Analysis & Trends

2021 PTAB Year in Review

Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

Sterne, Kessler, Goldstein & Fox is an intellectual property law firm of 175+ professionals devoted to providing outstanding patent and trademark legal services. Our services span the full range of IP services in the U.S. and globally, including IP strategy, patent and trademark prosecution, litigation in all IP venues, freedom-to-operate and other opinions, and transactional support.

For over 40 years, we have helped companies build and enforce worldwide IP portfolios. Sterne Kessler has a proven track record in the U.S. Patent and Trademark Office (USPTO), U.S. district courts, federal appeals courts, and the U.S. International Trade Commission (USITC). In the past five years, we have obtained more than 7,000 U.S. patents for our clients; have led nearly 200 district court cases in jurisdictions across the U.S.; were among the 20 most active firms at the USITC; and have handled more than 500 proceedings at the USPTO's Patent Trial and Appeal Board (PTAB).

Our appellate practice has deep experience that includes leading appeals of nearly 200 PTAB final written decisions for some of the best-known technology and pharmaceutical companies in the world, in addition to dozens of district court and USITC appeals. Our lawyers have clerked for Judges Bryson, Prost, Schall, Rader, and Reyna at the Federal Circuit, Judge Douglas H. Ginsburg at the DC Circuit, Judge Sandra Lynch at the First Circuit, and Justice Anthony M. Kennedy at the Supreme Court.

Our investments in developing industry and technical expertise have enabled our lawyers to truly understand the business and strategies of companies in industries as diverse as electronic hardware and semiconductors, software solutions, biotechnology (therapeutic and industrial), pharmaceuticals, automotive technology, medical devices, mobile communications, sporting goods, and consumer products. We integrate technical, patent and legal experience and knowledge in teams that can directly address our clients' needs.

Sterne Kessler's service model builds on the unrivaled technical depth of its professionals. Most have an advanced technical degree and/or significant industry or academic experience; more than 50 hold a Ph.D.; and well over 100 hold advanced technical degrees. Further, we have over a dozen former patent examiners on staff, strengthening our fundamental ability to obtain, defend and enforce patents.

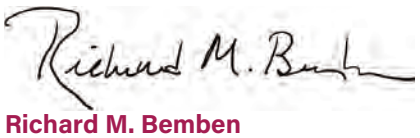
Editors' Introduction

Love it or hate it, ignore the USPTO Patent Trial and Appeal Board (PTAB) at your peril. The introduction of the PTAB as part of the America Invents Act over ten years ago has forever changed patent litigation. In its first final written decision for an *inter partes* review back in November 2013 in IPR2012-000001, the PTAB canceled all claims as obvious based on a four prior art reference combination, critically assessed claim construction, and denied a motion to amend. Change had certainly arrived. Thousands of petitions, hundreds of appeals, numerous constitutional challenges, and several PTO directors later, the PTAB's importance and impact continues to grow and evolve.

This *Year in Review* explores the PTAB evolution with a particular focus on the interface between district court and PTAB litigation through a series of articles analyzing many of the most significant developments that occurred over the past year. As a firm that has handled over a thousand PTAB proceedings – second-most of any firm and including four *inter partes* reviews filed during the PTAB's first week of operation - we apply our vast experience and data analytics to examine decisions and PTAB developments in order to provide practical insights to guide patent litigation strategy with a focus on the PTAB.

We begin our *Year in Review* by taking a fresh look at discretionary denials, including denials based on *Fintiv* and Section 325(d). Although this issue has garnered much attention, it does not appear to have significantly impacted overall institution rates, which changed slightly from 58% in 2020 to 59% in 2021. We then consider nuanced issues relating to Section 112 issues, antedating references, motions to amend, and dealing with "bad behavior" by experts – all important considerations given that claim cancellation rates increased from 70% in 2020 to 78% in 2021 for instituted claims ruled on in final written decisions. Notably, 2020 saw significant developments involving the interface between district court and PTAB litigation, which we explore in a series of articles covering estoppels, recovery, and evidentiary issues. We continue our analysis by digging deeply into selected industry-specific issues related to biologics, chemicals, and standard essential patents (SEPs). Finally, we conclude by examining *ex parte* reexaminations, which have moved back to center stage with requests surging by more than 35% relative to 2020.

As we did in our prior *PTAB Year in Review*, we encourage you to not simply read the articles, but to critically challenge our analysis and consider the impacts on your patent litigation and portfolio development strategies. We thank our authors and our entire PTAB team for making this publication possible. We appreciate your interest in this report and welcome the opportunity to discuss PTAB matters and how they may impact your business. If you have questions or comments, please do not hesitate to contact us directly to start the conversation.



Richard M. Bemben
Director
Electronics Practice Group

Eldora L. Ellison, Ph.D.
Director and PTAB Litigation
Practice Co-Chair

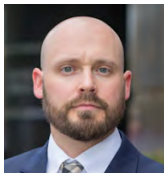
Michael D. Specht
Director and PTAB Litigation
Practice Co-Chair

Table of Contents

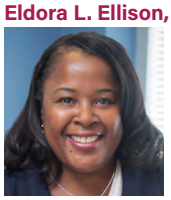
The data for the charts and graphs within this report was sourced from Docket Navigator® unless indicated otherwise.

Editors & Authors Biographies

Editors



Richard M. Bemben is a director in the Electronics Practice Group. His practice focuses on post-grant proceedings at the U.S. Patent and Trademark Office. Over the last decade, Richard has been counsel in nearly 100 PTAB proceedings and over a dozen Federal Circuit appeals, representing both patent owners and patent challengers in a variety of computer and electrical technologies. Richard was also an examiner for nearly six years in the digital imaging arts, gaining valuable insight into practicing before the U.S. Patent and Trademark Office.



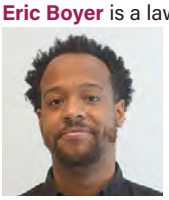
Eldora L. Ellison, Ph.D., is a director in the Biotechnology & Chemical and Trial & Appellate Practice Groups and co-chairs the firm's Patent Office Litigation Practice. Over the course of her 28-year career, Eldora has gained extensive experience in *inter partes* patent matters, building on a strong foundation in patent prosecution. Her experience includes representing clients in over 70 *inter partes* review and post-grant review proceedings, more than 15 patent interferences, and in various patent reexaminations and district court litigations.

Michael D. Specht is a director in the Electronics Practice Group and co-chairs the firm's Patent Office Litigation Practice. He has a unique combination of over 25 years of electronics, communications, and automotive technical, legal, and business development experiences. His practice spans high value patent prosecution and *inter partes* matters, including reexaminations, Patent Trial and Appeal Board, district court, and U.S. International Trade Commission litigation. He is a recognized PTAB thought leader, writing and speaking frequently on PTAB matters and having handled over 200 PTAB matters, including several during the PTAB's first week of accepting petitions.

Authors

Salvador M. Bezos is a director in the Electronics Practice Group. He helps clients develop enforceable patent portfolios in a wide range of technical areas, including user interfaces, financial software products, cloud computing, parallel and distributed computer architectures, computer graphics, networking, automotive technology, databases, and computer architectures. His extensive experience representing patent owners and petitioners before the Patent Trial and Appeal Board allows him to help inventors secure patents that can withstand validity challenges, including statutory subject matter issues in the business method and software areas.

Daniel S. Block is a director in the Electronics Practice Group. His practice primarily focuses on patent litigation at the U.S. International Trade Commission and in Federal district court. He has served as counsel in over 50 post-grant proceedings at the Patent Trial and Appeal Board representing both petitioners and patent owners. Daniel's technical expertise covers many areas of computing, including computer graphics, networking communications, web services, complex computer architectures, and storage systems.



Eric Boyer is a law clerk in Sterne Kessler's Biotechnology & Chemical Practice Group. Eric assists clients in freedom to operate analyses, prosecution, and PTAB litigation. Prior to joining Sterne Kessler, Eric was a law student at Emory University School of Law. While in law school, Eric was an active participant in the Black Law Students Association. Prior to law school, Eric was a research scientist at one of the largest U.S.-based, global pharmaceutical companies.

Paige E. Cloud is an associate in the Trial & Appellate Practice Group. Her practice focuses on cases in the U.S. District Courts and the U.S. International Trade Commission, including cases arising under the Hatch-Waxman Act. Paige has litigated cases involving a variety of technologies, including pharmaceuticals, medical devices, and electronics. Her practice includes representing both plaintiffs and defendants in venues such as the Patent Trial and Appeal Board through all steps of patent litigation, including fact discovery, expert discovery, trial preparation, and trial.

Jamie Dohopolski is a former associate in the Trial & Appellate Practice Group. She focused her practice on patent litigation. Jamie graduated from Stanford Law School, where she was an editor of Stanford Law Review and a member of Women of Stanford Law. She is currently a clerk at the U.S. Court of Appeals for the Federal Circuit.

Tyler J. Dutton is a director in the Electronics Practice Group. His practice emphasizes *inter partes* review proceedings at the U.S. Patent and Trademark Office. He has litigation experience developing invalidity and non-infringement positions at district court and the U.S. International Trade Commission as well as arguing several appeals before the U.S. Court of Appeals for the Federal Circuit. He also has tackled multiple antedating cases, including one of the first cases to successfully antedate a prior art reference in an *inter partes* review.

Jason D. Eisenberg, a director and practice group leader of the Electronics Practice Group, provides strategic counsel for global portfolio building, opinions, diligence, enforcement, and defense from nearly thirty years of patent experience. Jason gained his experience before law school as a public searcher and a U.S. Patent and Trademark Office patent examiner, during law school as a patent agent and extern at the Ohio Supreme Court, and after law school in private practice. Jason is the editor and frequent contributing author of the firm's PTAB Strategies and Insights newsletter.

Jason A. Fitzsimmons is a director in the Mechanical & Design Practice Group. Jason specializes in handling complex post-grant proceedings at the U.S. Patent and Trademark Office, obtaining patent protection for cutting edge technologies, and providing opinions of counsel. He is experienced with the issues faced by both patent owners and petitioners in *inter partes* reviews, as well as ex parte reexamination, *inter partes* reexamination, and derivation proceedings.

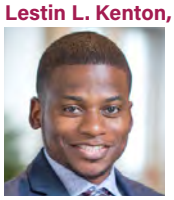
James R. Hietala is counsel in the Electronics Practice Group. James draws on nearly two decades of expertise in intellectual property law to provide unique strategic insights to clients. His capabilities stem from his work as in-house counsel in charge of patent office litigation, appeals, and lobbying efforts at the U.S. Patent and Trademark Office coupled with his experience as a private practice district court litigator on dozens of cases. James is a Certified Licensing Professional.

John D. Higgins is an associate in the Mechanical & Design Practice Group. His practice focuses on post-grant proceedings before the Patent Trial and Appeal Board, worldwide patent prosecution and portfolio management, and strategic patent counseling and due diligence. John has experience challenging and defending issued patents in various mechanical and electrical technologies.

Tyler S. Hoge is an associate in the Electronics Practice Group. Tyler concentrates his practice on patent preparation, prosecution, and litigation matters before the federal district courts and the United States International Trade Commission. He has represented clients in various electrical and mechanical fields, including the automotive industry, wireless communications, control systems, autonomous flight systems, financial systems, consumer electronics, and software.

David H. Holman, Ph.D., is a director in the Biotechnology & Chemical and Trial & Appellate Practice Groups. David's practice includes AIA post-grant proceedings, interferences, and preparation and prosecution of U.S. and foreign patent applications. His technical expertise is in the areas of immunology, microbiology, and molecular biology.

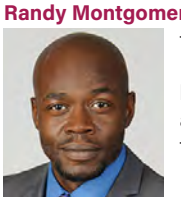
Lestin L. Kenton, Jr. is a director in the Electronics Practice Group. Lestin's practice areas include post-grant review proceedings at the U.S. Patent and Trademark Office, Section 337 Investigations before the U.S. International Trade Commission, infringement and validity opinions, patent portfolio evaluations, and the preparation and prosecution of patent applications along with pursuing global prosecution strategies. Lestin has extensive experience practicing before the Patent Trial and Appeal Board, challenging and defending already-issued patents.



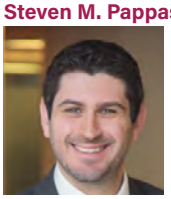
Pratibha Khanduri, Ph.D., is an associate in the Biotechnology & Chemical Practice Group. She is involved in all areas of patent procurement, exploitation, and enforcement. She has experience in post-grant proceedings before the Patent Trial and Appeal Board; litigation, including cases involving Abbreviated New Drug Applications; patentability, validity, and infringement analyses; and prosecution and freedom-to-operate analyses.

Tyler C. Liu is an associate in the Biotechnology & Chemical Practice Group. He has experience in the preparation and filing of petitions for *inter partes* review under the America Invents Act and has been involved in several IPR proceedings representing both patent owners and petitioners. He has also been involved in pharmaceutical patent litigations brought under the Hatch-Waxman Act.

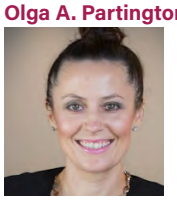
Randy Montgomery is an associate in the Electronics Practice Group, licensed only in GA and practicing under the supervision of D.C. Bar members. He focuses his practice on patent preparation and prosecution. Randy also has experience in opinion work, prior art searching, and litigation support. He has more than nine years' experience in the networking and telecommunications sectors.



Steven M. Pappas is an associate in the Electronics Practice Group, specializing in software, data storage systems, computer graphics, networking communications, and financial technologies. Steve's practice focuses on patent litigation and patent prosecution. Steve has been involved in dozens of post-grant proceedings before the Patent Trial and Appeal Board, including *inter partes* review, post-grant review, and covered business method review proceedings, representing both patent owners and petitioners.

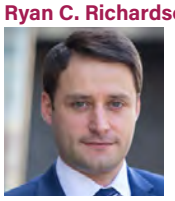


Olga A. Partington, Ph.D., is counsel in the Biotechnology & Chemical Practice Group. Olga has substantial experience in post-grant proceedings before the U.S. Patent and Trademark Office. She also has extensive experience in domestic and foreign patent prosecution, particularly chemical patents, and has been involved in pharmaceutical patent litigations. Olga holds a Ph.D. in Chemistry.

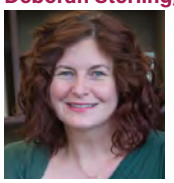


Pauline M. Pelletier is a director in the Trial & Appellate Practice Group. She focuses her practice on patent litigation before the courts and the U.S. International Trade Commission as well as post-grant trial, interference, and reexamination practice before the U.S. Patent and Trademark Office. Ms. Pelletier also represents clients before the U.S. Court of Appeals for the Federal Circuit. She previously served as a law clerk for then Chief Judge Randall R. Rader of the U.S. Court of Appeals for the Federal Circuit.

Ryan C. Richardson is a director in the Electronics and Trial & Appellate Practice Groups. Ryan's practice focuses on post-grant proceedings before the Patent Trial and Appeal Board, as well as U.S. district court litigation and U.S. International Trade Commission litigation. Ryan has handled dozens of contested cases before the PTAB involving technologies ranging from semiconductor fabrication and geographic information systems, to wireless communications. He also specializes in a variety of Standard Essential Patent (SEP) related issues ranging from procurement to litigation, and also including SEP licensing with respect fair reasonable and non-discriminatory (FRAND) obligations.



Deborah Sterling, Ph.D., is a director and chair of the Biotechnology & Chemical Practice Group. Her practice is focused in the biotechnology and pharmaceutical industries, where she counsels in all areas of patent procurement, including domestic and foreign patent preparation and lifecycle management strategies. Her practice also includes counseling clients on intellectual property strategy, including freedom-to-operate and patentability issues, validity and infringement issues, and due diligence investigations. Deborah's experience includes representing clients in over 75 post-grant proceedings, and in multiple patent interferences and reexaminations.



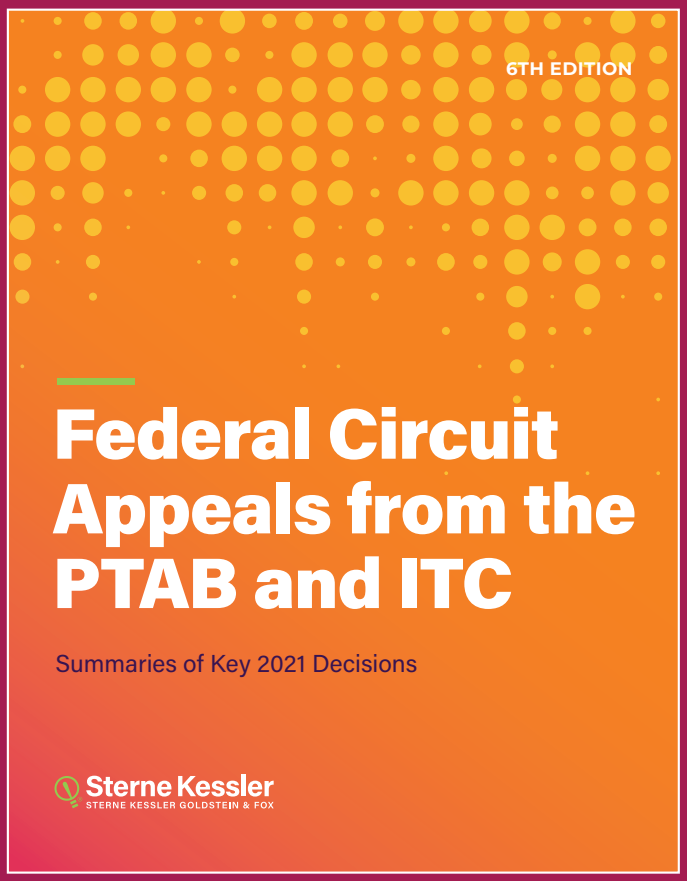
Timothy L. Tang is an associate in the Electronics Practice Group. His practice focuses on patent prosecution before the U.S. Patent and Trademark Office and patent office litigation at the Patent Trial and Appeal Board. Timothy's experience covers a broad variety of technical fields, including wired and wireless communications, communications theory, digital signal processing, data compression, database management, computer-networking, business methods, consumer electronics, computer-based applications, and Internet applications.

Jonathan Tuminaro, Ph.D., is a director in the Trial & Appellate and Electronics Practice Groups and focuses his practice on litigation at the U.S. International Trade Commission, U.S. district courts, and the Patent Trial and Appeal Board. Jonathan has served as counsel in nearly a dozen ITC investigations, dozens of district-court cases, and over 50 PTAB proceedings.

Grace Tuyiringire is an associate in the Trial and Appellate Practice Group, licensed only in CA and practicing under the supervision of D.C. Bar members. She concentrates her practice on complex patent litigation and has worked on cases involving pharmaceutical and biotechnology products. Prior to joining Sterne Kessler, Grace was an associate at a Los Angeles-based firm.

Lauren A. Watt is an associate in Sterne Kessler's Trial & Appellate Practice Group. She concentrates her practice in the area of patent litigation, including matters before federal district courts, the Patent Trial and Appeal Board, and the U.S. International Trade Commission.

Kirsten Weigel-Van Aken, M.D., is an associate in the Biotechnology & Chemical Practice Group, licensed only in FL and practicing under the supervision of D.C. Bar members. Kirsten assists in worldwide procurement of patents in biotechnology, chemical, and pharmaceutical industries. Her expertise includes patent prosecution in the areas of gene therapy, biologics, therapeutic antibodies, cell therapies, vaccines, diagnostics, and small and large molecule formulations.



Don't miss Sterne Kessler's "Federal Circuit Appeals from the PTAB and ITC: Summaries of Key 2021 Decisions" report. Now in its sixth year, the report provides insights into 14 significant Federal Circuit, ITC, and Supreme Court rulings spanning several topics within intellectual property law.

Available for download in the Publications section of sternekessler.com or by submitting a request via email to info@sternekessler.com.

Fintiv Continues To Take Center Stage

The Effect of Parallel Litigation at the PTAB in 2021

AUTHORS: RICHARD M. BEMBEN & STEVEN M. PAPPAS*

In 2021, *Fintiv*[1] continued to be one of the hottest and most controversial issues facing the patent bar.[2] The USPTO Patent Trial and Appeal Board's (PTAB) precedential *Fintiv* decision enumerated factors that the PTAB applies when evaluating whether to exercise its discretion to deny instituting an *inter partes* review (IPR) or post-grant review (PGR) in light of parallel district court or US International Trade Commission (ITC) litigation involving the same patent.[3] Because *Fintiv* can deprive parties—who file otherwise meritorious petitions—of review, some stakeholders criticize *Fintiv* as contrary to the Congressional intent of the America Invents Act (AIA) and seek to defang or eliminate *Fintiv* altogether. Others argue that *Fintiv* is rooted in sound policy that avoids duplicative and expensive litigation and increases the value of patents. Regardless of where one stands, *Fintiv* remains a key issue that must be analyzed by any party faced with the prospect of parallel patent litigation at the PTAB and any other trial tribunal.

Analyzing over 400 PTAB decisions, this article presents a data-driven analysis of the following key developments that emerged in 2021 with respect to the PTAB's evaluation and application of the *Fintiv* framework:

- **Petitioner Stipulations:** Following the PTAB's informative *Sand Revolution II*[4] and precedential *Sotera*[5] decisions, petitioners have been advancing stipulations that agree to forgo presenting certain invalidity challenges in parallel litigation if the PTAB institutes review. These stipulations vary in scope, and this article categorizes the various flavors of stipulation—from narrowest to broadest—and evaluates their efficacies. Unsurprisingly, advancing the broadest stipulation was most likely to favorably impact the *Fintiv* analysis for petitioners. But our findings on art- and ground-based stipulations may surprise you.
- **ITC vs. District Court:** One of the more controversial applications of *Fintiv* is when the PTAB denies AIA review based on parallel litigation at the ITC. Nevertheless, our data indicate that *Fintiv* denials based on parallel ITC litigation had a strong year in 2021. In fact, our findings indicate that ITC-based denials are on the rise while district court-based denials have fallen precipitously.
- **Denials By District:** In 2021, was the PTAB more likely to deny AIA review over parallel litigation in the Eastern or Western District of Texas? We reveal the answer below and explain some factors that may be driving our results. Spoiler alert: EDTX.

Before diving into these issues, we provide a brief background on *Fintiv* and general statistics on Fintiv denials.

Background and Lay of the Land

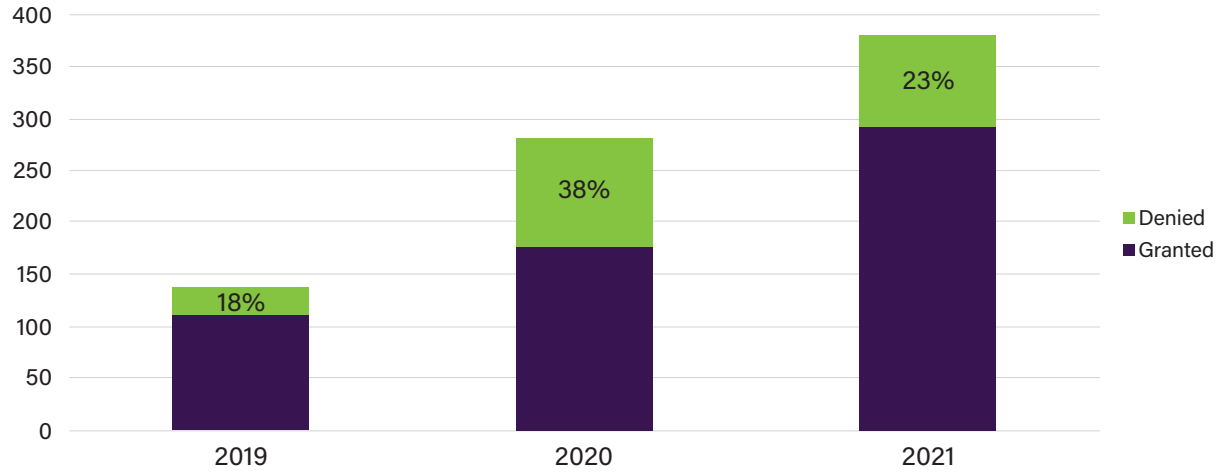
35 U.S.C. §§ 314(a) and 324(a) grant the Director of the US Patent and Trademark Office (USPTO) discretion to deny instituting an AIA trial. As explained in the PTAB's Trial Practice Guide, the PTAB interprets these statutes as permitting denial in light of "events in other proceedings related to the same patent, either at the Office, in district courts, or the ITC."[6] In *Fintiv*, the PTAB enumerated six non-exhaustive factors weighed by the PTAB when determining whether to exercise this discretion in view of parallel litigation: (1) whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted; (2) proximity of the court's trial date to the PTAB's projected statutory deadline for a final written decision; (3) investment in the parallel proceeding by the court and the parties; (4) overlap between issues raised in the petition and in the parallel proceeding; (5) whether the petitioner and the defendant in the parallel proceeding are the same party; and (6) other circumstances that impact the PTAB's exercise of discretion, including the merits.[7]

Following *Fintiv's* precedential designation in May 2020, parties saw a spike in *Fintiv*-based discretionary denials. At first a boon to patent owners, such denials fell significantly over the course of 2021 as an important new tool—the stipulation—became available and more widely used and understood by petitioners. In 2021, the PTAB also scrutinized trial dates of parallel cases more closely, shifting away from its prior approach of taking them at face value. Indeed, the PTAB often recognized that the facts surrounding parallel litigations are fluid, and even reversed some institution decisions when circumstances changed in parallel cases.[8]

The analysis in Figure 1 considered cases in which the PTAB evaluated the *Fintiv* factors. It does not include decisions that mention *Fintiv* but denied review for other reasons, such as the merits. Overall, the results show a lower rate of *Fintiv*-based denials in 2021 (23%) compared to 2020 (38%). Nevertheless, the statistics also show that *Fintiv* has become a routine part of the PTAB's and parties' analyses, with the PTAB addressing the *Fintiv* factors in almost 400 cases this year, significantly more than in previous years. The institution rate for cases in which the *Fintiv* factors were evaluated in 2021 (77%) is also significantly higher than the PTAB's overall institution rate for 2021 (59%).[9] One reason for this result may be that, when *Fintiv* is in play, patent owners may focus their preliminary responses more on discretionary denial arguments than on rebutting the grounds of unpatentability.

* A special thank you to our colleagues Bill Flanigen, Patrick Murray, Simran Parmar, and Reuben Moses, who helped gather and analyze the cases for this article.

Figure 1: *Fintiv* Denials by Year



** Cases through November 23, 2021.*

Breaking these cases down by quarter (see Figure 2), the PTAB's denial rate peaked in the second half of 2020, which aligns with *Fintiv's* precedential designation in May 2020. A decline is then seen in each subsequent quarter of 2021.

A number of factors—including the rise of petitioner stipulations; uncertainty of district court trial dates caused by the COVID pandemic, court congestion, and venue challenges; and public criticism of *Fintiv*—likely contributed to 2021's fall in Fintiv-based denials. The sections below address issues that have influenced the PTAB's discretionary denial analysis in 2021, as well as those that may influence the PTAB's analysis in the coming year.

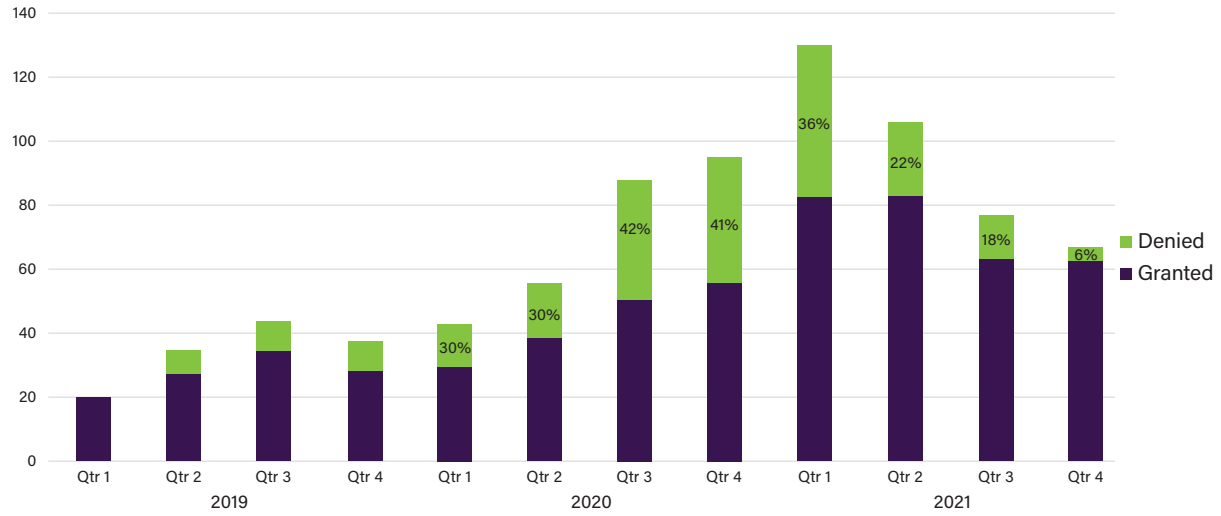
Petitioner Stipulations

One of the policy considerations undergirding *Fintiv* is reducing or eliminating duplicative litigation. The fourth *Fintiv* factor reflects this consideration, requiring an evaluation of the amount of overlap between the invalidity issues raised in the petition and in the parallel proceeding. Factor four weighs in favor of denial when the invalidity issues overlap and against denial when they do not.[10]

Seeking to mitigate concerns over duplicative litigation, petitioners have been filing stipulations that agree to forgo raising certain invalidity challenges in parallel proceedings. These stipulations fall into three general categories. From narrowest to broadest, they are: (1) ground-based stipulations, (2) art-based stipulations, and (3) stipulations tracking the "raised or reasonably could have raised" language of the estoppel provisions in 35 U.S.C. §§ 315(e) and 325(e), which we refer to as *Sotera* stipulations.[11]

The PTAB's informative *Sand Revolution II* decision illustrates the narrowest, ground-based stipulation. There, the petitioner stipulated that "if the IPR is instituted, Petitioner will not pursue the *same grounds* in the district

Figure 2: *Fintiv* Denials by Quarter



** Cases through November 23, 2021.*

Table 1: Effect of Petitioner Stipulations on *Fintiv* Denials

Type of Stipulation	# Cases	% Factor 4 Favored Denial	% Denied Under *Fintiv*
Sotera Stipulation	85	0.0%	4.7%
Art-based Stipulation	22	4.5%	9.1%
Ground-based Stipulation	80	12.5%	30.0%
No Stipulation	113	56.6%	35.4%

** Cases through November 23, 2021.*

court litigation."[12] The PTAB found this "mitigates to some degree the concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions"[13] and, consequently, that factor four "weigh[ed] marginally in favor of not exercising discretion to deny institution."[14]

Art-based stipulations are broader, agreeing not to pursue invalidity challenges in the parallel litigation based on any of the prior art used in the petition. *ByteDance Ltd. v. Triller, Inc.*, IPR2021-00099, is illustrative.[15] There, the petitioner stipulated, in the event of institution, it would not rely on any of the IPR references in the parallel litigation.[16] The PTAB ultimately granted institution based, in part, on a finding that "[b]ecause Petitioner's stipulation is broader than that offered in *Sand Revolution II* but narrower than that of *Sotera*, [factor four weighed] somewhat in favor of not exercising discretion to deny institution."[17]

On the other end of the spectrum, the PTAB's precedential *Sotera* decision illustrates the broadest stipulation, which tracks the language of the estoppel provisions in 35 U.S.C. § 315(e). In *Sotera*, the petitioner stipulated it "will not pursue in the District Court Litigation any ground raised or that could have been reasonably raised in an IPR."[18] The PTAB concluded that "Petitioner's stipulation here mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions."[19] Therefore, the PTAB found that *Fintiv* factor four "weighs strongly in favor of not exercising discretion to deny institution."[20]

Against this backdrop, we analyzed PTAB decisions from 2021 to understand the influence of various stipulations on the *Fintiv* analysis. As for our methodology, we first retrieved all cases in which the PTAB analyzed the *Fintiv* factors, removing cases where *Fintiv* was mentioned but not evaluated. Next, we identified the PTAB's determination of (a) whether *Fintiv* factor four weighed in favor or against institution, or was neutral[21]; and (b) whether the overall *Fintiv* analysis weighed in favor or against institution. When a rehearing request had been decided, we used the results from the rehearing decision instead of the original institution decision.

We then reviewed each case for the type of stipulation filed by Petitioner, if any. We allocated the cases into the three categories mentioned above, as well as a fourth category denoting where no stipulation was filed. Any cases that did not squarely fall into one of these four categories were omitted from our statistics. We did not remove cases in which stipulations were specific only to the claims at issue in the IPR; in most cases, this did not significantly affect the overlap of issues between proceedings. The results of our analysis are shown in Table 1 above.

Unsurprisingly, the results show that the broader the stipulation, the less likely it is that the PTAB will deny under *Fintiv*. Less than 5% of cases where the petitioner advanced the broadest, *Sotera* stipulation were denied under *Fintiv*. The results also show a strong correlation between the two broadest stipulations (*Sotera* and art-based) and the ultimate *Fintiv* outcome.

The results related to the art- and ground-based stipulations proved somewhat more surprising. Art-based stipulations allow the petitioner/defendant to continue to assert in the parallel litigation any prior art that could have been (but was not) raised before the PTAB—a significant advantage over *Sotera* stipulations. Yet the PTAB's treatment of art-based stipulations was nearly on par with that of *Sotera* stipulations, resulting in only slightly higher risk of (i) the PTAB weighing factor four in favor of denial and (ii) denying institution: less than a 5 percentage point difference for both metrics. From a risk/reward standpoint, art-based stipulations appear to be the best choice for petitioners who consider offering a stipulation to bolster their chances of winning at institution. On the flip side, patent owners should pay close attention to these statistics when developing their strategy for responding to a petition. Faced with a broad *Sotera* or art-based stipulation, a patent owner may opt to devote more resources to other arguments against institution. Even so, a patent owner should still evaluate whether the proffered stipulation truly eliminates overlap between the proceedings. For example, IPR challenges are limited to using patents and printed publications; product prior art cannot be used.[22] Patent owners should evaluate whether the IPR prior art is cumulative with any product prior art asserted in parallel litigation.

The results related to ground-based stipulations were also interesting. As expected, compared to art-based stipulations, a higher percentage of decisions considering ground-based stipulations found that factor four favored denial and ultimately denied institution under *Fintiv*. Compared to no stipulation, ground-based stipulations significantly increased the petitioner's chances of mitigating the PTAB's concerns regarding factor

Table 2: ITC vs. District Court Denials in 2021

Venue	# Cases	# Denied Under *Fintiv*	% Denied Under *Fintiv*
ITC	25	18	72.0%
District Court Only	347	68	19.6%

** Cases through November 23, 2021.*

four, but only appear to have a small impact on the ultimate *Fintiv* outcome. Our data indicate that advancing a ground-based stipulation only marginally increased a petitioner's ability to avoid a *Fintiv* denial.

