing constructions at the PTAB and in district court or the ITC based on the differences in the claim construction standards being applied in each forum.

On October 10, 2018, the US Patent and Trademark Office (USPTO) published a final rule package officially conforming the standard for construing unexpired claims in inter partes review (IPR), post-grant review (PGR), and covered business method (CBM) proceedings from the current broadest reasonable interpretation (BRI) standard to the *Phillips*[1] standard used by district courts and the International Trade Commission (ITC). The standard change is effective November 13, 2018. While it is too early to predict the impact the change will have on Patent Trial and Appeal Board (PTAB) proceedings, it should at least make it more difficult for parties to take inconsistent positions in proceedings before the PTAB, the federal district courts, and the ITC, and it may impact litigation and filing strategies as well.

Using the *Phillips* standard is not new to the USPTO, which currently interprets claims in expired patents under *Phillips*.[2] Construing a claim "in accordance with the ordinary and customary meaning of such a claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent" opens the door to additional relevant extrinsic evidence. Further, the USPTO will be guided by other principles articulated by the Federal Circuit regarding *Phillips*, such as the doctrine of construing claims to preserve their validity.[3] Assuming that the PTAB does not increase the word-count imits for briefs, practitioners will need to make judicious use of their resources. Administrative patent judges (APJs) will continue to provide preliminary claim constructions at institution and provide final constructions when entering final written decisions. Currently, it appears that the PTAB will not adopt a fully separate claim construction proceeding, instead relying on the current practice of addressing the preliminary claim constructions and additional evidence at oral hearing.

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1 *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

2 *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279 (Fed. Cir. 2017) (noting that "[t]he Board construes claims of an expired patent in accordance with *Phillips*... and [u]nder that standard, words of a claim are generally given their ordinary and customary meaning").

3 See *Phillips*, 415 F.3d at 1327-28.

Because the standard will be consistent across forums, the rule amendment also allows the USPTO to consider any prior claim construction determination concerning a term of the involved claims in a civil action or ITC proceeding that is timely made of record in an IPR, PGR, or CBM proceeding. While the USPTO is not bound by a district court or ITC claim construction order (that hasn't been adopted on appeal by the Federal Circuit), the reverse may not be true. Given the US Supreme Court's analysis in *B&B Hardware*, in a post-*SAS*[4] environment, preclusion may apply after a final determination since the "parties cannot escape preclusion simply by litigating anew in tribunals that apply… one standard differently."[5] Most importantly, the common approach of offering (slightly) differing constructions for unpatentability at the PTAB and noninfringement in district court will no longer be a viable option for accused infringers. Filing an IPR/CBM/PGR petition before the November 13 effective date will be critical in preserving this option for petitioners, so we can expect a rush of new petitions over the next 30 days.

Given *SAS*'s impact on institution rates, along with potential claim construction preclusion, district courts may be more willing to grant stays of litigation while the PTAB proceeding goes forth—particularly courts that don't have heavy patent dockets. *TC Heartland*[6] has increased patent filings in venues that don't have established practices or familiarity with the nuances of patent litigation. Under the prior standard, if even a single claim survived PTAB review applying BRI, the district court would have to perform claim construction under *Phillips*. Now, especially for district judges that don't perform claim construction on a regular basis, allowing a panel of APJs to perform the heavy lifting and conserve judicial resources may be appealing. However, timing is going to be a factor. While some courts will grant a stay on the filing of an IPR petition, others will wait until an institution decision. In those cases, a district court may reach a claim construction hearing and issue an order prior to the one-year bar. Filing a petition with the USPTO as early as possible after being accused of infringement is still the recommended strategy for accused infringers. For patent owners, a uniform process across all potential forums will prevent extended litigation and limit the accused infringer (the PTAB petitioner) to a single bite at the invalidity apple.

[4] *SAS Inst. Inc. v. Iancu*, 584 U.S. __ (Apr. 24, 2018).

[5] *See B&B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1307 (2015) (discussing analogous proceedings before the Trademark Trial and Appeal Board).

[6] *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017).

PRECEDENTIAL PTAB DECISION HOLDS INTER PARTES REVIEW CHALLENGERS CAN JOIN OWN PETITIONS

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A panel of the US Patent Trial and Appeal Board has identified "limited circumstances" in which a patent challenger can join its own inter partes review petition to add new issues. Parties seeking to join their own petitions should consider whether they can show undue prejudice, and the one-year time bar remains relevant.

The US Patent Trial and Appeal Board (PTAB) of the US Patent and Trademark Office issued its first precedential opinion in *Proppant Express Investments LLC v. Oren Technologies, LLC* on March 13, holding that so-called "issue joinder" is allowed under the America Invents Act.[1] As such, the panel cited "limited circumstances" under which parties can join their own petitions for inter partes review.

PROCEDURAL HISTORY

Petitioners Proppant Express Investments, LLC and Proppant Express Solutions, LLC filed two serial petitions requesting inter partes review of the same patent owned by Oren Technologies, LLC. The PTAB declined to institute on one ground in the first petition, finding that the petitioners had failed to account for all limitations of a challenged claim.[2] In the second, later-filed petition, the petitioners attempted to correct that error and also simultaneously filed a motion for joinder with the first petition.[3] The PTAB denied both the second petition and the motion for joinder, interpreting 35 USC § 315(c) as providing authority to join only "*other parties* to existing proceedings without introducing *new issues* of patentability."[4] The PTAB also denied the second petition under 35 USC § 315(b) because the petitioners had been served with a complaint alleging patent infringement more than one year before the date the second petition was filed.[5]

[1] No. IPR2018-00914, Paper No. 38, slip op. (PTAB Mar. 13, 2019).

[2] *Id.* at 2.

[3] *Id.*

[4] *Id.* (emphasis added).

[5] *Id.* at 2-3.

After the petitioners requested rehearing of the PTAB's denial of the second petition, the PTAB's Precedential Opinion Panel sua sponte ordered a review to address the following issues:

1. Under 35 USC § 315(c), may a petitioner be joined to a proceeding in which it is already a party?
2. Does 35 USC § 315(c) permit joinder of new issues into an existing proceeding?
3. Does the existence of a time bar under 35 USC § 315(b), or any other relevant facts, have any impact on the first two questions?[6]

PTAB HOLDS PETITIONERS CAN JOIN THEIR OWN PETITIONS IN 'LIMITED CIRCUMSTANCES'

After a lengthy discussion on statutory interpretation, the Precedential Opinion Panel—which in this case included Director Andrei Iancu, Commissioner for Patents Drew Hirshfeld, and Acting Chief Administrative Patent Judge Scott R. Boalick—answered "yes" to all questions.

First, the panel concluded that "35 U.S.C § 315(c) provides discretion to allow a petitioner to be joined to a proceeding in which it is already a party."[7] The panel noted that the statutory language does not exclude a person who is already a petitioner in a proceeding, nor does the legislative history clearly indicate that Congress intended to allow only a different petitioner to join a proceeding.[8]

Second, as to issue joinder, the panel concluded "35 U.S.C § 315(c)... provides discretion to allow joinder of new issues into an existing proceeding," again noting the statutory language contains no express prohibition against raising new issues and finding its interpretation to be consistent with the legislative history.[9]

Third, the panel concluded that "the existence of a time bar under 35 U.S.C. § 315(b) is one of several factors that may be considered when exercising our discretion under § 315(c)."[10] The panel noted, as to this point, "The statutory language is dispositive, as 35 U.S.C. § 315(b) provides an exception to its own time limitation for a request for joinder under 35 U.S.C. § 315(c)."[11] However, the panel warned that this exception must not "swallow the rule," as the one-year time bar is important.[12]

Finally, the panel advised the PTAB to only exercise its discretion in "*limited circumstances*—namely, where fairness requires it and to avoid undue prejudice to a party."[13] The panel identified one such circumstance: where "actions [are] taken by a patent owner in a co-pending litigation such as the late addition of newly asserted claims."[14] Attempts to game the system may be considered, as may be the state and schedule of an existing inter partes review.[15] However, the panel explicitly noted that mistakes or omissions will not implicate fairness and prejudice concerns.[16]

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[6] *Id.* at 3.

[7] *Id.* at 4.

[8] *Id.* at 6-8.

[9] *Id.* at 4, 11-13.

[10] *Id.* at 16.

[11] *Id.* at 17.

[12] *Id.* at 18.

[13] *Id.* at 19 (emphasis added).

[14] *Id.*

[15] *Id.*

[16] *Id.* at 5, 19.

PTAB DECLINES TO EXERCISE ITS DISCRETION IN THIS CASE

After laying out the legal analysis, the panel declined to grant the petitioners' motion for joinder for the second petition because it was based on the petitioners' failure to make out a proper case in the first petition.[17] "Because Petitioner[s'] own conduct created the need for it to request joinder, this case does not involve one of the limited circumstances in which the Board will exercise its discretion to allow same party and/or issue joinder."[18] The panel then declined to institute the second petition as untimely.[19]

Parties seeking to join their own petitions should consider whether they can show undue prejudice. It remains best practice to file all petitions before the one-year time bar when possible and preferably simultaneously to avoid 35 USC § 325(d) and 35 USC § 314(a) issues.

[17] *Id.* at 19.

[18] *Id.* at 20.

[19] *Id.* at 20-21.

PRECEDENTIAL PTAB DECISIONS CLARIFY LIVE TESTIMONY AT ORAL ARGUMENT

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While stating that live testimony will generally not be necessary, the Patent Trial and Appeal Board (PTAB) identifies "very limited circumstances" where live testimony before the board may be permitted.

The Office Patent Trial Practice Guide states "[o]ccasionally, the Board will require live testimony where the Board considers the demeanor of a witness critical to assessing credibility."[1]

The PTAB elevated two decisions on March 18 to precedential status, *K-40 Electronics, LLC v. Escort, Inc.*[2] and *DePuy Synthes Products, Inc. v. Medidea, LLC*.[3] Taken together, these decisions clarify when live testimony may be permitted or required.

PROCEDURAL HISTORY – *K-40*

In *K-40*, petitioners K-40 Electronics, LLC filed IPR petitions challenging two patents invented by a Steven K. Orr that claimed priority to June 14, 1999. Petitioner K-40 argued anticipation and obviousness under two references, neither of which was published prior to the patents' June 14, 1999, priority date, but both of which were filed earlier in 1999, making each §102(e) art.4 No backup §102(b) argument was provided.

Patent owner Escort, Inc. responded by attempting to antedate the prior art. To do so, Escort submitted declarations by Mr. Orr in each of the IPRs.[5] Escort then requested that Mr. Orr give live testimony to the board regarding his purported antedating work. Petitioner K-40 opposed, arguing that permitting this would "establish a 'de facto' rule permitting live testimony in all antedating disputes."[6] The board disagreed that this would permit live testimony generally, and set forth the following two factors:

1. "[T]he importance of the witness's testimony to the case, *i.e.*, whether it may be case-dispositive."[7]
2. Whether the witness is a fact witness or an expert.[8]

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1 Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48762 (Aug. 14, 2012).
2 No. IPR2013-00203, Paper No. 34 (PTAB May 21, 2014) (precedential Mar. 18, 2019)
3 No. IPR2018-00315, Paper No. 29 (PTAB Jan. 23, 2019) (precedential Mar. 18, 2019)
4 No. IPR2013-00203, Paper No. 1, at 5.
5 No. IPR2013-00203, Paper No. 34, at 2.
6 *Id.* at 3.
7 *Id.*
8 *Id.*

Applying those factors, the board determined that because the antedation would avoid all of the asserted prior art, Mr. Orr's testimony "may well be case-dispositive."[9] Petitioner argued that because Mr. Orr's testimony is uncorroborated, it would still not be case-dispositive, but the board held corroboration could be addressed during the live testimony.[10] Similarly, the board noted that while "the credibility of experts often turns less on demeanor and more on the plausibility of their theories," courts make credibility determinations to assess the candor of fact witnesses, which also weighed in favor of allowing the live testimony.[11]

As both factors supported live testimony, the board granted patent owner Escort's motion.[12] The board further limited the live testimony to just cross-examination and redirect to prevent changes to the testimony presented in Mr. Orr's declaration.[13]

PROCEDURAL HISTORY – *DEPUY*

In *DePuy*, petitioner DePuy petitioned for cancellation of US Patent No. 6,558,426 to Dr. Michael Masini.[14] In contrast to Escort, patent owner Medidea did not submit a declaration of Dr. Masini in response.

On January 17, 2019, after filing its Sur-Reply, patent owner Medidea requested permission to allow Dr. Masini to "participat[e] at the oral hearing."[15] In a one-page order, the board determined that this issue had been resolved by the Trial Practice Guide, which states that "[n]o new evidence or arguments may be presented at the oral argument."[16] As "Dr. Masini did not provide any declaration… in this proceeding… any testimony that Dr. Masini provides at the oral hearing would be new evidence and forbidden under [the Guide]."[17]

CONCLUSIONS

In making these two decisions precedential, the PTAB has confirmed that live testimony at the oral argument will be an uncommon occurrence. In addition to limiting live testimony to testimony that may be "case-dispositive," and indicating that live expert testimony will generally not be permitted, the board also made clear that even if the testimony were case dispositive, it cannot be "new."

Accordingly, parties wishing to introduce live testimony should first consider whether the board would consider the testimony to be (i) case-dispositive; (ii) from a fact witness and not an expert; and (iii) evidence previously submitted in a declaration.

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[9] *Id.* at 2.

[10] *Id.* at 4.

[11] *See id.* at 3.

[12] *Id.*

[13] *Id.*

[14] No. IPR2018-00315, Paper No. 1

[15] No. IPR2018-00315, Paper No. 29, at n.1.

[16] *Id.* at 2 *quoting* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,768 (Aug. 14, 2012).

[17] *Id.*

STATUTORY TIME BAR APPLIES TO PRIVITY AND RPI RELATIONSHIPS ARISING AFTER FILING OF IPR PETITION

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The Federal Circuit Court of Appeals recently held that the Section 315(b) time-bar analysis must assess privity and real-party-in-interest relationships that arise after the filing of an inter partes review petition; companies should take this ruling into account when considering a merger or other agreement that would result in such a relationship.

The US Court of Appeals for the Federal Circuit recently held that privity and real-party-in-interest (RPI) relationships arising after filing, but before institution, of an inter partes review (IPR) petition should be considered for determining the statutory time bar under 35 USC § 315(b). The provision provides that "[a]n inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privity of the petitioner is served with a complaint alleging infringement of the patent."

On June 13, the Federal Circuit applied the one-year time-bar provision to a petitioner that had announced its merger with a defendant in the district court litigation before filing the IPR petition, even though the merger had not closed at the time the IPR was filed. The time-bar provision, Section 315(b) of the America Invents Act, requires the Patent Trial and Appeal Board (Board) to deny institution of an IPR even if the petition otherwise complies with Section 312(a)(3). The Federal Circuit's holding makes clear that the Section 315(b) time-bar analysis requires assessing privity and RPI relationships not only at the time of filing, but also leading up to the institution decision.

THE DECISION

On November 4, 2009, Power Integrations International Inc. filed a complaint against Fairchild Semiconductor Corporation and Fairchild (Taiwan) Corporation (collectively, Fairchild) in the Northern District of California, alleging infringement of several patents, including US Patent No. 6,212,079 (the '079 Patent). *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, et. al., CAND-3-09-cv-05235, Dkt. 1 (N.D. Cal. 2009). Fairchild was served with the complaint two days later. In March 2014, a jury found Fairchild liable for infringing the '079 Patent and awarded Power Integrations $105 million in damages.[1]

[1] *See generally Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., et. al.*, CAND-3-09-cv-05235 (N.D. Cal.).

After the jury trial, Fairchild announced that it had entered into a merger agreement with ON Semiconductor (ON). In March 2016, ***while the merger was pending***, ON filed an IPR petition challenging the '079 Patent[2] and other IPR petitions invalidating several other Power Integration patents[3]. Although the merger was disclosed in the IPR proceedings, the IPR petitions were all filed before the merger was finalized.

The Board determined that the IPR was not time barred under Section 315(b) because there was insufficient evidence to show Fairchild had any control over the IPR at the time when the petition was filed.[4] The board also denied Power Integrations' request for additional discovery regarding the relationship between ON and Fairchild, reasoning that "Patent Owner has expressed no more than a suspicion (mere speculation) that such evidence exists and would be uncovered by additional discovery". *Id*. The Board found the '079 Patent and other Power Integrations patents unpatentable in the final written decisions of the IPRs. *Id*.

On appeal, the Federal Circuit vacated the Board's final written decision and concluded that "the § 315(b) time-bar can be 'decided fully and finally at the *institution stage*.'"[5] In holding so, the Federal Circuit further stated that "privity and RPI relationships arising after filing but before institution may time-bar institution under § 315(b)."[6] Section 315(b) provides:

> (b) Patent Owner's Action.—An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent. The time limitation set forth in the preceding sentence shall not apply to a request for joinder under subsection (c).[7]

The Federal Circuit agreed with Power Integrations' interpretation that Section 315(b) requires assessment of privity and RPI relationships arising after filing, but before institution, because the language of the statute precludes institution, not filing. "Section 315(b) is the gatekeeper to deny institution of petitions from time barred petitioners, their real parties in interest, and their privies."[8] According to the Federal Circuit, the "is filed" phrase in Section 315(b) only marks the end of the one-year window from the RPI's complaint service date. Although the merger was closed only four days before the institution of the IPR, the IPR was nevertheless time barred.

The Federal Circuit further reasoned that since the petitioner is under a continuing obligation to identify all PRIs in an IPR proceeding, a "time of filing" rule for assessing the time bar of Section 315(b) would make little sense in light of the ongoing obligation for updating the PRIs.

In addition, the Federal Circuit also rejected ON's arguments that Power Integrations is precluded from challenging the Section 315(b) time-bar decision by the Board because Power Integrations did not appeal the same decision from another IPR case. Although, in this case, the Federal Circuit agreed that the Board's Section 315(b) decision in the other nonappealed IPR case was essential to the final determination in that case, and also that ON has established the requirements of issue preclusion, the lack-of-incentive-to-litigate exception applies in this case. Power Integrations has no incentive to appeal other IPR decisions because there was no infringement finding associated with the asserted patents in that IPR.

FUTURE IMPLICATIONS

The Federal Circuit's decision in *Power Integrations* emphasizes the dilemmas companies may face when they enter into a merger agreement. Companies may not rely on the IPR petition filing date as the time to determine whether any privity or PRI relationships exist, but instead need to constantly assess privy and RPI relationships up until the institution of the IPR. Companies should take into account the implications of this finding when planning a merger or any other corporate agreement that would give rise to a privity or RPI relationship.

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2 *See generally ON Semiconductor Corp. v. Power Integrations, Inc*., No. IPR2016-00809 (P.T.A.B.).

3 *See generally ON Semiconductor Corp. v. Power Integrations, Inc*., Nos. IPR2016-01589, IPR2016-00995 and IPR2016-01597 (P.T.A.B.).

4 *See generally ON Semiconductor Corp. v. Power Integrations, Inc*., No. IPR2016-00809 (P.T.A.B.).

5 *See Power Integrations, Inc. v. Semiconductor Components Indus., LLC, DBA ON Semiconductor*, No. 2018-1607 (Fed. Cir. June 13, 2019) (citing *Wi-Fi One, LLC v. Broadcom Corp*., 878 F.3d 1364, 1372-73 (Fed. Cir. 2018) (emphasis added)).

6 *See generally Power Integrations, Inc. v. Semiconductor Components Indus., LLC, DBA ON Semiconductor*, No. 2018-1607 (Fed. Cir. June 13, 2019).

7 35 U.S.C. § 315(b).

8 *See Power Integrations, Inc. v. Semiconductor Components Indus., LLC, DBA ON Semiconductor*, No. 2018-1607 (Fed. Cir. June 13, 2019) (citing *Applications in Internet Time, LLC v. RPX Corp*., 897 F.3d 1336, 1365 (Fed. Cir. 2018) (Reyna, J., concurring), *cert. denied*, 139 S. Ct. 1366 (2019)).

PETITION GROUNDS

LAWMAKERS PROPOSE CHANGES TO FRAMEWORK OF SECTIONS 101 ON PATENT ELIGIBILITY AND 112(F) ON FUNCTIONAL CLAIMING

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Members of the US Senate Judiciary Subcommittee on Intellectual Property and House Intellectual Property Subcommittee recently released a bipartisan, bicameral draft bill to reform patent eligibility under 35 USC § 101 and amend the language of 35 USC § 112(f).

In the draft bill, "Additional Legislative Provisions" state that "[n]o implicit or other judicially created exceptions to subject matter eligibility, including 'abstract ideas,' 'laws of nature,' or 'natural phenomena,' shall be used to determine patent eligibility under section 101." The draft bill would expressly abrogate "all cases establishing or interpreting those exceptions to eligibility."

In addition, the draft bill states that "[t]he provisions of section 101 shall be construed in favor of eligibility," and it would strike the term "new" from the current "new and useful" requirement. "Useful," in turn, would be defined as "any invention or discovery that provides specific and practical utility in any field of technology through human intervention."

This proposal generally tracks the lawmakers' "Draft Outline of Section 101 Reform" released in April, which announced an intent to "[e]liminate, within the eligibility requirement, that any invention or discovery be both 'new and useful.'"

But other aspects of the draft bill deviate from the draft outline. For example, the draft bill does not list any categories of ineligible subject matter, such as "fundamental scientific principles" or "economic or commercial principles." Nor does the draft bill provide that otherwise-ineligible subject matter integrated into a "practical application" should be considered patent eligible. This concept instead appears to be incorporated into the "specific and practical utility" requirement.

The draft bill's "Additional Legislative Provisions" also instruct that the analysis under Section 101 should not turn on "the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; [and] the state of the art at the time of the invention."

Finally, in what may be a bargaining chip for anticipated opposition, the draft bill proposes amending 35 USC § 112(f) as follows:

> An element in a claim **~~for a combination may be~~** expressed as **~~a means or step for performing~~** a specified function without the recital of structure, material, or acts in support thereof, **~~and such claim~~** shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

POTENTIAL IMPLICATIONS

By abrogating the judicial exceptions to subject matter eligibility and exclusively focusing on an invention's utility, the draft bill apparently attempts to expand patent protection to at least some inventions currently considered to be abstract ideas, laws of nature, or natural phenomena. A claimed invention that is "useful" under Section 101 will be patentable so long as it complies with all remaining statutory requirements—e.g., it is novel, nonobvious, definite, and described such that a person skilled in the art could make and use it.

But the draft bill's proposed definition of "useful" may ultimately create more uncertainty than it solves. To be "useful," a process, machine, manufacture, composition of matter, or improvement thereof must be (1) an invention or discovery that (2) provides specific and practical utility (3) in any field of technology and (4) through human intervention. (Presumably, the utility must be provided through human intervention.) This definition may resurrect many of the judicial exceptions that the draft bill seeks to eliminate. In some cases, the components may create new uncertainties. For example:

- Can an abstract idea's utility be "specific and practical"?
- Are mental processes, products that exist exclusively in nature, and business methods in a "field of technology"?
- Do wholly automated processes, laws of nature, and natural phenomena provide utility "through human intervention"?

The most likely result of the draft bill appears to be that new diagnostic methods, as just one example, would pass the Section 101 threshold. A new diagnostic method, although based on a natural law, could "provid[e] specific and practical utility… through human intervention."

The effect on other types of claims is less certain. It is questionable whether the draft bill provides greater "predictability and stability to the patent eligible subject matter inquiry" than the current version of Section 101 and the case law that has interpreted it.

As for Section 112(f), the proposed amendment would remove the "means for" and "step for" language, thereby expressly shedding the provision's infamous "magic words," and instead giving means-plus-function scope to any element "expressed as a specified function without the recital of structure, material, or acts in support thereof."

But the practical effect of removing the "magic words" is likely minimal. The proposed amendment appears to simply reflect the US Court of Appeals for the Federal Circuit's en banc decision in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339 (Fed. Cir. 2015). In *Williamson*, the Federal Circuit explained that, although failure to use the word "means" creates a rebuttable presumption that Section 112(f) does not apply, the presumption can be overcome "if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function." *Id*. at 1348, 1349.

TIMELINE

The lawmakers backing the draft bill noted that the draft "is intended to solicit feedback[,]… is not final, and is subject to additional revision." The Senate Judiciary Subcommittee on Intellectual Property will hold hearings in June regarding "the state of patent eligibility in the United States." The hearings will feature three panels, each consisting of five witnesses.

USPTO ANNOUNCES GUIDANCE FOR SUBJECT MATTER ELIGIBILITY AND COMPUTER-IMPLEMENTED FUNCTIONAL CLAIM LIMITATIONS

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The US Patent and Trademark Office (USPTO) on January 4 announced the "2019 Revised Patent Subject Matter Eligibility Guidance" and "Computer-Implemented Functional Claim Limitations Guidance" for examiners and administrative patent judges.

2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE

The Revised Patent Subject Matter Eligibility Guidance[1] focuses on the first step of the *Alice/Mayo* test[2]–that is, whether a claim is "directed to" a judicial exception to patentability (i.e., laws of nature, natural phenomena, and abstract ideas).[3]

The Revised Guidance sets forth a "two-prong inquiry" for determining if a claim is "directed to" an abstract idea. Initially, examiners must determine whether the claim limitation(s) "when recited on their own or per se" fall into certain enumerated categories of abstract ideas. If so, examiners then determine whether the claim recites additional elements that integrate the abstract idea into a ***practical application***. Each of the two prongs is addressed below.