Of course, stipulations do not tell the whole story for any given proceeding. All facts need to be considered. For instance, if a patent is asserted in multiple co-pending litigations, or there are multiple defendants in the parallel litigation, even a *Sotera* stipulation may not be enough to avoid denial. In *Cisco Systems, Inc. v. Estech Sys., Inc.*, IPR2021-00332, for instance, the petitioner advanced a *Sotera* stipulation.[23] The parallel litigation, however, included six other defendants, and thus the patent owner argued that the petitioner "would be free to continue pursuing the same unpatentability arguments" in district court through the other defendants.[24] The petitioner proceeded to file additional stipulations on behalf of the other defendants, which the PTAB found mitigated any concerns raised by overlapping issues.[25] Nevertheless, the PTAB still denied institution based on an early trial date and significant investment in the parallel litigation—a rare instance where the *Sotera* stipulation did not carry the day.[26]

At bottom, petitioners and patent owners need to carefully analyze all facts surrounding potential overlap between the PTAB and parallel litigation. But understanding the impact of the various flavors of stipulation helps both sides evaluate their respective likelihood of success under *Fintiv*. Petitioners can gain a significant advantage at the PTAB by filing a broad stipulation at the expense of limiting their invalidity defenses in the parallel litigation. Such a broad stipulation may be beneficial to petitioners when the prior art presents nuanced technical issues better understood by PTAB judges than by juries, or to take advantage of the lower preponderance of the evidence standard at the PTAB compared with the clear and convincing evidentiary standard in district court. On the other hand, patent owners should analyze the stipulation language and associated facts to determine whether a petitioner's stipulation actually reduces overlap. More often than not, an argument can be made that similar issues will still arise in the parallel litigation due to similar available prior art, multiple defendants or co-pending litigations, or other factors.

Treatment of District Court vs. ITC Proceedings

The *Fintiv* analysis takes into account parallel litigations in both district court and at the ITC.[27] *Fintiv* explained that "even though the Office and the district court would not be bound by the ITC's decision, an earlier ITC trial date may favor exercising authority to deny institution under [*Fintiv*] if the ITC is going to decide the same or substantially similar issues to those presented in the petition."[28] Since the ITC cannot invalidate a patent and district court cases are often stayed pending resolution of ITC investigations, we were interested to see how the PTAB treated patents involved in ITC investigations compared to those only involved in parallel district court proceedings.

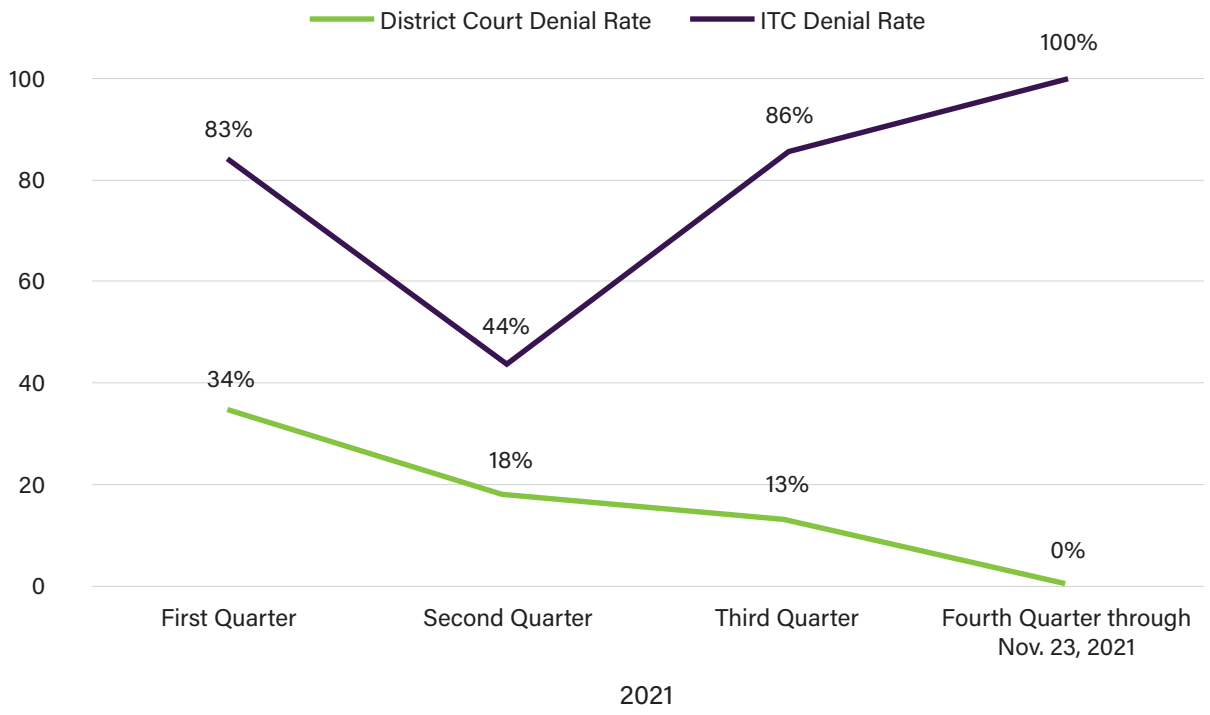
To gather statistics, we retrieved all cases from 2021 in which the PTAB analyzed the *Fintiv* factors, removing cases where *Fintiv* was mentioned but not evaluated. For each case, we determined whether the patent was also involved in an ITC proceeding. If so, the case was categorized as an "ITC" case. The remaining cases—those with patents not involved in ITC proceedings—were categorized as having only parallel district court proceedings. Any case denied for reasons other than *Fintiv* (e.g., based on deficient merits) was omitted from our statistics.

The results are rather striking (see Table 2 above). When considering parallel ITC investigations, the PTAB denied institution in favor of the parallel litigation about three quarters of the time. In contrast, when considering parallel district court proceedings, the PTAB denied institution in favor of the parallel litigation less than 20% of the time.

The results assessed on a quarterly basis in Figure 5 also show that the PTAB has continued to deny institution in favor of parallel ITC proceedings, while denials in favor of parallel district court proceedings have diminished significantly. Indeed, our results show that the denial rates for cases involving only parallel district court proceedings has decreased significantly each quarter in 2021 to almost zero while denial rates for cases having parallel ITC litigation recently increased.

The difference in denial rates may be attributed to the typically more aggressive and more certain schedules of ITC investigation. In *Nintendo Co., Ltd. v. GameVice, Inc.*, IPR2020-01197, for example, an IPR petition was filed less than two months after institution of the ITC investigation.[29] Yet the PTAB denied institution based on significant investment in the ITC investigation at the time of the institution decision and a final ITC determination scheduled almost six months before the PTAB's expected final written decision.[30] Patent Owners should keep these denial rates in mind when considering whether to raise *Fintiv* arguments, and when considering how much

Figure 5: Parallel ITC vs. District Court Litigation: *Fintiv* Denial Rates by Quarter



space or effort to devote to such arguments. A pending ITC investigation can greatly increase patent owners' chances of avoiding institution, whereas a pending district court case may no longer have the same impact.

Petitioners should also consider whether a PGR or IPR petition is cost-effective when an ITC trial will occur before the PTAB issues the final written decision. In such a case, a broad stipulation that eliminates any overlapping invalidity issues may be necessary to persuade the PTAB to institute. In *SharkNinja Operating LLC v. iRobot Corp.*, IPR2021-00545, for example, the PTAB instituted review even though a parallel ITC investigation was scheduled to be completed before the final written decision, and a motion to stay the ITC investigation had already been denied.[31] The petitioner, however, filed its petition only one day after the ITC initiated its investigation, and broadly stipulated that "it [would] not pursue any grounds that were raised or reasonably could have been raised in this IPR against the '511 patent in the ITC investigation or in district court."[32] The PTAB therefore stated: "In weighing the totality of the evidence, Petitioner's diligence in promptly filing the Petition and stipulation to avoid duplication both persuade us not to exercise discretion under § 314(a) to deny institution."[33] This decision highlights that, for both parties, timing and preparation is key to navigating parallel litigation.

Treatment of Different Districts

Fintiv factors one and two consider the likelihood of a stay being granted in the parallel litigation and the proximity of the court's trial date to the PTAB's projected final written decision deadline. Although the PTAB stated in *Fintiv* that it "generally take[s] courts' trial schedules at face value absent some strong evidence to the contrary,"[34] the PTAB has since recognized the uncertainty of district court case schedules, including scheduled trial dates, especially in the wake of the COVID-19 pandemic.[35]

Interestingly, our results indicate that the PTAB has treated certain districts differently when evaluating the expected course of a proceeding. For our analysis, we again retrieved all cases from 2021 in which the PTAB analyzed the *Fintiv* factors. For each patent involved in the retrieved cases, we searched the districts in which the patent had been asserted. Cases involving patents asserted in multiple districts, or transferred from one district to another, were omitted. By isolating PTAB cases with a parallel litigation in only one district, we ensure that the PTAB's decision is correlated to that district. Any case that was denied for reasons other than *Fintiv* (e.g., based on deficient merits) was omitted from our statistics. The results are shown in Table 3. We note, however, that we identified more than 100 cases involving patents asserted in multiple districts, and the PTAB has applied *Fintiv* to deny institution based on co-pending litigation that the petitioner was not involved in (e.g., litigation between the patent owner and a third party in a different district).[36]

The vast majority of patents were involved in litigations in the Western District of Texas (WDTX), Eastern District of Texas (EDTX), and District of Delaware (DDE), three venues commonly selected by plaintiffs. But the denial rate for patents asserted in the Eastern District of Texas remains far greater than that of the other two venues.

Table 3: *Fintiv* Denials by District in 2021

District	# Cases	# Denied Under *Fintiv*	% Denied Under *Fintiv*
WDTX	60	5	8.3%
EDTX	56	37	66.1%
DDE	48	3	6.3%
CDCA	7	0	0.0%
DMN	5	0	0.0%
SDTX	5	0	0.0%
EDVA	4	0	0.0%
NDCA	4	0	0.0%
EDMO	3	0	0.0%
MDFL	3	0	0.0%
SDFL	3	2	66.7%
MDNC	2	0	0.0%
DMD	1	0	0.0%
EDTN	1	0	0.0%
NDTX	1	0	0.0%
SDNY	1	0	0.0%

** Cases through November 23, 2021.*

The Eastern and Western Districts of Texas are both considered "rocket dockets." From that fact alone, we would expect the denial rates to be much closer. However, the differences between the Eastern and Western Districts of Texas show that the PTAB has applied more scrutiny in 2021 to the specific facts of each case.

Based on our results, part of the disparity between Eastern and Western Districts of Texas may be attributed to petitioner filed stipulations. We cross-referenced our district court data with our stipulation data to determine what types of stipulations were filed in the cases with parallel litigations in the Eastern and Western Districts of Texas (see Figure 6). We found for parallel proceedings in the Western District of Texas, the petitioner filed a broad stipulation in approximately 44% the cases, either stipulating to full estoppel, as in *Sotera*, or not to use the same art in the parallel litigation. By contrast, for parallel proceedings in the Eastern District, the petitioner filed such broad stipulations only about 30% of the time.

The numbers here, however, are not so extreme as to account for the large difference in denial rates. Instead, we speculate the PTAB has been treating trial dates in the Western District of Texas as less certain than the Eastern District. A number of factors may be at play, including that the Eastern District has a much longer history and track record of patent litigation and the well

Figure 6: Stipulations Filed in PTAB Cases with Parallel Litigations in WDTX or EDTX

** Cases through November 23, 2021.*

documented venue transfer issues playing out in the Western District. For example, the possibility of venue transfer from a "rocket docket" district (such as the Western District) to another district that builds more time into its schedule, and thus would set a later trial date, may affect the PTAB's analysis of *Fintiv* factor 2.[37] Court congestion and delays due to COVID are also likely factoring into the PTAB's decisions.

As for the District of Delaware, the slower pace of cases likely contributes considerably to the PTAB's analysis. In the few cases that were denied, the petitioner waited until days prior to its statutory deadline to file the petition.[38] The trial date was set to occur more than six months prior to the PTAB's final written decision, and the petitioner filed only a narrow stipulation not to pursue the same invalidity grounds in district court.[39]

Overall, both petitioners and patent owners should consider the location of the parallel district court proceeding in their planning. For cases pending in the Eastern District of Texas, petitioners will benefit greatly by diligently filing their petition, minimizing the chance that trial in the district court will occur before the PTAB's final written decision. In the Western District of Texas, petitioners may have more leeway on timing if coupled with broad stipulations that reduce overlap between the PTAB and district court.

All the data and all the ink related to *Fintiv* over the past year demonstrate that it had a significant impact on patent litigation across all tribunals in 2021. 2022 will likely be another very active year because, while PTAB denials based on *Fintiv* decreased in 2021, the number of cases addressing *Fintiv* (and thus parties arguing for and against *Fintiv* denial) increased. Plus, with a new Director likely at the helm of the PTO, various challenges to *Fintiv* playing out in the courts, and proposed legislation[40] to rein in the PTAB's discretion at institution, it remains to be seen whether *Fintiv* will survive another year. Check back in with us this time next year to find out.

---

[1] *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential).

[2] This article analyzes cases decided in the 2021 calendar year.

[3] *Fintiv*, Paper 11 at 6.

[4] *Sand Revolution II, LLC v. Continental Intermodal Group-Trucking LLC*, IPR2019-01393, Paper 24 (P.T.A.B. June 16, 2020) (informative).

[5] *Sotera Wireless, Inc., v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18 (P.T.A.B. Dec. 1, 2020) (precedential as to § II.A).

[6] November 2019 Consolidated Trial Practice Guide ("TPG"), 58.

[7] *Fintiv*, Paper 11 at 6.

[8] *See, e.g., Canadian Solar Inc. v. The Solaria Corp.*, IPR2021-00095, Paper 17 (P.T.A.B. Sept. 24, 2021) (reversing denial of institution because the challenged patent was removed from the parallel litigation); *SharkNinja Operating LLC v. iRobot Corp.*, IPR2021-00544, Paper 13 (P.T.A.B. Nov. 17, 2021) (reversing denial of institution based, in part, on a "stipulati[on] to accept full []estoppel upon institution"); *Phillip Morris Prods., S.A. v. RAI Strategic Holdings, Inc.*, IPR2020-00921, Paper 13 (P.T.A.B. Aug. 5, 2021) (reversing denial of institution due to a stay of the parallel district court litigation.

[9] PTAB Trial Statistics FY21 at p. 6 (available at https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2021__roundup.pdf). Note that the PTAB's published results pertain to fiscal year 2021 (Oct. 1, 2020 to Sep. 30, 2021).

[10] *Fintiv*, Paper 11 at 12–13.

[11] 35 U.S.C. § 315(e) states that upon a final written decision pertaining to a claim in a patent, a petitioner may not assert—in any of (1) another proceeding before the Patent Office, (2) a civil action arising in whole or in part under section 1338 of title 28, or (3) a proceeding before the International Trade Commission—"that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review." 35 U.S.C. § 325(e) applies to post grant review and has similar language.

[12] *Sand Revolution II*, Paper 24 at 11–12 (citing id., Paper 22 at 7; Exhibit 1015).

[13] *Id.* at 12.

[14] *Id.* at 12.

[15] *ByteDance, Ltd. v. Triller, Inc.*, IPR2021-00099, Paper 8 (P.T.A.B. Apr. 21, 2021).

[16] *Id.* at 12–13.

[17] *Id.* at 12–13, 15–16.

[18] *Sotera*, Paper 12 at 18.

[19] *Id.* at 19.

[20] *Id.*

[21] Of note, the Board found factor 4 neutral in only 11 cases. In every one of these cases, no stipulation was filed, and the Board generally found the factor neutral due to related factors. *See, e.g., London Luxury LLC v. E & E Co., Ltd.*, PGR2021-000083, Paper 10 at 12 (P.T.A.B. Nov. 15, 2021) (finding Fintiv factor 4 neutral due to lack of a scheduled trial date, even though there was "complete overlap between the issues and parties between the district court case and [the PTAB] proceeding.")

[22] 35 U.S.C. § 311(b)

[23] *Cisco Systems, Inc. v. Estech Sys., Inc.*, IPR2021-00332, Paper 11 at 11 (P.T.A.B. July 7, 2021).

[24] *Id.*

[25] *Id.*

[26] *Id.* at 12, 14.

[27] *See Fintiv*, Paper 11 at 8–9; TPG at 58.

[28] *Id.* at 8.

[29] *Nintendo Co., Ltd. v. GameVice, Inc.*, IPR2020-01197, Paper 13 at 15 (P.T.A.B. Jan. 12, 2021).

[30] *Id.* at 12–15, 22–23.

[31] *SharkNinja Operating LLC v. iRobot Corp.*, IPR2021-00545, Paper 11 at 6–10 (P.T.A.B. Sept. 8, 2021).

[32] *Id.* at 7–9.

[33] *Id.* at 9–10.

[34] *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12–13 (P.T.A.B. May 13, 2020) (informative).

[35] *Apple Inc. v. Parus Holdings, Inc.*, IPR2020-00686, Paper 9 at 13 (P.T.A.B. Sep. 23, 2020).

[36] *See Mylan Lab'ys Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375 (Fed. Cir. 2021), cert. denied, — S. Ct. — 2022 WL 145242 (Jan. 18, 2022).

[37] *See, e.g., Dish Network L.L.C. v. Broadband iTV, Inc.*, IPR2020-01267, Paper 15 at 17 (P.T.A.B. Jan. 21, 2021).

[38] *TA Instruments-Waters LLC v. Malvern Panalytical Inc.*, IPR2021-00210, Paper 9 (P.T.A.B. May 27, 2021); *TA Instruments-Waters LLC v. Malvern Panalytical Inc.*, IPR2021-00211, Paper 8 (P.T.A.B. May 27, 2021); *TA Instruments-Waters LLC v. Malvern Panalytical Inc.*, IPR2021-00213, Paper 8 (P.T.A.B. May 27, 2021).

[39] *TA Instruments-Waters LLC v. Malvern Panalytical Inc.*, IPR2021-00210, Paper 9 at 10–17 (P.T.A.B. May 27, 2021).

[40] *See, e.g.*, https://www.law360.com/articles/1426894/more-than-fintiv-what-to-know-about-the-ptab-revision-bill; https://www.ipwatchdog.com/2021/09/23/looming-leahy-bill-end-fintiv-practice-ptab/id=138020/.

Discretionary Denial under § 325(d): Strategic Implications of the PTAB's Advanced Bionic Framework

BY: JASON A. FITZSIMMONS AND JOHN D. HIGGINS

Summary

The USPTO Patent Trial and Appeal Board (PTAB) has increasingly used its discretionary denial authority in recent years. Although the PTAB's discretion under 35 U.S.C. § 314(a) and *Fintiv* grabbed many headlines in 2021, the PTAB's discretion under 35 U.S.C. § 325(d) can be equally fatal to an America Invents Act (AIA) petition. This articles focuses on the PTAB's discretion under Section 325(d).

The PTAB considers exercising its discretion under Section 325(d) when petitions raise the same or substantially the same prior art or arguments previously presented to the Office. Over the last four years, the PTAB cited Section 325(d) in about 25% of its institution decisions—significantly more than the share of institution decisions issued from 2013 to 2017 (see Figure 1 below). Somewhat under-the-radar, the PTAB's Section 325(d) jurisprudence has grown to include three precedential and eleven informative decisions.

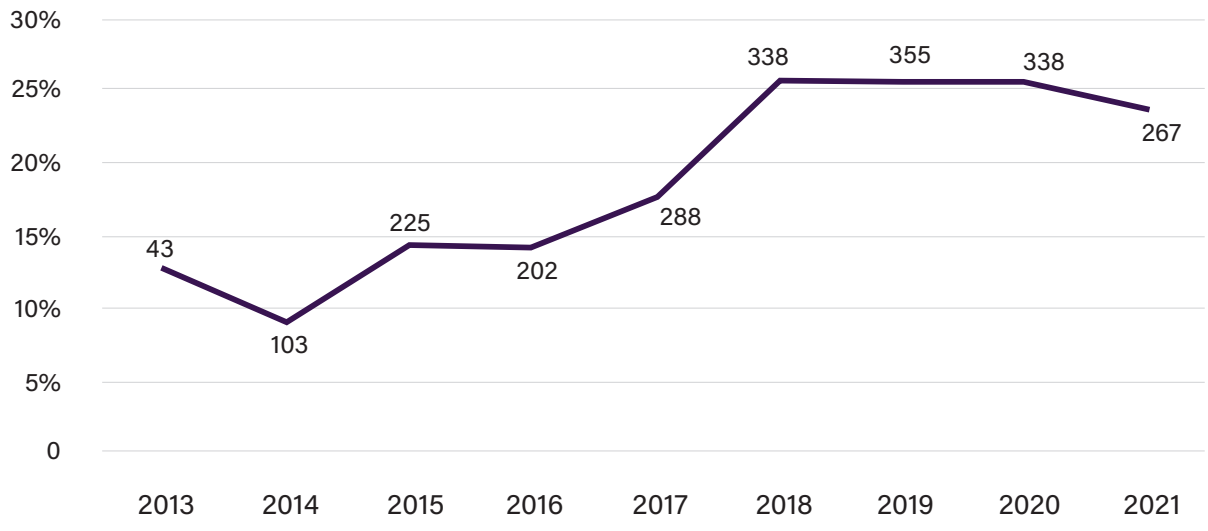
Practitioners must understand the important, and fact specific, analysis that the PTAB applies when evaluating whether to exercise discretion under Section 325(d). This is especially true because we believe the PTAB's jurisprudence on this issue, which is firmly rooted in the statutory text, is here to stay. By contrast, *Fintiv*'s fate is uncertain, as 2022 will likely bring a new Director of the USPTO who can abrogate *Fintiv*, as well as various legal challenges working their way through the federal courts and proposed legislation aimed at reining in the Director's discretion and potentially abolishing *Fintiv*.

Because discretion under Section 325(d) is a threshold issue that the PTAB addresses at institution, petitioners should proactively address the considerations of the PTAB's applicable framework. Indeed, merely raising an objectively meritorious ground of unpatentability may not be enough for petitioners to avoid Section 325(d) denial. On the other hand, when confronted with art or arguments previously presented to the Office, patent owners should take full advantage of a Section 325(d) defense to leverage the PTAB's willingness to exercise its discretion. Accordingly, a comprehensive understanding of the Section 325(d) framework is necessary to formulate winning strategies to either obtain or defend against institution. Here, we dissect the PTAB's Section 325(d) framework and explain how parties have either avoided or encouraged Section 325(d) denial.

The *Advanced Bionics* Two-Part Framework and Its Impact

On March 24, 2020, the PTAB designated *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GMBH*[1] *and two sections of Oticon Medical AB v. Cochlear Ltd.*[2] as precedential to provide balanced guidance on how the PTAB exercises its discretion under Section 325(d). While presented with the same issue—whether the same or substantially the same art was previously presented to the Office—the PTAB reached opposite conclusions in these decisions. In *Advanced Bionics*, the PTAB exercised its discretion to deny institution under Section 325(d), finding that the newly asserted art by the petitioner was the same or substantially the same

Figure 1: Share of Institution Decisions that Cite Section 325(d)



as art previously presented to the Office.[3] Conversely, in *Oticon Medical*, the PTAB determined that the newly asserted art was *not* the same or substantially same as art previously presented to the Office, and declined to exercise its discretion.[4] Thus, both petitioners and patent owners can glean helpful insight from these decisions.

In *Advanced Bionics*, the PTAB established the following "two-part framework" for evaluating whether to exercise discretion under Section 325(d):

1. whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and
2. if either condition of the first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.[5]

The *Advanced Bionics* two-part framework streamlines the process for applying the six non-exclusive factors enumerated in *Becton, Dickinson*—the PTAB's first precedential decision interpreting Section 325(d).[6] *Becton, Dickinson* factors (a), (b), and (d) pertain to whether the same or substantially the same art or argument was previously presented to the Office.[7] And *Becton, Dickinson* factors (c), (e), and (f) relate to whether the petitioner has demonstrated material error by the Office.[8] Institution decisions over the past year provide insight on how the PTAB applies the *Advanced Bionics* framework and, thus, potential strategies for both petitioners and patent owners.

Part I of the *Advanced Bionics* Framework

The first part of the *Advanced Bionics* framework evaluates (1) whether the same or substantially the same art previously was presented to the Office, and (2) whether the same or substantially the same arguments previously were presented to the Office.

Whether the same or substantially the same asserted art or argument was previously presented to the Office covers a broad range of proceedings, including examination of the underlying patent application, reexamination of the challenged patent, a reissue application for the challenged patent, and other AIA post-grant proceedings.[9] The PTAB may also look at applications directly related to the challenged patent, such as a parent application.[10] Previously presented art includes art cited by the examiner and art provided to the Office by the applicant (e.g., in an Information Disclosure Statement). [11]

- **Comment:** In assessing the similarity of asserted art to previously presented art, practitioners should also consider proceedings involving applications related to the challenged patent.

There is typically no dispute that the first part of the framework is satisfied when the asserted art was either cited by the examiner or provided to the Office by the applicant. But patent owners should not assume that the PTAB will *sua sponte* exercise its discretion if only some of the art was previously presented to the Office.

- **Patent Owner Tip:** The PTAB may decline to exercise its discretion when the patent owner does not dispute petitioner's assertions that previously presented art was not substantively considered during prosecution or that newly cited art is not cumulative to previously presented art.[12]

While patent owners typically must show that the asserted art is the same or substantially the same as previously presented art to seek discretionary denial, petitioners should proactively address this issue even before filing the petition. Petitioners can increase the likelihood of avoiding discretionary denial under Section 325(d) by relying on newly cited art as much as possible. Asserting new art—even if combined with previously presented art—forces the PTAB to further determine whether the newly asserted art is cumulative to the previously presented art and whether the previously presented art is being applied in a different way than it was when previously considered, before moving to the second part of the framework.

- **Petitioner Tip:** If the strongest prior art was previously presented to the Office (e.g., during prosecution), consider combining the previously presented art with new art to present a new combination for the PTAB to evaluate.

Indeed, the first part of *Advanced Bionics* framework may not be met even when one piece of asserted art was previously presented to the Office.[13] In declining to exercise its discretion to deny institution, at least one PTAB panel has held that "[t]he fact that one piece of art from the combination was previous previously presented and/or argued to the Office alone is insufficient to satisfy the first prong of *Advanced Bionics* two-part test."[14] This especially applies when the previously presented art is used "in a minor capacity" with newly cited art, such as using newly cited art as the primary reference and previously presented art as the secondary reference.[15] Thus, combining previously presented art with new art may not satisfy the first part of the *Advanced Bionics* test, persuading the PTAB to decline exercising its discretion.

- **Patent Owner Tip:** Do not assume that the first part of the *Advanced Bionics* framework is satisfied because the petition asserts one or more references previously presented to the Office; consider arguing that each newly asserted reference is substantially the same as previously presented art.

If a reference was not previously presented to the Office or if a previously presented reference is combined with new art, further analysis is needed before proceeding to the second part of the framework. That is, the PTAB must determine whether the asserted art is "substantially the same" as art or arguments previously presented to the Office.[16] This highly factual inquiry may be informed by evaluating *Becton, Dickinson* factors (a), (b), and (d).[17]

The PTAB deems newly asserted art "cumulative" when the art's relevant teachings provide nothing more than what was taught by previously presented prior art.[18] This may include teachings that are "structured substantially identically to those previously considered by the Office" and "relied on for the same proposition" as previously considered art.[19] Notably, the teachings between the newly asserted art and previously presented art do not need to "be identical or entirely cumulative, only [] substantially same" to satisfy the first prong of the *Advanced Bionics* framework.[20] Nonetheless, showing that newly asserted art is cumulative to previously presented art can be a rigorous task for the patent owner.

When facing an unpatentability ground based on a combination of new and previously presented art, patent owners should evaluate whether the relevant teachings of the new art present nothing more than what was previously considered by the Office. Given the detailed nature of this inquiry, patent owners should consider identifying any overlapping material similarities between the new art and the previously presented art. For example, a chart that maps corresponding structures and functions of the new art to previously presented art can help the PTAB easily identify the similarities between the teachings.

Although fact intensive, the PTAB's Section 325(d) jurisprudence provides helpful guideposts when performing this analysis. *Oticon Medical*, for example, demonstrates that the PTAB does not consider newly asserted art to be substantially the same as previously presented art when disclosing "different structures that serve different purposes."[21] PTAB panels have also declined to find a combination of new and previously presented art to be substantially the same when the new art addresses shortcomings of the previously presented art "in a different manner than the rejections made by the Examiner."[22]

Nevertheless, petitioners cannot assume that newly asserted art is immune from discretionary denial, particularly when the newly asserted art includes teachings analogous to the previously presented art.[23] As part of their due diligence, petitioners should thoroughly review the prosecution history to determine if any newly asserted art is cumulative to previously presented art. And petitioners should distinguish their unpatentability arguments from rejections provided by the Office during prosecution.

For example, when relying on the combination of new and previously presented art, petitioners should consider presenting obviousness rationales that are different than the motivations used by the examiner in any obviousness rejections. And if the prosecution history identifies any deficiencies in the previously presented art, consider combining new art that directly addresses those shortcomings.

- **Petitioner Tip:** Consider distinguishing the asserted unpatentability ground(s) from rejections raised during prosecution by including different rationales for combining references or relying on overlooked disclosures in previously presented art.

Part II of the *Advanced Bionics* Framework

If the petition presents the same or substantially the same art or arguments, the PTAB turns to the second part of *Advanced Bionics* framework—whether the Office erred "in a manner material to the patentability of the challenged claims."[24] The PTAB applies *Becton, Dickinson* factors (c), (e), and (f) to determine if there was a material error.[25]

Under Part II of the framework, petitioners must show that the Office erred in a manner material to the patentability of challenged claims. Petitioners' strategy for demonstrating an error by the Office should be guided by the level of detail in the record of the Office's previous consideration of the prior art.

When the record of the Office's previous consideration of the art is silent or not well-developed, simply showing that the previously presented art likely discloses a contested limitation may be enough to persuasively demonstrate a material error.[26] For example, some PTAB panels have declined to exercise discretion when the prosecution history provides little insight into the examiner's evaluation of the prior art and the petitioner demonstrates with a reasonable likelihood that the previously presented art discloses the allegedly patentable features.[27] This may occur when the underlying application was allowed without any substantive office actions or when the previously presented art was one of many references cited in an Information Disclosure Statement but not applied in an office action.[28] Because the PTAB tends to focus more on the merits of the petition when the prosecution record is not well-developed, petitioners should consider linking their arguments against discretionary denial with the merits of their unpatentability grounds.

- **Petitioner Tip:** Consider emphasizing that the Office overlooked the pertinence of the previously presented art, as demonstrated in the unpatentability grounds of the petition, when the record of the Office's previous consideration of the art is silent or not well-developed.

In these more clear-cut situations of material error, petitioners should consider keeping arguments against discretionary denial succinct, devoting more of their word count to the merits of the unpatentability grounds.

Similarly, patent owners should consider coordinating their arguments for discretionary denial with their arguments on the merits when the prosecution record is silent or not well-developed. For example, patent owners may look to the notice of allowance (or elsewhere in the prosecution history) to determine if the examiner indicated allowable subject matter of the issued claims.

If so, patent owners might emphasize that the previously presented art does not disclose or suggest the limitations that the examiner found missing in the prior art.[29]

- **Patent Owner Tip:** Determine if the examiner indicated in the prosecution history any limitations that were distinguishing features and consider emphasizing that the previously presented art does not disclose those limitations that the examiner found missing from the prior art.

On the other hand, when the prosecution history provides a detailed account of the examiner's evaluation of the prior art, petitioners must show persuasively that the examiner "erred in the evaluation of the prior art, for example, by showing that the [e]xaminer misapprehended or overlooked specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged claims."[30] In this scenario, the burden on the petitioner is significant. Simply presenting a different interpretation of previously presented art is unlikely to convince the PTAB to institute review.[31] Indeed, the PTAB in *Advanced Bionics* instructed that "[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability."[32] And failing to proactively identify overlooked disclosure in the previously presented art diminishes petitioners' chances of showing a material error.[33] Rather, petitioners should consider identifying the art considered by the examiner in the prosecution history and explaining any overlooked or misapprehended disclosure that was material to patentability.

- **Petitioner Tip:** When the record provides a detailed account of the Office's evaluation of the prior art, consider identifying and explaining any overlooked or misapprehended disclosure.

One example is demonstrating that the examiner overlooked an embodiment of an asserted reference that clearly shows the limitation at issue.[34] Another example is demonstrating that the previously presented art was not "extensively evaluated for the same purposes" that the petitioner relies upon the reference in the petition.[35] Petitioners may also show that the Office committed "an error of law," for example, by misconstruing a claim term that impacted the patentability of the challenged claims.[36] By implementing these strategies, petitioners may reduce the likelihood the PTAB exercises its discretion to deny the petition under Section 325(d).

Section 325(d) Applies to *Ex Parte* Reexaminations

Another option for challenging the validity of a patent is *ex parte* reexamination requests. The Federal Circuit's recent holding in *In re Vivint Inc.*, demonstrates that the Office may exercise its discretion under Section 325(d) to deny reexamination requests that assert the same or substantially same art as prior post-grant proceedings.[37] Parties to reexamination proceedings should thus evaluate whether and how Section 325(d) affects their positions.

Background

Alarm.com filed fourteen *inter partes* review (IPR) petitions against four patents asserted by Vivint.[38] The PTAB denied three IPR petitions against Vivint's '513 patent and one IPR petition against Vivint's '091 patent under Section 325(d) for abusive filing.[39] More than a year later, Alarm.com copied grounds from the '091 patent petition into a request for reexamination of the '513 patent.[40] The Office granted reexamination and denied Vivint's petitions seeking dismissal under Section 325(d).[41] In denying Vivint's petitions, the Office purported that it lacked the authority to consider petitions filed after the Reexamination Order and explained that Vivint could have sought a waiver to petition the Office before the Reexamination Order.[42] The Office ultimately rejected all the claims of the '513 patent in reexamination.[43] Vivint appealed, arguing that Alarm.com did not present a substantial new question of patentability.[44]

The US Court of Appeals for the Federal Circuit found that Alarm.com did present a substantial new question of patentability because the grounds repeated from the IPR petitions were never considered on the merits, since the PTAB denied institution of the IPRs.[45] But the Federal Circuit held that Section 325(d) discretionary denial applies to reexamination proceedings, even if the request presents a substantial new question of patentability.[46] Thus, the Federal Circuit found that Alarm.com's reexamination request was "another, fourth iteration" of an incremental petition, that continued the abusive filing practices after the '091 patent decision.[47] The Federal Circuit then held that the Office acted arbitrarily and capriciously by ordering reexamination and denying Vivint's petitions seeking dismissal under Section 325(d).[48] Accordingly, the Federal Circuit vacated the Office's decision finding that all the reexamined claims were unpatentable and remanded with instructions to dismiss the reexamination.[49]

Takeaway

The Federal Circuit's decision in *In re Vivint* will likely encourage the Office to exercise its discretion against reexamination requests that merely serve as serial challenges to a patent.

From a petitioner's perspective, previously asserted invalidity grounds that have been denied in IPR or post-grant review (PGR) proceedings should be reevaluated before being rehashed in a reexamination request. Similar to distinguishing an IPR petition from the examiner's positions during prosecution, petitioners should distinguish the grounds for reexamination from the art or arguments previously presented in IPR or PGR

petitions, by applying new art and asserting different obviousness rationales.

From a patent owner's perspective, the grounds raised in reexamination requests should be compared to the art and arguments previously presented in other proceedings, including IPR and PGR proceedings. Patent owners should timely petition the Office to exercise its discretion under Section 325(d), especially if the request merely reasserts the same or substantially same art from a prior proceeding.