First, to "increase clarity and consistently in how Section 101 is currently applied," the Revised Guidance provides groupings of subject matter considered to be an abstract idea.[4] These categories are the result of "extract[ing] and synthesiz[ing] key concepts identified by the courts as abstract ideas."[5]

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1 USPTO, "2019 Revised Patent Subject Matter Eligibility Guidance" *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-28282.pdf (filed Jan. 4, 2019) (hereinafter Revised Guidance).

2 The first step of the *Alice/Mayo* test is equivalent to Step 2A of the USPTO's Subject Matter Eligibility Guidance as incorporated into the Manual of Patent Examining Procedure.

3 *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014).

4 Revised Guidance at 4.

5 *Id.* at 9.

If an examiner believes claims that do not recite matter falling within these enumerated groupings should nevertheless be treated as reciting an abstract idea, the examiner may send a request for approval to the Technology Center Director with a justification for why such claim limitation is being treated as reciting an abstract idea.[6] Notably, the Revised Guidance notes that this will only occur in "the rare circumstance."[7] Additionally, the Revised Guidance states that "in the rare circumstance in which a panel of administrative patent judges (or panel majority) believes that a claim reciting a tentative abstract idea should be treated as reciting an abstract idea, the matter should be brought to the attention of the [Patent Trial and Appeal Board] leadership by a written request for clearance."[8]

ENUMERATED CATEGORY	INCLUDES
Mathematical concepts	Mathematical relationships, mathematical formulas or equations, and mathematical calculations
Certain methods of organizing human activity	Fundamental economic principles or practices, including hedging, insurance, mitigating risk; commercial or legal interactions, including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business relations; managing personal behavior or relationships or interactions between people, including social activities, teaching, and following rules or instructions
Mental processes	Concepts performed in the human mind, including an observation, evaluation, judgment, and opinion For this category, the Revised Guidance specifically notes that "[i]f a claim, under its broadest reasonable interpretation, covers performance in the mind but for the recitation of generic computer components, then it is still in the mental processes category unless the claim cannot practically be performed in the mind... Likewise, performance of a claim limitation using generic computer components does not necessarily preclude the claim limitation from being in the mathematical concepts grouping, *Benson*, 409 U.S. at 67, or the certain methods of organizing human activity grouping, *Alice*, 573 U.S. at 219-20."[9]

Second, if the claim falls within one of the above-mentioned categories, examiners must then determine whether the claim recites additional elements that integrate the identified judicial exception into a practical application. The Revised Guidance provides specific ***indicia*** of the additional elements being integrated into a practical application.[10] If a claim recites a judicial exception and fails to integrate that exception into a practical application, then the claim is "directed to" a judicial exception and the established second step of the *Alice/Mayo* test should be employed.

[6] *Id.* at 26.

[7] *Id.* at 11, 15, 17, 25.

[8] *Id.* at 26 n.42.

[9] *Id.* at 11 n.14.

[10] *See id.* at 19-21.

Examples from the Revised Guidance of circumstances where the judicial exception has been integrated into a practical application include:

ADDITIONAL ELEMENT	EXEMPLARY CASE CITED
Reflects an improvement in the functioning of a computer, or an improvement to other technology or technical field	*DDR Holdings, LLC* v. *Hotels.com, L.P.*, 773 F.3d 1245, 1257-59 (Fed. Cir. 2014)
Applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition	*Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066-68 (Fed. Cir. 2011); *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1135 (Fed. Cir. 2018)
Implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim	*Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 64-65 (1923)
Effects a transformation or reduction of a particular article to a different state or thing	*Diamond v. Diehr*, 450 U.S. 175, 184 (1981)
Applies or uses the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception	*Diehr*, 450 U.S. at 184, 187; see also *Finjan Inc. v. Blue Coat Sys., Inc.*, 879 F.3d 1299 (Fed. Cir. 2018); *Core Wireless Licensing, S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356 (Fed. Cir. 2018)

Examples from the Revised Guidance of circumstances where the judicial exception has not been integrated into a practical application include:

ADDITIONAL ELEMENT	EXEMPLARY CASE CITED
Merely recites the words "apply it" (or an equivalent) with the judicial exception, or merely includes instructions to implement an abstract idea on a computer, or merely uses a computer as a tool to perform an abstract idea	*Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 222-26 (2014); *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Credit Acceptance Corp. v. Westlake Servs.*, 859 F.3d 1044 (Fed. Cir. 2017)
Adds insignificant extra-solution activity to the judicial exception; or	*Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 79 (2012); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1375 (Fed Cir. 2011); *Parker v. Flook*, 437 U.S. 584, 590 (1978)
Does no more than generally link the use of a judicial exception to a particular technological environment or field of use	*Bilski v. Kappos*, 561 U.S. 593, 612 (2010); *Flook*, 437 U.S. at 588-90

The Revised Guidance further emphasizes that because the revised, two-step approach to step one of *Alice/Mayo* "does not evaluate whether an additional element is well-understood, routine, conventional activity," then a claim including "conventional elements may still integrate an exception into a practical application, thereby satisfying the subject matter eligibility requirement of Section 101."[11]

TAKEAWAYS

The Revised Guidance borrows in large part from case law from the pre-*Alice/Mayo*. For example, the Revised Guidance states that one example of a judicial exception being integrated into a practical application is where the limitation "effects a transformation or reduction of a particular article to a different state or thing"—the quintessential "machine-or-transformation test" inquiry.[12] Yet this category fails to acknowledge the US Supreme Court's emphasis in *Mayo* that satisfying the machine-or-transformation test, by itself, is not sufficient to render a claim patent-eligible, as not all transformations or machine implementations infuse an otherwise ineligible claim with an "inventive concept."[13] While the machine-or-transformation test may continue to provide a "useful clue" as to patent eligibility, it is not determinative.[14]

By taking a categorical approach to what constitutes an "abstract idea" in prong one of the Revised Guidance's two-prong approach, examiners may find it easier to determine that a limitation recites an abstract idea. As a result, the Revised Guidance should lead to a more even application and predictability across different examiners and art units. If that is the case, practitioners may see the battleground shift to whether the claim as a whole integrates the abstract idea into a practical application of that exception.

Time will tell whether the US Court of Appeals for the Federal Circuit is persuaded by the guidelines and explicitly or implicitly adopts the USPTO's new framework.[15] More importantly, however, is how long it takes the US Supreme Court to weigh in on any given aspect of the Revised Guidance.

EXAMINING COMPUTER-IMPLEMENTED FUNCTIONAL CLAIM LIMITATIONS FOR COMPLIANCE WITH 35 USC 112

The "Computer-Implemented Functional Claim Limitations Guidance" aims to assist USPTO personnel in examining claims "that contain functional language, particularly patent applications where functional language is used to claim computer-implemented inventions."[16]

First, the Section 112 Guidance addresses examining computer-implemented functional claims having ***means-plus-function limitations***.

Discussing the Federal Circuit's decision in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc), the Revised Guidance recommends that an applicant faced with a USPTO action stating the claim is being interpreted according to Section 112(f) may (1) present a sufficient showing to establish the claim limitation recites sufficient structure to perform the claimed function so as to avoid interpretation under Section 112(f); or (2) amend the claim limitation so as to avoid interpretation under Section 112(f) (*e.g.*, reciting sufficient structure to perform the claimed function).

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[11] *Id.* at 22.

[12] *See Bilski*, 545 F.3d at 961-62.

[13] *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) (quoting *Mayo*, 566 U.S. at 84).

[14] *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 716 (Fed. Cir. 2014).

[15] *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) ("The Guidelines, like the Manual of Patent Examining Procedure ('MPEP'), are not binding on this court, but may be given judicial notice to the extent they do not conflict with the statute.").

[16] USPTO, "Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 USC 112" at p. 1, *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-28283.pdf (filed Jan. 4, 2019) (hereinafter, Section 112 Guidance).

As to indefiniteness under Section 112(b) for a computer-implemented means-plus-function limitation, it is well established that "the structure disclosed in the specification [must] be more than simply a general purpose computer or microprocessor and that the specification must disclose an algorithm for performing the claimed function."[17] Absent a disclosed algorithm for performing a computer-implemented means-plus-function limitation, an applicant risks facing a finding of indefiniteness.[18] The requirement cannot be avoided by arguing that one of ordinary skill in the art is capable of writing software to convert a general purpose computer to a special purpose computer to perform the claimed function.[19] Plus, the disclosed algorithm must be sufficient to perform the entire claimed function(s),[20] and ambiguous words in the claim may likewise lead to a determination that a computer-implemented functional claim is indefinite.[21] Finally, the Revised Guidance reminds examiners and applicants alike that a claim found to be indefinite under Section 112(f) will also lack written description under Section 112(a) and may fall short of the enablement requirement under Section 112(a).

Second, the Section 112 Guidance addresses written description and enablement issues for computer-implemented functional claims that recite only the idea of a solution or outcome to a problem without reciting the details of how the solution or outcome is accomplished.

For computer-implemented functional claims, the Section 112 Guidance underscores that whether there is adequate written description support requires examining the sufficiency of both the disclosed hardware and the disclosed software given the interrelationship and interdependence of computer hardware and software.[22]

As to enablement, the Section 112 Guidance explains it "is of particular importance with respect to computer-implemented inventions" that a specification need not disclose what is well known in the art "due to the high level of skill in the art and the similarly high level of predictability in generating programs to achieve an intended result without undue experimentation."[23] But, an "applicant cannot rely on the knowledge of one skilled in the art to supply information that is required to enable the novel aspect of the claimed invention when the enabling knowledge is in fact not known in the art."[24]

TAKEAWAYS

In large part, the Section 112 Guidance focuses on synthesizing the current standards and case law in the context of computer-implemented functional claims. The standards and case law are nothing new to practitioners. But the emphasis on certain tenants of those standards may signal that particular scrutiny will be paid to computer-implemented functional claims, especially as applicants continually seek to patent next-generation technologies.

[17] *Id.* at 10 (quoting *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1312 (Fed. Cir. 2012)).

[18] *Id.* at 10-11.

[19] *Id.* at 12.

[20] *Id.* at 13.

[21] *Id.* at 14-15.

[22] *Id.* at 18-19.

[23] *Id.* at 20.

[24] *Id.* at 20.

FEDERAL CIRCUIT: 'CONSISTING ESSENTIALLY OF' RISKS INDEFINITENESS AND NO INTENT FROM ANDA LABEL'S PERMISSIVE USE

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A split Federal Circuit panel recently upheld the district court's judgment of invalidity and noninfringement because the phrase "consisting essentially of" rendered the asserted claims indefinite and the proposed ANDA label did not induce infringement. While aspects of the decision are fact specific, practitioners should nonetheless remain mindful of a few key points.

In assessing the indefiniteness of the phrase "consisting essentially of," the majority in *HZNP Medicines LLC v. Actavis Laboratories UT, Inc.*[1] explained that courts should first identify and assess the "basic and novel properties" of the claimed formulation during claim construction under the definiteness standard from *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). If any one of these properties is indefinite, then the phrase "consisting essentially of" would likewise be indefinite.

As to the indirect infringement issue, the majority held that Actavis's proposed drug label did not show evidence of a specific intent to induce infringement. Whereas the claimed method requires application of a second topical agent, Actavis's proposed drug label permitted—but did not require—post-product application of sunscreen, insect repellant, or a second topical medication. Thus, even if a user applied a second topical agent as recited in the claims, the label alone would not encourage or promote that use.

BACKGROUND

HZNP Medicines LLC and Horizon Pharma USA, Inc. (together, Horizon) are the assignees of various Orange Book–listed method-of-use patents and formulation patents covering the PENNSAID® 2% product. Actavis Laboratories UT, Inc. (Actavis) filed an Abbreviated New Drug Application (ANDA) seeking to market a generic version of PENNSAID® 2%. After Actavis provided Horizon with its Paragraph IV certification, Horizon filed suit, alleging that Actavis's proposed drug label infringes Horizon's patents.

[1] Nos. 2017-2149, -2152, -2153, -2202, -2203, -2206, slip op. (Fed. Cir. Oct. 10, 2019).

The district court ultimately held, among other things, that (1) Horizon's formulation patents that used the phrase "consisting essentially of" were indefinite, and (2) Actavis's label did not induce infringement of the method-of-use patents. Horizon appealed.[2]

MAJORITY OPINION

Indefiniteness: 'Consisting Essentially of'

Horizon challenged the district court's holding that the phrase "consisting essentially of" included in some of the formulation claims was indefinite. Affirming the district court's decision, the majority noted that this phrase has the following "distinct meaning within [Federal Circuit] jurisprudence": "permit[s] inclusion of components not listed in the claim, provided they do not materially affect the basic and novel properties of the invention."[3] Applying this meaning to its analysis, the majority next assessed what qualified as "basic and novel properties" of the claimed formulations before determining whether those properties were definite.