The next year should provide insight on how *In re Vivint* impacts the Office's handling of the surge in requests for reexamination. But petitioners should not be surprised if the Office chooses to exercise its discretion under Section 325(d) more often during reexamination, particularly where the grounds are the same or substantially the same as an IPR or PGR, just as the PTAB has exercised its discretion more frequently in AIA post-grant proceedings.

1. IPR2019-01469, Paper 6 (P.T.A.B. Feb. 13, 2020) (precedential) ("*Advanced Bionics*").
2. IPR2019-00975, Paper 15 (P.T.A.B. Oct. 16, 2019) (precedential as to §§ II.B and II.C) ("*Oticon Medical*").
3. *Advanced Bionics*, Paper 6 at 11-22.
4. *Oticon Medical*, Paper 15 at 10-20.
5. *Advanced Bionics*, Paper 6 at 8.
6. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, ¬IPR2017-01586, Paper 8, 17-18 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) ("*Becton, Dickinson*") (explaining that the PTAB considers the following non-exclusive factors when evaluating discretion under § 325(d): (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which a Petitioner relies on the prior art or a Patent Owner distinguishes the prior art; (e) whether a Petitioner has pointed out sufficiently how the Examiner erred in its evaluation the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petitioner warrant reconsideration of the prior art or arguments.)
7. *Advanced Bionics*, Paper 6 at 10.
8. *Id.*
9. *Id.* at 7-8, 10.
10. *Becton Dickinson*, Paper 8 at 16.
11. *Advanced Bionics*, Paper 6 at 10; *see also Weatherford U.S. v. Enventure Global Technology Inc.*, IPR2020-01661, Paper 19 (P.T.A.B. April 15, 2021).
12. *See Edwards Lifesciences Corp. et al. v. Colibri Heartvalve LLC*, IPR2020-01649, Paper 8 at 20-21 (P.T.A.B. Mar. 26, 2021) (declining to exercise its discretion when patent owner did not dispute petitioner's contentions that none of the previously presented references were considered during prosecution); *H-E-B, LP, v. Digital Retail Apps, Inc.*, IPR2020-00149, Paper 25 at 72 (P.T.A.B. May 19, 2020) (declining to exercise its discretion when patent owner did not contest petitioner's allegations that the asserted references were not before the Examiner during prosecution).
13. *Thorne Research, Inc. v. Trustees of Dartmouth College*, IPR2021-00491, Paper 18 at 7-9 (P.T.A.B. Aug. 12, 2021) (declining to exercise its discretion to deny institution after finding that the combination of a reference cited during prosecution and two newly asserted references were not the same or substantially the same art previously presented to the Office).
14. *Id.* at 8.
15. *Grimco, Inc. v. Principal Lighting Group, LLC*, IPR2021-00968, Paper 13 at 19-21 (P.T.A.B. Nov. 22, 2021); *but see In re Mouttet*, 686 F.3d 1322, 1333 (Fed. Cir. 2012) (explaining that "where the relevant factual inquiries underlying an obviousness determination are otherwise clear, characterization by the examiner of prior art as 'primary' and 'secondary' is merely a matter of presentation with no legal significance.").
16. *Advanced Bionics*, Paper 6 at 8.
17. *Id.* at 10.
18. *See Gardner Denver v. Utex Industries, Inc.*, IPR2020-00333, Paper 12 at 13-14 (P.T.A.B. Aug. 5, 2020) (denying institution upon finding that newly asserted references Kalsi and Kohl are no more relevant than references that were presented during prosecution); *Roku, Inc. v. Universal Elecs., Inc.*, IPR2019-01619, Paper 11, 16-17 (P.T.A.B. April 2, 2020) (denying institution upon finding that newly applied Zetts was cumulative to previously presented Kim, even though Kim was not considered for the same limitation in reexamination); *Advanced Bionics*, Paper 6 at 13-19.
19. *Dropworks, Inc. v. The University of Chicago*, IPR2021-00100, Paper 9 at 13-14 (P.T.A.B. May 14, 2021).
20. *Id.*
21. *Oticon Medical*, Paper 15 at 10-20 (finding a newly raised reference—Choi—different from a previously presented reference because Choi's implant screw grooves were located at a different portion of the screw compared to the implant screws of the previously presented art, and thereby, providing an advantage not considered by the examiner during prosecution).
22. *Agrofresh Solutions Inc. v. Lytone Enterprise, Inc.*, IPR2021-00451, Paper 11 at 12-13 (P.T.A.B. July 27, 2021); *see also London Luxury v. E & E Co., LTD.*, PGR2021-00083, Paper 10 at 17-22 (P.T.A.B. Nov. 15, 2021).
23. *See e.g., Evapco Dry Cooling, Inc., v. SPG Dry Cooling USA*, IPR2021-00687, Paper 11 at 24-25 (P.T.A.B. Sep. 24, 2021) (finding a newly asserted reference not cited during prosecution as being substantially the same as the references that were before the Examiner during prosecution).
24. *Advanced Bionics*, Paper 6 at 8.
25. *Id.* at 10.
26. *Id.*
27. *Samsung Electronics Co., Ltd., et al. v. Evolved Wireless LLC*, IPR2021-00943, Paper 9 at 10-12 (P.T.A.B. Dec. 1, 2021); *Carrier Fire & Security America's Corp. v. Sentrilock, LLC*, IPR2021-00664, Paper 12 at 21-23 (P.T.A.B. Sept. 16, 2021).
28. *See Satco Products Inc. v. The Regents of the Univ. of California*, IPR2021-00662, Paper 13 at 25 (P.T.A.B. Nov. 8, 2021); *Samsung Electronics at 11-12; Carrier Fire*, Paper 12 at 21-23.
29. *Albany International Corp. v. Kimberly-Clark Worldwide, Inc.*, PGR2021-00019, PGR2021-00019, Paper 22 at 15-17 (P.T.A.B. June 22, 2021) (exercising discretion to deny institution after finding that an overlooked portion of a previously presented reference was no more pertinent in providing any teachings of allowable subject matter indicated by the examiner).
30. *Advanced Bionics*, Paper 6 at 21.
31. *See Weatherford*, Paper 19 at 16-17.
32. *Advanced Bionics*, Paper 6 at 9.
33. *Evergreen Theragnostics, Inc., v. Advanced Accelerator Applications SA*, PGR2021-00003, Paper 10 at 18 (P.T.A.B. Apr. 14, 2021); Albany International Corp., Paper 22 at 16.
34. *Volkswagen Group of America, Inc. v. Michigan Motor Technologies*, IPR2020-00452, Paper 12 at 31-33 (P.T.A.B. Sept. 9, 2020).
35. *Continental Automotive Systems, Inc. v. Horizon Global Americas Inc.*, IPR2021-00322, Paper 7 at 19 (P.T.A.B. May 28, 2021); *see also Dish Network LLC et al. v. Sound View Innovations, LLC*, IPR2020-01041, Paper 13 at 21-22 (P.T.A.B. Jan. 19, 2021).
36. *Advanced Bionics*, Paper 6 at 8-9, fn. 9 ("Another example may include an error of law, such as misconstruing a claim term, where the construction impacts patentability of the challenged claims.")
37. *In re Vivint Inc.*, 14 F.4th 1342, 1350 (Fed. Cir. 2021).
38. *Id.* at 1346.
39. *Id.*
40. *Id.* at 1346-1347.
41. *Id.* at 1347-1348.
42. *Id.*
43. *Id.* at 1348.
44. *Id.*
45. *Id.* at 1350.
46. *Id.*
47. *Id* at 1353.
48. *Id.*
49. *Id.* at 1354.

Developments in Antedating Asserted Art at the PTAB

BY: TYLER S. HOGE AND TYLER J. DUTTON

Summary

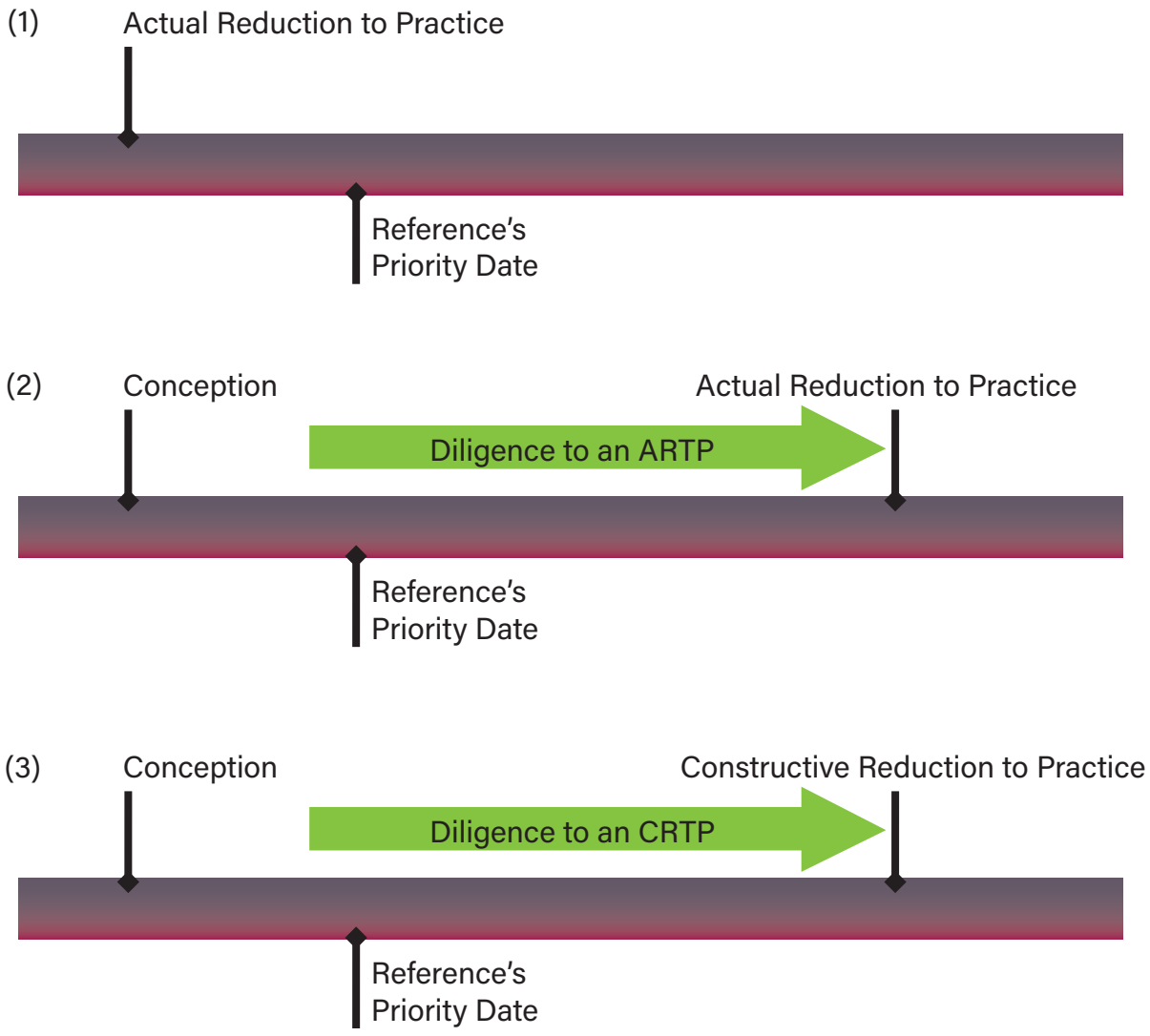
USPTO Patent Trial and Appeal Board (PTAB) decisions in 2021 show that antedating a prior-art reference remains a viable option to knock out a ground in an *inter partes review* (IPR) petition—patent owners were successful in such an endeavor 57% of the time. However, the decisions in 2021 reaffirm that patent owners need to prepare for an arduous (and expensive) fight—one that involves several declarations to corroborate inventor testimony and authenticate documents. But unlike early PTAB cases where patent owners needed to appeal to the US Court of Appeals for the Federal Circuit to reverse or vacate unfavorable decisions, patent owners have increasingly been able to obtain favorable outcomes at the PTAB. This appears to be due to patent owners submitting better corroborating evidence.

The Three Approaches to Antedating a Reference

When faced with certain prior-art references that predate the patent owner's effective filing date of a pre-America Invents Act (AIA) patent,[1] the patent owner can show that it is entitled to an earlier priority date. This is called "antedating." If the patent owner antedates a reference successfully, that reference is not *prior* art.

During an AIA review proceeding, a patent owner can knock out an entire ground of unpatentability if it can antedate a §102(a) or §102(e) reference. Under pre-AIA law, a patent owner can antedate a §102(a) or §102(e) reference using three approaches, shown in Figure 1 below: (1) an actual reduction to practice ("ARTP")[2] before the reference's priority date; (2) conception[3] before the reference's priority date plus diligence[4] from before the

Figure 1: Three Approaches to Antedating a Reference



reference's priority date to an ARTP; or (3) conception before the reference's priority date plus diligence before the reference's priority date to a constructive reduction to practice ("CRTP").[5]

Proving these elements is highly fact specific and the caselaw has well-established evidentiary requirements for making these showings. For example, inventor testimony by itself is insufficient to show conception, diligence, and/or a reduction to practice. *See Loral Fairchild Corp. v. Matsushita Elec. Indus. Co.*, 266 F.3d 1358, 1363 (Fed. Cir. 2001) (citing *Cooper v. Goldfarb*, 154 F.3d 1321, 1330 (Fed. Cir. 1998)). Instead, a patent owner must corroborate inventor testimony with evidence that supports the inventor's testimony. *In re NTP, Inc.*, 654 F.3d 1279, 1291 (Fed. Cir. 2011). The sufficiency of corroboration is determined using a "rule of reason." *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1170 (Fed. Cir. 2006) (citing *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993). Requiring that an inventor's testimony be corroborated "provides additional safeguard[s] against [the] court being deceived by inventors" that may be tempted to mischaracterize past events. *Id*. Corroborating evidence "may consist of testimony of a witness, other than the inventor, to the actual reduction to practice or it may consist of evidence of surrounding facts and circumstances independent of information received from the inventor." *Id.* at 1171. Patent owners should, however, avoid using the testimony of a co-inventor as corroborating evidence. *See, e.g., Lacks Indus. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1350 (Fed. Cir. 2003) (opining that the Special Master rightly refused to accept cross-corroboration of oral testimony as being adequate).

2021 Decisions

The PTAB evaluated antedating arguments in seven cases in 2021; the outcomes of these seven unique decisions are presented in Figure 2 below. Patent owners were successful under the first approach and the third approach for antedating (shown in Figure 1). Patent owners did not attempt to antedate a reference using the second approach in any case decided in 2021.

Takeaways from 2021 PTAB Decisions

2021 PTAB decisions demonstrate that successfully antedating a reference continues to be a fact specific and challenging undertaking, often requiring patent owners to submit and persuasively explain considerable amounts of evidence. That said, because the caselaw is now more developed, patent owners have insight into and predictability surrounding the types and amounts of evidence necessary to prevail. For example, in prior years, the PTAB was stringent, too stringent in some cases, on what type of evidence corroborates inventor testimony about diligence. *See, e.g., ATI Techs. ULC v. Iancu*, 920 F.3d 1362 (Fed. Cir. 2019); *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004 (Fed. Cir. 2016). The Federal Circuit clarified that a patent owner does not need to prove that the inventor *continuously* exercised reasonable diligence throughout the critical period. *Perfect Surgical*, 841 F.3d at 108-09 (Fed. Cir. 2016). Instead, the patent owner must only show there was reasonably continuous diligence. *Id.* As such, small gaps during the critical period are not dispositive, and can be reasonable when the corroborating evidence as a whole is considered. *Id*.

It appears that patent owners in subsequent AIA trials have taken notice, developing extensive records to support their antedating arguments. Four IPRs decided in 2021—each of which resulted in the patent owner successfully antedating a reference—highlight this point. In *CallMiner*, the patent owner submitted three declarations to support its case: (1) an inventor declaration; (2) a declaration from a non-inventor, fact witness to corroborate the inventor's testimony; and (3) an expert declaration to explain why the evidence shows a reduction to practice. *CallMiner, Inc. v. Mattersight Corp.*, IPR2020-00220, Paper 59, 60-84 (June 16, 2021). In *Medtronic*, the patent owner went further, submitting two inventor declarations, an expert declaration, and four declarations by non-inventor, fact witnesses. *Medtronic,*

Figure 2: 2021 PTAB Decisions Evaluating Antedated Arguments

Decision	Approach(es)	Antedated
Intuitive Surgical, Inc. v. Ethicon Endo-Surgery, LLC (IPR2019-00991)	(3)	Yes
Apple Inc. v. Yu (IPR2019-02158)	(3)	No
Foursqure Labs, Inc. V. Mimzi, LLD (IPR2019-01287)	(3)	No
Mylan Pharmaceuticals Inc. v. Merck Sharp & Dohme Corp. (IPR2020-00040)	(1)	Yes
Medtronic, Inc. et al. v. Teleflex Medical Devices (IPR2020-00126, IPR2020-00128, IPR2020-00129,IPR2020-00132,IPR2020-00134, IPR2020-00135, and IPR2020-00137)	(1) and (3)	Yes
CallMiner, Inc. v. Mattersight Corp. (IPR2020-00220)	(1)	Yes
Stahls' Inc. v. Schwendimann (IPR2020-00633, IPR2020-00635, and IPR2020-006410)	(1)	No

Inc. v. Teleflex Innovations S.A.R.L., Paper 128, 17-71 (June 17, 2021). And in the *Intuitive Surgical* and *Mylan* IPRs, the patent owners submitted numerous declarations by non-inventor, fact witnesses to corroborate inventor testimony and authenticate documents. *Intuitive Surgical, Inc.,* IPR2019-00991, Paper 48 at 17, 24; *Mylan Pharm s.*, IPR2020-00040, Paper 91 at 44. In each of these cases, the PTAB found the non-inventor, fact witness testimony persuasive to corroborating the inventors' testimony.

These cases also demonstrate that testimony from non-inventor, fact witnesses (and preferable a disinterested fact witness) is a potent tool for antedating an asserted prior-art reference. Patent owners' likelihood of success appears to markedly decrease without such evidence to corroborate facts and authenticate documents. In cases where the patent owner relied on inventor testimony and lab notebooks without testimony from a non-inventor, the PTAB determined that the patent owner failed to meet its burden for corroboration. *Stahls' Inc.,* IPR2020-00641, Paper 42 at 19-30; *Apple Inc.*, IPR2019-01258, Paper 29 at 45-48.

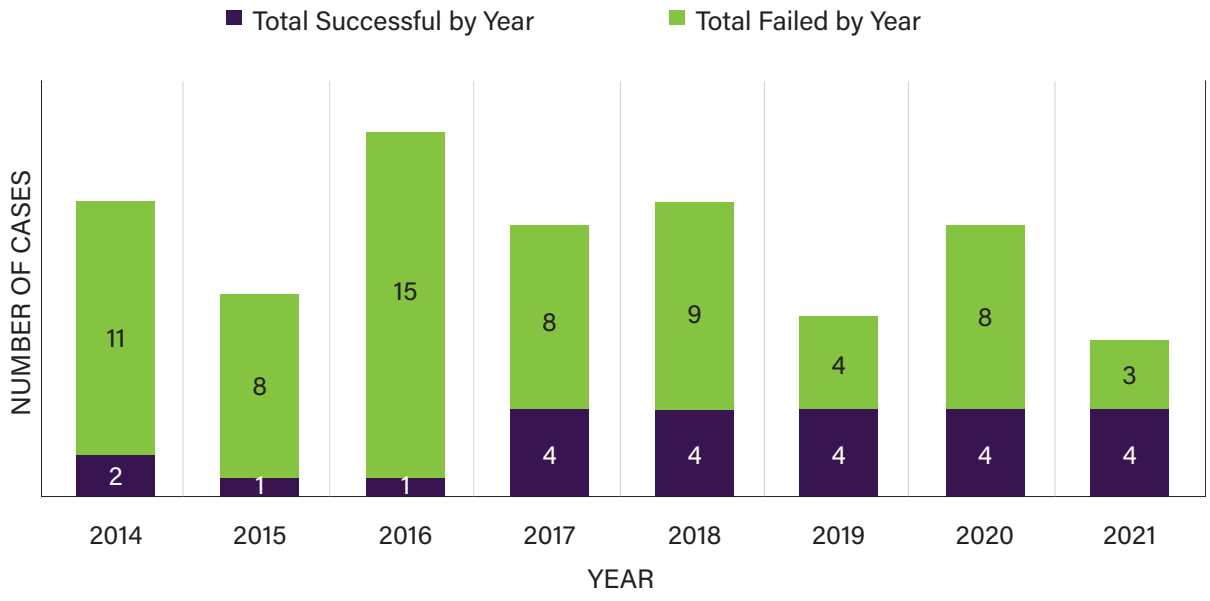
Contextualizing 2021 Decisions within Historical Data[6]

The data in Figure 3 shows the number of Final Written Decisions per year in which the patent owner was successful at antedating a reference. Before 2016, patent owners had a very low success rate, bottoming out in 2016 at 6.25%. But over the last five years, there was a dramatic shift in the patent owner's success rate. In 2017-2020, patent owners were successful between 30-50% of the time. 2021 was a little above this range. While the complexity of these types of cases and the small sample size make it challenging to infer causality, this increase in success rate since 2016 suggests that patent owners better-understand the PTAB's high evidentiary demands for antedating a reference.

Higher success rates post-2016 may also suggest that the PTAB has adjusted to Federal Circuit reversals and remands, to the benefit of patent owners. Over the past several years, patent owners have been arguing to the Federal Circuit that the PTAB is placing too high of a burden to prove earlier conception, diligence, and/or reduction to practice. For example, patent owners argued that the PTAB applied the higher standard of *continuous* reasonable diligence instead of reasonable continuous diligence. *See ATI Techs.*, 920 F.3d at 1369; *Perfect Surgical*, 841 F.3d at 1012. The Federal Circuit agreed, vacating and at times reversing PTAB decisions for applying an incorrect heightened standard for diligence. *See ATI*, 920 F.3d at 1374-75 (reversing the PTAB's decision on diligence); *Perfect Surgical*, 841 F.3d at 1012 (vacating and remanding the PTAB's decision on diligence). The Federal Circuit has also vacated and at times reversed PTAB decisions because the PTAB misapplied the rule of reason standard for corroborating inventor testimony. *See Intellectual Ventures II LLC v. Motorola Mobility LLC*, 692 F. App'x 626, 629 (Fed. Cir. 2017) (non-precedential) (vacating and remanding because "the Board did not make proper application of the rule of reason to determine whether there was sufficient corroboration of inventor testimony to demonstrate prior conception."); *REG Synthetic Fuels, LLC v. Neste Oil Oyi*, 841 F.3d 954, 965 (Fed. Cir. 2016) (reversing the PTAB's decision on conception and remanding for further fact findings on diligence and reduction to practice).

The PTAB's 2021 decisions suggest that it is adjusting in response. The PTAB in 2021, for example, stated that patent owners need to corroborate inventor testimony only under a "rule of reason" standard, not some other higher standard. *See Medtronic, Inc.*, IPR2020-00135,

Figure 3: Antedating a Reference



Paper 128 at 16; *see also CallMiner, Inc.*, IPR2020-00220, Paper 59 at 79-80 (stating that corroboration is sufficient when "a reasonable mind might accept the evidence as adequate."). The PTAB also cited the *ATI* case—a case where the US Court of Appeals for the Federal Circuit reversed a PTAB decision for applying the wrong standard for diligence—to explain why patent owners need to show only *reasonably* continuous diligence, not a heightened diligence standard. *See Intuitive Surgical, Inc.*, IPR2019-00991, Paper 48 at 23.

The PTAB's application of more patent-owner friendly precedent suggests that antedating will remain a viable option for patent owners in 2022. Although patent owners have had higher success rates recently, antedating a reference is no small feat. It requires extensive evidence, cooperative witnesses, and a strong legal team to piece together and persuasively present the evidence.

1. A pre-AIA patent is a patent with an effective filing date before March 16, 2013. The America Invents Act (and its first-to-file provisions) apply to patents filed on or after this date.
2. For an ARTP, the patent owner must show that the inventors: (1) constructed an embodiment or performed a process that meets all the claim elements; and (2) determined that the invention would work for its intended purpose. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998).
3. Conception is the mental formulation of a complete idea for the claimed subject matter. *Townsend v. Smith*, 36 F.2d 292, 295 (C.C.P.A. 1929).
4. Diligence is work that is reasonably necessary for a reduction to practice. *See Keizer v. Bradley*, 270 F.2d 396, 396-99 (C.C.P.A. 1959).
5. A "constructive reduction to practice occurs when a patent application on the claimed invention is filed." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986).
6. Cases included in this research were identified in Docket Navigator using the following search criteria: Patent Trial and Appeal Board; Final Written Decision – Patentability of Challenged Claims; on or after January 1, 2014; and "conception" OR "reduction to practice."

Case Studies and Trends at the PTAB Involving 35 U.S.C. § 112

DAVID HOLMAN, PH.D., ELDORA ELLISON, PH.D., ERIC BOYER, KIRSTEN WEIGEL-VAN AKEN, M.D.

Summary

Over the last 20-plus years, US Court of Appeals for the Federal Circuit cases concerning written description and enablement have become a hot-button issue in the chemical and life sciences practices. The year 2021 was no different, with *Amgen v. Sanofi*[1] (enablement) decided in February and *Juno v. Kite*[2] (written description) decided in August.[3] Both *Amgen* and *Juno* involved genus claims with functional language, and both cases seemingly exacerbated the uphill battle for patent applicants and patentees to obtain and defend such claims. Indeed, the Federal Circuit's recent stance on § 112 for chemical and life science genus claims has caused some to feel that the "sky is falling."[4] In light of the current § 112 landscape at the Federal Circuit, we examined the USPTO Patent Trial and Appeal Board's (PTAB) recent views on written description and enablement law in the chemical and life sciences. For this work, we reviewed PTAB decisions from Technology Center 1600 (Biotechnology & Organic Chemistry), issued between January 2020 and November 2021. Our review included decisions from *ex parte* appeals and America Invents Act (AIA) post-grant proceedings (including decisions on institution and final written decisions).

We found that the sky is not falling, at least not at the PTAB. For example, we identified several recent *ex parte* appeals in which patent applicants successfully obtained broad genus claims after the PTAB's reversal of Examiners' § 112 written description and/or enablement rejections. The PTAB also – at least in some cases – considered evidence of routine screening to favor enablement of genus claims. While none of the PTAB cases highlighted below is currently designated precedential or informative, they nonetheless indicate that the PTAB's application of § 112 offers patent owners in the chemical and life sciences a glimmer of hope. Below we highlight cases from our review, placing the PTAB decisions into three primary categories: (i) written description cases applying the representative species / common structural features rubric; (ii) written description cases applying the *Capon* factors; and (iii) enablement cases applying the routine screening rubric.

Written description: cases applying representative number of species / common structural features rubric.

In *AbbVie Deutschland v. Janssen Biotech*, 759 F.3d 1285 (Fed. Cir. 2014)—an antibody case involving genus claims with functional language—the Federal Circuit applied the representative number of species / common structural features rubric:

> [A] sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.

AbbVie, at 1299.

In August 2021, the Federal Circuit applied this rubric in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021). The asserted claims in *Juno* were drawn to a nucleic acid polymer encoding a chimeric antigen T-cell receptor (CAR T-cell) comprising three segments: an intracellular signaling segment, a co-stimulatory segment comprising a specific amino acid sequence, and a binding segment (scFv). *Id.*, at 1334. Juno's specification disclosed two exemplary scFvs that bind to specific targets (CD19 and PSMA). *Id.*, at 1333. Juno argued that other scFvs were known in the art, and that scFvs were interchangeable components with a shared, common structure. *Id.*, at 1336.

The Federal Circuit acknowledged that scFv sequences were known in the art, and that scFvs share a common structure (seemingly satisfying the common structural features rubric), but nevertheless concluded that Juno's specification lacked written description. The court stated:

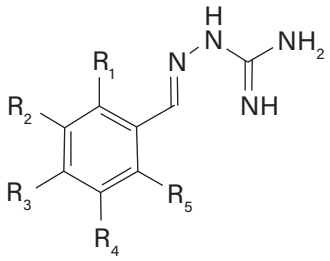
> [T]he written description of the '190 patent discloses only two scFv examples and provides no details regarding the characteristics, sequences, or structures that would allow a person of ordinary skill in the art to determine *which* scFvs will bind to which target. That scFvs in general were well-known or have the same general structure does not cure that deficiency.

Juno at 1339-1340 (emphasis added). In other words, as the court stated: "For the claimed functional scFv genus, the '190 patent does not disclose representative species or common structural features to allow a person of ordinary skill in the art to distinguish between scFvs that achieve the claimed function and those that do not." *Id.* at 1342.

How is the PTAB applying representative species / common structural features?

While the outlook for some biotech patent owners at the Federal Circuit may seem bleak at the moment, patent applicants continue to successfully obtain genus claims. For example, in *Ex parte Way*, No. 2019-006053 (PTAB, July

Figure 1: Chemical structure in *Ex parte* Way



9, 2020), the claims were drawn to a "method of treating a demyelinating disorder" comprising administering a compound "of Formula I" (see Figure 1), "wherein R_1, R_2, R_3, R_4, and R_5 are independently hydrogen, deuterium, halogen, haloalkyl, alkyl, alkoxy, hydroxyl, aryl, or aryloxy." *Way*, at 2. Way's specification disclosed working examples using a single compound (guanabenz) within the scope of the claimed genus of compounds. The Examiner rejected the claims for lack of written description and enablement. *Id.*, at 3. On appeal, the PTAB reversed the Examiner's written description rejection,[5] stating that Way's specification provided structural limitations that correlated with the claimed function: "Claim 2 recites a *reasonably small genus* of compounds with specific and complete *structural limitations that are correlated with the function* of treating a demyelinating disorder." *Way*, at 9 (emphasis added).

Applicants in the biologics space have also successfully overturned § 112 rejections at the PTAB. In *Ex parte Keler*, No. 2019-006094 (PTAB, June 10, 2020), the applicant claimed a "method for inducing or enhancing an immune response" using a monoclonal antibody which binds to human CD27, "wherein the antibody comprises heavy and light chain variable region sequences having at least 95% identity to SEQ ID NOs: 37 and 43, respectively." *Id.*, at 2. Keler's specification disclosed three exemplary antibodies with the claimed 95% sequence identity, and further disclosed data pertaining to binding, blocking, competition, and complement-mediated cytotoxicity. On appeal, the PTAB reversed the Examiner's written description rejection, holding that the three example antibodies exhibit a common structure that correlates with the claimed function, thus satisfying written description:

> The Specification further demonstrates that these *species exhibit both the structure* recited in claim 10 (i.e., comprises heavy and light chain variable region sequences having at least 95% identity to SEQ ID NOs: 37 and 43) *as well as the recited function* (i.e., they bind to human CD27 and induce/enhance an immune response) . . . . Thus, Appellant's *description correlates the structure of these species to the claimed function*.

Keler, at 11 (emphasis added).

Ex parte Campbell, No. 2021-000865 (PTAB, July 20, 2021), is similar to *Way*. Campbell's claims recited "a method of treating an autoimmune disease or condition, a systemic inflammatory disease or condition, or transplant rejection" comprising administering an anti-OX40L antibody having 90% sequence identity in the antibody's heavy and light chain variable regions to specific sequences disclosed in the application. *Id.* at 2-3. Campbell's specification disclosed two example antibodies, both meeting the claimed sequence identity limitations, and further disclosed experimental data such as ligand/receptor neutralization and IL-2 secretion assays. *Id.*, at 9, 15.

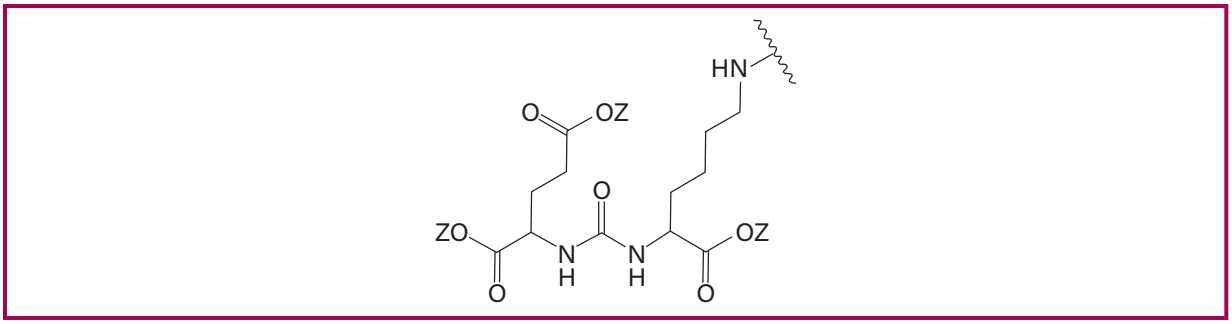
On appeal, the PTAB reversed the Examiner's §112 rejection, holding that the specification disclosed a representative number of species and that the claimed genus shared common structural features:

> "[T]he claimed antibodies are not exclusively claimed functionally, *but are also claimed structurally*, i.e., by requiring that the light and heavy chains have a structure corresponding to 90–95% of the recited SEQ ID NOS. Furthermore, *the number of possible substitutions is relatively small*: the variable regions of the antibodies comprise approximately 100 amino acid sequences, and so the total number of potential substitutions is no more than 10–12 . . . Additionally, the Specification provides at least two embodiments antibodies: 2D10 and 10A07, that are *fully functional in their antigen-binding capabilities*.

Campbell, at 15 (emphasis added).

Recent PTAB decisions from AIA proceedings appeared to include more mixed outcomes when it comes to §112. One reason may be that AIA trials, unlike *ex parte* appeals, are *inter partes* proceedings where a motivated adversary presses the patentability issues. In the PTAB's decision on institution in *Advanced Accelerator Applications v. Molecular Insight Pharms*, PGR2021-00048, Paper 7 (PTAB, July 29, 2021), the challenged claims recited a method of treating a patient with prostate cancer comprising administering a therapeutically effective amount of a glutamate-urea-lysine PSMA-binding moiety comprising the structure shown in Figure 2, wherein each Z, independently, is H or C_1-C_4 alkyl. *Id.*, at 4. The specification disclosed *in vitro* binding data (IC_{50} values) for about two dozen compounds, and provided biological data for a single compound. *Id.*, at 18, 24.

Figure 2: PSMA-binding moiety in Advanced Accelerator



At the institution stage, the PTAB instituted post-grant review because it determined it was more likely than not that the challenged claims lacked written description:

> [T]he '461 patent *does not disclose a sufficiently representative number of species* because the patent only provides PSMA-binding data for a *handful of compounds*, many of which show poor binding, and only provides further biological in vivo testing for one compound, MIP-1072. Given the apparent breadth of the challenged claims, this *limited number of disclosed compounds and limited data* does not appear sufficient to provide adequate written description support. We also find that the record sufficiently shows that the '461 patent *does not disclose structural features common to members of the genus*.

Id. at 24. Although *Advanced Accelerator* is still in trial,[6] the decision at institution illustrates that the PTAB is carefully scrutinizing the representative species/common structural features rubric. And we found several other PTAB AIA decisions applying rationales similar to *Advanced Accelerator*. *See e.g., Syngenta Crop Protection AG v. FMC Corporation*, PGR2020-00028, Paper 33 (PTAB, Aug. 31, 2021) (finding claims covering "more than a billion different compounds" unpatentable for lack of written description, when the specification failed to "divine a relationship between structure and activity, given that the test data is clustered around a narrow range of structures."); *Allgenesis Biotherapeutics v. Cloudbreak Therapeutics*, IPR2020-01438, Paper 7 (PTAB, Feb. 18, 2021) ("disclosure of a single species [of multikinase inhibitor] cannot be extrapolated to the genus.").