The majority agreed with the district court that the asserted formulation patents identify five basic and novel properties of the claimed formulations: (1) better drying time, (2) higher viscosity, (3) increased transdermal flux, (4) greater pharmacokinetic absorption, and (5) favorable stability.[4] The specification not only lists each of these five properties as separate subheadings, but it also explains the importance of each and how these properties in the claimed formulation improve the prior art.[5]

The majority next explained that courts must apply the *Nautilus* definiteness standard at the claim construction stage to each of the basic and novel properties to assess whether any one fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. If any property were indefinite, the phrase "consisting essentially of" would be indefinite as well.

To support its position that the *Nautilus* definiteness standard applies, the majority explained that the use of "consisting essentially of" in the claims "incorporate[s] into the scope of the claims an evaluation of the basic and novel properties."[6] Thus, by using the phrase "consisting essentially of" in the claims, "a drafter cannot later escape the definiteness requirement by arguing that the basic and novel properties of the invention are in the specification, not the claims," because this "contravenes the legal meaning associated with the phrase."[7]

The majority therefore applied the *Nautilus* definiteness standard to the claimed formulation's basic and novel properties. The majority agreed with the district court's determination that the basic and novel property of "better drying time" was indefinite because the specification provided two different methods for evaluating "better drying time" that failed to provide consistent results at consistent times.[8] Thus, the majority concluded that the basic and novel property of "better drying time" is indefinite, which renders the entire phrase "consisting essentially of" indefinite.

The majority stressed that "the phrase 'consisting essentially of' is not *per se* indefinite"[9] and that its holding does not require "that the patent owner draft claims to an untenable level of specificity."[10] Instead, it explained that "on these particular facts, the district court did not err in determining that the phrase 'consisting essentially of' was indefinite in light of the indefinite scope of the invention's basic and novel property of a 'better drying time.'"[11]

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2 Actavis cross-appealed the district court's judgment of nonobviousness. For brevity, this LawFlash does not address this issue.

3 *HZNP Meds.*, slip op. at 22 (internal citations omitted).

4 *Id.* at 23.

5 *Id.*

6 *Id.* at 24.

7 *Id.*

8 *Id.* at 29-30.

9 *Id.* at 24.

10 *Id.* at 33.

11 *Id.*

Finally, the majority addressed Judge Newman's dissenting opinion (discussed below) that the claimed formulation cannot be indefinite as it expressly claims a list of ingredients.[12] Relying on the "well-established 'principle that claim language should not [be] treated as meaningless,'" the majority noted that the dissent's position would "render the claim meaningless because it would have us read the term 'essentially' out of the phrase 'consisting essentially of,' resulting in the separate and distinct claim phrase, 'consisting of.'"[13]

Induced Infringement: Permission Does Not Amount to Encouragement

Horizon also challenged the district court's finding that Actavis's label did not induce infringement of the method-of-use patents.[14] According to Horizon, Actavis's label tracks closely with the asserted claims, thereby proving Actavis's specific intent to induce infringement.[15]

The majority rejected Horizon's arguments and affirmed. Looking first to the claim language, the majority explained that the method claim requires three distinct steps: (1) applying the claimed formulation, (2) waiting for the area to dry, and (3) applying sunscreen, insect repellant, or a second topical medication.[16]

Actavis's label, in contrast, instructs a user to do the following:

- Apply diclofenac sodium topical solution to clean, dry skin. (2.1)
- Dispense 40 mg (2 pump actuations) directly onto the knee or first into the hand and then onto the knee. Spread evenly around front, back and sides of the knee. (2.1)

. . . .

- Wait until area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances. (2.2)

. . . .

- Avoid wearing clothing over the diclofenac sodium topical solution-treated knee(s) until the treated knee is dry.
- Protect the treated knee(s) from natural and artificial sunlight.
- Wait until the treated area is dry before applying sunscreen, insect repellant, lotion, moisturizer, cosmetics, or other topical medication to the same knee you have just treated with diclofenac sodium topical solution.
- Until the treated knee(s) is completely dry, avoid skin-to-skin contact between other people and the treated knee(s).[17]

Comparing the method claim's steps to the label's instruction, the majority concluded that the label does not encourage infringement because it only requires the first step of applying the claimed formula; it makes the remaining steps optional—that is, *if* a user wants to cover the treated area, *then* the user should wait until the area is dry.[18] And even so, the label warns the user to wait until the treated area is dry before covering the area with not only "a sunscreen, or an insect repellant"—as recited in the claim—but also clothing, cosmetics, lotion, water, moisturizer, and other topical substances.[19]

[12] *Id.* at 21.

[13] *Id.* at 21.

[14] *Id.* at 34, 37-38.

[15] *Id.* at 37-38.

[16] *Id.* at 39.

[17] *Id.* at 35.

[18] *Id.* at 39-40.

[19] *See id.* at 30, 35, 39.

Because the label does not *require* subsequent application of other products, the majority further reasoned that the label indicates substantial noninfringing uses.[20] As such, intent to induce infringement could not be inferred even if Actavis had actual knowledge that some users may infringe the patent.[21] In short, although the evidence when viewed in Horizon's favor established that some users *may* infringe, it did not establish that the label in fact instructs users to infringe.[22]

JUDGE NEWMAN CONCURRING IN PART, DISSENTING IN PART

Indefiniteness: "Consisting Essentially of"

Judge Newman first dissented from the panel majority's holdings that (1) the claim term "consisting essentially of" rendered the claims indefinite, and (2) the knowledge of persons skilled in the art cannot fill any gap in providing the properties of compositions claimed with that term.[23] According to Judge Newman, using the term "consisting essentially of" does not invalidate the claims when the specification describes the claimed formulation's properties, regardless of whether the claims repeat those properties.[24]

Criticizing the majority's refusal to consider information in the *US Pharmacopoeia* when the claim is in the form "consisting essentially of," Judge Newman reiterated that "knowledge in the field of the invention must always be considered" where "definiteness is to be evaluated from the perspective of someone skilled in the relative art."[25]

In addition, Judge Newman rebuked the majority's distinction between "consisting of" and "consisting essentially of" as "unsupported in precedent." [26] She acknowledged that precedent distinguishes the two phrases and teaches that "'consisting of' limits the claimed invention [without] limit[ing] aspects unrelated to the invention"; "[h]owever, no precedent has held that 'consisting essentially of' composition claims are invalid unless they include the properties of the composition in the claims."[27]

Judge Newman further accused the majority of ignoring the clear and convincing evidence standard for establishing invalidity for indefiniteness.[28] In Judge Newman's view, there was no evidence—let alone clear and convincing evidence—that persons of ordinary skill in the art would not have understood the components of the composition claims with reasonable certainty.[29]

Induced Infringement

Judge Newman next dissented from the majority's holding that Actavis cannot be liable for induced infringement where a user might not follow the label's instructions.[30] In particular, she reasoned that the majority opinion effectively created a new rule: "[T]he provider of the product with instructions to use it in accordance with the infringing method cannot be liable for inducement to infringe."[31]

That patients may not always comply with instructions "does not insulate the provider from infringement liability," Judge Newman explained.[32] Therefore, in her view, the summary judgment of noninfringement was "incorrect in law."[33]

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[20] *Id.* at 40.

[21] *Id.*

[22] *Id.*

[23] Dissent at 2.

[24] *Id.* at 5-6.

[25] *Id.* at 8.

[26] *Id.* at 9-10.

[27] *Id.* at 10.

[28] *Id.* at 11.

[29] *Id.*

[30] *Id.* at 12.

[31] *Id.*

[32] *Id.*

[33] *Id.*

CONCLUSION

Although aspects of the majority's decision are fact specific, practitioners should nonetheless remain mindful of the following key points. First, although the phrase "consisting essentially of" is not per se indefinite, each basic and novel property of the claimed invention must satisfy the *Nautilus* definiteness standard. Failure to do so may render the phrase "consisting essentially of" indefinite and the claim invalid. Second, if a generic's proposed drug label mentions but does not require users to perform all of the patented method's precise steps, the label alone may be insufficient to create a material issue of fact concerning specific intent to induce infringement.

PATENT ELIGIBILITY DEBATE TOUCHES ON MEDICAL DEVICE INDUSTRY

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Two recent letters to the US Senate stand on opposite sides of the debate over patent subject matter eligibility. Proposed legislation could reform Sections 101 and 112 of the US Patent Act, changing the way patent subject matter eligibility is determined, with possible effects on medical device innovation, affordability, and availability.

Patent subject matter eligibility continues to create headlines. Most recently, a group of law professors, former chief judges of the US Court of Appeals for the Federal Circuit (CAFC), and former heads of the US Patent and Trademark Office (USPTO) sent a letter[1] to the US Senate Judiciary Committee's Intellectual Property Subcommittee (IP Subcommittee) in support of recently proposed legislation that would change the way patent subject matter eligibility is determined.

The Patent Lawyers Letter stands in opposition to a letter from the American Civil Liberties Union (ACLU) and other medical, health, and civil rights organizations arguing against the proposed legislation.[2] The two letters make clear that the debate on patent eligibility is far from over, and could lead to additional revisions of the bill.

ACLU LETTER AND JUNE HEARINGS

In June 2019, the IP Subcommittee held hearings on "The State of Patent Eligibility in America." The hearings gathered feedback on a bipartisan draft bill to reform Sections 101 and 112 of the US Patent Act.[3] While a final bill was originally expected before the August recess, it has not been released.

Before the hearings, the ACLU sent a letter to the IP Subcommittee arguing that the proposed legislation "would authorize patenting products and laws of nature, abstract ideas, and other general fields of knowledge[,] permit patenting of human genes and naturally-occurring associations between genes and diseases[, and] create barriers to patients."[4] The letter advocated for "narrower paths" to addressing current patent eligibility law rather than "rewriting current 101 standards."[5]

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1 M.B. Abramowicz et al., Letter to Congress re 101 Reform (July 30, 2019) (Patent Lawyers Letter).

2 ACLU et al., Coalition Letter Opposing Draft Legislation of Section 101 of Patent Act (June 3, 2019) (ACLU Letter).

3 Senator Thom Tillis (R-NC), Press Release, Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act, https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act (May 22, 2019) (Tillis and Coons Press Release).

4 ACLU Letter.

5 *Id.*

At the hearings, many witnesses noted a lack of clarity in recent patent eligibility jurisprudence. For example, former Federal Circuit Chief Judge Paul Michel testified:

> In my view, recent cases are unclear, inconsistent with one another and confusing. I myself cannot reconcile the cases. That applies equally to Supreme Court and Federal Circuit cases. Nor can I predict outcomes in individual cases with any confidence since the law keeps changing year after year. If I, as a judge with 22 years of experience deciding patent cases on the Federal Circuit's bench, cannot predict outcomes based on case law, how can we expect patent examiners, trial judges, inventors and investors to do so?[6]

Proponents of the legislation expressed concern that the uncertainty and narrowing of patent eligibility in the United States results in capital investment, jobs, and talent increasingly going to "foreign competitors [that] have clarified and broadened eligibility and otherwise strengthened their patent systems."[7] Senators Tillis (R-NC) and Coons (D-DE), co-authors of the draft bill, noted that a lack of confidence in the patent system stifles "the free flow of information" and prevents others from "build[ing] upon those discoveries."[8]

Further, proponents argued that companies developing new medical devices rely on a clear, strong, and predictable patent regime to protect their inventions, recover R&D costs, and fund research.[9] They argued that if a company is unable to secure patent protection for innovative medical devices, the company may not be sufficiently incentivized to invest additional resources in these innovative technologies.

Witnesses favoring the proposed legislation pointed out that recent claims to specific medical device systems, such as a digital microscope for use in ophthalmic surgery and a laser device system applied to a human tissue region in surgery coupled with a control computer, were rejected by the USPTO as "abstract." Similarly, a court found a heart monitoring device used to detect heart disease by identifying changes in variability of heartbeat timing not to be patent eligible because "monitoring the irregularity of a heartbeat is an abstract idea, and... the monitor [is] operated by using a general computer."[10] The witnesses noted that, as a result of the current patent eligibility jurisprudence, they no longer know what "laws of nature," "natural phenomena," and "abstract ideas" actually mean and what inventions may fall into these unpatentable categories.

Conversely, opponents of the proposed legislation argued that rewriting Section 101 as proposed "will raise the price of healthcare... [because] [s]cientists, researchers, and small companies could be forced to pay royalties to patent-holders on patented naturally occurring correlations, human genes isolated from the body, and abstract concepts, if they are allowed to engage in research at all. Patent-holders will be able to exclude others from whole fields of knowledge and will charge monopoly prices to the public. Patients will lack access to confirmatory testing. Market-participants will be unable to improve upon inventions or testing accuracy during the patent-period."[11]

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[6] The State of Patent Eligibility in America: Hearings Before the Subcommittee on Intellectual Property, US Senate, 116th Cong. (2019) (Patent Eligibility Hearings), Testimony of Judge Paul R. Michel (Ret.).

[7] Patent Eligibility Hearings, Response to Questions from Senator Blumenthal by Judge Paul R. Michel.

[8] Senator Thom Tillis (R-NC), Tillis and Coons: What We Learned At Patent Reform Hearings, Thom Tillis, U.S. Senator for North Carolina, https://www.tillis.senate.gov/2019/6/tillis-and-coons-what-we-learned-at-patent-reform-hearings (June 24, 2019) (Tillis and Coons Joint Statement).

[9] Patent Eligibility Hearings, Testimony of Natalie Derzko (Derzko Testimony).

[10] Patent Eligibility Hearings, Testimony of Jeffrey Birchak (Birchak Testimony).

[11] Patent Eligibility Hearings, Questions for the Record, Kate Ruane.

PATENT LAWYERS LETTER

The Patent Lawyers Letter contended that "the proposed amendments preclude 'implicit or judicially created exceptions to subject matter eligibility'" and do not alter a "fundamental requirement in the patent statutes that only inventions or discoveries falling within the statutory categories in § 101… are eligible for patent protection."[12] The letter argued that, historically, Section 101 precluded "only a limited number of technological inventions from patentability, because [Sections] 102, 103, and 112 have ensured that the patent system promotes only innovative efforts in inventions and discoveries." [13] Thus, the letter reasoned, "the draft legislation returns the US patent system back to its core function in promoting the innovations—the useful arts."[14]

The Patent Lawyers Letter also addressed the ACLU's arguments regarding negative effects of the proposed bill on the cost and availability of medicines and other medical innovations to patients. The letter noted that patent protection plays a critical role in incentivizing the substantial investment required to translate the results of basic research into high-quality, commercially available products and to educate physicians on the value of such new products. This, in turn, "promotes greater access for patients to cutting-edge, live-saving technologies."[15]

IMPLICATIONS FOR MEDICAL DEVICE INNOVATORS

Medical devices have traditionally been the very types of "technical and concrete" inventions that the sponsors of the draft bill, Senators Tillis and Coons, are trying to protect.

In fact, in their post-hearing joint statement, Senators Tillis and Coons emphasized the importance of fixing the current system in which "technical and concrete" inventions may be patent ineligible regardless of whether they are novel.[16] They promised to "investigate ways to sharpen the 'field of technology' requirement to ensure that critical advances like artificial intelligence and medical diagnostics qualify, but not economic transactions or social interactions."[17]

With advancements in medical device technologies and increasing integration of software, patent eligibility considerations implicate a growing realm of medical devices. If the draft bill is enacted, a broader range of subject matter could be patent eligible and more medical device technologies may have stronger commercialization potential in the United States. While the new legislation could make the patent eligibility of medical devices more predictable, it may also weaken a company's ability to fight patents asserted by patent trolls or competitors.

It may be some time before patent eligibility is dramatically expanded in the United States, especially as a final bill has yet to be released and no timetable has been given.[18] Even when (and if) a final version of the bill passes, there will be continued uncertainty given that new statutory language will be tested in litigation.

Meanwhile, it is advisable for medical device companies to be mindful of the US Supreme Court's existing patent eligibility jurisprudence, and especially of the three exclusions of ineligible subject matter jurisprudence—laws of nature, natural phenomena, and abstract ideas—both in litigation and when drafting patent applications.

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[12] Patent Lawyers Letter.

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] Tillis and Coons Joint Statement.

[17] *Id.*

[18] According to some commentators, the delay is due to disagreement on the language of the research exemption, which potentially creates a safe harbor for fundamental research. It is also possible that additional revisions of the bill are under consideration to balance interests of patent holders and patient advocacy groups, to clarify the meaning of a number of statutory terms, and to resolve the debate regarding Section 112(f) amendment.

UPDATES ON DIAGNOSTIC METHOD PATENT ELIGIBILITY

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New and developing efforts by Congress may change the way patent subject matter eligibility is determined for years to come, changing the landscape for medical diagnostic methods. This congressional action comes following intense pleas from some judges of the US Court of Appeals for the Federal Circuit and has the potential to unravel decades of US Supreme Court precedent relating to the current patent eligibility test.

In recent years, US courts have increasingly scrutinized the eligibility of patents covering methods of diagnosing medical conditions. New diagnostic methods require intense and costly research to develop and are vital to the medical industry. Some have argued that they are among the most meritorious candidates for patent protection. But diagnostic methods often rely on scientific concepts that are ineligible for patenting, such as naturally occurring phenomena in the human body.

The eligibility of diagnostic methods for patent protection is governed by 35 U.S.C. § 101,[1] under a two-part test set forth in the Supreme Court's 2014 decision in *Alice v. CLS Bank*, and credited to the Court's 2012 decision in *Mayo Collaborative v. Prometheus Laboratories*.[2] The Court set forth a two-part framework for assessing patent eligibility. First, a court must determine whether a claim is directed to unpatentable subject matter: laws of nature, natural phenomena, and abstract ideas. If so, the claim is eligible for patent protection only if it contains an inventive concept that transforms the unpatentable natural law into a patent-eligible invention.

Naturally, the Court's analysis implicates diagnostic method patents because laws of nature and natural phenomena are used in the medical field. Indeed, in *Mayo* itself, the Court invalidated the diagnostic method patent at issue, which claimed a method of evaluating medication dosage levels. In applying the two-part framework, the Court reasoned that the patent concerned the naturally occurring relationships between metabolites in the blood and that the "the steps add nothing of significance to the natural laws themselves."

The *Mayo* decision has restricted patentability of diagnostic method patents in the years since the decision, leading to the invalidation of patents in other high-profile cases such as the Supreme Court's 2013 decision in *Molecular Pathology v. Myriad Genetics*, the Federal Circuit's 2015 decision in *Ariosa Diagnostics v. Sequenom*, the Federal Circuit's 2017 decision in *Cleveland Clinic v. True Health Diagnostics*, and the Federal Circuit's 2018 decision in *Roche Molecular Systems v. Cepheid*.[3]

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[1] 35 U.S.C. § 101 states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

[2] *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

[3] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2014); *Roche Molecular Systems, Inc. v. Cepheid*, 905 F.3d 1363 (Fed. Cir. 2018); *Cleveland Clinic Found. v. True Health Diagnostics, L.L.C.*, 859 F.3d 1352 (Fed. Cir. 2017); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

This pattern of striking down diagnostic method patents has led to intense lobbying on Capitol Hill and proposals put forth by the American Intellectual Property Law Association, American Bar Association, and Intellectual Property Owners Association, all culminating in discussions of amending § 101. Last month, the Senate Judiciary Committee held extensive hearings on "The State of Patent Eligibility in America" to discuss potential amendments to the subject matter eligibility sections in the Patent Act.[4]

Under the proposed amendments to § 101, diagnostic method patents would survive eligibility challenges more often. The proposals would statutorily abrogate the so-called "judicial exceptions" that are directed to unpatentable subject matter—laws of nature, natural phenomena, and abstract ideas—and require only a practical application: "The term 'useful' means any invention or discovery that provides specific and practical utility in any field of technology through human intervention."[5] This amendment has the potential to upend the patent subject matter eligibility analysis.

At the other end of Pennsylvania Avenue, many Federal Circuit judges have expressed a need for changes in the § 101 analysis. This criticism came to a head earlier this month in *Athena Diagnostics v. Mayo Collaborative*, when the Federal Circuit, sitting *en banc*, denied Athena's petition for rehearing in a case that invalidated Athena's diagnostic method patents. Professor Dennis Crouch's blog post on this case nicely sums up the unusual decision: "Athena Loses on Eligibility – Although 12 Federal Circuit Judges Agree that Athena's Claims Should be Eligible."[6] As Professor Crouch points out, Federal Circuit judges, in eight separate opinions, called for Supreme Court or congressional intervention on the question of patent eligibility of diagnostic method patents. No matter which branch decides to act, all those with vested interests in diagnostic method patents should pay close attention to these developments. Although the timeline is not entirely certain, the system of evaluating the eligibility of such patents may soon be drastically changed.

[4] A high level summary of the proposed changes to § 101 can be found on Senator Thom Tillis's website: https://www.tillis.senate.gov/services/files/3491a23f-09c3-4f4a-9a93-71292704c5b1.

[5] In the proposed amendments, this clause would be added to Title 35 at Subsection 100(k).

[6] Dennis Crouch, Athena Loses on Eligiblity – Although 12 Federal Circuit Judges Agree that Athena's Claims Should be Eligible, https://patentlyo.com/patent/2019/07/eligiblity-although-eligible.html, PatentlyO (July 3, 2019).

IN SPLIT DECISION, FEDERAL CIRCUIT INVALIDATES DIAGNOSTIC METHOD PATENT

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A split panel of the US Court of Appeals for the Federal Circuit held on February 6 that claims to an assay for diagnosing myasthenia gravis are not patent eligible because they are directed to a natural law. The majority decision in *Athena Diagnostics v. Mayo Collaborative Services* is in line with a series of decisions by the Federal Circuit in which diagnostic method claims were found to be not patent eligible.[1]

Athena is the exclusive licensee of US Patent No. 7,267,820, which is based upon the discovery that autoantibodies to the MuSK protein cause myasthenia gravis. The '820 patent claims methods for diagnosing myasthenia gravis by detecting MuSK autoantibodies. Claim 9 of the '820 patent describes a specific test for MuSK autoantibodies using a radioimmunoassay, and was the most specific claim considered by the court. According to claim 9, MuSK is radioactively labeled with Iodine-125, a radioactive isotope of Iodine, and then contacted with a bodily fluid. If the bodily fluid contains MuSK autoantibodies, the autoantibodies and Iodine-125-labeled protein will form immune complexes. The immune complexes are collected and then monitored for the presence of the radioactive label, which indicates a diagnosis of myasthenia gravis.

Patent eligibility is analyzed under a two-step test set forth by the US Supreme Court in *Mayo* and *Alice*.[2] The first step is to determine whether the claims are directed to a natural law, abstract idea, or other patent-ineligible subject matter. The second step asks whether the claims contain an inventive concept that transforms the claims into a patent-eligible application of the underlying ineligible subject matter.

The majority opinion authored by Judge Alan Lourie focused on claim 9 as it was the most specific one at issue. In the first step, the majority identified "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK related neurological diseases like [myasthenia gravis]" as a natural law because it "exists in nature apart from any human action." The majority determined that the claims are "directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law." In the second step, the majority recognized that the additional steps did not represent "an inventive application beyond the discovery of the natural law itself" because the patent itself described the detection steps as standard techniques in the art.

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1 *See Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015) (detecting paternally inherited fetal DNA in maternal blood); *Genetic Technologies Ltd. v. Merial L.L.C.*, 818 F.3d 1369 (Fed. Cir. 2016) (detecting a coding region of DNA by amplifying a linked non-coding DNA sequence); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017) (diagnosing atherosclerotic cardiovascular disease by detecting elevated myeloperoxidase); *Roche Molecular Systems v. Cepheid*, No. 2017-1690 (Fed. Cir. Oct. 9, 2018) (diagnosing infection with *Mycobacterium tuberculosis* by amplifying the *M. tuberculosis rpoB* gene).

2 *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012); *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014)

Judge Pauline Newman dissented. In her view, the majority's analysis of patent-eligibility was incorrect because the court should have considered the claims as a whole, including all their elements and limitations. Judge Newman concluded that viewed as such, the claims are for a novel multistep method of diagnosis, not a law of nature. In Judge Newman's opinion, it was incorrect for the majority to separate the claim steps according to whether they are performed using conventional techniques, and then to ignore the presence of the conventional steps in the analysis. Section 101 does not turn on whether any claim steps are "standard techniques," according to Judge Newman. "The appropriate analysis of the role of conventional steps in claims to a new method is under Sections 102 and 103, not Section 101."

The split decision in *Athena* reflects competing views on the application of the Mayo test to diagnostic method claims, but the outcome of the case is patent ineligibility in yet another diagnostic method case.

ADMINISTRATIVE PATENT JUDGES ARE SAFE FOR NOW, BUT WILL SCORES OF PTAB DECISIONS GET A DO-OVER?

THE US COURT OF APPEALS FOR THE FEDERAL CIRCUIT RECENTLY HELD THAT THE STATUTORY SCHEME GOVERNING THE ADMINISTRATIVE PATENT JUDGES OF THE PATENT TRIAL AND APPEAL BOARD IS IN VIOLATION OF THE APPOINTMENTS CLAUSE OF THE US CONSTITUTION.