In contrast to *Advanced Accelerator*, the PTAB determined in *SweeGen, Inc. v. PureCircle Sdn Bhd*, PGR2020-00070, Paper 14 (Jan. 19, 2021), that the petitioner failed to show it was more likely than not to prevail on its §112 written description arguments. In *SweeGen*, the claims recited a method of adding a glucose unit to a steviol glycoside comprising contacting the steviol glycoside with an enzyme comprising UDP-glucosyltransferase. The PTAB rejected the petitioner's assertion that the claimed scope was overbroad in view of the specification: "We agree with Patent Owner that a person of ordinary skill in the art could envision the steviol glycosides and UDP-glucosyltransferases encompassed by the claims because they have *common structural features*." *SweeGen*, at 32 (emphasis added). Thus, in contrast to *Advanced Accelerator*, the PTAB panel in *SweeGen* noted that members of the genus shared common structural features.

This snapshot of PTAB decisions in TC1600 indicates that the PTAB seems to apply the representative number of species / common structural features rubric in a relatively balanced manner that, at least in some cases, favors the patent applicant or patentee. Time will tell if the PTAB begins applying a stricter standard in light of *Juno*.

Written description: cases applying the *Capon* factors

We also reviewed PTAB decisions to assess how the PTAB applied *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). *Capon* established the following well-known factors for assessing written description of a genus claim in the biological arts:

> [T]he determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Capon, at 1359. Since *Capon* was decided in 2005, patentees and patent applicants alike have often interpreted it as confirming that common knowledge in the art—such as known nucleotide sequences—need not be disclosed in the specification to support written description.

The Federal Circuit in *Juno* acknowledged this principle, stating that a patentee need not "in all circumstances" disclose nucleotide or amino acid sequences "when such sequences are already known in the prior art." *Juno*, at 1337. However, the Court in *Juno* distinguished *Capon*:

> Our *Capon* decision neither made the determination Juno alleges nor determined that the inventors there satisfied the written description requirement. *Instead, we vacated the Board's decision for imposing too high a standard to satisfy the written description requirement, and remanded* for the Board to consider the

> evidence and determine whether the specification adequately supported the claims at issue . . . *Capon* does not support Juno's arguments regarding its exceedingly broad functional claim limitations.

Id., at 1338 (emphasis added). With this new insight from *Juno*, we investigated how the PTAB is applying *Capon*.

How is the PTAB applying *Capon*?

Juno does not appear to have impacted the PTAB's stance on *Capon* in TC1600—at least not yet. Indeed, we found PTAB decisions issued before and after *Juno* that applied the same interpretation of *Capon*. For example, in *Ex parte Harriman*, No. 2020-004459 (PTAB, Feb. 10, 2021), decided before *Juno*, the claims recited a transgenic chicken comprising human immunoglobulin genes. The specification did not disclose any specific chicken or human immunoglobulin sequences, and provided only prophetic examples. The Examiner rejected the claims for lacking written description, asserting that the specification did not disclose any "transgene comprising an exogenous 'pre-arranged human light chain Ig gene' for targeted integration." *Harriman* at 8. In reversing the §112 rejection, the PTAB expressly relied on *Capon*, stating that "a pre-rearranged human Ig light chain variable region simply requires knowledge of human Ig light chain variable region sequences, which are replete in Genbank and other sources." *Id.* at 11. The PTAB explained: "Consistent with *Capon,* the ordinary artisan may select any known described deposited sequences for joinder by PCR or other well-known methods and use in the invention."

Id.; see also, *Ex parte Roninson*, No. 2019-006086 (PTAB, June 9, 2020) (applying *Capon* in reversing Examiner's §112 rejection); *Ex parte Terbrueggen*, No. 2018-004820 (PTAB, April 1, 2020) (applying Capon in reversing Examiner's §112 rejection; affirming on other grounds).

In *Ex parte Oliver*, No. 2021-000044 (PTAB, Oct. 8, 2021), decided after *Juno*, the claims recited a method for preparing a biomolecule analyte comprising hybridizing oligonucleotide probes to a single-stranded human DNA or human RNA template, performing a base extension reaction (e.g., PCR), terminating the reaction such that a single-strand region is adjacent to a hybridized probe, and reacting the product with a binding moiety. The Examiner argued that the specification did not provide any specific sequences for the template or oligonucleotide probes, and did not describe, e.g., how to direct a probe to polyA sequences that are not adjacent to one another. *Id.*, at 9-10. The PTAB rejected the Examiner's hypothetical, and, citing *Capon*, stated that a skilled artisan would have relied on the general knowledge in the art:

> [W]e are not persuaded that Examiner's postulated hypothetical, which *would have been recognized as inoperable by those of ordinary skill in this art*, at the time of Appellant's claimed invention, supports a conclusion that Appellant's claimed invention lacks written descriptive support. *See, e.g., Capon*, 418 F.3d at 1359 ('It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim.')

Oliver, at 10 (emphasis added).

Similarly, in *Ex parte Landegren*, No. 2021-001167 (PTAB, Nov. 17, 2021), decided after *Juno*, the claims recited a method of selecting a target region of interest (ROI) in a target nucleic acid, comprising a specific oligonucleotide probe capable of hybridizing with itself to form a stem loop structure, and a series of steps involving hybridizing a probe to the target nucleic acid, base extension reactions (e.g., PCR), ligations to circularize the extended probes, and further amplification. The Examiner rejected the claims under §112(a), asserting that the probes comprise multiple sequences that can bind to multiple undisclosed targets, that the ROI can range from 10 to 100,000 nucleotides in length, but the specification only discloses three example target sequences. *Landegren*, at 4-5. In reversing the §112 rejection, the PTAB cited *Capon* and leaned on the knowledge in the art:

> In *view of the state of the art and the knowledge of those working in the areas such as nucleic acid hybridization, ligation, and amplification*, the Examiner has not shown that the description provided by the Specification of the claimed method, and of the probes used in it, would fail to show possession to those of ordinary skill in the art.

Landegren, at 9 (emphasis added).

While this sample size is small, it appears—at least for now—that *Juno* has not had much of an impact at the PTAB.

Enablement: cases applying the routine screening rubric

Enablement cases at the Federal Circuit are also a topic of debate lately. In *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), the claims at issue recited a method of treating hepatitis C virus (HCV) infection with a particular type of nucleoside compound. Idenix argued that the key to its invention and the treatment of HCV infection is the use of "2'-methyl-up" nucleosides. *Idenix*, at, 1154. Gilead argued that Idenix's claim was overbroad, and Idenix's patent specification provided no guidance in determining which of the "billions and billions" of potential 2'-methyl-up nucleosides are effective in treating HCV. *Id.*, at 1157. Idenix's specification provided four examples. *Id.,* at 1161. The Court held that, even though synthesis of the 2'-methyl-up compounds was routine, "[T]he immense breadth of screening required to determine which 2'-methyl-up nucleosides are effective against HCV can only be described as undue experimentation." *Id.*, at 1162. The Court affirmed the district court's judgment that Idenix's claims were invalid for lack of enablement. *Id.*, at 1165.

In February 2021, the Federal Circuit decided *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021).

Amgen's claims recited an antibody that binds at least one or at least two specific amino acid residues in the PCSK9 receptor and blocks binding of PCSK9 to its ligand, LDLR. The Federal Circuit noted that functional claim limitations "*pose high hurdles* in fulfilling the enablement requirement for claims with broad functional language" and "the use of broad functional claim limitations *raises the bar for enablement*." *Amgen*, at 1087 (emphasis added). Similar to *Idenix*, the Federal Circuit in *Amgen* held that the skilled artisan must be able to make and screen every antibody within the genus for the claims to be enabled, explaining that "the scope of the claims encompasses millions of candidates claimed with respect to multiple specific functions, and that it would be necessary to *first generate and then screen each candidate antibody* to determine whether it meets the double-function claim limitations." *Amgen*, at 1088 (emphasis added). The Court affirmed the district court's judgment that Amgen's claims were invalid for lacking enablement. *Id.*

How is the PTAB applying routine screening for enablement?

We found varying views from the PTAB on routine screening and enablement. For example, in *Ex parte Way*, *supra*, the PTAB assessed and weighed each of the *Wands*[7] factors, noting that the specification disclosed routine screening assays that weighed in favor of enablement. *Way*, at 7. Similarly, in *SweeGen*, *supra*, the PTAB again assessed the *Wands* factors to find that the petitioner failed to establish it was more likely than not to prevail on its enablement challenge. There, the PTAB stated that, "although there is some unpredictability in the art, the *testing appears to have been routine* and information known in the art as well as homology modeling could have been used to make the field somewhat more predictable and reduce the amount of experimentation needed." *SweeGen*, at 24 (emphasis added).

However, in *Advanced Accelerator*, *supra*, the PTAB leaned into *Idenix* and *Amgen*, stating that "the sheer number of candidate compositions that must be synthesized and then assayed weighs against enablement. This is especially true in light of the lack of guidance in the specification as to which of these compounds would have such therapeutic activity." *Advanced Accelerator*, at 20. Likewise, in *Syngenta Crop Protection*, *supra*, the PTAB acknowledged that synthesis and screening of compounds was routine, but—relying on *Idenix*—concluded that the *volume* of synthesis and screening weighed against enablement: "[S]imilar to *Idenix*, despite the high level of skill in the art and routine nature of synthesis and screening techniques, the 'immense breadth of screening required to determine which [compounds] are effective [herbicides] can only be described as undue experimentation.'" *Syngenta*, at 40 (quoting *Idenix* at 1162).

Finally, in *Genome & Co. v. University of Chicago*, PGR2019-00002, Paper 40 (PTAB, April 14, 2020), the PTAB found the claims unpatentable for lack of enablement due, in part, to the specification's focus on antibodies. In *Genome*, the claims recited a method of treating cancer that involved administering "an immune checkpoint inhibitor," but did not recite any specific type of checkpoint inhibitor. In finding the claims unpatentable for lacking enablement, the PTAB stated, "While the Specification defines [checkpoint inhibitors] broadly as including a protein or polypeptide that binds an immune checkpoint as well as an interfering nucleic acid molecule, the CPIs listed in the Specification are almost exclusively antibodies." *Genome*, at 15. The PTAB explained, "the Specification gives no guidance as to how to select a CPI that, other than those recited in the Specification, is useful in the practice of the invention." *Id.*, at 28.

Some of these recent PTAB decisions may sound similar to *Idenix* or *Amgen* in that the PTAB considered the breadth of the claimed genus to outweigh the benefits of routine synthesis and screening for enablement. *See e.g., Advanced Accelerator; Syngenta*. Patent applicants and owners, however, need not give up on arguing that routine screening favors enablement, as some panels deciding cases arising from TC1600 still found that routine screening weighed in favor of enablement of a genus claim. *See e.g., Way; SweeGen*.

Conclusion

While recent decisions from the Federal Circuit have arguably increased § 112 scrutiny for patent owners in the chemical and life sciences, the sampling of PTAB cases in TC1600 presented here indicates that perhaps the sky is not falling; at least, not at the PTAB. At least not yet. Many patent applicants and patentees were able to successfully obtain (or defend) genus claims at the PTAB. It remains to be seen whether such claims can withstand scrutiny in litigation, but there is nevertheless value in genus claims even without asserting them in litigation. For example, genus claims can be valuable tools in licensing negotiations, attracting investors, asset sales/acquisitions, or simply serving as public notice to competitors.

1. *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021), *petition for cert. filed*, _____ (U.S. Nov. 22, 2021) (No. 21-757).
2. *Juno Ther., Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021).
3. The Federal Circuit also issued two decisions concerning written description in November 2021: *Indivior UK v. Dr. Reddy's Labs.*, 2020-2073 (Fed. Cir. Nov. 24, 2021) (addressing description of claimed ranges); and *Biogen Int'l v. Mylan Pharms. Inc.*, 2020-1933 (Fed. Cir. Nov. 30, 2021) (addressing description of a "therapeutically effective amount").
4. *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021), rehearing denied, 850 F.App'x 794, 796 (Fed. Cir. 2021).
5. Discussed further below, the PTAB in Way also reversed the enablement rejection.
6. According to a Joint Stipulation from the parties, the Patent Owner's Response is due January 21, 2022.
7. *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

Expert Bad Behavior: The Problem and Potential Solutions

AUTHORS: DANIEL S. BLOCK AND DAVID W. ROADCAP

Introduction

Imagine sitting in a conference room with your carefully crafted set of questions for a deposition, and you are exploring the basis for an opposing expert's opinions. But instead of giving thoughtful answers, the expert simply states "I don't have an opinion on that" on the basis that the material was not explicitly discussed in her declaration. Or maybe the expert simply regurgitates her written testimony or answers a different (unasked) question. Practitioners will likely tell you that such scenarios, and a range of other recalcitrant, evasive, and unreasonably obstructive behavior have recently become too common in USPTO Patent Trial and Appeal Board (PTAB) depositions. Of course, no attorney wants their client's expert to actively help an opposing counsel, who is generally seeking to craft admissions that will undermine the expert's testimony. But there needs to be limits on inappropriate behavior, or at least some consequences for bad behavior. Otherwise, the ability to cross-examine witnesses loses any meaning and becomes a waste of resources, while undermining the effectiveness and integrity of the PTAB process.

Almost every major brief filed in a post-grant proceeding is accompanied by an expert declaration, and these declarations support the technical and factual arguments made in the brief. Moreover, expert analysis and testimony are more often than not critical evidence that the PTAB will use in reaching a decision regarding the patentability of a set of claims. Therefore, effective examination and rebuttal of expert testimony can be key to crafting responsive pleadings and eventual success in defending or challenging patents before the PTAB. Conversely, parties have strong incentives to have their experts defend their testimony as aggressively as possible.

As discussed below, parties currently have limited recourse to address bad behavior by witnesses. The Board pays little attention to witness behavior, essentially never strikes or excludes testimony, and rarely mentions expert behavior as a factor in diminishing witness credibility. We suggest two practical solutions to curb expert bad behavior: more regular live testimony of witnesses in front of PTAB judges, and the normalization of more severe consequences for unreasonable behavior during deposition.

There is very little cost associated with a witness's bad behavior

One potential avenue of recourse for parties encountering expert bad behavior is a motion to strike the witness's direct testimony. However, there is little reason to believe that such an approach will be fruitful without change.[1] Our searching[2] identified 164 motions to strike that related to expert testimony for which the Board issued a decision. Of those motions, the Board granted or partially granted only 21. And within the group of 21, there were no decisions in which the Board struck expert testimony based on behavior during deposition. Rather, almost all of the successful motions to strike related to expert testimony as improper sur-reply evidence, or declarants that were not made available for deposition. Instead of being receptive to motions to strike expert testimony, the Board generally maintains that witness behavior is part of a credibility determination that goes to the weight, rather than the admissibility of the declaration testimony.[3]

Given that the Board often indicates that it prefers to analyze the weight to be given to testimony, we have looked for evidence that witnesses' bad behavior during deposition has resulted in the witness losing credibility with the Board and harming the case of the proponent of the testimony. However, there is little evidence that this occurs, as the Board rarely mentions witnesses' demeanor as a factor in reaching a final decision. Even when the Board does address demeanor, the most common result is that the Board avoids the issue. For example, in *Intel Corp. v. Pact XPP Schweiz AG*, the Board dismissed assertions that an expert was "improperly recalcitrant" and "demonstrated a lack of knowledge of the subject matter" by noting that the testimony in question was not related "to the portions of [testimony] . . . on which we rely for our decision."[4] Similarly, when faced with assertions that a witness was "nonresponsive" and gave "evasive answers at deposition [that] undermine his credibility," the Board responded only by asserting that it is capable of "assign[ing] the appropriate weight to be accorded evidence."[5]

An alternative avenue of recourse is for parties to contact the Board directly during the course of the deposition and ask for relief, *e.g.*, in the form of witness instructions or additional deposition time. While tracking the frequency of such calls is difficult because they often are not reflected in the written record of a case, we performed searches for documents that reference conference or telephone calls relating to experts[6]. As shown in the chart on pg. 31, such calls were common during the first few years of PTAB practice, but the number has drastically reduced in recent years. We posit that this difference is at least in part due to a lack of successful results from those calls.

Year	Documents Referencing Expert-Related Calls
2012	1
2013	127
2014	257
2015	87
2016	98
2017	78
2018	91
2019	12
2020	13
2021	2

What can be done to curb bad behavior?

In view of the limited recourses for witness bad behavior, there is a need for new or improved mechanisms to deter such behavior. We suggest that there are already at least two mechanisms in place, both of which could serve that purpose if appropriately strengthened by the PTAB and used more often by PTAB practitioners.

First, we recommend facilitating more frequent live testimony of witnesses in front of PTAB judges. As noted by the PTAB's Trial Practice Guide, "[c]ross-examination may be ordered to take place in the presence of an administrative patent judge, which may occur at the deposition or oral argument."[7] The Board recognizes that such live testimony can be useful when "the Board considers the demeanor of a witness critical to assessing credibility."[8] Such live testimony could be a solution to bad witness behavior because it will provide judges with a more complete view of witness demeanor than snippets of testimony provided in briefs. Moreover, witnesses would be motivated to at least appear to be reasonable and honest in front of the case's decision-makers. And witnesses may be less likely to behave badly in a deposition if they know such testimony could be used for impeachment purposes during live cross-examination.

However, for live testimony to have any appreciable impact on post-grant proceedings, it must become much more commonly used. As noted in the Board's precedential *K-40 Electronics* decision, the Board allows such live testimony only "under very limited circumstances."[9] That case noted that two factors that would favor live testimony are whether the witness's testimony "may be case dispositive" and whether the witness is a fact witness.[10] Live expert testimony has been discouraged because "the credibility of experts often turns less on demeanor and more on the plausibility of their theories."[11] In view of this limiting standard, live testimony has been requested in only 20 different cases, and granted in only three, during the lifetime of post-grant proceedings.[12] Therefore, establishing a more plausible and regular path to having live testimony is necessary for it to serve the purpose of deterring bad behavior. One plausible path is to allow for a limited time frame in which parties may question witnesses on pre-selected issues that are "case dispositive" as part of the oral arguments in a case. This would allow for judges to observe demeanor first-hand. With this in mind, it is also incumbent on PTAB practitioners to aggressively request live testimony when inappropriate and overly evasive expert behavior occurs.

Second, the PTAB should normalize striking or expunging of testimony in extreme cases of bad behavior, or perhaps more regularly provide commentary indicating when witness testimony is given less weight in view of unreasonable behavior during deposition. It is understandable that the PTAB is hesitant to strike expert testimony in view of the extreme prejudice to parties if central evidence supporting their case is struck or expunged. But exemplary cases demonstrating that there is a line beyond which behavior is not tolerated could prove a powerful deterrent to at least the most extreme behaviors. Again, it is incumbent upon PTAB practitioners to bring this type of bad behavior to the PTAB's attention, so the PTAB can better appreciate the extent of the issue.

Implementing either of these solutions could provide a strong incentive for witnesses to behave in a more reasonable and honest manner during deposition, further strengthening the effectiveness and integrity of the PTAB process.

1. Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, pp. 80 (noting that striking an "entirety or a portion of a party's brief is an exceptional remedy").
2. We used DocketNavigator.com to identify motions to strike.
3. *See, e.g., 10X Genomics, Inc. v. The University of Chicago*, IPR2015-01157, Paper 30, p. 2 (P.T.A.B. May 26, 2016) ("The panel noted that any nonresponsiveness of a witness to questioning during cross-examination would go to the weight given to that witness's direct testimony, but that a motion to strike the testimony altogether was not warranted).
4. IPR2020-00540, Paper 30, p. 11 (P.T.A.B. Sept. 8, 2021).
5. *Intel Corp. v. Pact XPP Schweiz AG*, IPR2020-00542, Paper 31, pp. 19, 28-29 (P.T.A.B. Sept. 7, 2021).
6. There are a variety of reasons for which a Board call may reference experts, so this data is not entirely reflective of just calls related to experts' bad behavior. Nevertheless, the trend is clear—there have been a diminishing number of Board calls about experts.
7. Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019, pp. 31-32.
8. *Id.* at 31-32; *see also K-40 Electronics, LLC v. Escort Inc.*, IPR2013-00203, Paper 34, p. 2 (P.T.A.B. May 21, 2014) (precedential).
9. *K-40 Electronics, LLC*, IPR2013-00203, Paper 34, p. 2.
10. *Id.* at 2-3.
11. *Id.* at 2-3.
12. Live testimony has been allowed in IPR2013-00203 (Paper 34), IPR2018-01524 (Paper 40), and IPR2015-00977 (Paper 32).

In reference to the firm's PTAB expertise, a peer says:

"Continues to excel in inter partes review and other USPTO proceedings, and represents a fine choice of counsel for startups and emerging companies."

— Chambers & Partners (2020)

IPR Estoppels: A Power Imbalance for Plaintiffs and Defendants

BY: PAIGE E. CLOUD AND JONATHAN TUMINARO, PH.D.

Introduction

Inter partes review (IPR) proceedings raise complex estoppel issues that courts are grappling with and patent litigants must consider. Because patent challengers can assert invalidity in three different tribunals (the district courts, the United States International Trade Commission (ITC), and the Patent Trial and Appeals Board (PTAB)), estoppels and their impact have taken on an increasingly important role in patent litigation. Congress created IPR-specific estoppel under 35 U.S.C. § 315(e) to protect *patent holders* from re-litigating the same issues in multiple forums. Congress, however, did not grant *patent challengers* the same statutory protections, forcing patent challengers to rely on common-law doctrines, such as collateral estoppel, to prevent re-litigation of the same issues in subsequent proceedings. But 315(e) estoppel and collateral estoppel provide different protections at different times leading to somewhat counterintuitive results that parties must factor into their litigation strategies.

Background on Collateral Estoppel and 315(e) Estoppel

Despite similar names and features, collateral estoppel and 315(e) estoppel are not the same. Collateral estoppel stems from common law and the constitution.[1] Collateral estoppel is said to be "demanded by the very object for which civil courts have been established" because "the aid of judicial tribunals would not be invoked for the vindication of rights of person and property if, as between parties and their privies, conclusiveness did not attend the judgements of such tribunals in respect of all matters properly put in issue, and actually determined by them."[2] In other words, collateral estoppel was created to promote finality in litigation by barring a party from bringing the same claims again and again.

Under Federal Circuit law, collateral estoppel applies in patent cases when the following factors are met: (1) the party against whom collateral estoppel is asserted had a full and fair opportunity to litigate the issues in the prior proceeding; (2) the issue was actually litigated; (3) the controlling facts and applicable legal rules were the same in both actions; (4) the issue in the prior litigation was a critical and necessary part of the prior determination; and (5) the issue in the prior proceeding was actually decided.[3] And, while mutuality of parties was initially required, courts have moved away from that constraint.[4] Collateral estoppel can arise from various proceedings, such as district-court litigations or *inter partes* proceedings in front of the PTAB. This article, however, is limited to collateral estoppel that arises from an IPR decision.

While collateral estoppel stems from the common law, 315(e) estoppel is purely statutory and gets its name from the section of the US code in which it is codified.[5] Estoppel under § 315(e) applies on a claim-by-claim basis and bars (1) an IPR petitioner from (2) asserting invalidity of a patent claim on (3) "any ground that the petitioner raised or reasonably could have raised during that inter partes review."[6] 315(e) estoppel applies to subsequent proceedings in front of the PTAB, the ITC, or district courts.[7] This statutory estoppel serves many of the same functions as collateral estoppel, such as saving judicial resources and establishing finality, but it also serves a patent-specific function: to prevent harassment of patent owners. With the creation of the PTAB and the ITC, patent challengers now have three different arenas in which they can argue invalidity. 315(e) estoppel ensures that patent challengers have only one bite at the apple and cannot use the different forums to lodge multiple invalidity attacks against a single patent owner. And, importantly, 315(e) estoppel applies win or lose. Even after a victory, the IPR petitioner is unable to make the same arguments in a later proceeding.

Comparing the Estoppels

While the two estoppel provisions serve similar functions, there are several differences between them. These differences can create a disparity of power between plaintiffs and defendants in patent litigation. And, as discussed below, these differences can lead to an air of uncertainty to both parties after an IPR proceeding.

A. When Does Estoppel Attach?

A significant distinction between collateral estoppel and 315(e) estoppel is at what point the estoppel attaches. Collateral estoppel applies when the parties have "been afforded the opportunity to exhaust [their] 'day in court.'"[8] Under Federal Circuit case law, collateral estoppel will not apply to PTAB decisions until the PTAB's final written decision is affirmed on direct appeal by the Federal Circuit.[9] In contrast, 315(e) estoppel attaches once there is a final written decision by the PTAB[10]—months or sometimes years before collateral estoppel might apply. Indeed, 315(e) applies even as the PTAB decision is being appealed.[11]

Because collateral estoppel and 315(e) estoppel attach at different times, it can lead to a situation where *a plaintiff* is permitted to assert infringement of a claim previously found unpatentable by the PTAB, but *the*

defendant is not permitted to assert invalidity of that very same claim. This happened in *TRUSTID v. Next Caller*.[12] There, the PTAB issued a final written decision holding certain patent claims unpatentable. In a parallel district-court action, the court held that the PTAB's final written decision triggered 315(e) estoppel to preclude the defendant from asserting that those patent claims were invalid at the upcoming trial.[13] The district court reasoned, however, that collateral estoppel did not preclude the plaintiff from asserting infringement of those "unpatentable" claims at the trial because the PTAB's final written decision was still pending appeal and, under Federal Circuit precedent, collateral estoppel would not attach until all appeal rights had been exhausted.[14] While seemingly counterintuitive, this result is what the law demands.[15] In short, collateral estoppel will preclude a patent owner from asserting infringement ***only after*** a final written decision has been affirmed on appeal; whereas 315(e) estoppel will preclude a defendant from asserting invalidity ***as soon as*** the final written decision issues.

Despite 315(e) estoppel arising sooner, it comes with some uncertainty. When the Federal Circuit vacates or remands a PTAB decision, the final written decision no longer stands—and neither does 315(e) estoppel.[16] In about 20% of PTAB appeals, the Federal Circuit vacates and remands some portion of the PTAB's decision.[17] Thus, depending on the claims at issue, 315(e) may disappear 20% of the time (although, it will almost inevitably return).

Because there is a nearly 1-in-5 chance that a PTAB final written decision will be vacated or remanded, parties are apt to be wary when the PTAB's decision goes up for review by the Federal Circuit. And district courts have struggled with what to do with 315(e) estoppel when the Federal Circuit vacates a final written decision. For instance, the Eastern District of Texas took on this issue when the Federal Circuit reversed and remanded two patent claims the PTAB found valid in an earlier IPR proceeding while the same parties were litigating in the district court.[18] There, the court determined that the plaintiff was no longer estopped with respect to the two claims because the final written decision was vacated by the Federal Circuit.[19] The court grappled with the idea that a final written decision was "inevitable and imminent," but noted that "it is not for the Court to direct the parties how to allocate their resources in this action."[20] The case emphasizes the point that, while 315(e) estoppel arises quickly, parties relying on it might later find themselves on a rollercoaster of estoppel: one moment it applies, and the next it's gone only to return once more.

B. What Issues Are Estopped?

At first blush, the scope of 315(e) estoppel may seem broader than collateral estoppel: collateral estoppel requires the "issue being litigated" to be exactly the same as the issue in the prior litigation; whereas 315(e) estoppel applies to invalidity arguments that were raised or reasonably could have been raised in an IPR proceeding. Interestingly, however, a number of district courts contemplating collateral estoppel have defined "issue" to mean invalidity as a whole. In other words, the question asked is whether the defendants previously asserted any type of *invalidity* argument rather than if the defendants have asserted a specific ground of invalidity, such as an invalidity argument based on a specific set of prior-art references.[21] But other courts, like Delaware, understand "issue" to apply to each ground of invalidity rather than invalidity itself.[22] This split in ideology means that the breadth of collateral estoppel rests entirely on the jurisdiction in which the subsequent proceeding resides.

In contrast, courts almost uniformly agree that 315(e)'s estoppel "reasonably could have raised" standard applies to any reference that the IPR petitioner actually knew of or that "a skilled searcher conducting a diligent search reasonably could have been expected to discover."[23] Thus, some district court jurisdictions might entirely bar a party from asserting invalidity arguments under collateral estoppel even though it is permissible through 315(e).[24]

So if a patent owner has the option to assert either collateral estoppel or 315(e) estoppel, which estoppel is the best choice? The answer may depend on the jurisdiction. In the "broad collateral estoppel" jurisdictions where courts apply collateral estoppel broadly to bar a defendant from arguing *any type of invalidity*, a patent owner could argue that collateral estoppel precludes all invalidity arguments, rather than 315(e) estoppel, which would preclude only those patents and printed publications that "reasonably could have been raised" in the PTAB.[25] In contrast, in the "narrow collateral estoppel" jurisdictions (like Delaware), a patent owner would prefer 315(e)'s "reasonably could have raised" standard, which is likely to preclude more prior-art references than collateral estoppel. Thus, jurisdiction may dictate which estoppel is best for patent holders after a final written decision is affirmed.

C. Who Can Assert the Estoppel?

Collateral estoppel and 315(e) estoppel apply to different parties.

Collateral estoppel can be asserted by any party involved in a prior proceeding to invalidate a patent (e.g., IPR, reexamination, ITC validity determination). And collateral estoppel can be used by a defendant who was not a party to the previous attempt to invalidate the patent. For instance, in cases where the patent was previously invalidated during an IPR, a new defendant can estop the patent holder from asserting that same patent against it using collateral estoppel.[26]

In contrast, the preclusive effects of 315(e) estoppel apply only to an IPR petitioner who was a real party-in-interest to an IPR petition receiving a final written

decision against the patent in question.[27] Thus, only a patent holder—or their subsequent assignees—can assert 315(e) estoppel to preclude a previous real party-in-interest to an IPR petition from seeking to invalidate a patent in a later proceeding.

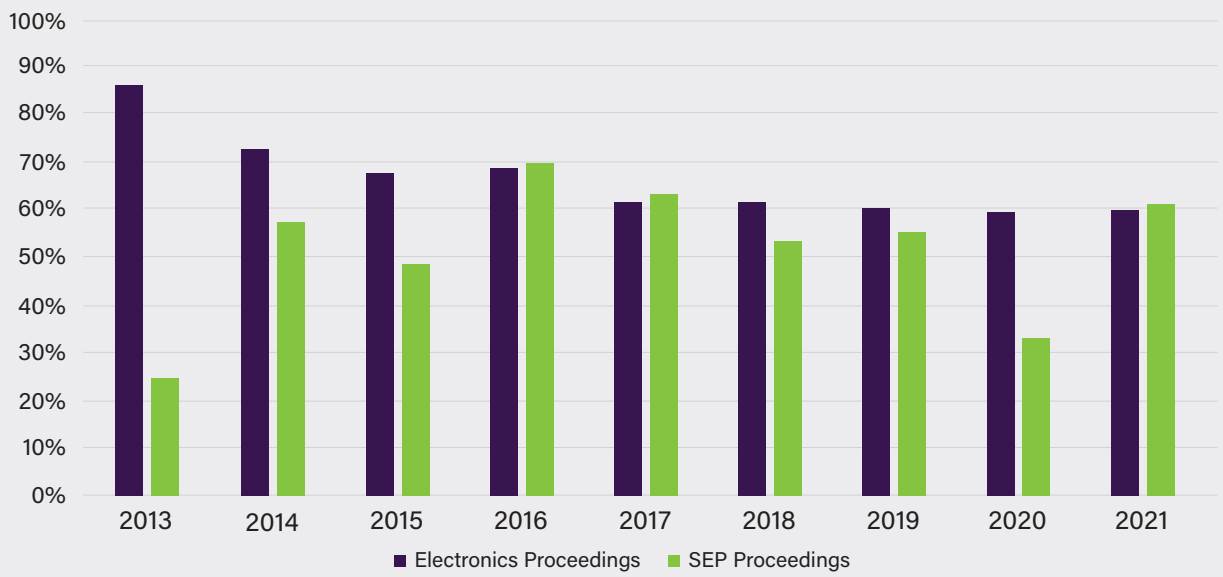
Looking Towards the Future

The dynamic between collateral estoppel and 315(e) estoppel leads to a lot of questions and future developments may have some answers. First, it will be interesting to see whether courts continue to allow plaintiffs to assert patent claims the PTAB previously found invalid while precluding defendants from asserting invalidity defenses that could have been raised in a prior IPR. This concept seems illogical—but is entirely supported by case law. Likewise, litigation strategies may change if certain jurisdictions continue to view invalidity as a whole to be the "identical issue" for purposes of collateral estoppel. Even if those jurisdictions narrow the scope to only preclude patents or printed publications asserted under §§ 102 and 103, the jurisdictions could still completely bar the arguments under collateral estoppel even if they would be allowed under § 315(e). Finally, how courts handle the issue of judicial resources when it comes to final written decisions that have been vacated will likewise affect the parties. Allowing litigation to go forth on issues in which a final written decision and estoppel is imminent seems to disregard the purpose of estoppel in the first place. But the statute is clear on what triggers 315(e) estoppel: the PTAB's final written decision. These issues and more will be telling as courts continue to determine estoppel issues and how to apply them.