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The Federal Circuit weighed several factors in determining whether administrative patent judges were principal or inferior officers, ultimately severing the portion of the America Invents Act that provided removal protection and holding that as inferior officers, administrative patent judges can continue presiding over inter partes reviews going forward. But the Federal Circuit vacated and remanded the case to the Patent Trial and Appeal Board for a new written decision before a new panel of administrative patent judges. The government appears likely to seek a rehearing en banc to avoid the Patent Trial and Appeal Board having to redo prior final written inter partes review decisions that could be considered invalid, i.e., issued by "unconstitutionally" appointed administrative patent judges.

Since the introduction of inter partes reviews (IPRs) in 2012, challengers have called into question the constitutionality of various parts of the America Invents Act (AIA). Oil States Energy Services sought to invalidate the IPR process, but the US Supreme Court ruled that it does not violate Article III or the Seventh Amendment of the US Constitution.[1] Still others have challenged the process as violating the due process clause. Until recently, all challenges were unsuccessful. But on October 31, 2019, the US Court of Appeals for the Federal Circuit held that the statutory scheme for appointing administrative patent judges (APJs) to the Patent Trial and Appeal Board (PTAB) violates the Appointments Clause of the US Constitution.

The IPR process is a hybrid proceeding at the US Patent and Trademark Office (USPTO)—part administrative review and part trial that assesses patents challenged by third-party petitioners (often defendants in related patent infringement lawsuits). After a petitioner files a petition challenging one or more claims of a patent, the PTAB decides whether to institute a trial. Then, if the IPR trial is instituted, a panel of three APJs conducts the trial and issues a written decision regarding the patentability of the challenged patent claims.

In *Arthrex, Inc. v. Smith & Nephew, Inc*., after the PTAB instituted IPR of a patent owned by Arthrex, a panel of APJs ruled that the challenged claims were unpatentable as anticipated. In its appeal to the Federal Circuit, Arthrex asserted that the APJs who decided its IPR were not constitutionally appointed pursuant to the Appointments Clause of Article II of the US Constitution. The Federal Circuit agreed.[2]

Under the Appointments Clause, "principal officers" must be confirmed by the US Senate, but "inferior officers" need not be. Quoting the Supreme Court, the Federal Circuit noted that "'inferior officers' are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate."[3] To determine whether PTAB APJs are "principal" or "inferior" officers, the Federal Circuit examined three factors pertaining to the power of APJs versus that of the appointed officials who direct them:[4]

1. How APJs' work is reviewed
2. How APJs are otherwise supervised
3. How APJs can be removed from office[5]

With respect to review power, the Federal Circuit determined that the USPTO director—a presidentially appointed officer—does not have the power to "single-handedly review, nullify or reverse a final written decision issued by a panel of APJs."[6] Although the government argued that a number of the director's lesser review powers were sufficient, the Federal Circuit noted that these powers either could not actually affect a given decision or could not be wielded unless a party to the decision appealed.[7] The Federal Circuit contrasted this with the power of military judges on the US Coast Guard Court of Criminal Appeals, who are considered inferior officers as they have "no power to render a final decision on behalf of the United States unless permitted to do so by other Executive Officers."[8] Because PTAB panels of APJs issue final decisions on behalf of the USPTO, the Federal Circuit concluded this factor weighed in favor of finding that APJs are principal officers.

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1 *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (Apr. 24, 2018).

2 Opinion, *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 2018-2140, ECF No. 69 (Oct. 31, 2019) (herein, Opinion).

3 *Id.* at 8 (quoting *Edmond v. United States*, 520 U.S. 561, 662-63 (1997)).

4 *Id.* at 9.

5 The Federal Circuit acknowledged there are other factors to consider, not applicable here, including limited duties, limited jurisdiction, and limited tenure. *Id.* at 19.

6 *Id.* at 10.

7 *Id.*

8 *Id.* at 12.

Conversely, the Federal Circuit concluded that the USPTO director has sufficient supervisory power such that APJs are inferior officers. This is because, in addition to having authority over an APJ's pay, the director has the power to take actions such as promulgating regulations governing IPR conduct, issuing policy directives, and approving the designation (or de-designation) of a written decision of the PTAB as precedential.[9]

The Federal Circuit next considered the removability of APJs, determining that no appointed officer had sufficient power to remove APJs from their jobs. By statute, APJs are protected from removal without cause, further weighing in favor of finding that APJs are principal officers.[10] The Federal Circuit noted that removal power is not required for officers to be "inferior officers," but the lack of such power must be coupled with strong review and supervisory powers.[11]

The Federal Circuit determined that on balance, the factors indicated that APJs are principal officers, in violation of the Appointments Clause.[12] The Federal Circuit then considered whether this required the entire AIA to be invalidated. Believing such a drastic remedy was not required, the Federal Circuit instead severed the portion of the statute that provided removal protections to APJs.[13] With that change, the Federal Circuit held that APJs are "inferior officers" and can perform their work without running afoul of the Appointments Clause.[14]

Finally, to address the issue of the IPR written decision issued by "unconstitutionally" appointed APJs in *Arthrex*, the Federal Circuit vacated the decision and remanded the case for a new hearing and reconsideration by a new panel of APJs.[15]

While further decisions will be necessary to determine the fate of IPRs in general, and existing IPR written decisions that are on appeal in particular, a few contours seem fairly clear.

First, the Federal Circuit and other bodies have moved relatively quickly to reject *Arthrex*-type arguments where appellants did not raise the issue in their opening appeal briefs to the Federal Circuit. For example, in *Customedia Techs., LLC v. Dish Network Corp.*,[16] the Federal Circuit rejected the appellant's late challenge, nothing that "Customedia did not raise any semblance of an Appointments Clause challenge in its opening brief or raise this challenge in a motion filed prior to its opening brief. Consequently, we must treat that argument as forfeited in this appeal."[17] The *Arthrex* court noted, however, that such a challenge is not required before the PTAB in the first instance because there is nothing the PTAB can do by itself to correct the problem.[18]

Second, the government appears to be taking steps to avoid having to redo the PTAB's prior final written decisions. It has sought to stay or extend time to intervene in a number of cases, noting its intention to seek rehearing en banc in *Arthrex*, presumably to press for the position that the statute is not unconstitutional and that even if it were, remand would not be required.[19] The deadline for the government to seek en banc review of *Arthrex* is December 16, 2019.[20]

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[9] *Id.* at 13-14.

[10] *Id.* at 16.

[11] *Id.*

[12] *Id.* at 20.

[13] *Id.* at 26-27 (citing 35 U.S.C. § 3(c), in turn referring to 5 U.S.C. § 7513(a), which allows APJ removal "only for such cause as will promote the efficiency of the service").

[14] *Id.*

[15] *Id.* at 27-30.

[16] 2019 WL 5677704, at *1 (Fed. Cir. Nov. 1, 2019).

[17] *See also Kingston Tech. Co. Inc. v. Polaris Innovations Ltd.*, No. 18-1778, ECF No. 50 (Nov. 5, 2019) (order denying Kingston's motion to vacate and remand in light of *Arthrex*); id. at ECF No. 51 (Nov. 6, 2019) (order affirming per curiam).

[18] Opinion at 5-6.

[19] See, e.g., *Steuben Foods, Inc. v. Nestle USA, Inc.*, Nos. 20-1082, -1083, ECF No. 15, Nov. 13, 2019 (government motion to stay proceedings or extend time to respond), ECF No. 18, Nov. 18, 2019 (order extending deadline to intervene to December 18); *Virnetx Inc. v. Cisco Sys., Inc.*, No. 19-1671, ECF No. 25, Nov. 13, 2019 (government motion to stay proceedings or extend time to respond), ECF No. 29, Nov. 18, 2019 (order extending deadline to intervene to December 18); *The Chamberlain Grp., Inc. v. One World Techs., Inc., dba Techtronic Indus. Power Equip.*, Fed. Cir. Nos. 2019-1314, -1315, ECF No. 37, Nov. 13, 2019 (government motion to stay proceedings or extend time to respond). But *see Chamberlain Grp.*, ECF No. 40, Nov. 15, 2019 (order denying Chamberlain's motion for supplemental briefing regarding *Arthrex* as waived and denying the government's motion to stay or extend time to intervene).

[20] *Virnetx*, ECF No. 25 at 2.

Third, the Federal Circuit may grant rehearing en banc. A week after *Arthrex*, a different panel of Federal Circuit judges suggested that it may not be necessary for the PTAB to redo all of its prior decisions. Although the Federal Circuit in *Bedgear, LLC v. Fredman Bros Furniture Co*. vacated and remanded the PTAB decision at issue in view of *Arthrex*, a concurrence by Judges Dyk and Newman suggested that the statutory construction in *Arthrex* could have been made retroactive. The concurrence stated that "a judicial construction of a statute or a holding that a part of the statute is unconstitutional and construing the statute to permit severance are necessarily retrospective as well as prospective," and "the statute here must be read as though the PTAB judges had always been constitutionally appointed, 'disregarding' the unconstitutional removal provisions."[21] Although Judge Stoll did not join the *Bedgear* concurrence, other Federal Circuit judges have signaled their willingness to consider the issue further. In *Polaris Innovations Limited v. Kingston Technology Co. Inc*.,[22] Judges Reyna, Wallach, and Hughes ordered supplemental briefing on the issues addressed in *Arthrex*. Thus, the Federal Circuit appears poised to weigh in further.

Finally, Congress is already looking at ways to address the issue. On November 19, the House Judiciary Committee's Subcommittee on Courts, Intellectual Property, and the Internet heard testimony from law professors (https://judiciary.house.gov/legislation/hearings/patent-trial-and-appeal-board-and-appointments-clause-implications-recent-court) regarding the *Arthrex* decision and what legislative changes it might make to the statute.

[21] Nos. 2018-2082, -2083, -2084 at 3, 5 (citing *Marbury v. Madison*, 1 Cranch 137, 178 (1803)).

[22] No. 18-1768, ECF No. 90 (Nov. 8, 2019).

PROBLEM SOLVING: A REHEARING PROPOSAL

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For decades, all three branches of the US government have tried their hand at implementing various laws, rules, and procedures to curb both the necessity and the expense of US patent litigation, much of which was initiated by non-practising entities. One such Congressionally-created mechanism – the America Invents Act (AIA) of 2011 allows a limited means to seek review of a patent issued by the US Patent and Trademark Office (USPTO). AIA trials promised to be significantly less expensive and more efficient than district court post-grant validity determinations.

In 2014, the first year of the streamlined proceedings, 75% of petitions for AIA trials were instituted on at least some of the challenged claims;[1] and by one year later, over 80% of final written decisions for instituted AIA trials resulted in a finding of unpatentability.

While AIA trials have helped reduce the overall cost of US patent litigation, for patent owners, they have also significantly reduced the value of patent portfolios. For six years, the courts and the Patent Trial and Appeal Board (PTAB) have tweaked and twisted the AIA trial process, most recently with the Supreme Court of the US' *SAS Institute v. Iancu* decision.[2] At the same time, institution, settlement, and unpatentability rates have steadily decreased. Some argue that these changes have resulted in a more equitable AIA trial process.[3] Others believe that certain changes will only benefit the patent bar by increasing expenses without meaningfully changing outcomes.

At least one significant mechanism of AIA trials, however, remains in desperate need of reform: reviews of institution decisions. While final written decisions are appealable to the Court of Appeals for the Federal Circuit, institution decisions are final and non-appealable, except for a handful of narrow exceptions.[4] This provides the PTAB with broad discretion on decisions on institution, with little oversight.

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1 These numbers reflect IPR petitions only, although any statistical change including petitions for covered business methods ("CBMs") and petitions for post-grant review ("PGRs") would likely have been negligible. *See* USPTO, *AIA Progress* at 4 (July 16, 2015), https://www.uspto.gov/sites/default/files/documents/071615_aia_stat_graph.pdf.

2 138 S.Ct. 1348 (2018).

3 AIA trial processes have grabbed the attention of Congress as well. On March 20, 2018, US Representatives Steve Stivers and Bill Foster introduced H.R. 5340, titled 'Support Technology & Research for Our Nation's Growth and Economic Resilience (STRONGER) Patents Act.' In late June 2017, US senators Chris Coons, Tom Cotton, Dick Durbin, and Mazie Hirono introduced a version of the bill to the US Senate. The bill proposes a number of changes to AIA trial practice, including among other things (1) requiring the USPTO to use the district court standard for claim construction; (2) changing the burden of proof to clear and convincing evidence; (3) requiring that the petitioner must have a business or financial reason for standing; and (4) specifying that the panel that decides whether to institute a US states senator for Delaware, *The STRONGER Patents Act of 2017*: Section by Section, https://www.coons.senate.gov/imo/media/doc/STRONGER%20Patents%20Act%20of%202017%20Section-By-Section.pdf (last visited Mar. 21, 2018).

4 For example, in *Wi-Fi One v. Broadcom*, 878 F.3d 1364 (Fed. Cir. 2018), the Federal Circuit sitting *en banc* held that the USPTO director's time-bar determinations under 35 U.S.C. § 315(b) are not exempt from judicial review. *Id.* at 1375.

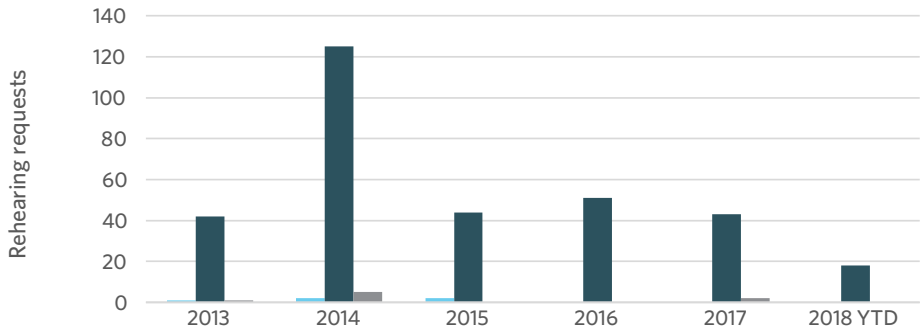
CURRENT POSITION

In AIA trials, a party dissatisfied with the PTAB panel's institution decision may request a rehearing[5] where the challenging party has the burden of showing that a decision should be modified.[6] The party's "request must specifically identify all matters the party believes the board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply."[7] At the institution stage, the challenging party must also demonstrate that the board abused its discretion. Without an institution decision, neither party can appeal the board's denial.

Currently, a request for rehearing is assigned to the same three-member panel that issued the institution decision. This practice results in the original panel reviewing its own decision for an abuse of discretion.[8] In other words, the original panel is asked whether it abusively "misapprehended or overlooked" evidence or misapplied the law in reaching its own decision on institution – the one that the panel spent time and effort to recently author.

As such, it is not surprising that administrative patent judges (APJs) rarely grant requests for rehearing of their own institution decisions. Parties have filed approximately 338 requests for rehearing of institution decisions. The board has granted only 13, and eight of the 13 were granted in part (around 4%), see figure 1. Stated differently, the board has granted roughly 4% of requests for rehearing of institution decisions since the AIA's inception.

Figure 1: Success rate of requests for rehearing of decisions on institution at the PTAB



	2013	2014	2015	2016	2017	2018 YTD
Granted	1	2	2	0	0	0
Denied	42	125	44	51	43	18
Partial	1	5	0	0	2	0

Given these staggering statistics, requests for rehearing are perceived by the patent bar as futile gestures that lack any meaningful procedural or substantive due process. Indeed, for a denial of institution, the board does not have any timeline or regulations controlling when a decision (one that usually denies the request) should issue. In fact, some practitioners report having waited more than 10 months for a decision, which was ultimately a denial.

That neither a decision on institution nor a rehearing request for that decision is appealable to the Federal Circuit compounds the perceived injustice.[9] Declining institution rates – from 87% in 2013 to only 62% as of the USPTO's most recent report for 2018 – further exacerbate concerns, [10] see figure 2.

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[5] *See* 37 C.F.R. § 42.71(d).

[6] *See* 37 C.F.R. § 42.71(d).

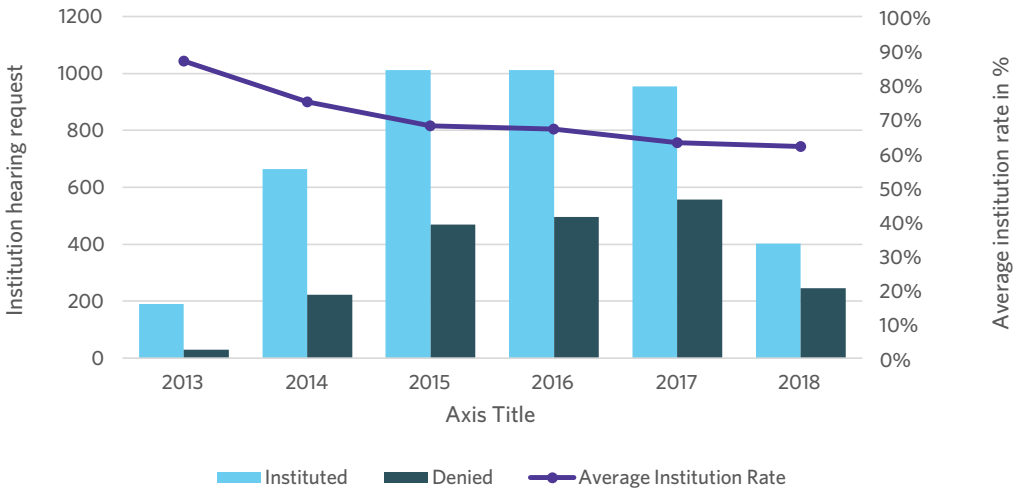
[7] *Id.*

[8] 37 C.F.R. § 42.71(c). A decision is an abuse of discretion if it is based on an erroneous interpretation of law, a factual finding is not supported by substantial evidence, or an unreasonable judgment is made in weighing relevant factors. *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005); *Arnold P'ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004); *In re Gartside*, 203 F.3d 1305, 1315–16 (Fed. Cir. 2000).

[9] *Cuozzo* Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2139-41 (2016).

[10] USPTO, Trial Statistics – Patent Trial and Appeal Board (Feb. 2018), https://www.uspto.gov/sites/default/files/documents/trial_statistics_20180228.pdf.

Figure 2: PTAB institution rates



The Supreme Court of the US' 5-4 decision in *SAS Institute v. Iancu*,[11] plus the board's subsequent guidance[12] provides some degree of relief. All institution decisions are now binary: the board will either institute as to all claims and grounds or none. If the board institutes on all claims and grounds, a final written decision will result, which is appealable.[13] If the board declines institution, the decision on institution remains unreviewable. With this backdrop, the issue of requests for rehearing of institution decisions has understandably sparked interest across the industry.[14]

ADDITIONAL APJ

We propose a solution that the board can implement via an Administrative Procedures Act (APA) rule change, thus avoiding the need for congressional intervention. Requests for rehearing of decisions on institution should be assigned to, and reviewed by, at least one additional APJ who was not part of the original panel. When a party requests a rehearing of the decision on institution, the additional APJ would conduct a "first review" to evaluate the request's grounds *de novo*. As part of the "first review" process, the additional APJ would submit a proposed, nonbinding public recommendation for the original panel's consideration. Then, after considering the proposal alongside the rehearing request, the original panel would issue a written decision on the request.

Though unlikely to offer the impartiality of judicial review by the Federal Circuit or by an entirely different three-member panel, one additional APJ's "first review" and recommendation would, at a minimum, apply another pair of eyes to the review. This process, in turn, would be one step toward improving public perception of, and confidence in, the meaningful availability of a rehearing process.

For example, where the original panel is unconsciously biased against reversing its own initial decision, the additional APJ affords a degree of objectivity that the current practice circumvents. And, if one APJ on the original panel harboured doubts but was overruled by the other APJs, the one doubting APJ can more easily side with the outside APJ's recommendation. Thus, public perception of institution decision making and overall institutional legitimacy would likely improve.

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[11] 138 S.Ct. 1348 (2018).

[12] *See* PTAB, "Guidance on the impact of SAS on AIA trial proceedings," USPTO.gov (Apr. 26, 2018), https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

[13] 35 U.S.C. § 141(c); 37 C.F.R. § 90.3(a).

[14] See, e.g., Letter from D. Suchy & S. Partridge to W. Ross, ABA-IPL Comments on "PTAB Procedural Reform Initiative," ABA-IPL, *available at* https://www.americanbar.org/content/dam/aba/administrative/intellectual_property_law/advocacy/advocacy-20170731-comments.authcheckdam.pdf; Letter from M. Whitaker to J. Matal, Response to the Request for Comments on "PTAB Procedural Reform Initiative," AIPLA (July 14, 2017), https://www.aipla.org/docs/default-source/advocacy/documents/aipla-letter-on-ptab-procedures-7-14-2017.pdf?sfvrsn=80da13ce_3.

The additional APJ's outside perspective and objectivity may decrease the chance of inconsistencies or mistakes in the original institution decision, – that is, the additional APJ may catch errors that those immersed in the materials missed, thereby providing an important quality check on otherwise unreviewable administrative decision making.

Importantly, this proposal requires no statutory or regulatory overhaul. Title 35 Section 6(a) already provides that "[e]ach appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by *at least three members of the PTAB*, who shall be designated by the director."[15] Moreover, the regulations for rehearings do not conflict with the proposal's underpinnings.[16]

Naturally, that the panel "shall be designated by the director"[17] may raise concerns about "stacking." As such, the authors further recommend that the additional APJ be designated at the same time that the initial three-judge panel is constituted.

Then, the additional APJ need only take action if and when a party requests rehearing of the decision on institution. Designating the additional APJ at the proceeding's outset while reserving involvement unless and until a rehearing is requested. This would not only avoid the "stacking" issue, but also increase efficiency and lessen expense as compared to an entirely separate three-member panel addressing rehearing requests.

Requiring the additional APJ to issue a formal recommendation would resolve any concerns about *ex parte* decision making between the original APJs and the additional APJ. To be clear, this proposal contemplates an order, not necessarily a separate *memorandum* or *opinion*.

The order may be as simple as a standard checklist to indicate the basis for its recommendation and a short recitation of the reasons for its recommendation (e.g., statement of points believed to have been misapprehended or overlooked by the original panel). This document would thus balance the need for accountability with the value of judicial economy.

The authors further propose requiring a modest fee (e.g., $1,000-$2,500) for requesting rehearing of institution decisions, one forgiven or reduced for small or micro-entity status.

The benefits of this fee are at least twofold. First, given the oft-voiced concerns about limited financial resources for USPTO, the fee would lessen any financial burden imposed by the additional APJ's work. It would also deter parties from frivolously filing rehearing requests as a matter of course after any institution decision regardless of the request's merits. As such, the modest fee would naturally limit the workload imposed on the board.

SUMMARY

The current approach to requests for rehearing of decisions on institution has become a regular concern for patent owners, petitioners, and practitioners. It should be a concern for the PTAB as well. The results of current procedures, as borne out in the statistics, erode public perception of the opportunity for meaningful review, threaten institutional legitimacy, and raise due process concerns, particularly in an area where the Federal Circuit and the Supreme Court have recently voiced concern.

To combat this, the authors propose that an additional APJ be added at the time that the three-APJ panel is constituted, the additional APJ provide a "first review" of any requests for rehearing of the institution decision, and additional APJ provide a recommendation to the original three-APJ panel. Fitting within the current statutory and regulatory framework, this proposal for review with an additional APJ is prime for rulemaking. Critically, it would provide a much-needed shift toward better public perception, efficient yet meaningful review, and greater consistency and accuracy in PTAB decision making.

[15] 35 U.S.C. § 6(c) (emphasis added).

[16] *See* 37 C.F.R. § 42.71.

[17] 35 U.S.C. § 6(c).

CHINA'S INTELLECTUAL PROPERTY SYSTEM: IMPORTANT CHANGES FOR MEDTECH COMPANIES

CHINA HAS RECENTLY MADE SIGNIFICANT STRIDES IN AMENDING ITS INTELLECTUAL PROPERTY (IP) LAWS IN A MANNER THAT PROVIDES SUBSTANTIAL BENEFITS AND PROTECTIONS FOR MEDTECH IP OWNERS.

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As of November 1, 2019, China has taken another step in changing several aspects of its patent examination guidelines, along with the amendments to its trademark, trade secret, and unfair competition law. This LawFlash discusses these important changes to Chinese IP law and their implications for medtech companies.

UPDATES TO CHINESE PATENT EXAMINATION

The amendment to China Guidance for Patent Examination (Amended Guidance) took effect on November 1 and involves a series of changes that will alter the course of patent prosecution in China. Below we provide some of the key takeaways from the Amended Guidance that medtech companies should consider in their Chinese patent portfolio strategies.

Deferred examination for up to three years

While most applicants are eager to urge the examination process forward to obtain patents as soon as possible, medtech companies—especially in the early stages—must balance the desire to aggressively pursue issued patents with other constraints, such as financing or changes in product development. As such, medtech companies can benefit by controlling how quickly prosecution of their application proceeds.

The Amended Guidance enables an applicant to request deferred examination of its application for a period of one, two, or three years either (1) at the time of requesting substantive examination for invention applications or (2) at the time of filing the application for utility model and design applications. Applicants should note that there is no cost to apply for deferred examination. However, the notice on the Form of Substantive Examination Application updated in November 2019 by the China Patent and Trademark Office states that "the deferral period cannot be altered and the deferral application cannot be withdrawn once it is submitted." Therefore, applicants should be careful in preparing and submitting the application for deferred examination.

As an important reminder, although applicants may delay examination for invention applications, the request for deferred examination does not delay publication of invention applications.