---

1. *San Remo Hotel, L.P. v. City and County of San Francisco, Cal.*, 545 U.S. 323, 336 (2005).
2. *Southern Pacific R. Co. v. United States*, 168 U.S. 1, 49 (1897).
3. *See Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1537 (Fed. Cir. 1995).
4. *See Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322, 326 (1979).
5. *See* 35 U.S.C. § 315(e).
6. *Id.*
7. *Id.*
8. *U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.*, 645 Fed. Appx. 1026, 1030 (Fed. Cir. 2016).
9. *See Canfield Scientific, Inc. v. Drugge, et. al.*, No. 16-cv-04636, 2018 WL 2973404 (D.N.J. June 13, 2018).; *see also Pers. Audio, LLC. v. CBS Corp.*, 946 F.3d 1348, 1354 (Fed. Cir. 2020) ("[W]e held that district court actions had to terminate when a [PTAB] unpatentability ruling as to the relevant patent claims was affirmed on appeal."). Federal Circuit patent cases remain largely undisturbed by the Supreme Court. In fact, the Supreme Court typically only hears 1-2 patent cases a year. *See* Lisa Larrimore Ouellette, Michael Risch, and Camilla Hrdy, *Supreme Court Patent Cases*, Written Description Blog, https://writtendescription.blogspot.com/p/patents-scotus.html (last visited Dec. 5, 2021) (listing patent cases decided by the Supreme Court). As a result, collateral estoppel will largely remain untouched.
10. 35 U.S.C. § 315(e).
11. *See SiOnyx, LLC. v. Hamamatsu Photonics K.K.*, No. 15-13488-FDS, 2018 WL 4177941, at *18 (D. Mass. Aug. 30, 2018).
12. *See TRUSTID, Inc. v. Next Caller Inc.*, No. 18-cv-172 , 2021 WL 3015280, at *3-*4 (D. Del. July 6, 2021).
13. *See id.*
14. *See id.*
15. *See id.*
16. *See General Access Sols., Ltd. v. Spring Spectrum, et. al.*, No. 20-cv-00007, 2020 WL 12572917, at *2-*3 (E.D. Tex. Dec. 1, 2020).
17. Kerry S. Taylor and Clayton R. Henson, *IPR Appeals: Outcomes in Fed. Circ. Remands to PTAB*, LAW360 (Feb. 7, 2017), https://www.law360.com/articles/884927/ipr-appeals-outcomes-in-fed-circ-remands-to-ptab.
18. *General Access*, 2020 WL 12572917, at *2-*3.
19. *Id.*
20. *Id.*
21. *See XpertUniverse, Inc. v. Cisco Sys., Inc.*, No. 17-cv-03848, 2018 WL 2585436, at *3-*4 (N.D. Cal. 2018); *Rudolph Techs., Inc. v. Camtek Ltd.*, No. 17-cv-1734, 2016 WL 8668504, at *4-*6 (D. Minn. Aug. 8, 2016). *Crossroads Sys. (Texas), Inc. v. Dot Hill Sys. Corp.*, No. 03-ca-754, 2006 WL 1544621, at *5 (W.D. Tex. 2006).
22. *See Sprint Commc'ns Co. L.P. v. Charter Commc'ns, Inc.*, No. 17-cv-1734, 2021 WL 982726, at *5-*6 (D. Del. March 16, 2021).
23. *See Palomar Techs, Inc. v. MRSI Sys., LLC*, 18-cv-10236, 2020 WL 2115625, at *3-*4 (D. Mass May 4, 2020); *Novartis Pharmas. Corp. v. Par Pharma Inc.*, No. 14-cv-1494, 2019 WL 9343055, at *2-*3 (D. Del. Apr. 11, 2019).
24. For example, if the party seeking invalidity finds a new prior art reference after the initiation of an IPR despite previously conducting a diligent search. *See f'real Foods, LLC. v. Hamilton Beach Brands, Inc.*, No. 16-41-CFC, 2019 WL 1558486, at *1-*2 (D. Del. Apr. 10, 2019) (finding that 315(e) estoppel did not apply to prior art that defendants found after the initiation of an IPR despite highly skilled patent searches conducting a diligent search).
25. It's important to note that, given the narrow issues able to be litigated in an IPR, courts that prohibit litigating issues of validity as a whole based on collateral estoppel may not apply the same rules when the prior proceeding is an IPR. *See Zitovault, LLC. v. Int'l Business Machines Corp.*, No. 16-cv-0962, 2018 WL 2971178, at * 2 (N.D. Tex. Apr. 4, 2018) (finding that issue preclusion did not apply because "[d]efendants could not have raised all of the invalidity defenses in the IPR").
26. *See Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 333-34 (1971).
27. *See* 35 U.S.C. § 315(e).

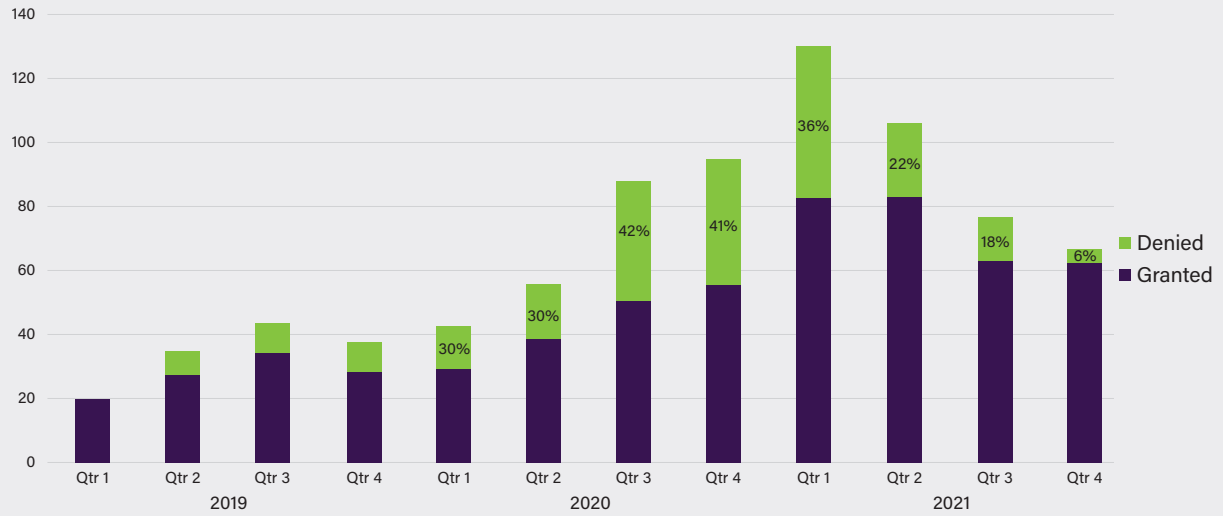
SEPs: Not as Strong as they Seem?



Overall Statistics since the Establishment of the PTAB: 65% for Electronics Proceedings 57% for SEP Proceedings

For more insights, see "Standard Essential Patents at the PTAB: Are SEPs Faring any Differently than non-SEPs?," p. 63

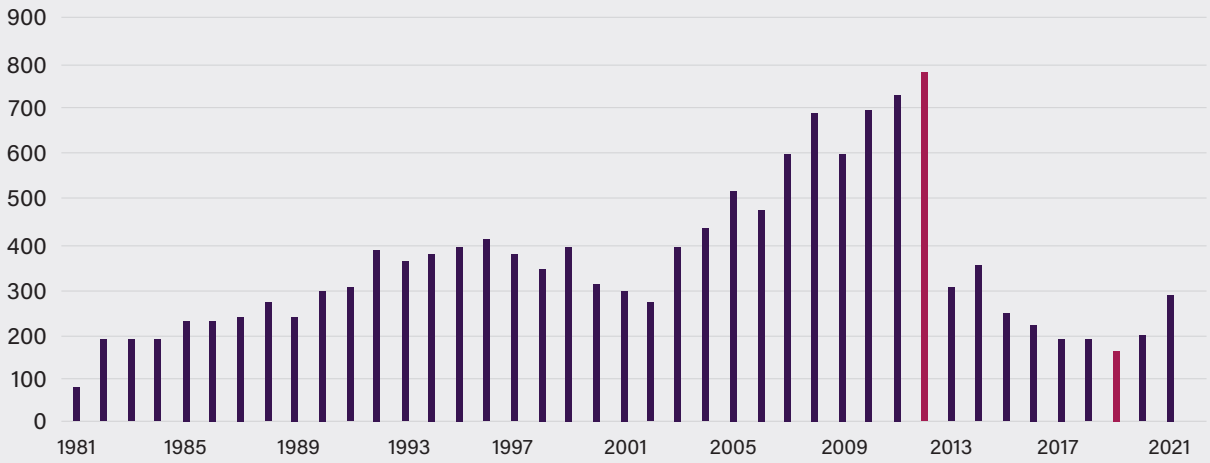
The Rise and Fall of *Fintiv* Denials?



Breaking these cases down by quarter, the PTAB's denial rate peaked in the second half of 2020, which aligns with *Fintiv*'s precedential designation in May 2020. A decline is then seen in each subsequent quarter of 2021.

For more insights, see "*Fintiv* Continues to Take Center Stage," p. 9

Ex Parte Reexam Request Last 41 Years



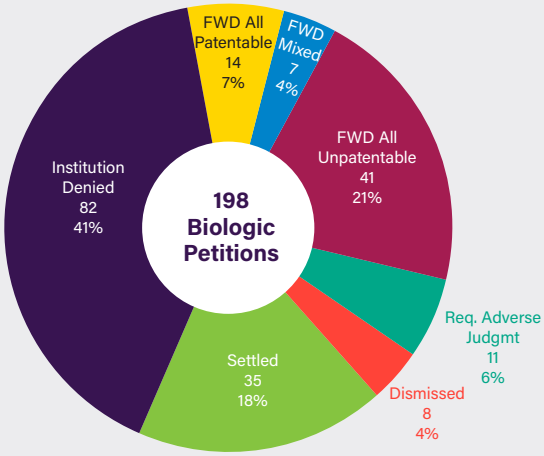
Source: USPTO, except for 2021
By USPTO Fiscal Year

After a peak of nearly 800 filings in 2012 – the year the AIA came into effect – as expected *ex parte* reexamination filings steadily declined until 2019, when they took a somewhat unexpected turn.

For more insights, see "Resurgence and Perils of *Ex Parte* Reexaminations," p. 48

What's so Special about Biologic Patents?

Outcomes of AIA petitions challenging biologic patents
(Sept. 16, 2012 to June 30, 2021)



Source: USPTO

Note: The outcome of decisions on institution responsive to requests for rehearing are included. Joined and pending petitions are excluded.

For more insights, see "Biologics at the PTAB:
Statistics and Insights into Notable Biologics Decisions," p. 53

Evidentiary Issues When Leveraging the Records in Parallel Proceedings Involving the PTAB

BY GRACE TUYIRINGIRE AND PAULINE M. PELLETIER

Parallel proceedings before the USPTO Patent Trial and Appeal Board (PTAB) are a common feature of district court litigation, and it is common for the factual records to overlap between these tribunals. As a result, questions often arise regarding whether the record before the PTAB can serve as evidence in district court, and vice versa. This article examines various ways in which parties have sought, successfully and unsuccessfully, to leverage the record from one tribunal before the other.

Leveraging the record in the context of claim construction.

A. Citing the PTAB record in district court.

In 2021, district courts were faced with deciding whether the record before the PTAB can serve as evidence of claim scope in related district court proceedings. In *Midwest Athletics & Sports Alliance LLC v. Ricoh USA, Inc.*, the district court granted the defendants' motion for summary judgment of non-infringement after finding that the plaintiffs' statements related to claim construction during an *inter partes* review (IPR) amounted to prosecution disclaimer.[1] In defending its patent in an IPR, the plaintiffs contended that a "gloss enhancing process is not a simple fusion step" and "a fusion step and a gloss enhancing step" were two separate processes.[2] The district court found that those statements, made in the IPR, constituted a prosecution disclaimer that precluded construing the term "gloss enhancing process" to encompass "fusing."[3] In this way, the record before the PTAB served as evidence supporting claim construction before the district court.

Similarly, in *CertainTeed Gypsum, Inc. v. Pac. Coast Building Prods., Inc.*, the patentee proposed a construction for a claim term as encompassing a structure formed by combining two traditional gypsum boards.[4] However, in the context of an appeal during original prosecution, the patentee had argued to the PTAB that it was impossible to manufacture the claimed invention by combining two traditional gypsum boards. The patentee secured allowance of the claims on this basis. In litigation, the district court considered the record before the PTAB and found it to be evidence contradicting the patentee's proposed claim construction. In this way, the district court treated the record before the PTAB as evidence relevant to claim construction.

Litigants have also argued that the record before the PTAB shows that their opponent has taken inconsistent positions. In *Garrity Power Services LLC v. Samsung Electronics Co., Ltd.*, the plaintiff argued that the defendant was barred from proposing a construction for a claim term in district court because the defendant did not propose a construction for that claim term in its IPR petition.[5] The district court disagreed, reasoning that the PTAB construes claim terms only where necessary to resolve the disputes in the IPR, in the limited context of reviewing validity. The district court thus did not find the defendant's decision not to propose a construction before the PTAB to preclude the defendant from proposing a construction in district court, where claim construction may be necessary for other reasons (e.g., to resolve questions of infringement).

In *Avanos Med. Sales, LLC v. Medtronic Sofamor Danek USA, Inc.*, the district court rejected the defendant's contention that the patentee took a position in litigation inconsistent with its position before the PTAB.[6] After the challenged claims survived an IPR, the defendant argued that claim construction was needed—despite the parties having previously agreed that the claim term's plain meaning applied—because the patentee's construction of the claim term for purposes of infringement was inconsistent with a position it took before the PTAB. The district court denied the defendant's request for further claim construction, finding that the patentee's positions in the parallel proceedings were not inconsistent. The district court further noted that the defendant had pointed to its own expert's annotated figures as evidence of the patentee's inconsistency, stating that the defendant "cannot attribute its own positions from the IPR to [the patentee] in order to initiate a dispute regarding the claim term."[7] The decision in *Avanos* illustrates the importance of substantiating assertions that an opponent has taken an inconsistent position between tribunals.

Also in *Deere & Co. v. AgCo Corp*, the district court rejected the defendant's allegations that the patentee's arguments advanced during the parallel PTAB proceeding were inconsistent with those advanced before the district court.[8] In *Deere*, the defendant had moved for additional claim construction in the district court, arguing that the patentee's claim constructions during the IPR were "diametrically opposed" to and "fundamentally inconsistent" with positions that the patentee had taken in litigation.[9] After reviewing the papers and exhibits from the IPR, however, the district court found that these allegations were unreasonable, stating that "going forward, [it] will view with skepticism arguments and representations by Defendant."[10] Like *Avanos*, the decision in *Deere* illustrates that district courts will scrutinize the record being cited to them.

B. Citing the district court record at the PTAB.

The record in district court has also been cited to the PTAB, most notably by patentees seeking denial of institution. For example, in *Bumble Trading LLC v. KinectUS LLC*, the PTAB examined whether inconsistent claim-construction arguments by the petitioner favored denial as part of *Fintiv* Factor 6 ("other circumstances").[11] In *Bumble Trading*, the patentee argued that the petitioner had "proposed a claim construction in [the district court] that it does not reiterate in the Petition;" specifically, that certain terms should be construed by the district court while stating in the IPR petition that all terms should receive their plain and ordinary meaning.[12] The PTAB rejected the patent owner's argument, finding that the district court's construction (based on the plain and ordinary meaning) was "consistent with" what the petitioner stated in the IPR petition. The PTAB further observed: "That there was an inconsistency between the Petition and what was argued initially in [the district court] does not persuade us that there is a current substantive disagreement over the meanings of certain terms." The PTAB also noted that the patentee had not identified "any particular interpretation of a specific claim term upon which this Decision turns," further indicating that any dispute was apparently immaterial for purposes of the IPR.[13]

Relatedly, in *Zillow Group, Inc. v. Int'l Bus. Machines Corp.*, the PTAB instituted IPR after rejecting the patentee's arguments that denial was warranted because the petitioner had contended before the district court that the claims were indefinite.[14] The PTAB explained that "Patent Owner cites no authority nor are we aware of any for the proposition that we may not assess the patentability of claims in an *inter partes* review because the Petitioner also challenges those claims as indefinite in District Court."[15] The PTAB nevertheless directed the parties to notify the PTAB should the district court determine that any challenged claims are indefinite. Thus, despite indefiniteness serving as a limit on the PTAB's ability to resolve patentability in an IPR, the panel in *Zillow* declined to extend this to a defendant's *contentions* of indefiniteness.[16]

Challenges to the admissibility of outside records.

In district court, parties have sought to exclude evidence from related PTAB proceedings on various grounds, including that the evidence is inadmissible hearsay or that the evidence lacks probative value. In *Chanbond v. Atlantic Broadband*, the plaintiff sought to admit as evidence a petitioner's expert testimony from a previous IPR.[17] The defendant opposed, arguing that, among other reasons, the expert's testimony was hearsay. The district court agreed, excluding the expert testimony as inadmissible hearsay not subject to the exception for unavailable declarants under Fed. R. Evid. 804(b)(1) because the defendant (via its predecessor-in-interest, the petitioner) did not have a similar motive to develop the expert's testimony in the IPR. The district court noted that the issues in the IPR were limited to invalidity, and did not include infringement. The district court also rejected the plaintiff's argument that the IPR evidence was admissible as among the materials considered by its expert, thus satisfying Fed. R. Evid. 703. The district court found, however, that the plaintiff's expert did not actually rely on the IPR testimony to form his expert opinion. In addition to excluding the IPR testimony itself, the district court excluded any mention of it, citing Fed. R. Evid. 403 and explaining that the IPR testimony "has at most little probative value, which is substantially outweighed by the risk of unfair prejudice, confusion, and waste of time, as the introduction of such testimony would open the door to arguments about [the prior art in the IPR] (which is referred to frequently in the proposed testimony, but which the jury would not otherwise hear about), explanation of what an IPR is, explanation as why [the asserted claim] was not part of the [PTAB's] decision, and possibly the explanation of the relationship between [Defendant and the petitioner]."[18] The district court's decision in *Chanbond* therefore illustrates multiple rationales for excluding IPR evidence, including the potential for jury confusion.

> "Parties have sought to leverage evidence from parallel proceedings at the PTAB and in district courts to support claim construction arguments or to argue that their opponent has taken inconsistent positions. When using this strategy, practitioners should be mindful of potential pitfalls."

Similarly, in *Blackbird Tech LLC v. Feit Elec. Co.*, the defendant moved to exclude the PTAB's decision not to institute an IPR brought by a third party who was not involved in the litigation.[19] The district court agreed, noting there would be no probative value in explaining the IPR process, including the PTAB's framework for deciding whether to institute—in particular for discretionary reasons unrelated to the prior art at issue—and that doing so would waste time and risk confusion and unfair prejudice. Nevertheless, the district court permitted the plaintiff to cross-examine the defendant's expert on statements the expert made in the context of the IPR if the IPR itself was not mentioned. The district court also permitted the defendant to point out that the prior art references in question were not considered by the Patent Office based on the face of the patent, however, the district court did not permit the defendant to mention the IPR itself.

In sum, parties have sought to leverage evidence from a parallel proceeding to support claim construction arguments or argue that their opponent has taken inconsistent positions. In 2021, the district courts and the PTAB alike analyzed these contentions carefully,

scrutinizing the record being cited to them and considering whether it is relevant to the issues each is tasked with resolving. One practical consideration illustrated by many of these decisions is that parties should be mindful not to mischaracterize the record or make tenuous arguments, as this will do more harm than good. Also, parties should be conscious that explaining the IPR process, and the institution calculus in particular, can be an impediment to getting PTAB decisions before a jury.

1. No. 2:19-cv-00514, ECF No. 219 (E.D. Pa. Aug. 23, 2019) (Wolson).
2. *Id.* at 14.
3. *Id.*
4. *CertainTeed Gypsum, Inc. v. Pacific Coast Building Products, Inc.*, No. 5:19-cv-00802, ECF No. 182 (N.D. Cal. Sept. 16, 2021) (Koh).
5. *Garrity Power Services LLC v. Samsung Electronics Co., Ltd.*, No. 2:20-cv-00269, ECF No. 102 (E.D. Tex. Aug. 4, 2021) (Payne).
6. *Avanos Med. Sales, LLC v. Medtronic Sofamor Danek USA, Inc.*, No. 2:19-cv-02754, ECF. No. 271 (W.D. Tenn. Sept. 17, 2021) (McCalla).
7. *Id.* at 5.
8. *Deere & Co. v. AgCo Corp.*, No. 1:18-cv-00827, ECF No. 215 (D. Del. July 27, 2021) (Connolly).
9. *Id.* at 1.
10. *Id.* at 2.
11. *Bumble Trading LLC v. KinectUS LLC*, IPR2021-00765, Paper 13 (Oct. 21, 2021) (Ahmed, joined by Daniels and Engels).
12. *Id.* at 18.
13. *Id.*
14. *Zillow Group, Inc. v. Int'l Bus. Machines Corp.*, IPR2020-01656, Paper 8 (Mar. 15, 2021) (Peslak, joined by Barrett and Cherry).
15. *Id.* at 11.
16. *See Samsung Elecs. Am., Inc. v. Prisua Eng'g Corp.*, 948 F.3d 1342, 1353 (Fed. Cir. 2020) ("[T]he proper course for the Board to follow, if it cannot ascertain the scope of a claim with reasonable certainty for purposes of assessing patentability, is to decline to institute the IPR or, if the indefiniteness issue affects only certain claims, to conclude that it could not reach a decision on the merits with respect to whether petitioner had established the unpatentability of those claims under sections 102 or 103.").
17. *Chanbond v. Atlantic Broadband*, No. 1:15-cv-00842, ECF No. 565 (D. Del. Apr. 19, 2021) (Andrews).
18. *Id.* at 8.
19. Blackbird Tech LLC v. Feit Elec. Co., No. 1:15-cv-00056, ECF No. 196 (D. Del. Dec. 17, 2020) (Andrews).

"The eminent DC boutique is steeped in the art of prosecution, a 'market leader in post-grant proceedings' and a force to be reckoned with in hardcore district court, ITC and Federal Circuit patent litigation."

— Intellectual Asset Management (2020)

Interplay Between PTAB Proceedings and Recovery in District Court

BY JAMIE DOHOPOLSKI AND PAULINE M. PELLETIER

In 2021, district courts were faced with resolving numerous requests by parties seeking attorney fees based on conduct in related USPTO Patent Trial and Appeal Board (PTAB) proceedings. Many of these requests came in the wake of the US Court of Appeals for the Federal Circuit's decision in *Dragon Intellectual Property, LLC v. Dish Network, LLC*, which held that a party's success "in invalidating the asserted claims before the Board" can contribute to whether the case is exceptional for purposes of 35 U.S.C. § 285.[1] District court decisions on these requests suggest that while success in invalidating claims at the PTAB alone may not be enough to demonstrate an exceptional case, the record before the PTAB can justify an award of attorney fees where the record indicates that a party's positions were baseless or unreasonable. Yet even where an exceptional case has been found, district courts in 2021 have been reluctant to award fees and other costs incurred in parallel PTAB proceedings under Section 285. Separately, petitioners who prevail before the PTAB may be able to use those invalidity findings to avoid enhanced damages under 35 U.S.C. § 284. We expect these issues, regarding the interplay between the PTAB and recovery in district court, to further develop in the year ahead.

An adverse decision by the PTAB alone is generally not enough.

Decisions over the last year suggest that exceptional case findings require more than just a loss at the PTAB—whether in the form of a final decision on patentability or an institution decision. For example, in *Genentech, Inc. v. Eli Lilly and Co.*, the district court denied the defendant's motion for an exceptional case finding based on the patentee's request for adverse judgment in a related PTAB proceeding. In deemphasizing the significance of the patentee's request for adverse judgment, the district court reasoned that the presumption of validity had applied in the district court and that, rather than an admission that its litigation positions were baseless, the patentee's decision "tend[ed] to indicate that Plaintiff reevaluated its claims and rightfully moved to dismiss" in light of the reasoning in the PTAB's decision to institute.[2]

Similarly, in denying the defendant's motion for an exceptional case finding in an infringement suit involving Orange Book-listed patents, the district court in *In re Kerydin (Tavaborole) Topical Solution 5% Patent Litigation* considered the similarities and differences between the claims of related patents that had been invalidated before the PTAB.[3] The district court observed that the loss of claims elsewhere in a patent family, and a loss generally, "is not an unusual occurrence—someone loses in every case—and it certainly does not by itself entitle the winner to fees."[4] Thus, *Genentech* and *In re Kerydin* reflect the view the merely losing on the merits in the context of a related *inter partes* review (IPR) does not, in and of itself, make a case exceptional.

Patentees have also argued that a defendant's inability to present invalidity defenses at trial due to IPR estoppel supports an exceptional case finding. Yet in *Ironburg Inventions Ltd., v. Valve Corporation*, the district court denied a plaintiff's motion for attorney fees based on this theory noting that "the IPRs, claim construction, and motion practice" were why no invalidity issues were presented to the jury, the IPRs having "narrowed the matters for the jury's consideration," and those circumstances "do not inure to [Plaintiff's] benefit in its quest for attorney fees."[5]

In *IQASR LLC v. Wendt Corporation*, the district court declined to find a case exceptional and declined to consider the impact of the PTAB's decision with respect to indefiniteness, noting that the PTAB's decision denying institution specifically indicated that it was expressing no opinion on the issue of indefiniteness and should not be interpreted as a finding regarding definiteness.[6]

But a PTAB record can contribute to an exceptional case finding.

Two district court decisions in 2021 found cases to be exceptional based, at least in part, on what happened before the PTAB. In *Princeton Digital Image Corp. v. Ubisoft Entertainment SA*, the district court found a case exceptional and awarded attorney fees to the defendant.[7] The district court's finding was based on the patentee's disavowal of claim scope to save the validity of claims in the related IPR, which had the effect of making its infringement positions "baseless" and "prolong[ing] this litigation unreasonably and caus[ing] [the defendant] to incur needless litigation expenses."[8] The district court thus awarded attorney fees from the time of the district court's claim construction to its grant of summary judgment with respect to noninfringement.

In *Ameranth, Inc. v. Domino's Pizza, Inc.*, numerous asserted claims were invalidated in a covered business method ("CBM") review before the PTAB, in findings that were later affirmed on appeal with further claims found unpatentable by the Federal Circuit.[9] One patent remained, which the district court found invalid on summary judgment for lack of patent-eligible subject

matter. This judgment was also affirmed on appeal. Before the district court, defendants moved for an exceptional case finding and attorney fees. Citing the weakness of the remaining asserted patent in light of the history of related invalidity proceedings involving similar claims, the district court agreed that the case was exceptional "[c]onsidering this pattern of continued bullishness in the face of numerous defeats."[10]

In terms of defeating a motion for attorney fees, plaintiffs have invoked PTAB decisions denying institution as evidence that there was a reasonable basis to assert claims in district court. In *Konami Gaming Inc. v. High 5 Games, LLC*, the defendant succeeded in invalidating means-plus-function claims as indefinite on summary judgment and then moved for an exceptional case finding and attorneys fees.[11] The district court denied the motion, reasoning that "while ultimately flawed" the plaintiff's litigation positions regarding the means-plus-function claims were "not objectively baseless or unreasonable to an outside evaluator with knowledge of patent law," and cited as support that the PTAB had denied defendant's IPR petitions on the merits in this regard.[12]

In the realm of damages, a finding of unpatentability by the PTAB can preclude enhanced damages despite a finding of willful infringement. In *Ironburg Inventions Ltd. v. Valve Corp.*, the jury found willful infringement.[13] The plaintiff moved for enhanced damages. However, the district court denied the request for enhanced damages on the basis that the evidence of willful infringement pertained only to features present in a claim found unpatentable by the PTAB.

Fees incurred before the PTAB have not been awarded.

District courts have also been asked to award attorney fees under Section 285 that were incurred in the context of related PTAB proceedings. In 2021, two district courts declined to do so. In *Dragon Intellectual Property, LLC v. Dish Network L.L.C.*, the district court found that the case was exceptional, but declined to award fees and costs incurred in the context of the related IPRs, explaining that IPRs are not "cases" within the meaning of Section 285.[14] The district court noted, however, that the PTAB has authority to grant costs arising from IPR proceedings, including attorney fees, in certain circumstances.[15] And while sanctions by the PTAB are by no means common, they have been issued, including in the form of an award of "costs and fees."[16]

Similarly, in *Prolitec, Inc. v. ScentAir Technologies, Inc.*, the district court agreed that the case was exceptional and awarded attorney fees to cover certain motions brought in court and other costs, but the district court expressly declined to award costs incurred before the PTAB, including translation services and court reporting expenses. The district court reasoned that "it is not clear that" the relevant statute authorizes the Court to award IPR-related costs, and even if the statute did, the "costs [would be] too attenuated to this case."

In sum, the interplay between PTAB proceedings and recovery in district court remains an evolving area of the law, one that the district courts will continue to grapple with in the years to come. The decisions in 2021 indicate that district courts are likely to consider evidence about what occurred before the PTAB, however, whether the record supports an exceptional case will be a fact-driven question taking into account the totality of the circumstances. We look forward to monitoring trends in this area, and providing updates on significant developments in 2022.

1. "A district court 'in exceptional cases may award reasonable attorney fees to the prevailing party.' 35 U.S.C. § 285." *Dragon Intellectual Property, LLC v. Dish Network, LLC*, 956 F.3d 1358, 1361 (Fed. Cir. 2020).
2. *Genentech, Inc. v. Eli Lilly and Co*, No. 3:18-cv-01518, ECF No. 91, 20 (S.D. Cal., Mar. 23, 2021) (Sammartino).
3. *In re Kerydin (Tavaborole) Topical Solution 5% Patent Litigation*, No. 1:19-md-02884, ECF No. 87 (D. Del. June 23, 2021) (Hall).
4. *Id.* at 6.
5. *Ironburg Inventions Ltd., v. Valve Corp.*, No. 2:17-cv-01182, ECF No. 495, 6-7 (W.D. Wash. Sept. 27, 2021) (Zilly).
6. *IQASR LLC v. Wendt Corp.*, No. 1:16-cv-01782, ECF No. 209 (D. Colo. Aug. 30, 2021) (Krieger).
7. *Princeton Dig. Image Corp. v. Ubisoft Entm't SA*, No. 1:13-cv-00335, ECF No. 400 (D. Del. Sep. 3, 2021) (Stark).
8. *Id.* at 9.
9. *Ameranth, Inc. v. Domino's Pizza, Inc.*, No. 3:12-cv-00733, ECF No. 134 (S.D. Cal. Feb. 5, 2021) (Sabraw).
10. *Id.* at 21.
11. *Konami Gaming Inc. v. High 5 Games, LLC*, No. 2:14-cv-01483, ECF No. 209 (D. Nev. Oct. 25, 2021) (Boulware).
12. *But see Ameranth, Inc. v. Domino's Pizza, Inc.*, No. 3:12-cv-00733, ECF No. 134 (S.D. Cal. Feb. 5, 2021) (disagreeing that denial of institution supported the patent owner's argument that it had a "reasonable basis" to argue its patent claims were valid at the district court).
13. No. 2:17-cv-01182, ECF No. 458 (W.D. Wash. May 26, 2021) (Zilly).
14. No. 1:13-cv-02066, ECF No. 218 (D. Del. Aug. 16, 2021) (Hall).
15. Indeed, the Federal Circuit has observed that "the Board has its own means for regulating litigation misconduct," citing 37 C.F.R. §§ 42.12 (a)(2), (7) and 41.12 (b)(6) as "allow[ing] the Board to impose sanctions including 'attorney fees' against a party for misconduct including '[a]dvancing a misleading or frivolous argument or request for relief' and 'actions that harass or cause unnecessary delay or an unnecessary increase in the cost of the proceeding.'" *Amneal Pharms. LLC v. Almirall, LLC*, 960 F.3d 1368, 1372 n.1 (Fed. Cir. 2020).
16. *Atlanta Gas Light Co. v. Bennet Regulator Guards, Inc.*, IPR2015-00826, Paper 39 (P.T.A.B. Dec. 6, 2016) (awarding costs and fees for failure to timely disclose highly material real party in interest); *see also Apple Inc. v. Voip-Pal.com, Inc.*, 976 F.3d 1316, 1320 (Fed. Cir. 2020) (affirming the PTAB's exercise of discretion to "fashion[] its own sanction" in a case where the P.T.A.B. sanctioned the patentee for improper *ex parte* communications).

A Niche Within a Niche: The PTAB's Evolving Motion to Amend Practice

BY: LESTIN L. KENTON, JR., PRATIBHA KHANDURI, PH.D., AND TIMOTHY L. TANG

Summary

On March 15, 2019, the United States Patent and Trademark Office (USPTO) introduced a new Motion to Amend (MTA) Pilot Program.[1] The Pilot Program gave patent owners an option to (1) receive Preliminary Guidance on the merits of their MTA from the Patent Trial and Appeal Board (PTAB) and (2) submit a revised MTA addressing any issues raised in the Preliminary Guidance. This article explores whether and how the Pilot Program has affected MTA outcomes. Overall, after the introduction of the Pilot Program, MTA grant outcomes appeared to drastically improve for patent owners, especially for Electronics, Mechanical, and Business Method technology groups. Upon closer examination, however, the Pilot Program appears to be solidifying the MTA grant trends that first started in 2017-2018, likely in response to the Federal Circuit's 2017 decision in *Aqua Products, Inc. v. Matal*.[2]

The filing of an MTA, including those invoking the Pilot Program (since 2019), essentially creates a separate proceeding within an America Invents Act (AIA) proceeding. A niche within an already specialized PTAB practice, the MTA practice is highly nuanced and proceeds on a compressed schedule—particularly when invoking the Pilot Program. MTAs can be a powerful tool for patent owners to obtain claims that are "blessed" by the PTAB, which some consider to be "gold-plated" claims. To balance this advantage for patent owners, petitioners have nearly a full arsenal of invalidity tools at their disposal (Sections 101, 102, 103, and 112) to combat an MTA, some of which would not have been otherwise available in the proceeding.[3] Needless to say, the nuances of MTA practice can catch inexperienced or unaware practitioners off-guard, potentially adding substantial cost and altering the risk/reward analysis. Practitioners thus should fully understand MTA practice and trends, as well as the various strategies for submitting or opposing an MTA when developing their positions. This article discusses overall MTA statistics, as well as statistics related to MTAs invoking the Pilot Program. And, in view of these statistics, this article provides practice tips for both patent owners and petitioners dealing with MTAs.

The Statistics: Recent Motion to Amend Decisions

A. Overall MTA Success Rates

To analyze the impact of the Pilot Program, we examined relative success rates[4] for (1) all MTAs (2013-2021), (2) MTAs in the time period prior to the Pilot Program but after the *Aqua Products* decision (2017-2018), and (3) MTAs after the Pilot Program (2019-2021). While the overall number of MTAs increased after the Pilot Program, the Program does not appear to have much impact on the overall success rate compared to the 2017-2018 success rate. These trends are depicted in FIG. 1 (Motions to Amend Decisions – Numbers) and FIG. 2 (Motions to Amend Decisions – Percentage).[5]

Figure 1: Motions to Amend Decisions – Numbers

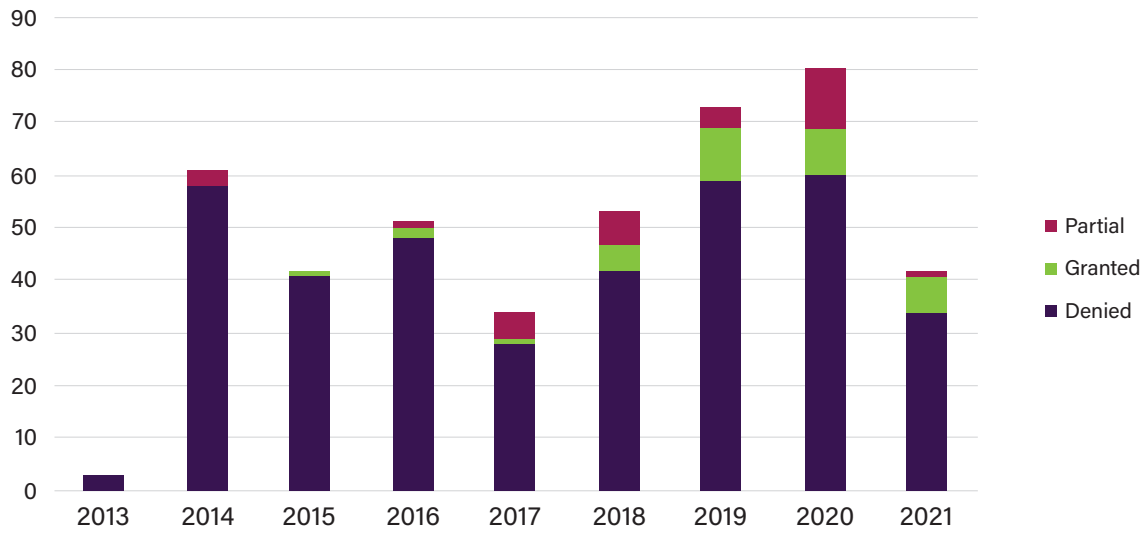


Figure 2: Motions to Amend Decisions – Percentage

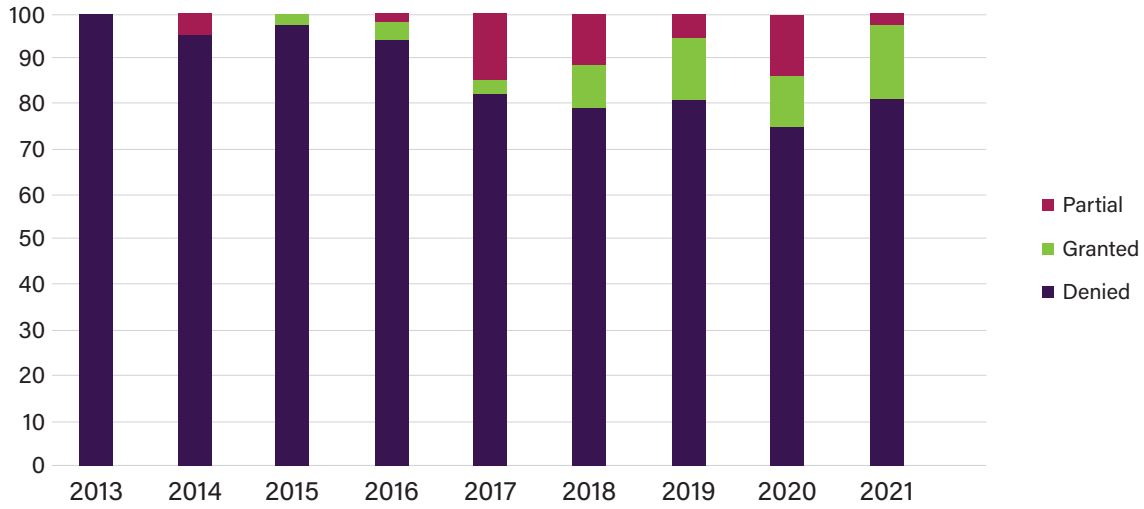


FIG. 1 shows that the number of MTAs decided increased from 53 in 2018 (before the Pilot Program) to 73 in 2019 and 80 in 2020 (after the Pilot Program). This significant increase in the number of MTAs decided in 2019 and 2020 may be a result of the PTAB's signaling a renewed interest in evaluating amended claims in AIA reviews via the Pilot Program. In 2021, however, the number of MTAs decided decreased to 42.

FIG. 2 depicts the same data as FIG. 1 but as normalized percentages. FIG. 2 shows that in 2019-2021, even after the Pilot Program became available, the overall MTA success rate was about 21.5%[6] (19.2% in 2019, 25% in 2020, and 19% in 2021) compared to the overall pre-Pilot Program MTA success rate of 19.5% in 2017-2018 (17.6% in 2017 and 20.8% in 2018). Because these results appear to show that availability of the Pilot Program did not significantly improve patent owners' success rate, we needed to dig deeper to understand whether and how the Pilot Program affected MTA practice. As we suspected, the story becomes more interesting when the success rates are assessed based on technology.

Historically, MTAs have fared worse in Bio/Chem proceedings compared to other technology groups, but this trend seems to have reversed after the PTAB introduced the Pilot Program. In 2013-2018, the PTAB decided 40 Bio/Chem MTAs but granted only three (7.5% success rate). Looking closer at 2017-2018, the PTAB decided 15 Bio/Chem MTAs but granted only one (6.7% success rate). However, the success rate for Bio/Chem MTAs increased to 12% in 2019-2021 when the PTAB decided 25 MTAs and granted three.[7] Thus, this data indicates that the recent Pilot Program may have helped improve the MTA success rate for Bio/Chem patent owners.

For Electronics proceedings, in 2013-2018, the PTAB decided 141 MTAs and granted 14 (9.9% success rate). Looking closer at 2017-2018, the PTAB decided 49 MTAs and granted 11 (22.4% success rate). The success rate for Electronics MTAs remained similar in 2019-2021 when the PTAB decided 104 MTAs and granted 23 (22.1% success rate).[8] Thus, the Pilot Program does not seem to have much impact on Electronics proceedings. Instead, in these proceedings, a more impactful change appears to have occurred in 2017-2018 when the MTA success rate increased dramatically, and the Pilot Program seems to have continued the trend.

Similarly, the trend that started in 2017 for Mechanical/Business Method proceedings continued after the Pilot Program. In 2013-2018, the PTAB decided 62 Mechanical/Business Method MTAs and granted seven (11.3% success rate). In 2017-2018, the PTAB decided 23 Mechanical/Business Method MTAs and granted 5 (21.7% success rate). In 2019-2021, the PTAB decided 66 Mechanical/Business Method MTAs and granted 16 (24.2% success rate).[9] Again, the most impactful change appears to have occurred in 2017-2018, with a slight increase in MTA success rate after the introduction of the Pilot Program.

Thus, Bio/Chem patent owners appear to have benefitted the most from the Pilot Program while the Electronics and Mechanical/Business Method technology spaces largely continued the 2017-2018 trends after the Pilot Program. Overall, the one-two punch of *Aqua Products* and the Pilot Program appears to have increased the success rate of MTAs across all technology groups.

B. MTA Success Rates after Receiving Preliminary Guidance in the Pilot Program

Since its introduction in 2019, patent owners have invoked the Pilot Program and received Preliminary Guidance in 129 proceedings. Of those proceedings, the PTAB has issued final written decisions (FWD) addressing the merits of an MTA in 67 proceedings and has granted 18 MTAs (seven fully and 11 partially).[10] Thus, in 2019-2021, the proceedings receiving Preliminary Guidance and reaching FWD had an overall MTA success rate of 26.9%,

which is better than the overall success rate of 21.5% for all MTAs (with or without Preliminary Guidance) decided in 2019-2021. This indicates that patent owners have benefited from the PTAB's Preliminary Guidance decisions under the Pilot Program.

The benefits of Preliminary Guidance however have not been evenly distributed across the technology groups. Although the Pilot Program seems to have improved the success rate of Bio/Chem MTAs, these MTAs fared no better after receiving Preliminary Guidance: none of the successful 18 MTAs that received Preliminary Guidance were in Bio/Chem technology group. Instead, 13 MTAs were in Electronics while 5 MTAs were in the Mechanical/Business Methods technology groups.

Beyond these statistics, studying the Preliminary Guidance trends based on the issues raised is useful for both patent owners and petitioners in developing best practices. To start, in an MTA, a patent owner must satisfy its burden of showing that the proposed substitute claims meet the statutory and regulatory requirements of 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121.[11] But 55% of Preliminary Guidance decisions (71 out of 129) found that the patent owners failed to show a reasonable likelihood of meeting the statutory and regulatory requirements. Thus, when submitting an MTA, patent owners should pay careful attention to ensure that all statutory and regulatory requirements are met.

Additionally, 90.7% of Preliminary Guidance decisions (117 out of 129) found that petitioners demonstrated a reasonable likelihood that the proposed substitute claims were fully or partially unpatentable. This included the cases where patent owners failed to meet statutory and regulatory requirements and the claims were unpatentable in view of prior art and other statutory grounds. Thus, petitioners continue to successfully demonstrate unpatentability at this stage despite the originally perceived benefit of the Preliminary Guidance in the Pilot Program for the patent owners.

Upon receiving the Preliminary Guidance, a patent owner may file a revised MTA to address the issues that the PTAB identified in the Guidance. For example, the revised MTA may address failures to meet statutory or regulatory requirements or unpatentability grounds raised by petitioners. Patent owners filed revised MTAs in 70.5% of proceedings (91 out of the 129).[12] Out of these 91 proceedings, 56 had FWDs on the merits.[13] Of these 56 proceedings, 11 revised MTAs were fully or partially granted (19.6%). Thus, patent owners receiving negative Preliminary Guidance and submitting a revised MTA still had an overall success rate of about one in five (19.6%).

Although patent owners have about the same probability of success with a revised MTA as the overall MTA success rate (21.5% in 2019-2021 for all MTAs), the overall likelihood of success increased when they succeed at the Preliminary Guidance stage. In the most obvious case, the best result for a patent owner is when (1) it demonstrates the likelihood to meet the statutory and regulatory guidelines and (2) the petitioner does not demonstrate a likelihood of unpatentability at the Preliminary Guidance stage. Three proceedings fit this criteria and all three (100%) resulted in fully granted MTAs at FWD.[14] In contrast, if the Preliminary Guidance indicates that the patent owner has not met its burden of meeting the MTA requirements, the patent owner's success rate plummets to 20% at FWD.[15] This is regardless of whether a petitioner has demonstrated a likelihood of unpatentability at the Preliminary Guidance stage and whether a revised MTA was filed.

Thus, the PTAB's Preliminary Guidance is an important factor for predicting the ultimate success of an MTA at FWD. For patent owners, receiving an indication at the Preliminary Guidance stage that there is a reasonable likelihood that the MTA has met the statutory and regulatory requirements and the petitioner has not demonstrated unpatentability of the proposed substitute claims results in the greatest chance of success. For petitioners, identifying that the patent owner has not met its burden for an MTA or demonstrating unpatentability at least under one of Sections 101, 102, 103, and 112 significantly reduces the patent owner's chances of success even if a revised MTA is filed.

Tips for Patent Owners

In view of these statistics, patent owners should recognize that MTAs are obtainable, with an overall success rate of 21.5%. This success rate increases to 26.9% when patent owners obtain Preliminary Guidance from the PTAB. Measured by success rate alone, patent owners are thus better off requesting Preliminary Guidance. Other factors, such as budget, remaining patent term, and overall strength of the invalidity contentions may also guide a patent owner's MTA strategy.

To maximize success, patent owners should ensure that the MTA satisfies the statutory and regulatory requirements under 35 U.S.C. § 316(d) and 37 C.F.R. § 42.121. As discussed above, the data shows that patent owners have faced difficulties meeting these requirements, with 55% of Preliminary Guidance decisions indicating that the patent owner failed to meet the requirements. Additionally, when filing an MTA, patent owners should ensure that the substitute claims can survive petitioners' potential unpatentability challenges under Sections 101, 102, 103, and 112. Patent owners should anticipate these issues upfront when submitting the substitute claims in a MTA and not wait to address them later in a revised MTA. For example, when crafting substitute claims, patent owners should ensure that the claims are not indefinite and are enabled under Section 112, and meet subject matter eligibility under Section 101.

With respect to the patentability challenges under Sections 102 and 103, patent owners should ensure that the substitute claims would overcome, at least, the art already cited in the proceeding, including the art not

asserted in a ground in the petition. This may include the art cited during prosecution, in the technology background in an expert declaration submitted in the proceeding, or the art cited in a parallel district court litigation. Patent owners should also remember that petitioners can introduce new art in their oppositions, and therefore, patent owners should attempt to anticipate the type of art that may be used and craft claims that would not be rendered unpatentable by the newly introduced art. Understanding the prior art landscape is thus an important consideration when deciding whether to file an MTA.

On the question of whether to pursue an MTA contingent on finding any of the existing claims unpatentable, patent owners have succeeded in both contingent and non-contingent MTAs. For example, out of the seven MTAs that received Preliminary Guidance and were fully granted at FWD in 2019-2021, three were contingent and four were non-contingent.[16] A contingent MTA, however, is likely a better choice in situations where the patent owner prefers the original claims. A contingent MTA may also be appropriate when the patent owner is not restricted by the costs of filing the patent owner's response to the petition in addition to a separate contingent MTA.

On the question of whether a revised MTA is worth pursuing after receiving a negative Preliminary Guidance, patent owners should consider filing a revised MTA. Out of the seven MTA proceedings that received Preliminary Guidance and were fully granted at FWD in 2019-2021, four included revised MTAs.[17] These revised MTAs corrected the deficiencies in meeting the statutory and regulatory requirements of an MTA and addressed art-based unpatentability challenges and indefiniteness and written description issues. Thus, patent owners have succeeded even after receiving a negative Preliminary Guidance and should consider filing a revised MTA.

Tips for Petitioners

Even with *Aqua Products* and the Pilot Program, the overall MTA denial rate is still 75-80%, indicating that petitioners typically have the upper hand in MTA outcomes. But petitioners should not take this advantage for granted.

As much as possible, petitioners should prepare for a potential MTA when preparing the petition. For example, petitioners should try to identify art relevant to all the embodiments described in the specification of the challenged patent in addition to art relevant to the challenged claims. Finding such art when preparing the petition and including this art in a technology background, for example, may be helpful later on when preparing an opposition to the patent owner's MTA in a compressed MTA practice schedule. Because patent owners are not allowed to introduce new matter, if all of the embodiments described in the specification are already addressed in the art identified at the petition stage, petitioners should be able to efficiently generate new prior art grounds using those references.

To maximize success, petitioners may also consider presenting all relevant challenges in their opposition to the MTA and not wait for the patent owner to file a revised MTA after the Preliminary Guidance. This includes attacking the patent owner's failure to meet its statutory and regulatory burdens, as well as raising unpatentability challenges under Sections 101, 102, 103, and 112. Petitioners should also consider unpatentability challenges based on new art.

In 66.7% of the proceedings (four of six) where the petitioner failed to demonstrate a reasonable likelihood of unpatentability at the Preliminary Guidance stage, the PTAB granted the MTA in the FWD.[18] To avoid this scenario and reduce the MTA success rate, petitioners should tailor their oppositions to specifically address the substitute claims and arguments presented by patent owners in the MTAs. When making art-based arguments, the oppositions should explain in detail how the proposed substitute claims are taught by the art and/or why a person of ordinary skill in the art would have been motivated to combine or modify the art with a reasonable expectation of successfully arriving at the substitute claims. Petitioners should not simply rely on the arguments presented in the petition, as the PTAB has ruled against petitioners that failed to fully explain any new positions in their oppositions.[19]

Should the patent owner elect to submit a revised MTA, the petitioner should oppose it with the same thoroughness as its opposition to the MTA. As a reminder, of the 56 proceedings with revised MTAs reaching FWD on the merits, only 11 revised MTAs were fully or partially granted (19.6%). Petitioners should therefore recognize that the odds are still in their favor even if patent owners submit a revised MTA.

In conclusion, the combination of *Aqua Products* and the MTA Pilot Program has given patent owners many tools when pursuing a MTA. The MTA statistics reflect that the Pilot Program has continued a trend of an improved overall MTA success rate that started with *Aqua Products* in 2017. While the statistics are helpful, the petitioners and patent owners should keep in mind that MTA success is very fact specific and they should continue to tailor their arguments and proposed amendments to the facts in the proceeding.

1. The PTAB has extended the MTA Pilot Program to September 16, 2022.
2. *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (holding that the PTAB cannot place the burden of establishing patentability of the substitute claims on the patent owner in IPR proceedings).
3. *See Uniloc 2017 LLC v. Hulu, LLC*, 966 F.3d 1295 (Fed. Cir. 2020) (holding that the PTAB may consider challenges under 35 U.S.C. § 101 to proposed substitute claims in an IPR).
4. Both partially and fully granted MTAs were considered as successes when determining the success rates.
5. FIG. 1 and FIG. 2 represent Final Written Decisions (FWDs) resolving MTAs on the merits.
6. The overall success rate is calculated based on the raw numbers for the total MTAs and fully or partially granted MTA for 2019-2021 and not as average of the success rate for 2019, 2020, and 2021.
7. Overall, out of 65 total Bio/Chem MTAs decided in 2013-2021, six have been granted—a success rate of 9.2%.
8. Out of 245 total Electronics MTAs decided since the introduction of AIA proceedings, 37 have been fully or partially granted—a success rate of 15.1%.
9. Out of 128 total Mechanical/Business Method MTAs decided since the introduction of AIA proceedings, 23 have been fully or partially granted—a success rate of 18.0%.
10. In 2019-2021, the PTAB issued 195 FWDs addressing MTAs. Out of these, the patent owners requested and received Preliminary Guidance in 128 cases, but in many cases the PTAB did not address the merits of the MTA in the FWD. *See, e.g., Chemco Systems, L.P. v. RDP Techs., Inc.*, Case IPR2019-01563, Paper 38, 34-35 (PTAB Mar. 1, 2021) (dismissing contingent MTA because challenged claims were not unpatentable). Only 67 out of the 129 cases receiving Preliminary Guidance have reached a FWD on the merits.
11. The patent owner must show the following to meet the MTA requirements: (1) the amendment proposes a reasonable number of substitute claims; (2) the amendment does not seek to enlarge the scope of the claims of the patent or introduce new subject matter; (3) the amendment responds to a ground of unpatentability involved in the trial; and (4) the original disclosure sets forth written description support for each proposed claim.
12. Of the 117 proceedings where petitioners demonstrated the likelihood that the proposed claims were fully or partially unpatentable at the Preliminary Guidance stage, 88 proceedings had revised MTAs (75%).
13. After receiving the Preliminary Guidance or after a revised MTA, some proceedings were terminated and did not reach a FWD. *See, e.g., Volkswagen Group of America, Inc. v. Michigan Motor Techs. LLC*, Case IPR2020-00226, Paper 32 (Mar. 19, 2021) (Joint Motion to Terminate filed after Patent Owner filed a Revised Motion to Amend).
14. *Smartmatic USA Corp. v. Election Systems & Software, LLC*, Case IPR2019-00527, Paper 32 (PTAB Aug. 5, 2020); *Snap Inc. v. BlackBerry Ltd.*, Case IPR2019-00715, Paper 37 (PTAB Sept. 1, 2020); and *Satco Products, Inc. v. Seoul Semiconductor Co.*, Case IPR2020-00410, Paper 47 (PTAB July 21, 2021).
15. Out of the 35 proceedings reaching FWD after a Preliminary Guidance decision indicating that the patent owner had not shown a reasonable likelihood to meet the statutory and regulatory guidelines, only 7 MTAs were fully or partially granted at FWD: 20%.
16. Contingent MTAs were filed in *Smartmatic USA Corp. v. Election Systems & Software, LLC*, Case IPR2019-00527, Paper 32 (PTAB Aug. 5, 2020); *Metall Zug AG v. Carl Zeiss Meditec AG*, Case IPR2020-00300, Paper 34 (PTAB June 17, 2021); *Satco Products, Inc. v. Seoul Semiconductor Co.*, Case IPR2020-00410, Paper 47 (PTAB July 21, 2021); Non-Contingent MTAs were *Snap Inc. v. BlackBerry Ltd.*, Case IPR2019-00715, Paper 37 (PTAB Sept. 1, 2020); *SZ DJI Technology Co., Ltd. v. Autel Robotics USA LLC*, Case IPR2019-00846, Paper 33 (PTAB Sept. 21, 2020); *AFD Petroleum (Texas) Inc. et al v. Frac Shack Inc.*, Case IPR2019-00995, *NXP USA, Inc. v. Impinj, Inc.*, Case IPR2020-00514, Paper 37 (PTAB Aug. 11, 2021).
17. *SZ DJI Technology Co., Ltd. v. Autel Robotics USA LLC*, Case IPR2019-00846, Paper 17 (May 15, 2020); *AFD Petroleum (Texas) Inc. et al v. Frac Shack Inc.*, IPR2019-00995, Paper 16 (May 13, 2020); *Metall Zug AG v. Carl Zeiss Meditec AG,* Case IPR2020-00300, Paper 22 (Jan. 22, 2021); and *NXP USA, Inc. v. Impinj, Inc.,* Case IPR2020-00514, Paper 23 (Mar. 16, 2021).
18. Granted MTAs in *Smartmatic USA Corp. v. Election Systems & Software, LLC*, Case IPR2019-00527, Paper 32 (PTAB Aug. 5, 2020); *Snap Inc. v. BlackBerry Ltd.*, Case IPR2019-00715, Paper 37 (PTAB Sept. 1, 2020); *AFD Petroleum (Texas) Inc. et al v. Frac Shack Inc.*, Case IPR2019-00995, Paper 32 (PTAB Oct. 15, 2020); and *Satco Products, Inc. v. Seoul Semiconductor Co.*, Case IPR2020-00410, Paper 47 (PTAB July 21, 2021). Denied MTAs in *Free Stream Media Corp. v. Gracenote, Inc.*, Case IPR2020-00219, Paper 36 (PTAB June 15, 2021) and *Red Diamond, Inc. v. Southern Visions, LLP*, Case PGR2019-00045, Paper 38 (PTAB Oct. 13, 2020).
19. *See, e.g., Snap Inc. v. BlackBerry Ltd.*, Case IPR2019-00715, Paper 37, 106-07 (PTAB Sept. 1, 2020) (rejecting the petitioner's motivation to combine arguments for not showing "*why* a person of ordinary skill in the art would have made the asserted combination," stating that the "[p]etitioner provides no explanation of the modification other than [a] conclusory and vague assertion . . .. Accordingly, we are not persuaded that Petitioner has carried its burden. . ."); *see generally id.*, 101-19.

The Resurgence and Perils of *Ex Parte* Reexaminations

AUTHORS: JASON EISENBERG, SAL BEZOS, JAMES HIETALA, AND RANDY MONTGOMERY

Ex parte reexaminations have re-emerged as an increasingly important component of patent litigation and licensing negotiations. With the passage of the America Invents Act ("AIA") and the advent of *inter partes* reviews ("IPRs") and post grant reviews ("PGRs") in 2012, *inter partes* reexamination were discontinued and *ex parte* reexamination fell out of favor. Over the last few years IPR institution rates have declined. *Ex parte* reexamination requests have increased dramatically—often providing a second chance for petitioners who were unsuccessful in IPR proceedings. The esoteric and nuanced reexamination rules and procedures combined with the complex interplay between reexaminations and AIA trials/litigation proceedings raise unique and often times befuddling issues that parties must consider. This article sheds light on these issues, including summarizing the reexamination process and examining estoppel issues associated with establishing a substantial new question ("SNQ") of patentability—the limiting function to allow an *ex parte* reexamination request granted. Lastly, we explore the impact of the recent *Vivint* US Court of Appeals for the Federal Circuit[1] decision that may subject hundreds of *ex parte* reexaminations that relied on art used in failed IPR petitions to termination.

Background

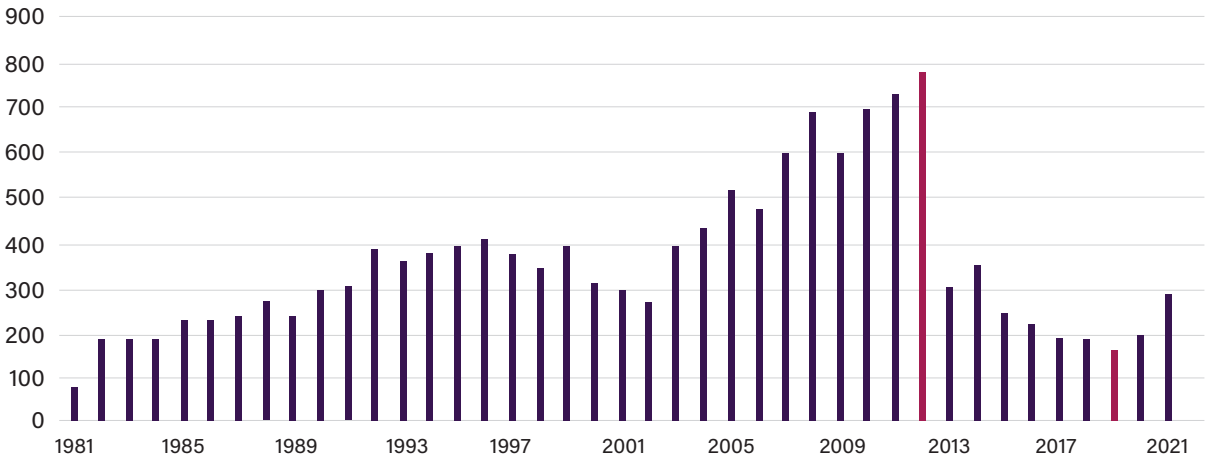
An *ex parte* reexamination is a powerful tool for third-party requesters—often defendants in a patent lawsuit—to attack the validity of patent claims without the estoppel risks associated with IPR and PGR proceedings. Patent Owners, on the other hand, can use *ex parte* reexaminations as a faster alternative to reissue to strengthen their patent claims against invalidity challenges in later or parallel AIA, district court, or US International Trade Commission (ITC) trials. A reexamination request can challenge the validity of one or more claims in the patent on proposed novelty or obviousness grounds based only on patents and other printed publications. Parties can file a reexamination at any time after a patent is granted and up to six years after it expires.

Ex Parte Reexamination Requests, Grant Rates, and Success Rates

After a peak of nearly 800 filings in 2012 — the year the AIA came into effect—as expected *ex parte* reexamination filings steadily declined until 2019, when they took a somewhat unexpected turn. At that time, *ex parte* reexamination numbers began to rise, and continue to rise today. As shown in Figures 1 and 2, reexamination filings have significantly increased, but remain far below pre-AIA levels.

A surge in reexamination requests following a "failed" AIA challenge accounts for a portion of the overall growth of reexamination filings. As shown in Figure 3, about a third of all such do-over reexaminations were filed in the past two years. Nonetheless, these do-over filings do not fully explain the recent increase in popularity of *ex parte* reexaminations.

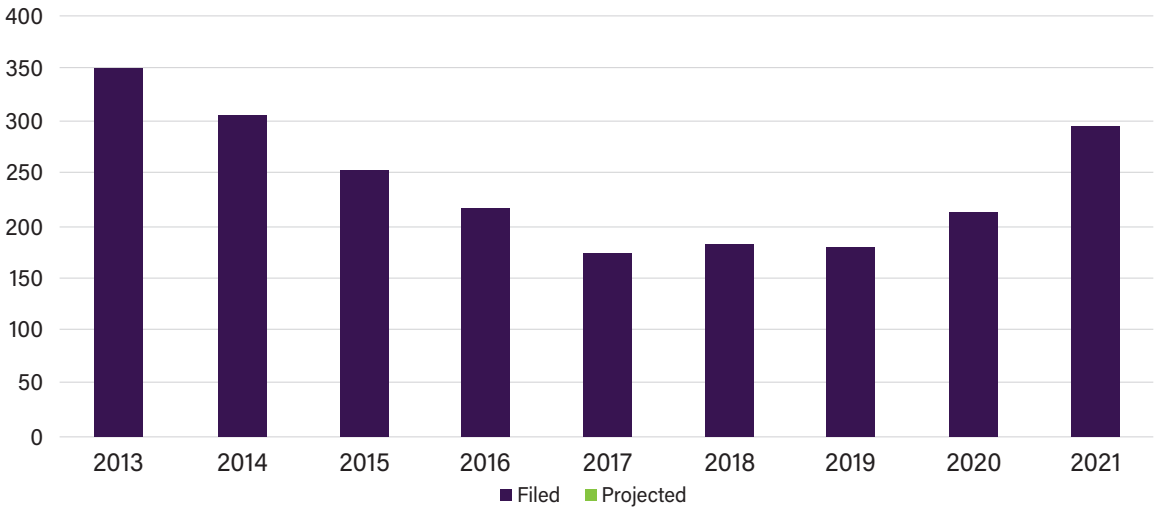
Figure 1: *Ex Parte* Reexam Requests Last 41 Years



Source: USPTO, except for 2021
By USPTO Fiscal Year

After a peak of nearly 800 filings in 2012 – the year the AIA came into effect – as expected *ex parte* reexamination filings steadily declined until 2019, when they took a somewhat unexpected turn.

Figure 2: *Ex Parte* Reexam Requests since AIA



Source: USPTO

Ex parte reexamination filings have significantly increased since AIA, but remain far below pre-AIA levels.

The overall increase in filings since 2019 appears to be attributable to three primary factors: (1) *Fintiv* (35 U.SC. § 314(a)) and 35 U.SC. § 325(d) discretionary denials, (2) IPR/PGR petitioners who failed on the merits, and (3) accused infringers who either sought to avoid PTAB-related estoppels or delayed filing at the PTAB until after a 35 U.SC. § 315 bar but still wanted to seek a PTO invalidity challenge.

Turning to reexamination results, a stark difference exists between the threshold for receiving a grant of a reexamination request and invalidating the claims of a patent. As shown in Table 4 on pg. 50, grant of reexamination requests has hovered around 95%.

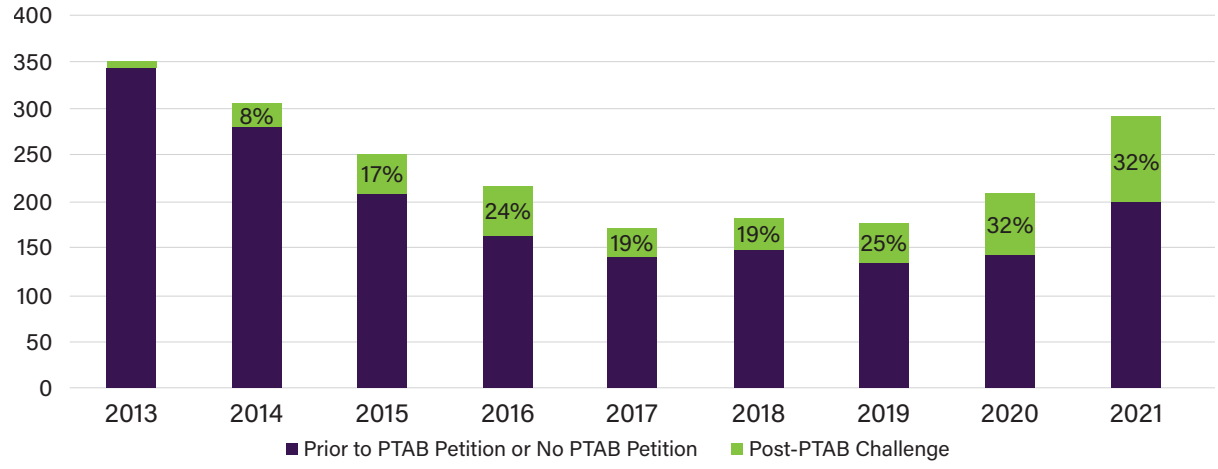
Although grant rates are high, however, invalidating all the claims of a patent is rare, coming in at around 15 % (whether or not a patent owner or a third party files the request), as shown in Tables 5 and 6.

Rather, patent owners typically take advantage of being able to amend—a more difficult task and unpredictable in AIA proceedings—and have obtained favorable outcomes from reexaminations with strategic amendments, sometimes adding additional claims directed to infringing products.

Ex Parte Reexamination Proceeding Complexities

A complex set of rules govern *ex parte* reexaminations. From a requester perspective, a successful reexamination request requires at least three things: excellent prior art supported by detailed claim charts, a strong expert declaration, and a reexamination request that ties everything together. A strong expert declaration must

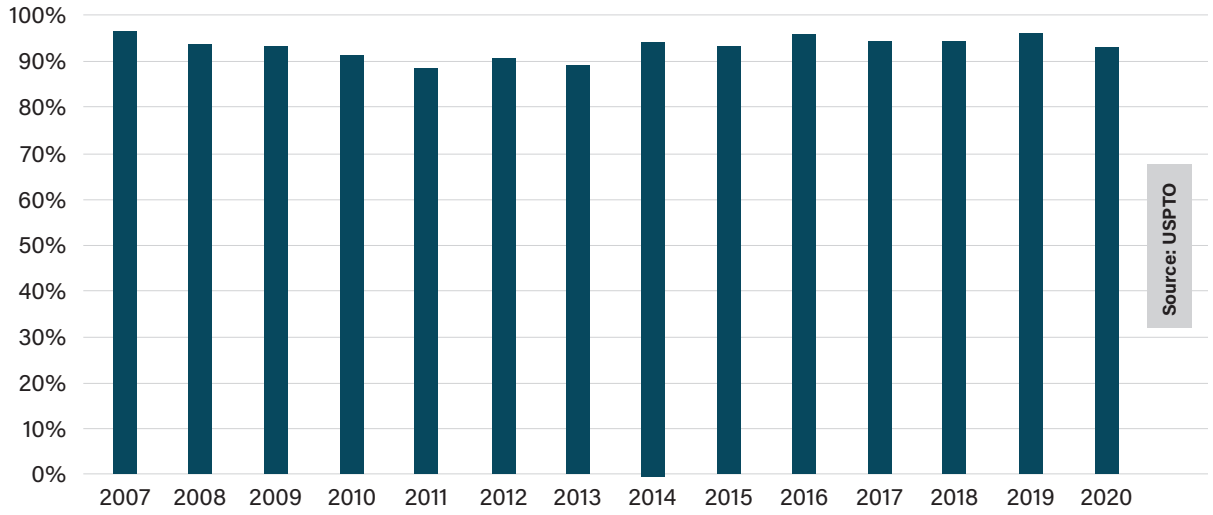
Figure 3: Reexam-Request Patents – PTAB Challenge Status



Note: 2021 Total Projected

About a third of all do-over reexaminations were filed in the most recent two years. Nonetheless, these do-over filings, do not fully explain the recent increase popularity of *ex parte* reexaminations.

Table 4: *Ex Parte* Reexam Grant Rate



A review of reexamination results shows a stark difference exists between the threshold for receiving a grant of a reexamination request and invalidating the claims of a patent.

demonstrate why the claimed invention is in the public domain through a thorough technical tutorial, how and why it is obvious to combine the art, while demonstrating a high expectation of success in achieving the reference combination. Additionally, and often a shortcoming in requests, the request must demonstrate there are no legal, statutory, or rule-based estoppels, bars, or issues that prevent the establishment of an SNQ of patentability.

Like all patent litigation, claim construction considerations are fundamentally important. Anticipation and obviousness positions must be based on solid claim construction positions and consider alternative constructions and all potential amendments for unclaimed subject matter. Importantly, although the broadest reasonable interpretation claim construction standard applies for *most* reexaminations, the ordinary and customary meaning standard applies when a patent expiration occurs during reexamination. These claim construction nuances are another issue that may trip up the unwary.

Finally, despite the somewhat misleading "ex parte" characterization of reexaminations, under the new regime discussed below, requesters need to monitor the reexamination proceeding as a requester may file opposition or rebuttal briefs addressing certain patent owner filings.

From a patent owner perspective, there are three critical reexamination aspects. First, although reexaminations are *ex parte*, they are extremely asymmetric attacks. Second, while reexaminations have a historical reputation of being slow to achieve a final determination, the reality is that the active prosecution aspect of reexaminations happens very quickly and the timeline for prosecution leaves no little flexibility. Third, reexamined patents usually emerge, but with amended claims that are narrower, which trigger intervening rights and potentially reduced damages.

The proceeding takes place *ex parte* with no opportunity for the requester (i.e., patent challenger) to participate after filing the reexamination request with few exceptions. Yet the *ex parte* nature understates the significant advantage the requester has even though its last word typically comes in the reexamination request.

A reexamination request has no page limit and can be hundreds or thousands of pages, while raising dozens of SNQs and proposed rejections. Moreover, the requester has no time limit to file a reexamination request. And after a request is filed and before the CRU decides whether to grant the request, a patent owner cannot respond to a reexamination request, except as explained below. Indeed, the PTO will *discard* any response from the patent owner submitted before the PTO issues an Office action.[2]

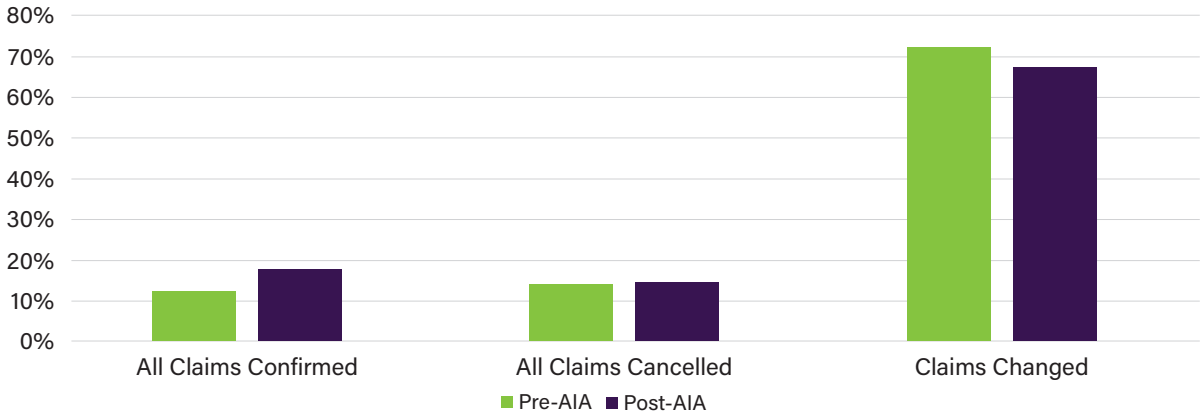
Unlike a reissue proceeding that may not impact the as-issued patent if the proceeding is abandoned, reexamination does not permit the patent owner to stop the reexamination without abandoning some or all claim scope completely.