Patenting of inventions related to embryonic stem cells allowed

One of the significant changes under the Amended Guidance relates to the protection of embryonic stem cells. Inventions related to the use of human embryos were previously impermissible under Chinese patent law and denied for the reason of "violation of social morality." However, medtech companies are now able to pursue patent protection for inventions that satisfy the "14-day rule": a human embryo research limitation that permits research of human embryonic stem cells for a maximum of 14 days after the point of fertilization. Although the Amended Guidance does not permit in vivo development, this change presents a major opportunity for medtech and biomedicine companies.

Consistent use of applicant name in divisional applications, assignment documents, and power of attorney documents

Medtech companies must be wary of the new emphasis on applicant-naming requirements under the Amended Guidance. Often, whether through acquisition, merger, or other corporate events, medtech companies must develop and integrate new patent families into their existing patent portfolios. However, under the Amended Guidance, if the applicant named in a divisional application is different from the applicant named in the parent application, the divisional application will be considered to have not been filed ab initio. This incurable defect can be avoided by filing the divisional application in the name of the currently named applicant in the parent application (whether or not a name change has been recorded in the parent application). Further, medtech companies must also be wary of the requirement that the patent assignment bear the same signature as the power of attorney when the application is filed. The practice of having a single "company representative" that signs all assignment and power of attorney documents on behalf of the company is not as common in the United States as it is, for example, in Japan, China, and Korea, where company representatives may often use company stamps. In fact, given that the fast-moving world of medtech startups often produces high turnover in company leadership, medtech companies will need to be especially careful and, where possible, strive to maintain signatory consistency for formal documents.

Correcting the loophole of 'unlimited divisional applications'

Under Chinese patent law, if the claims of a patent application are not directed to a single patentable or technical concept, a patent examiner should reject the claims as lacking "unity." Pursuant to the Amended Guidance, with respect to a first divisional application where a notice of further division is issued by examiner ex officio or the examiner rejects the claims as lacking unity in an office action (collectively, unity rejection), the applicant may apply for a second divisional application *only if the first divisional application receiving unity rejection (or the parent application of the first divisional application) is still pending*. Otherwise, a second divisional application will not be permitted.

This is a change from the prior guidance, which allowed the filing of a second divisional application after a first divisional application received a unity rejection as long as there was a related, pending application in the patent family (co-pendency with the first divisional application was not required). Some practitioners considered that the prior guidance permitted the filing of unlimited further divisional applications. The Amended Guidance closes this perceived loophole and now requires that medtech applicants more carefully develop and implement strategies to pursue divisional applications in their patent portfolios.

Prioritized examination for key technologies

The Amended Guidance now makes it possible for medtech applicants to request prioritized examination if the technology (1) is related to the industry advocated by the government; (2) has a significant effect on national or public interests; or (3) has certain market demand. Generally, applications that concern green technology, electric automobiles, new generation of information technology, and biomedicine technology might fall into this scope. However, as health and medical issues become increasingly important to the Chinese government, medtech companies may benefit from the new opportunity to access prioritized examination. Generally, applications allowed to enter the prioritized examination queue should expect examination to begin within a period of months, not the current one- to two-year delay period.

Substantive issues can be discussed by calling the examiners

Prior to the Amended Guidance, telephone communication with patent examiners was only possible to discuss formal defects that were of minor significance and unlikely to cause misunderstandings. The Amended Guidance now enables examiners and applicants to discuss substantive issues, including their understanding of the claimed inventions and related prior art references, by telephone. This change allows medtech companies valuable access to Chinese patent examiners and facilitates improved advocacy in protecting critical technology.

Easier to initiate interviews with examiners

The Amended Guidance removed certain criteria that were previously necessary when initiating an examiner interview. For example, an applicant can now initiate an examiner interview (1) before the examiner has issued the first office action in the application; and (2) at times other than the time of issuance of the first office action or when the examiner offers an interview. As such, under the Amended Guidance, the patent applicant or the examiner can request or offer an interview at any time during the substantive examination proceeding. This important change allows medtech companies to more easily access Chinese patent examiners and will likely lead to improved communication and efficiency in the examination process.

Increased patent examiner burden of proof in showing that a claimed feature was "well-known knowledge in the art"

The Amended Guidance enhances patent examiners' burden of proof when they issue rejections that are in any way based upon "well-known knowledge in the art." Examiners are now required to provide evidence that supports their reliance on such "knowledge" while also being vulnerable to challenge by applicants if such evidence is not provided or is otherwise insufficient. Even in the absence of an applicant's objection, the Amended Guidance still requires examiners to provide relevant evidence in the office action if they identify the key technical features of the invention as being "well-known knowledge in the art." This important evidentiary requirement will certainly aid medtech applicants given that such technology often requires a specific, nuanced scientific or biological understanding that may be unappreciated or oversimplified by nonapplicants.

UPDATES TO CHINESE TRADEMARK, TRADE SECRET, AND UNFAIR COMPETITION LAWS

In addition to these changes to patent examination standards, medtech companies should also be aware of other changes to the trademark, trade secret, and unfair competition laws in China. Indeed, with a growing domestic need for a fairer market and international trade pressures, China has made important amendments to its IP laws regarding trademark, trade secrets, and other unfair competition. The following select points will be important for medtech companies to be aware of when protecting nonpatent Chinese IP rights.

Refusing trademark registrations if 'bad faith' is shown

The amended Chinese trademark law also took effect on November 1, 2019. The new trademark law will benefit medtech companies that have been targeted by others who filed "copycat" trademark applications without a genuine desire to use the trademarks in commerce. Under the amendment, such "bad faith" in a trademark application now constitutes practical grounds in all examination, opposition, and invalidation proceedings. The amendment also requires trademark agencies to reject an application if they know or have reason to know that the application was filed in bad faith; otherwise, the trademark agency may be subject to administrative or even criminal liability.

Enhanced statutory and punitive damage awards in trademark litigation

The amendment to the trademark law also enhances the upper limit of statutory damages from the previous limit of RMB 3 million (approximately $426,000) to RMB 5 million (approximately $710,000). Because a statutory damages award is widely applied in civil trademark litigations in China, brand owners are now expected to be even more active in protecting their brands.

In addition, the amendment increases the punitive damage award from up to three times the damage award that is determined by a statutory formula (i.e., determined by one of these three methods: (1) the trademark owner's actual losses; (2) the gains of the infringer; or (3) the reasonable multiples of the underlying trademark licensing fee, if neither method (1) nor (2) works) to up to five times the damage award.

However, given that punitive damages were very rarely awarded in the past—punitive damages can only be awarded under a finding of malicious infringement or other severe conditions—China has also made additional amendments and judicial interpretations to make the punitive damages determination clearer and more effective. Medtech brand owners will certainly benefit from these additional limits and greater clarity when pursuing damages awards.

Changes to trade secret damage awards and the burden of proof

China also amended its anti-unfair competition law in April 2019 to strengthen the protection of trade secrets. Similar to the revisions of the trademark law, the amendment of the trade secret law increased the statutory damages award limit to RMB 5 million (approximately 710,000 USD), and prescribed punitive damages of up to five times the damages calculated by a statutory formula. As before, punitive damages can only be awarded under a finding of malicious infringement or other severe conditions.

The 2019 Anti-Unfair Competition Law also prescribed a shift in the burden of proof for establishing infringement of a trade secret. To prove trade secret misappropriation, a plaintiff must show that (1) the plaintiff owned a valid trade secret; (2) the information acquired, disclosed, used, or licensed by the defendant is the same as or substantially identical to the trade secret; and (3) the defendant used an improper means to acquire, disclose, use, or license the trade secret. Under the new law, the burden shifts to the defendant to show that it is using a different means that is not the trade secret. This change in the burden of proof will allow medtech companies to more closely guard their trade secrets in litigation, while making it more difficult for defendants to manipulate their way out of an otherwise valid trade secret claim.

TAKEAWAYS

These many changes demonstrate China's commitment to evolving and improving its IP protection for medtech companies. As these changes are factored into portfolio strategies, medtech companies may thereby improve their effectiveness in achieving their goals in and out of the Chinese marketplace.

PROTECTING DIAGNOSTIC METHODS: *ATHENA*'S PATENT ELIGIBILITY WISDOM

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At the same time Congress is weighing a proposal that would amend Section 101 of the Patent Act, Athena Diagnostics has asked the US Supreme Court to review its diagnostic method patent case and thus clarify the Court's Section 101 precedent. Action by either body could affect patent eligibility law for years to come.

What jurisprudential guidance do companies have for navigating the patent eligibility maze? Here's the latest one: a case decided by eight separate opinions from eight separate judges. In *Athena Diagnostics v. Mayo Collaborative*, the US Court of Appeals for the Federal Circuit denied Athena's petition for rehearing en banc in a case that invalidated Athena's patent for methods of diagnosing neurotransmission or developmental disorders.[1] On October 1, 2019, Athena filed a petition for a writ of certiorari, asking the US Supreme Court to review the Federal Circuit's decision.[2]

ATHENA'S PETITION

In denying Athena's request for rehearing, many Federal Circuit judges joined with Athena's request for certiorari—several judges expressly called on the Supreme Court to reassess the two-part framework set forth in its 2014 decision in *Alice v. CLS Bank* and credited to its 2012 decision in *Mayo Collaborative v. Prometheus Laboratories*.[3] For example, Judge Hughes stated in a concurring opinion that he "would welcome further explication of eligibility standards in the area of diagnostics patents."[4] Similarly, in Judge Dyk's concurrence, he stated that the Supreme Court should "refine the *Mayo* framework as to diagnostic patents."[5]

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1 *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, L.L.C., 927 F.3d 1333 (Fed. Cir. 2019).

2 Petition for Writ of Certiorari, *Athena Diagnostics*, Inc., No. 19-430 (https://www.supremecourt.gov/DocketPDF/19/19-430/117672/20191001160357068_19-xxxx - Athena Diagnostics Inc. v. Mayo Collaborative Services LLC - cert. petition.pdf).

3 This two-part framework consists of first determining whether a claim is directed to unpatentable subject matter—i.e., laws of nature, natural phenomena, and abstract ideas—and if so, the claim is eligible for patent protection only if it contains an inventive concept that transforms the unpatentable natural law into a patent-eligible invention. *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

4 927 F.3d at 1337.

5 *Id.* at 1344.

Athena used such calls in its October 1 petition to the high court. Indeed, in its leading argument, the petition states:

> All twelve active judges of the Federal Circuit agreed that the current patent-eligibility standard as applied by the Federal Circuit is problematic, particularly in the context of diagnostic claims. Numerous judges thus solicited this Court's review of this case to clarify the patent eligibility standard.[6]

Although Athena's petition is peppered with references to the state of subject matter eligibility in a general sense, Athena presented its question to the Court in relatively narrow terms. Athena asked the Court to decide

> [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 condition using novel man-made molecules and a series of specific chemical steps never previously performed.[7]

On the one hand, this question is limited to the diagnostic method patent context, and more specifically, to patents purportedly containing some level of novelty. On the other hand, the petition is largely phrased in more general terms, and expressly urges that "the Court should review this case to clarify its Section 101 precedent."[8]

IMPENDING CONGRESSIONAL ACTION

The *Athena* case is being teed up for Supreme Court review at the same time Congress is weighing a proposal that would amend Section 101 of the Patent Act (the Proposed Bill). The Proposed Bill, introduced by Senators Chris Coons and Thom Tillis, along with Representatives Doug Collins, Hank Johnson, and Steve Stivers in May, includes, inter alia, the following provisions (https://www.tillis.senate.gov/services/files/E8ED2188-DC15-4876-8F51-A03CF4A63E26):

1. The provisions of Section 101 shall be construed in favor of eligibility.
2. No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under Section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.
3. The eligibility of a claimed invention under Section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to Sections 102, 103, or 112 of this title.
4. Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title. The term "useful" means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

The reader should especially note that the third *proposed* change is the Proposed Bill's express de-emphasis of the newness or "novelty" of an invention.[9] In fact, in the Proposed Bill, the word "new" is removed from the statute entirely. Another significant change is the proposed abrogation of years of Supreme Court precedent through the Proposed Bill's elimination of the "judicially created exceptions to subject matter eligibility." Two of those enumerated exceptions—laws of nature and natural phenomena—are implicated in the diagnostic method patent cases.

There is a potential for major changes to patent subject matter eligibility. In theory, both the Supreme Court and Congress could act on these important issues in ways that would have far-reaching implications. Whether and how the high court and legislature change the law will soon be seen, but any action could drastically impact the landscape for diagnostic method patents for decades to come.

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[6] Petition for Writ of Certiorari at 13, *Athena Diagnostics, Inc.*, No. 19-430.

[7] *Id.* at i.

[8] *Id.* at 13.

[9] 35 U.S.C. § 101 currently states: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

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