Reexaminations are very fast and leave virtually no timing flexibility for the patent owner. Only after the PTO orders the reexamination does the patent owner have an opportunity to respond. Even then, best practice suggests that a patent owner does not respond because the patent owner's statement following a reexamination order triggers the opportunity for a reply from the requester. 37 C.F.R. § 1.535. This gives the requester a valuable second opportunity to attack the patent.

Once a reexamination begins, the timeline is aggressive and unforgiving. Typically, within five months of instituting the reexamination, the patent office issues a first Office action on the merits. The Office action can either reject the claims based on the request or reject the claims entirely independent of the request relying

Table 5: *Ex Parte* Reexam Outcomes

Patent Owner Requester



Source: Analysis of USPTO Statistics
Pre-AIA: Compared cumulative outcomes reported in FY12 to FY08
Post-AIA: Compared cumulative outcomes reported in FY20 to FY12

Although grant rates are high, invalidating all the claims of a patent is rare, coming in at around 15 % (whether or not a patent owner or a third party files the request), as shown in Tables 5 and 6.

on completely new art. It is more typical, however, for the Examiner to write an Office action based on the reexamination request. The patent owner has a non-extendable by right two-month period to respond to the first Office action.[3] Here we want to note a very important distinction from original prosecution that can create issues for the uninformed.

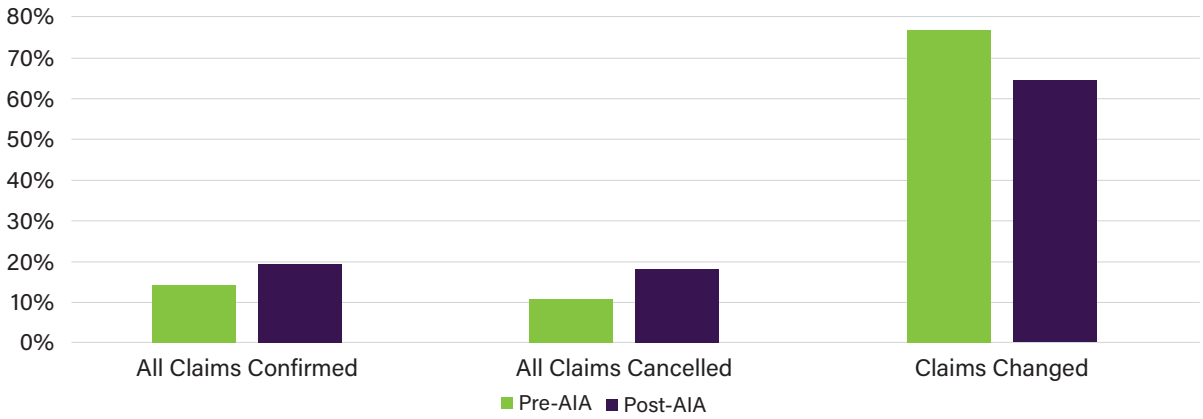
During *ex parte* prosecution, patent owners can retroactively take those extensions by right and without limitation to receive needed flexibility. For example, extensions of time can allow better arguments and perhaps inventors or experts to be marshalled in support of a response. Even so, applicants try to avoid extensions of time because they are costly, both in dollars and in modifications to the patent term.

In reexaminations, though, extensions of time are not retroactive or by right. Indeed, a patent owner must request an extension *before* the initial response due date and must comply with the deadline unless the patent office grants the extension. The language of the rule, Rule 1.550(c) seems reasonable—extensions are available with "sufficient cause" and "not for more than a reasonable time." In practice, while extensions of two-weeks to one month are often granted, a longer extension is essentially impossible absent extenuating circumstances such as acts of nature, incapacity, or death.

A patent owner may make claim amendments and add new, narrower claims in a reexamination proceeding. But these must be made to the non-final Office action and a patent owner cannot wait for a final Office action

Table 6: *Ex Parte* Reexam Outcomes

Third Party Requester



Source: Analysis of USPTO Statistics
Pre-AIA: Compared cumulative outcomes reported in FY12 to FY08
Post-AIA: Compared cumulative outcomes reported in FY20 to FY12

to file amendments as they will not be entered absent a showing of good cause that the evidence or argument was unavailable.[4] Requests for continued examination to enter post final Office action claim amendments in reexamination are not permitted.

The Patent Office tries to conduct reexaminations such that the second Office action is final.[5] Once the action becomes final, the patent owner has limited options. The patent owner has no right to further prosecute. So either an after Final reply taking allowable subject matter or proposing very narrowing amendments for allowability needs to be filed or a notice of appeal. If the Examiners decline to change their mind in response to an after-final submission, the patent owner's only recourse is an appeal to the Board.[6]

Ultimately, based on the statistics shown above, most reexamination patents do eventually issue. But the result is that the claims are almost always amended. This is deeply problematic for patent owners as claims amended in reexamination cannot always be used to recover past damages because of intervening rights, a very complex area of the law.

Ex Parte Reexamination in a New State of Flux: The Impact of *Vivint.*

With the surge in do-over reexamination requests after a failed AIA proceeding, the interpretation of *ex parte* reexamination rules will likely continue to evolve as they adapt to the interplay with IPR proceedings. One such evolving interpretation involves the relationship between establishing an SNQ and 35 U.S.C. § 325(d), which has become increasingly important and relevant. In particular, do the SNQ and § 325(d) tests require different and explicit requester, patent owner, and CRU analysis before or after granting or denying a request?

The SNQ standard has a long history. 35 U.S.C. § 303(a) states in relevant part, "within three months following the filing of a request for reexamination . . . the **Director will** determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request." A prior art patent or printed publication raises an SNQ where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether the claim is patentable.[7] The SNQ standard, for which inquiry is based upon fact analysis and performed on a case-by-case basis, seeks to protect the patentee from harassing invalidity challenges. The SNQ requirement protects patentees from having to respond to, or participate in unjustified reexaminations. Further, the requirement bars reconsideration of any argument already decided by the Office, whether during the original examination or an earlier reexamination.[8]

On the other hand, 35 U.S.C. § 325(d) provides, in pertinent part, that "in determining whether to . . . order a proceeding under . . . chapter 30 [the chapter relating to ex parte reexamination], . . . the **Director may** take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." Congress included this section in the AIA to similarly stop harassment of patent owners.

The relationship of what is an SNQ and what qualifies for denial of grant under § 325(d) is unclear. For example, is the bar to proving an SNQ higher or lower than the bar to denying a request because it includes substantially the same art or arguments? Are the same or different factors considered for each? Does the CRU have to address each separately in an Order, or even address them at all explicitly? Does issuing an Order granting reexamination imply the CRU considered both these provisions and moved forward anyway? The Federal Circuit recently suggested as much in *In re Vivint*, 14 F.4th 1342, 1350 (Fed. Cir. 2021). The issues,[9] while still in a state of flux, addressed in *Vivint* are still evolving and critical to effective reexamination practice.

Thus, best practice requires that a requestor address both why they have established a SNQ and why the Office should not deny the request under § 325(d). The patent owner needs to be ready to respond through petition practice if they believe the requester or CRU is wrong in their analysis.

1. *In re: Vivint*. 14 F.4th 1342 (Fed. Cir. 2021).
2. MPEP § 2249.
3. MPEP § 2266
4. MPEP § 2260.
5. MPEP § 2271.
6. MPEP § 2273.
7. MPEP § 2242.
8. House Report 96-1307, 96th Cong., 2d Sess. (1980).
9. In another case, *Alarm.com Inc. v. Hirshfeld,* Case No. 2021-2102, Alarm.com filed three *ex parte* reexaminations after three failed IPRs. The CRU sua sponte denied them under 35 U.S.C. § 315(e)(1) before a decision on grant was issued. Alarm.com sought review of the Director's vacatur decisions under the Administrative Procedure Act (APA), 5 U.S.C. §§ 706(2)(A), (C). *Alarm.com Inc. v. Hirshfeld,* No. 1:21-cv-170. The district court dismissed Alarm.com's complaint on the ground that APA review of the Director's decision was precluded by the *ex parte* reexamination procedures. Alarm.com appealed to the Federal Circuit. On February 24, 2022, the Federal Circuit reversed the district court's determination that Alarm.com was precluded from challenging the Office's action and remand for further proceedings consistent with their opinion.

Biologics at the PTAB: Statistics and Insights into Notable Biologics Decisions

AUTHORS: TYLER C. LIU & DEBORAH STERLING, PH.D.

SUMMARY

In June 2021, the US Patent and Trademark Office (USPTO) published an update to its study of America Invents Act (AIA) trials involving challenges to Orange Book-listed and biologic patents from September 16, 2012, through June 30, 2021.[1] Here, we review the statistics and then give an overview of notable biologics decisions to date. With the number of petitions aimed at biologics patents growing from 8 petitions filed in FY2020 to at least 23 in FY2021, a more complete picture of how successful PTAB proceedings are in the biologics space will soon come into focus.

STATISTICS

Since post-grant proceedings became available, only 4% of all AIA petitions challenge Orange Book patents, and only 2% of petitions challenge biologic patents.[2] The number of AIA challenges to Orange Book patents has decreased every year since 2015.[3] Similarly, the number of biologic patent challenges have decreased year over year from 2017 to 2020.[4] 2021 was the first year to see a rise in the number of challenges to biologic patents since 2017.

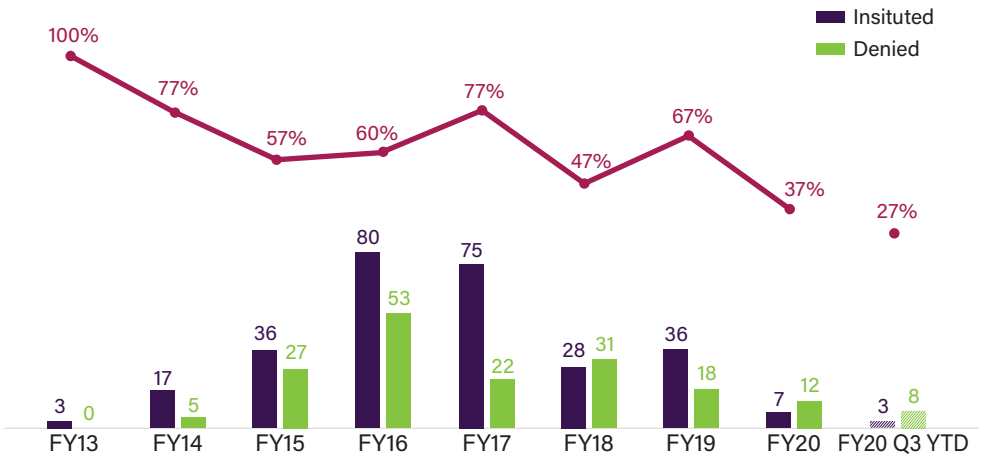
The all-time institution rate for Orange Book patents since 2012 averages 62%—close to the average across all technologies—while petitions challenging biologics have a 55% all-time average institution rate,[5] the lowest rate for all utility patents.[6] Noticeably, though, the institution rate for Orange Book patents, shown in Figure 1 below, has been on a generally downward trajectory over time, averaging 37% in 2020 and 27% in 2021.[7] Challenges to biologic patents have seen a similar decline, with the institution rate falling by more than half from FY2019 to FY2020[8] and in 2021, to its lowest rate to date: 33%.[9] *See* Figure 2.

As shown in Figures 3 and 4 below, only 15% of Orange Book patent challenges result in final written decisions finding all claims unpatentable[10]; 21% of biologic patent challenges result in final written decisions finding all claims unpatentable.[11] On a claim-by-claim basis, 31% of instituted Orange Book patent claims were found unpatentable, while a much larger 59% of instituted biologics claims were found unpatentable.[12]

As shown in the figures below, once instituted, biologic patent challenges are significantly more likely to result in final written decisions finding all claims unpatentable than challenges to Orange Book patents. This outcome disparity can be explained by the larger variety of claims covered by biologic patents, including claims to manufacturing methods, processes, and metabolites, which may be easier to challenge at the USPTO Patent Trial and Appeal Board (PTAB). In contrast, Orange Book patents only cover compound, formulation, and method claims.

Orange book listed patents typically come with Hatch-Waxman litigation, which factors significantly into the strategy of when, or even whether to challenge Orange Book patents at the PTAB. Some stakeholders find

Figure 1: Institution Rate (Orange Book Patents) Sept 16, 2012 to June 30, 2021



Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e. petitions instituted plus repitions denied). The outcome of decisions on institution responsive to requests for rehearing are excluded.

Source: USPTO

that there is less benefit to be realized from a win at the PTAB against an Orange Book patent due to the automatic 30-month stay of approval under the Hatch-Waxman framework. Others continue to find value in bringing PTAB challenges, for example, to put pressure on patent owners to settle, to clear out patents that are easier to challenge on a shorter 18-month timeline, or to get parallel district court litigation stayed pending the outcome of the PTAB challenge.

As for biologics patents, a relatively small number of biologics have been at the stage where they face potential competition from biosimilars in court (for example, only eight molecules have been involved in BPCIA litigation so far). That said, not every biologic requires waiting until a biosimilar challenge is ripe before approaching the PTAB. In fact, biosimilar makers seem to be filing challenges at the PTAB even before seeking FDA approval for their biosimilar products. Thus, biosimilar makers could be filing at the PTAB rather than engaging in the patent dance altogether. Based on the significant rise in biologic patent challenges in 2021 compared to filings from 2017-2020, the statistics seem to support this strategy as a method for biosimilar makers to clear out biologic patents standing in the way of FDA approval. In addition, with the approval of more biologics in the coming years, biosimilar makers could find value in filing PGRs due to the availability of additional Section 112 grounds that can be included in these proceedings.

To the extent that anything concrete can be taken from the USPTO's statistics, it is that the biologic patent cancellation rate could be affecting the number of filings at the PTAB as reflected by the substantial increase in the number of filings in 2021. Some notable biologic post-grant proceedings are discussed next.

PTAB BIOLOGICS PROCEEDINGS

A. Rituximab (RITUXAN)

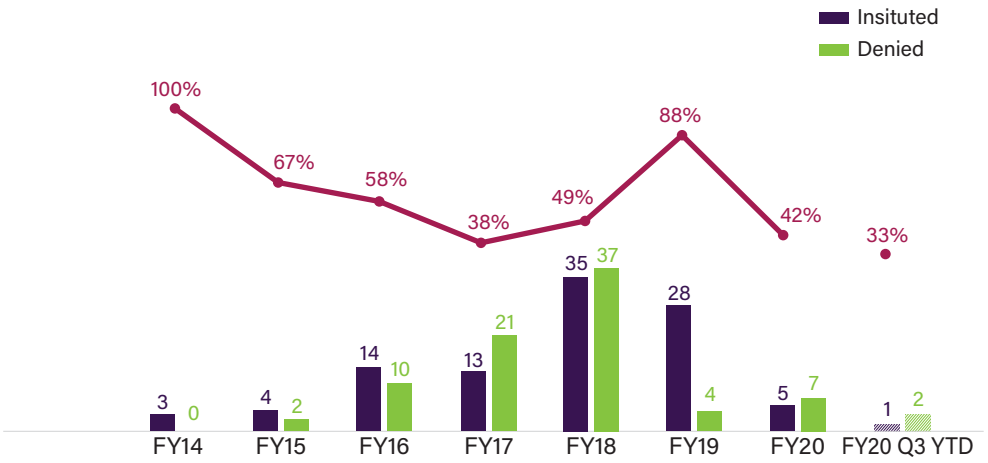
Since 2015, there have been 27 *inter partes* reviews (IPR) filed challenging 10 different patents covering rituximab. Out of the 10 patents challenged across the 27 proceedings, only two have been found to be unpatentable: U.S. Patent Nos. 8,821,873 and 9,296,821. Two other IPRs both challenging U.S. Patent No. 7,820,161, while instituted, ultimately failed to prove that the claims were unpatentable. All other IPRs were either terminated because of settlement or denied institution.

The '873 patent is directed to a method of treating a patient with diffuse, large-cell lymphoma by administering anti-CD20 antibodies (e.g. Rituximab) in combination with stem cell transplantation. Pfizer filed a petition challenging all claims of the '873 patent as obvious in two grounds over multiple prior art references.[13] The PTAB consolidated the two grounds into one and ultimately found that the prior art provided a motivation for combining rituximab with stem cell transplantation and supported a POSA's reasonable expectation of success in this combination treatment. Accordingly, the PTAB found all challenged claims unpatentable as obvious.[14]

The '821 patent covers methods for treating low-grade or follicular Non-Hodgkin's lymphoma by administering an effective amount of rituximab during a chemotherapeutic regimen. Celltrion filed a petition challenging all claims of the '821 patent.[15] After instituting on all grounds in view of *SAS Inst., Inc. v. Iancu*, 138 S.Ct. 1348 (2018), the PTAB held a subset of claims unpatentable as obvious, and the others anticipated.[16]

The '161 patent covers a method of treating rheumatoid arthritis in a human by administering more than one intravenous dose of a therapeutically effective

Figure 2: Institution Rate (Biologic Patents) Sept. 16, 2012 to June 30, 2021



No institution decisions for biologic patents before FY14
Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e. petitions instituted plus repitions denied). The outcome of decisions on institution responsive to requests for rehearing are excluded.

Source: USPTO

amount of rituximab and methotrexate. Celltrion filed a petition, with Pfizer joining, challenging all claims of the '161 patent in three separate obviousness grounds.[17] Because Celltrion did not put forth separate arguments with respect to references in two of the other grounds, the PTAB combined the references and instituted review on a single obviousness ground based on four references, one of which was the Rituxan Label.[18] Biogen and Genentech (Patent Owners) challenged the admissibility of the Rituxan Label as prior art by arguing that the copyright date and the presence of the label on the FDA website did not establish that the label was publicly accessible. The PTAB agreed. Celltrion separately submitted a webpage copy of the Rituxan label along with a declaration from the Office Manager from Internet Archives explaining that the webpage copy of the label was a true and accurate copy of the printout. However, the PTAB held that Celltrion had not shown that the Rituxan Label was broadly disseminated and publicly accessible or that persons interested and ordinarily skilled in treating rheumatoid arthritis would have identified and visited Genentech's website before the critical date. The PTAB then analyzed the instituted ground without reference to the Rituxan Label and held that the remaining references did not teach several limitations. As such, the PTAB confirmed the challenged claims.

Genentech has also asserted its patents related to Rituxan in four BPCIA litigations, all of which have settled or been voluntarily dismissed.

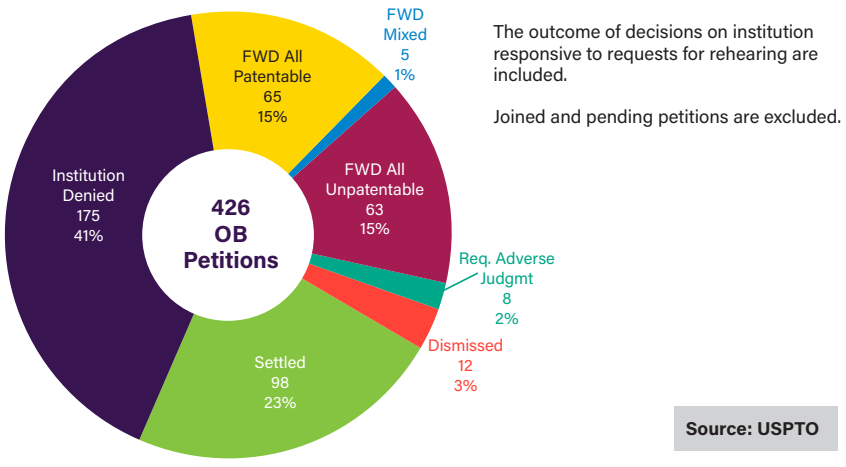
B. Trastuzumab (HERCEPTIN)

Since 2014, seven petitioners have filed 36 IPRs challenging 12 different patents, with mixed results. Of those 36 IPRs only 13 were successful in cancelling at least some claims. More specifically, the PTAB cancelled claims in four patents: U.S. Patent Nos. 6,407,213; 7,807,799; 7,846,441; and 7,892,549.

The '213 patent covers a humanized antibody, while the '799 patent covers a method of purifying a protein that comprises a CH2/CH3 region by subjecting a composition to affinity chromatography at a specified temperature. The '441 patent is directed to a method for treating a human patient with a malignant progressing tumor or cancer by administering an antibody and a taxoid, while the '549 patent covers a method for treatment of a patient with breast cancer that overexpresses ErbB2 receptor comprising administering a combination of an antibody, a taxoid, and a growth inhibitory agent.

Interestingly, the PTAB granted a rare request for rehearing after denying institution of Hospira's (now Pfizer) petition challenging the '441 patent.[19] The challenged claims are directed to a method for the treatment of a human patient with a malignant progressing tumor or cancer comprising administering a combination of an anti-ErbB2 antibody and a taxoid, "in the absence of an anthracycline derivative."[20] Neither party construed the term "in the absence of an anthracycline derivative" in the petition or preliminary response. However, in denying institution, the PTAB agreed with Patent Owner's argument that the evidence of record is "insufficient to suggest that an ordinary artisan would have *avoided* anthracyclines while pursuing the combination therapy with anti-ErbB2 antibody and a taxoid in a treatment regimen." Hospira requested rehearing, arguing that the PTAB erred in construing the limitation "in the absence of an anthracycline derivative" as requiring "avoidance" of that derivative.[21] By construing this term in that way, Hospira contended that Genentech would be able to capture compositions that simply do not include such a derivative.[22] Hospira argued that because of this improper construction, the PTAB erred in denying institution of the obviousness ground that included a reference that suggested a therapeutic composition consisting of an anti-ErbB2 antibody and paclitaxel

Figure 3: Outcomes of AIA Petitions Challenging OB Patents (Sept. 16, 2012 to June 30, 2021)



(taxoid) and does not suggest that doxorubicin (an anthracycline derivative) must necessarily be included as part of the same treatment regimen. The PTAB found Hospira's reasoning persuasive and instituted trial on the previously denied obviousness ground, subsequently cancelling all challenged claims based on that same ground.[23]

Genentech has asserted patents related to Herceptin in six BPCIA litigations. Five of the six cases settled and Celltrion voluntarily dismissed the sixth on appeal.

C. Bevacizumab (AVASTIN)

In September 2016, Hospira, Inc. filed IPRs against two patents covering Genentech's Avastin, which is used to treat colorectal, lung, glioblastoma, kidney, cervical, and ovarian cancer. U.S. Patent No. 7,807,799 is directed to methods of purifying antibodies, including claims to purifying anti-VEGF antibodies, while 7,622,115 is directed to methods of treating cancer using bevacizumab.[24]

The PTAB held that the challenged claims of the '799 patent were unpatentable as anticipated and obvious over the prior art,[25] and the '115 patent claims unpatentable as obvious.[26] The Federal Circuit affirmed in both cases.[27, 28]

Genentech has filed six complaints against biosimilar developers of AVASTIN. Of the six BPCIA litigations, five have been dismissed and one has settled.

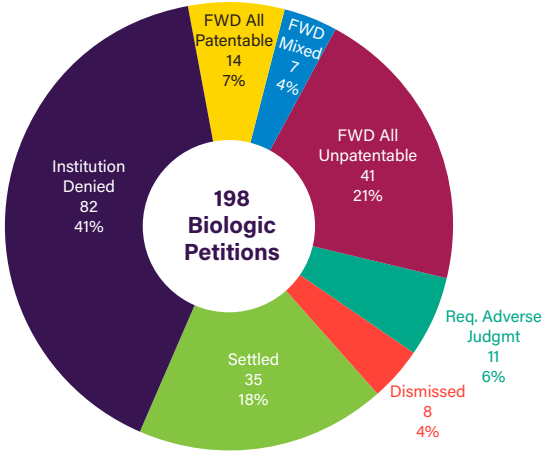
D. Botulinum Toxin *Galderma, SA et al v. Medy-Tox Inc.* PTAB-PGR2019-00062

In September 2019, Galderma filed a petition for post-grant review of Medy-Tox's U.S. Patent No. 10,143,728, covering an animal protein-free botulinum composition that exhibits a longer lasting effect than a comparative animal protein containing botulinum composition.[29] Botulinum toxin can be used to treat muscle disorders, excessive sweating, and migraine and is commonly used for cosmetic purposes, such as wrinkle reduction.

The petition challenged the '728 patent on numerous grounds: enablement, indefiniteness, and written description.[30] Following institution, Medy-Tox did not file a Response, but instead filed a non-contingent Motion to Amend, seeking to cancel claims 5-6 and replace the remaining claims with substitute claims 11-18, in accordance with the PTAB's 2019 Pilot Program Concerning Motion to Amend Practice and Procedures.[31] The PTAB issued preliminary guidance that Medy-Tox had not satisfied the statutory and regulatory requirements associated with filing a motion to amend in a post-grant review and that Petitioner had shown a reasonable likelihood that proposed substitute claims are unpatentable. In view of the guidance from the PTAB, Medy-Tox then filed a revised non-contingent motion to amend proposing narrower claims by canceling original claim 6 and replacing the remaining claims 1-5 and 7-10 with substitute claims 19-27.[32] The PTAB addressed the patentability of proposed substitute claims 19-27 and issued a final written decision on July 16, 2021 and found the substitute claims unpatentable for lack of written description support and lack of enablement.[33]

As such, patent owners should be aware of the risks involved in amending claims challenged in a petition before considering such a motion. Although the Pilot Program provides an opportunity for the patent owner to get a preview of the PTAB's thinking on the patentability of amended claims, it is no guarantee of success. In fact, as shown above, following the PTAB's guidance in its decision on certain amended claims and then filing a second non-contingent motion to amend may bring about additional challenges from the petitioner. In fact, patent owners should be aware that even in situations where the PTAB finds that substitute claims do not enlarge the scope of the original claims, the PTAB can still revisit its preliminary decision and find claims unpatentable. The PTAB makes it very clear that a Preliminary Guidance only provides information indicating initial, preliminary, non-binding views on whether the patent owner has shown a reasonable likelihood that it has

Figure 4: Outcomes of AIA Petitions Challenging Biologic Patents (Sept. 16, 2012 to June 30, 2021)



Source: USPTO

satisfied the statutory and regulatory requirements associated with filing a motion to amend and whether petitioner has established a reasonable likelihood that the substitute claims are unpatentable. As such, patent owners should consider other potential avenues for amending claims, such as continuing prosecution, or reissue or reexamination proceedings. And if a patent owner amends claims in an IPR or PGR, the patent owner should carefully consider the possibility that the petitioner may challenge the amended claims for lack of enablement or lack of written description.

E. Adalimumab (HUMIRA): *Fresenius Kabi USA, LLC et al v. Coherus Biosciences, Inc.* PTAB-PGR2019-00064[34]

In September 2019, Fresenius Kabi filed a petition challenging U.S. Patent No. 10,155,039, owned by Coherus BioSciences and generally directed to "stable" adalimumab antibody formulations suitable for long-term storage without substantial loss in efficacy. Fresenius asserted that the challenged claims lacked enablement and written description, and were indefinite.[35] On March 19, 2020, the PTAB denied institution of the PGR on the ground that Fresenius incorrectly construed the term "stable" in the context of the claims.[36] Fresenius construed the term "stable" to refer to long term storage of adalimumab, while Coherus construed "stable" to only require stability suitable for its intended pharmaceutical application. The PTAB agreed with Coherus' construction. Based on that construction, the PTAB found that Fresenius had failed to demonstrate that the challenged claims are unpatentable for lack of written description because the specification clearly teaches structural features required for achieving a stable adalimumab composition.[37] Similarly, the PTAB held that the claims did not need to be enabled for maximum stability as Fresenius had asserted, and thus were enabled.[38]

Fresenius also argued that claims directed to a composition free of "citrate and phosphate buffers" were indefinite. Fresenius argued that the term was subject to two reasonable constructions: (1) a construction that the claims exclude citrate buffer, phosphate buffer, and the combination of the two or (2) the claims exclude only the combination.[39,40] The PTAB held that the term was not indefinite and that the intrinsic evidence taught that the claims must exclude the combination of both buffers. Accordingly, the PTAB held that Fresenius had failed to show indefiniteness.

Petitioners and patent owners alike should avoid construing claims without adequate support in the specification. The case above demonstrates that the outcome can hinge almost entirely on claim construction, especially when the petitioner has construed the claims beyond what the inventor had described as the invention and based its arguments solely on that construction.

The '039 patent was also involved in a concurrent litigation between Amgen and Coherus in the District of Delaware, which ended up settling on November 26, 2019.[41]

F. Pegfilgrastim (NEULASTA) *Pfizer Inc. et al v. Amgen Inc.* PTAB-IPR2021-00528

In February 2021, Pfizer filed a petition challenging a subset of claims in Amgen's U.S. Patent No. 8,273,707, which covers methods for purifying a protein, such as pegfilgrastim.[42] Neulasta decreases the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.

The petition raised both anticipation and obviousness grounds. The PTAB then granted institution with respect to all grounds set forth in the petition on August 17, 2021.[43] Hospira challenged the claims of the '707 patent based upon five grounds: two anticipation grounds and three obviousness grounds. The PTAB first considered one of the obviousness grounds and determined that Hospira had established a reasonable likelihood of success at establishing that the challenged claims were obvious. As a result, the PTAB instituted trial on all grounds—in view of *SAS Inst., Inc. v. Iancu*—without comment on the remaining grounds, instead inviting the parties to develop the record on those grounds at trial. A final written decision is expected by August 17, 2022.

Amgen has sued Mylan, Coherus, Adello Biologics, and Hospira alleging infringement of the '707 patent.[44] Coherus won, and the Federal Circuit affirmed, on the grounds that prosecution history estoppel bars Amgen from succeeding on its infringement claim under the doctrine of equivalents.[45] Mylan and Amgen stipulated that the Court could enter a judgment of noninfringement in favor of Mylan. Amgen dismissed all claims against Adello Biologics on November 22, 2019. Hospira filed a motion for summary judgment of noninfringement on August 6, 2021; the parties are waiting for an oral hearing on that motion.

G. Filgrastim (NEUPOGEN) *Lupin Limited et al v. Amgen Inc.* PTAB-IPR2021-00326

In December 2020, Lupin filed a petition challenging claims in U.S. Patent No. 9,856,287, covering Amgen's NEUPOGEN (filgrastim).[46] Like Neulasta, Neupogen is a drug that treats cancer patients by stimulating growth of white blood cells, making patients less vulnerable to infections.

The '287 patent covers methods of refolding complex proteins, such as filgrastim, at high concentrations. The PTAB denied institution for multiple reasons.[47] The PTAB noted several times in its Institution Decision that Lupin's expert did not adequately support his conclusions.[48] For example, the PTAB agreed with Amgen that a key reference, Vallejo, did not disclose the limitation

"wherein the thiol-pair ratio is in the range of 0.001-100." Lupin's expert argued that Vallejo's disclosure taught a thiol-pair ratio of 3, which is within the range claimed. However, the PTAB found that Lupin's expert did not adequately consider another disclosure in Vallejo which would have impacted the thiol-pair calculation that Lupin's expert performed. The PTAB also disagreed with Lupin's argument relating to a limitation calling for the thiol-pair buffer to "maintain the solubility of the preparation," which the PTAB interpreted as relying on inherency—a notoriously difficult theory to prove at the PTAB.[49]

Importantly, this decision serves as a reminder that even if a Petitioner does not explicitly rely on inherency for a particular argument, the PTAB may interpret an expert's testimony as based on inherency if inadequate support is provided for his or her conclusions. Accordingly, Petitioners should take note of this decision and carefully support all conclusions in an expert's declaration.

Amgen has asserted the '287 patent against Tanvex BioPharma USA, Accord BioPharma, and Adello Biologics. Amgen dismissed the actions against all three parties in late 2019.[50]

Notably, despite no assertion of infringement, both Fresenius Kabi USA and Adello Biologics LLC challenged the '287 patent in post-grant proceedings. Fresenius filed two petitions in 2019. The PTAB denied the first petition and the parties settled the second.[51] Adello Biologics filed one petition challenging the '287 patent, which also settled.[52]

H. Insulin Glargine (LANTUS) *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH* PTAB-IPR2019-01657 and IPR2019-01658

In October 2019, Mylan filed two petitions challenging RE47,614 from Sanofi-Aventis covering Lantus (insulin glargine), licensed to treat diabetes. The '614 patent is directed to a drug delivery device which can house a liquid medicament, such as insulin. [53]

In both petitions, Mylan presented a single obviousness ground. Because both obviousness grounds were very similar, the PTAB instituted review of the first petition and denied institution of the second on grounds that the second petition did not contain sufficiently material differences to support instituting an additional IPR of the '614 patent.[54,55]

Interestingly, similar to *Galderma, SA et al v. Medy-Tox Inc.* (PGR2019-00062), Sanofi filed a contingent motion to amend cancelling the challenged claims and substituting new claims 19-22. After Sanofi filed the motion to amend, the PTAB issued Preliminary Guidance determining that Sanofi had shown a reasonable likelihood that it had satisfied the statutory and regulatory requirements associated with filing a motion to amend claims 19, 20, and 22, but not for claim 21, and that Mylan had shown a reasonable likelihood that claims 19, 20, and 22 are unpatentable, but not claim 21.[56] Sanofi subsequently withdrew the motion to amend. As a result, the PTAB only needed to consider the instituted claims, which the PTAB subsequently cancelled in view of the prior art.[57]

CONCLUSION

Very few petitions challenging biologics patents go through to a final written decision, making distinct trends specific to large molecules difficult to identify. Instead, the challenges seem to rise and fall on issues that arise in post-grant proceedings regardless of technology: claim construction, failure of proof, public accessibility to prior art, etc. In particular, decisions by the PTAB recently have suggested that patent owners of biologics patents should think carefully before amending claims even after receiving preliminary guidance from the PTAB. In addition, given the PTAB's willingness to deny institution purely on claim construction grounds, practitioners should pay special attention to claim construction positions to make sure they are adequately supported. That said, at least 23 petitions challenging biologic patents have been filed this year alone, which will provide more decisions to guide practitioners in this field.

1. PTAB Orange Book patent/biologic patent study: FY21 Q3 (June 2021) Update, https://www.uspto.gov/sites/default/files/documents/PTABOB-biologicpatentstudy8.10.2021draftupdatedthruJune2021.pdf, 2021.
2. *Id.* at 2.
3. *Id.* at 5.
4. *Id.* at 5-6.
5. *Id.* at 11-12.
6. *Id.* at 10.
7. *Id.* at 11.
8. *Id.* at 12.
9. *Id.*
10. *Id.* at 13
11. *Id.* at 14.
12. *Id.* at 17-18.
13. *Pfizer Inc. v. Biogen Inc.*, IPR2017-01168, Paper 59 (P.T.A.B. Oct. 31, 2018).
14. *Id.*
15. *Celltrion Inc. v. Biogen Inc.*, IPR2017-01095, Paper 2 (P.T.A.B. March 15, 2017).
16. *Celltrion* IPR2017-01095, , Paper 60 at 70-71(P.T.A.B. Oct. 4, 2018).
17. *Celltrion Inc. v. Genentech Inc.*, IPR2016-01614, Paper 2 (P.T.A.B. Aug. 15, 2016); *Pfizer Inc. v. Genentech Inc.*, IPR2017-01115, Paper 2 (P.T.A.B. Mar. 24, 2017).
18. *Celltrion* IPR2016-01614, Paper 12 at 8-9 (P.T.A.B., Feb. 24, 2017).
19. *Pfizer Inc. v. Genentech Inc.*, IPR2017-00731, Paper 29 (P.T.A.B. Jan. 20, 2017).
20. *Id.* at 17.
21. *Id.*
22. *Id.* at 17-18.
23. *Pfizer Inc.*, IPR 2017-00731, Paper 120 at 44 (P.T.A.B. Oct. 3, 2018).
24. *Hospira, Inc. et al v. Genentech, Inc.*, IPR2016-01837, Paper 1 (P.T.A.B. Sept. 16, 2016); *Hospira, Inc. et al v. Genentech, Inc.*, IPR2016-01771, Paper 1 (P.T.A.B. Sept. 9, 2016).
25. *Hospira, Inc. et al v. Genentech, Inc.*, IPR2016-01837, Paper 1.
26. *Hospira, Inc. et al v. Genentech, Inc.*, IPR2016-01771, Paper 40.
27. *Genentech v. Hospira & U.S.*, Case No. 18-1933 (Fed. Cir. 2020).
28. *Genentech v. Hospira & U.S.*, Case No. 18-1959 (Fed. Cir. 2019).
29. *Galderma, S.A. v. Medy-Tox Inc.*, PGR2019-00062, Paper 2 (P.T.A.B. Sept. 4, 2019).
30. *Id.* at 11.
31. *Galderma, S.A. v. Medy-Tox Inc.*, PGR2019-00062, Paper 21 (P.T.A.B. Aug. 5, 2020).
32. Galderma, S.A., PGR2019-0062, ., Paper 30 (P.T.A.B. Dec. 11, 2020).
33. *Galderma, S.A.*, PGR2019-0062Paper 66 at 33-34 (P.T.A.B. July 16, 2021).
34. Fresenius submitted a Request for Rehearing, which the Board denied on January 27, 2021.
35. *Fresenius Kabi USA, LLC v. Coherus Biosciences, Inc.*, PGR2019-00064, Paper 3 (P.T.A.B. Sept. 17, 2019).
36. *Fresenius Kabi USA*, PGR2019-0064. Paper 10 at 11-18 (P.T.A.B. Sept. 17, 2019).
37. *Id.* at 14-15.
38. *Id.* at 15-18.
39. *Id.* at 18-19.
40. *Fresenius Kabi USA*, PGR2019-0064, Paper 12 (P.T.A.B. Jan, 27, 2021).
41. *Coherus Biosciences, Inc. v. Amgen Inc.*, Case No. 1:19-cv-00139 (DDE).
42. *Pfizer Inc. v. Amgen Inc.*, IPR2021-00528, Paper 2 (P.T.A.B. Feb. 10, 2021).
43. *Pfizer*, IPR2021-00528, Paper 7 (P.T.A.B. Aug. 17, 2021).
44. *Amgen Inc. et al. v. Coherus Biosciences, Inc.*, Case No. 1:17-cv-00546 (DDE); *Amgen Inc. et al. v. Adello Biologics, LLC*, Case No. 2:18-cv-03347 (DNJ); *Amgen Inc. et al. v. Hospira, Inc. et al.*, Case No. 1:20-cv-00201 (DDE); *Amgen Inc. et al. v. Mylan Inc. et al.*, Case No. 2:17-cv-01235 (WDPA).
45. *Amgen Inc. v. Coherus Biosciences, Inc.*, Case No. 2018-1993 (Fed. Cir. 2019).
46. *Lupin Limited v. Amgen Inc.*, IPR2021-00326, Paper 1 (P.T.A.B. Dec. 15, 2020).
47. *Lupin*, IPR2021-00326, Paper 8 (P.T.A.B. July 12, 2021).
48. *Id.* at 8-12.
49. *Id*.
50. *Amgen Inc. et al. v. Tanvex BioPharma USA, Inc. et al.*, Case No. 3:19-cv-01374 (SDCA); *Amgen Inc. et al v. Accord BioPharma*, Case No. 0:18-cv-61828 (SDFL); *Amgen Inc. et al. v. Adello Biologics, LLC*, Case No. 2:18-cv-03347 (DNJ).
51. *Fresenius Kabi USA, LLC et al. v. Amgen, Inc. et al.*, IPR2019-00971, Paper 13 (P.T.A.B. Oct. 16, 2019); *Fresenius Kabi USA, LLC et al. v. Amgen, Inc. et al.*, IPR2020-00314, Paper 17 (P.T.A.B. June 19, 2020).
52. *See Adello Biologics, LLC et al. v. Amgen Inc. et al.*, PGR2019-00001, Paper 28 (P.T.A.B. Dec. 6, 2019).
53. *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01657, Paper 3 (P.T.A.B. Oct. 7, 2019); *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01658, Paper 3 (P.T.A.B. Oct. 7, 2019).
54. *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01657, Paper 9 (P.T.A.B. Apr. 2, 2020); *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01658, Paper 9 (P.T.A.B. Apr. 2, 2020).
55. *Id*.
56. *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01657, Paper 27, 3-4, 8 (P.T.A.B. Oct. 14, 2020).
57. *Mylan*, Paper 39 at 58-59.

"Impressive IP boutique, highly valued for its ability to prepare and prosecute utility, design and covered business method patents for companies active in a variety of industry sectors including computer software and engineering and life sciences. Continues to excel in inter partes review and other USPTO proceedings, and represents a fine choice of counsel for companies of all sizes."

— 2021 Chambers & Partners USA

Is the Tide Turning on Chemical Patent Challenges at the PTAB?

BY: DEBORAH STERLING, PH.D. AND OLGA A. PARTINGTON, PH.D.

The so-called "Lead Compound Analysis" is the primary legal framework for assessing chemical obviousness. Despite the USPTO Patent Trial and Appeal Board's (PTAB) initial apparent reluctance to operate under this framework, the PTAB has been faithfully applying the lead compound framework in America Invents Act (AIA) proceedings, leading to largely favorable outcomes for patent owners. But the decisions we have seen from the PTAB in 2021 relating to chemical obviousness might be early indicators that the PTAB is starting to deviate from the lead compound framework, raising the question—are chemical compound claims facing vulnerability in AIA proceedings?

Twenty years ago, the US Court of Appeals for the Federal Circuit articulated a standard for assessing obviousness of chemical compounds—the so-called Lead Compound Analysis (LCA).[1] Under this approach, a person of ordinary skill in the art ("POSA") must have had a reason to select a prior art compound as a "lead," and a reason to modify the prior art compound with a reasonable expectation of success.[2]

To qualify as a "lead" under the LCA, the compound must possess some beneficial property that somehow distinguishes it from other prior art compounds.[3] In contrast, under the historical predecessor to the LCA framework (*In re Dillon*), one could establish *prima facie* obviousness of a claimed compound if it was structurally similar to a prior art compound with an established utility, and if the prior art provided any reason to make the claimed compound.[4] As such, the LCA raised the standard of *prima facie* obvious of a chemical compound from using only structural similarity to inform selection of a starting point for modification to having to show that the prior art compound to be modified exhibits more beneficial properties than other compounds found in the art. And by focusing on the most promising prior art compound rather than the structurally closest prior art compound, the LCA imposed a much higher burden for showing obviousness in chemical arts, arguably benefiting patent owners.

The PTAB was slow to adopt the LCA, continuing to operate under the historical approach to compound obviousness under *Dillon* in *ex parte* appeals.[5] This reluctance from the PTAB to apply the more stringent LCA in pre-AIA *ex parte* cases contributed to early speculation that pharmaceutical compound patents might be successfully challenged in AIA proceedings.

But the prediction proved wrong. From 2012 through 2020, the PTAB faithfully applied a strict LCA framework in post-grant proceedings, routinely rejecting arguments that *any* reason for modifying a structurally similar prior art compound with a stated utility is sufficient to establish a *prima facie* case of obviousness (*i.e.*, the *Dillon* approach).[6] As one panel explained, "*Dillion* [sic] relates to the rejection-and-response regime of patent examination, rather than the adjudicatory process of an *inter partes* review" and "the burden shifting analysis applied in prosecution 'does not apply in the adjudicatory context of an IPR.'"[7] The PTAB's consistent adherence to the lead compound framework in AIA proceedings led to a nearly universal survival of compound claims, maintaining the public's faith in the general strength of chemical compound patents.

But two 2021 PTAB decisions from two separate panels—both declining to apply lead compound analysis as the exclusive test for obviousness—have cast a shadow on the fate of compound patents in this tribunal.

NOF Corporation v. Nektar Therapeutics

NOF challenged claims 1–12 of U.S. Patent No. 9,187,569 B2 ("the '569 patent"), directed to "branched, reactive water soluble polymers useful for conjugating to biologically active molecules," as being obvious over prior art.[8] Notably, when the patent owner invited the PTAB to "apply the lead compound analysis when assessing whether the claimed genus of chemical compounds would have been obvious over the prior art of record," the PTAB turned down the invitation.[9] Briefly, the PTAB "decline[d] to apply the lead compound analysis as the exclusive test for obviousness," looking instead "to the general law of obviousness for guidance."[10] In the PTAB's view, the LCA "is not the only way to demonstrate obviousness of a claimed compound or genus of compounds," and that "any rigid application of the lead compound analysis risks running afoul of the broad, flexible obviousness test set forth by the Supreme Court of the United States in *KSR*."[11] Under this framework, the petitioner prevailed with regard to all but three surviving claims.[12]

To our knowledge, this is the first expressly-articulated refusal by the PTAB to rely on the lead compound framework as the exclusive test in the chemical obviousness arena of the AIA proceedings.[13]

Alzheon Inc. v. Risen (Suzhou) Pharma Tech Co., Ltd.

Alzheon petitioned the PTAB seeking review of US Patent 10,472,323 B2 ("the '323 patent"), arguing that all claims would have been obvious over the prior art.[14] The '323 patent relates to "isotope-enriched 3-amino-1-propanesulfonic acid ('3APS' or 'tramiprosate') and derivatives, compositions thereof, and methods of

using them in therapeutic applications, such as in the prevention and treatment of Alzheimer's disease."[15] The claims of the '323 patent are directed to isotopically-substituted tramiprosate and its derivative L-valyl-3-aminopropanesulfonate ("Val-APS") and, specifically, where deuterium is substituted for hydrogen at the 3-carbon (*e.g.*, "D2-Val-APS").

Tramiprosate—a known drug that was developed as a treatment for Alzheimer's disease—was known to be extensively metabolized *in vivo*. To improve the therapeutic effectiveness of tramiprosate, the art taught the use of prodrugs and derivatives of tramiprosate that will generate tramiprosate *in vivo* after administration to a subject. One such prodrug, Val-APS, was disclosed by Kong to "significantly increase[] the bioavailability (Cmax and AUC) of tramiprosate, compared to administration of tramiprosate alone."[16] Kong further taught "isotopically labeled compounds where one or more atoms have an atomic mass different from the atomic mass most abundantly found in nature."[17]

Alzheon argued that the only difference between Kong's Val-APS and the claimed D2-Val-APS is the substitution of deuterium for hydrogen at the third carbon, and that it would have been obvious to a person of ordinary skill in the art to substitute deuterium for hydrogen at the third carbon of Val-APS to form D2-Val-APS.[18] The patent owner, invoking the lead compound framework, argued that a person of ordinary skill in the art would not have had a reason to select tramiprosate or Val-APS as a lead compound for development.[19] To this end, the patent owner argued that "the prior art considered tramiprosate to be a failure, and that there were many other drugs that were considered by the art to be more promising than tramiprosate in treating Alzheimer's disease."[20]

In the institution decision, the PTAB found the patent owner's argument that there would have been no reason to consider tramiprosate—a clinically "failed drug"—as a lead compound "largely irrelevant."[21] The PTAB emphasized that "the question before us is whether the claimed compositions are *structurally* obvious over the cited prior art compositions, and not whether they are, or would have been at the time of filing, effective in the treatment of Alzheimer's disease."[22] The PTAB further explained that "the circumstances under which a 'lead compound' obviousness analysis should be employed" involve "a new chemical compound," and such circumstances "do not apply" here because tramiprosate, and its prodrug Val-APS, are not new chemical compounds: "[t]he chemical structure of tramiprosate and Val-APS are unchanged by the substitution of hydrogen isotopes."[23] The PTAB then concluded that in answering a question of whether a deuterated drug is *prima facie* obvious over its non-deuterated isotopolog, "the standard set forth in *In re Dillon* appears to be the closest applicable standard to apply."[24]

"[A]fter a string of LCA patent-favorable decisions in the chemical obviousness space, the PTAB has surprised us this year by its apparent willingness to deviate from the strict application of the lead compound framework in assessing obviousness of compound claims."

Notably, the only case known to us (not already mentioned here) where the PTAB cancelled chemical compound claims on a theory of obviousness involved isotopically-substituted compounds.[25] The *Alzheon* proceeding also involves an obviousness challenge to isotopically-substituted compound claims, and it will be interesting to follow to see if claims related to known chemical compounds where the modification is an isotopic substitution are emerging as vulnerable in AIA proceedings.

In sum, after a string of LCA patent-favorable decisions in the chemical obviousness space, the PTAB has surprised us this year by its apparent willingness to deviate from the strict application of the lead compound framework in assessing obviousness of compound claims. While it is too early to tell whether the PTAB will continue with this trend, or if the *NOF* and *Alzheon* cases present an anomaly based on their specific facts, one has to wonder if chemical compound claims are becoming more vulnerable to AIA challenges. In any event, both petitioners and patent owners should recognize that the PTAB is becoming more open to taking a more flexible approach to assessing obviousness of chemical compound claims, and both parties should consider making obviousness arguments that are more expansive than just LCA.

1. *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).
2. *See, e.g., Otsuka Pharm. Co. Ltd. v. Sandoz Inc.*, 678 F.3d 1280, 1291-92 (Fed. Cir. 2012); *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed.Cir. 2007).
3. Otsuka Pharm., 678 F.3d at 1292 ("In determining whether a chemist would have selected a prior art compound as a lead, the analysis is guided by evidence of the compound's pertinent properties.")
4. 919 F.2d 688, 692 (Fed. Cir. 1990).
5. *See, e.g., Ex parte Cao*, Appeal 2010-004081 (BPAI Sept. 19, 2011); *Ex parte Mayorga*, Appeal 2010-012157 (BPAI Sept. 29, 2011); *Ex parte Gaul*, Appeal 2011-010047, at 6 (BPAI Jan. 28, 2013); *Ex parte Dong*, Appeal 2011-010047, at 6-7 (PTAB Jan. 28, 2013).
6. *See, e.g., Mylan Pharmaceuticals v. Gilead Sciences*, IPR2014-00887 (PTAB Dec. 9, 2014) (Paper 16) (Rehearing Denied; Paper 22); *Torrent Pharms. Ltd. v. Merck Frosst Canada & Co.*, IPR2014-00559, slip op. 7 (PTAB Jan. 7, 2015) (Paper 10) (Petitioner's request for rehearing denied); *Apotex v. Merck Sharp & Dohme*, IPR2015-00419 (PTAB Oct. 27, 2015) (Paper 18) (Rehearing Denied; Paper 22); *Sawai USA, Inc. v. Nissan Chemical Industries*, IPR2015-01647 (PTAB Feb. 4, 2016) (Paper 9); *Mylan Pharmaceuticals v. Astrazeneca AB*, IPR2015-01340 (PTAB Aug. 18, 2017) (Paper 79); *Par Pharmaceuticals v. Novartis AG*, IPR2016-00084 (PTAB June 23, 2017) (Paper 19); *Argentum Pharmaceuticals v. Research Corporations Technologies*, IPR2016-00204 (PTAB May 23, 2016) (Paper 19); *Mylan Pharmaceuticals, Inc. v UCB Pharma GMBH*, IPR2016-00512 (PTAB July 19, 2017) (Paper 37); *Mylan Laboratories Limited v Aventis Pharma*, IPR2016-00627 (PTAB Aug. 23, 2016) (Paper 10) (rehearing denied, Paper 12); *Fustibal v. Bayer healthcare LLC*, IPR2016-01490, (PTAB Feb. 8, 2017) (Paper 9); *Micro Labs v. Santen*, IPR2017-01434 (PTAB Nov. 29, 2017) (Paper 11); *Sawai Inc. v. Astellas Pharma Inc.*, IPR2018-00079 (PTAB May 4, 2018) (Paper 7); *Initiative for Medicines v. Gilead Pharmasset*, IPR2018-00122 (PTAB May 21, 2018) (Paper 10); *SFC Co. v. LG Chem LTD*, IPR2020-00178.
7. *Sawai Inc. v. Astellas Pharma Inc.*, IPR2018-00079 at 14 (Paper 7).
8. *NOF Corporation v. Nektar Therapeutics*, IPR2019-01397, 3 (PTAB Aug. 5, 2021) (Paper 70). The technical details of this case are complex and not relevant to our discussion of the law applied by the Board in assessing obviousness.
9. *Id.* at 10.
10. *Id.* at 11.
11. *Id.*
12. *Id.* at 56-57.
13. Admittedly, the PTAB has not always applied the LCA in chemical AIA cases. For example, the PTAB also did not apply the lead compound analysis in assessing obviousness of a chemical genus in IPR2017-02005. There, the PTAB did not agree with the Petitioner that the modified prior art subgenus would be "almost entirely within the scope of" the claimed genus, and declined to institute trial. *Gilead Sciences v. Regents of the University of Minnesota*, IPR2017-02005, 17 (PTAB May 29, 2020) (Paper 40).
14. *Alzheon Inc. v. Risen (Suzhou) Pharma Tech Co., Ltd.*, IPR2021-00347, 2 (PTAB July 14, 2021) (Paper 10).
15. *Id.* at 3.
16. *Id.* at 10.
17. *Id.*
18. *Id.* at 13.
19. *Id.* at 20.
20. *Id.* at 22.
21. *Id.* at 25.
22. *Id.* at 25-26.
23. *Id.* at 26.
24. *Id.* at 30.
25. *Incyte Corporation v. Concert Pharmaceuticals, Inc.*, IPR2017-01256 (PTAB Apr. 8, 2019) (Paper 119) (request for Director's review pending).

Standard Essential Patents at the PTAB: Are SEPs Faring any Differently than non-SEPs? – Impacts and Analysis

BY: RYAN C. RICHARDSON AND LAUREN A. WATT

Standard Essential Patents are on the Rise, as is Litigation

Standard-essential patents (SEPs) are on the rise as connectivity, a present-day necessity, relies on standards subject to SEPs. It is estimated that by 2025, more than 26 billion home and workplace devices will be connected to the internet and have embedded software or sensors.[1] The economic impact of these "connected" devices is estimated to be approximately $10 trillion per year by 2025.[2] It is no surprise then that in the last several years, the number of issued SEPs has increased dramatically; one report states that the number of patent families declared essential in 2020 was 17.6 thousand, almost triple the number in 2015.[3] In addition to a surge in quantity, the relevance of SEPs has broadened—wireless and telecom standard technology has become prevalent in everything from biotech and automotive products to home appliances. Consequently, the impact of patents covering standard essential technology will be felt across all major industries.

Predictably, the number of SEPs involved in litigation follows the progression of the technology. With the increased adoption of 4G technology, there was a subsequent rise in litigation of SEPs; the more products that were 4G compliant meant more potential infringers, which led to increased SEP litigation.[4]

It is highly likely that the adoption of 5G technology will similarly cause another spike in SEP litigation in the coming years.

The Threat of Injunctive Relief

As the widespread adoption of standardized technologies continues to rapidly increase, the number of technology implementers that find themselves entangled in SEP disputes will also increase. Technology implementers therefore must be aware of the potential risks involved with SEP litigation. This includes understanding who the SEP holders are, their relative business objectives, and their SEP litigation history. But regardless of the existing SEP landscape, the biggest risk to potential infringers will always be the threat of an injunction.

Previously, SEP-based injunctions had not been viewed as a viable option. SEPs are generally FRAND-encumbered, meaning that the SEP holder has made a promise to license its SEPs on fair reasonable and non-discriminatory terms, which has been viewed by many courts as an admission that monetary damages are adequate compensation.[5] But in 2019, the US Patent and Trademark Office (USPTO), US Department of Justice (DOJ), and National Institute of Standards and Technology (NIST) issued a joint statement to clarify their collective view that SEPs should be eligible for injunctive relief.[6] The statement provided that, as with all other patents, infringement of SEPs should be analyzed for potential injunctive relief under the *eBay* framework.[7] In 2020, the DOJ repeated this position in a letter to the Institute of Electrical and Electronics Engineers.[8] While the availability of SEP-based injunctions has once again been thrown into a state of flux with a new administration and leadership changes in key positions within the DOJ and Federal Trade Commission (FTC), the possibility of injunctive relief in an SEP dispute remains.

"[T]he relevance of SEPs has broadened—wireless and telecom standard technology has become prevalent in everything from biotech and automotive products to home appliances. Consequently, the impact of patents covering standard essential technology will be significant across all major industries."

With injunctions a clear possibility, *inter partes* reviews (IPRs) offer a strategic option for defendants. A pending or already-instituted IPR decreases a patentee's chances of obtaining an injunction against a defendant in district court,[9] and increases the likelihood of obtaining a stay of the district court proceedings. Thus, filing an IPR petition early in the course of litigation is critical to the technology implementer's defense. Moreover, US Patent Trial and Appeal Board (PTAB) judges are generally more receptive to invalidity arguments relating to highly complex technology (which is often the case with SEPs), more so than district court judges and juries, thereby making the PTAB an attractive forum for technology implementers seeking to defend against SEP litigation.[10] Conversely, mitigating the effect of an IPR on a request for injunctive relief should be a primary focus of an SEP holder. To this end, SEP holders should research available forums and select an injunction-friendly court if possible. SEP holders should also lay out specific details in the complaint to paint the technology implementer as an unwilling licensee (an important factor in determining the availability of injunctive relief involving SEPs), and should seek expedited discovery under FRCP 26(d), which could factor into whether the PTAB decides to use its discretion to deny institution of the IPR.

Petitioners are successfully challenging SEPs at the PTAB

Unsurprisingly, the number of IPRs filed against SEPs has also followed the progression of the technology, and the widespread adoption of agreed-upon standards. As illustrated in Figure 1 below, IPR filings against SEPs saw spikes in 2013-2014 and again in 2020-2021 following the rollouts of 4G and 5G, respectively.

Petitioners challenging SEPs have had similar success at the PTAB as those challenging regular patents, dispelling any notion that SEPs are necessarily higher quality. As shown in Figure 2 (pg. 65), IPRs involving electronics-based SEPs have similar institution rates as proceedings involving non-SEP electronics patents.[11] The two outlier years—2013 and 2020—which saw significantly lower institution rates for IPRs involving electronics-based SEPs coincided with the rollout of new standards. These lower institution rates are likely due to the unsettled nature of the technology and available universe of prior art.

Additionally, Figure 3 (pg. 65) shows that IPRs involving electronics-based SEPs have similar claim cancellation rates as proceedings involving non-SEP electronics patents, and actually have higher chances of having all claims cancelled.

One important factor behind the high claim cancellation rates for IPRs involving SEPs—which generally cover highly complex technology with only incremental improvements over existing technology—is the choice of prior art. Seventy-six percent of all IPRs filed against SEPs used non-patent literature (NPLs) as prior art, and 66% of these proceedings specifically used NPLs that were produced explicitly for the purpose of developing and refining standards (SEP NPLs), e.g., technical specifications/reports or working group documents produced under the auspices of a standard-setting organization. While the use of NPLs, and specifically SEP NPLs, has led to high claim cancellation rates (75% and 86%, respectively), such references come with their own set of challenges. It can be difficult to prove that these references are printed publications that were publicly accessible sufficiently early, which—despite their compelling substance—has led to relatively low institution rates (45% for NPLs and 53% for SEP NPLs).

Considerations for Petitioners and Patent Owners

In light of the pros and cons of utilizing NPLs, petitioners should consider presenting both a set of patent-based grounds *and* a set of non-patent-based grounds in a single IPR petition (if possible) challenging an SEP. Doing so may allow petitioners to both avoid the lower institutions rates and take advantage of the higher claim cancellation rates associated with using NPLs as prior art. If it is not possible to fit both sets of grounds in a single petition, then petitioners should consider filing two petitions and highlighting the potential for a public accessibility challenge to the set of non-patent-based grounds as justification for instituting both petitions. At the very least, this approach will increase the likelihood that the SEP holder will raise any public accessibility challenge prior to institution, and may in turn increase the chances that the PTAB will address or resolve these issues at institution.

Additionally, petitioners should engage experts to authenticate references that have personal experience with the relevant standard setting organizations (SSOs) that produced the SEP NPLs being considered for prior art. This may mean that the petitioner engages multiple experts: one to authenticate the NPLs and another to

Figure 1: IPRs filed against SEPs

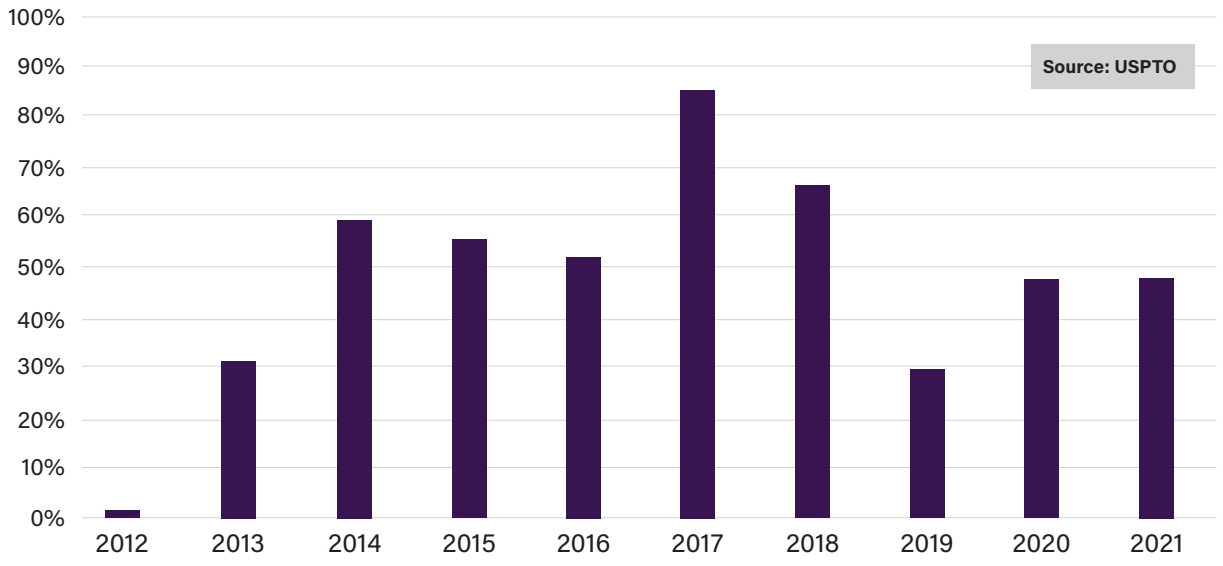
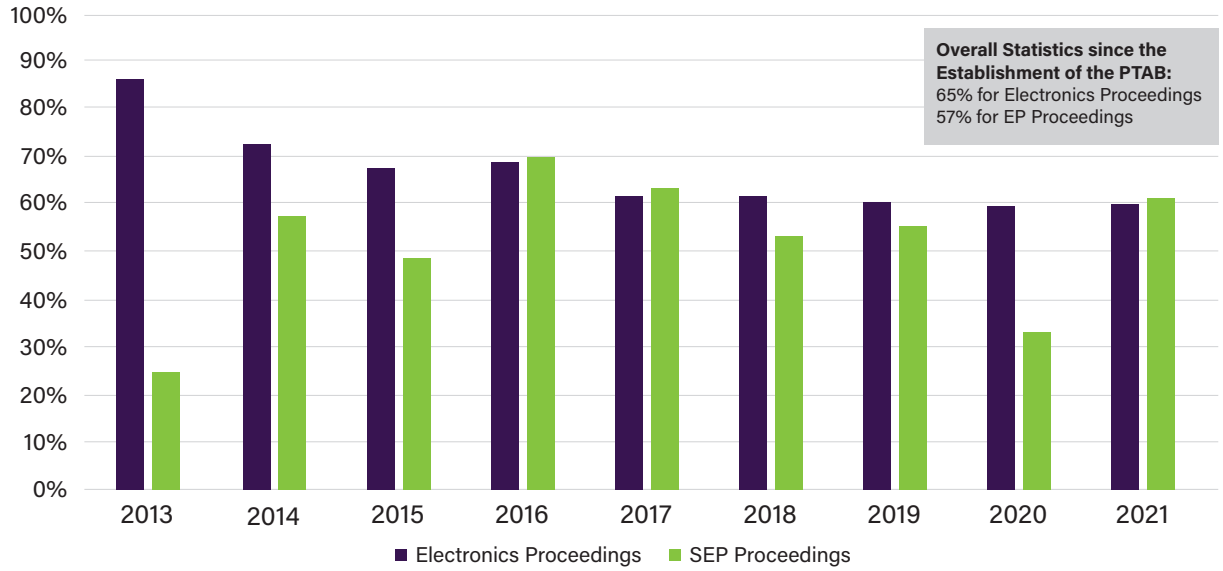


Figure 2: Proceeding Institution Rate (Electronics IPRs)



speak to patentability, including factors relevant to obviousness and reasons to combine the prior art.

Petitioners should also be aware of possible priority date issues that can impact the available pool of prior art. SEP holders tend to file applications as early as possible as they compete to get their proposed technology adopted as the standard. The earlier the application, the more likely that continuation or divisional applications were filed in an attempt to have these later-filed claim sets read on the final version of the standard. This means that if the SEP being challenged claims priority to an earlier filed application, the claims of the challenged SEP may not be supported by the earlier application(s). This could prevent the patent owner from getting an earlier priority date, thereby increasing the available pool of prior art by a couple months or even years. This can make all the difference when dealing with SEPs that are generally in highly congested technology spaces and may cover only incremental changes.

On the other side, patentees' strategies should include challenging the public availability of the asserted references at the institution stage. This may include engaging multiple experts as well, where one is specifically tasked with rebutting the documentation and distribution practices of the relevant SSOs. Patentees should also contact the named inventor(s) to get the complete invention story, including facts relevant to objective indicia evidence. As technology implementers will often argue that SEPs only cover incremental changes to previous versions of a standard, being able to tell a compelling story of why those changes would not in fact have been obvious will be important. Finally, in light of the highly congested technology spaces that SEPs generally cover, patentees should also fully understand art cited and applied during prosecution of the entire SEP family. Additionally, patentees should consider developing a fulsome record during prosecution of the SEPs, including citing all relevant references in an IDS. Patentees should then seek to leverage recent precedential decisions to show that art or arguments applied in the IPR are redundant of art or arguments presented during prosecution.[13] Indeed, the PTAB has demonstrated "a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown."[14]

SEPs Moving Forward

IPRs will continue to play a critical role in the prevalence and impact of SEPs. The PTAB has become well-versed in dealing with SEP challenges, and in comparison to district court judges and juries, PTAB judges are generally more receptive to complex technical positions and unpatentability arguments. Thus stakeholders will benefit from incorporating PTAB strategy into their overall litigation plans.

Figure 3: Claim Cancellation Outcomes at FWD (Electronics IPRs)[12]

	All Claims Cancelled	Some Claims Cancelled	No Claims Cancelled	Total Number of Claims
SEP Proceedings	78%	5%	17%	137
Electronics IPRs	71%	15%	14%	2506

1. Yann Ménière, Ilja Rudyk & Javier Valdes, *Patents and the Fourth Industrial Revolution: The Inventions Behind Digital Transformation* 10 (Eur. Pat. Off. ed., 2017).
2. *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Setting Out the EU Approach to Standard Essential Patents*, at 1, COM (2017) 712 final (Nov. 29, 2017) (noting the potential is up to EUR 9 trillion per year in developed countries).
3. Tim Pohlmann, *SEP Litigation Trends: What Does the Data Say?* 1 (IPlytics GmbH ed., 2021).
4. *Report: Litigation Landscape of Standard-Essential Patents* 2 (Darts-IP ed., 2019).
5. *Realtek Semiconductor Corp. v. LSI Corp.*, 946 F. Supp. 2d 998 (N.D. Cal. 2013).
6. U.S. Pat. & Trademark Off., U.S. Dep't of Just. & Nat'l Inst. of Standards & Tech., Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments, at 4-5 (Dec. 19, 2019).
7. *Id*. at 6.
8. Letter from Makan Delrahim, Assistant Att'y Gen., U.S. Dep't of Just., to Sophia A. Muirhead, Gen. Couns. & Chief Compliance Officer, Inst. of Elec. & Elecs. Eng'rs, Inc. (Sept. 10, 2020).
9. *See, e.g., Order, DNA Genotek Inc. v. Spectrum Sols. L.L.C.*, Case No. 16-CV-1544 JLS (NLS) (S.D. Cal. Oct. 6, 2016) (denying a preliminary injunction for patent infringement based on an IPR filed against the asserted patent); *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1263 (Fed. Cir. 2012) (vacating a preliminary injunction because "the district court incorrectly concluded that [Defendant] failed to raise a substantial question of validity regarding the asserted claims of the [] patent").
10. Importantly, courts have held that an implementer cannot be criticized for challenging the validity of an SEP, and doing so does not render the implementer an unwilling licensee (a label that in some jurisdictions can increase the likelihood of an injunction). *See, e.g., Motorola Mobility LLC*, 156 F.T.C. 147, 205-06 (2013).
11. A Docket Navigator search of motion success indicated petitions against non-SEP patents have a 65% institution rate and petitions against SEPs have a 57% institution rate.
12. Statistics provided by Docket Navigator and refer to the percentage of the total claims that made it to a final written decision.
13. *See, e.g. Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469 (P.T.A.B. Feb. 13, 2020); *Oticon Med. AB v. Cochlear Ltd.*, IPR2019-00975 (P.T.A.B. Oct. 16, 2019); *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586 (P.T.A.B. Dec. 15, 2017).
14. *Advanced Bionics*, IPR2019-01469, at 9.

"The appellate practice here is a strong one, with contributions coming from many and staunch leadership. The overall picture at Sterne Kessler is one of excellence."

— Intellectual Asset Management "IAM Patent 1000 2021"

This page intentionally left blank.

Visit us at sternekessler.com
to stay up to date on our news and events.

Podcast ▪ Newsletters ▪ Webinars
Client Alerts ▪ Articles ▪ Events

Sterne Kessler
STERNE KESSLER
GOLDSTEIN & FOX

Sterne, Kessler, Goldstein & Fox PLLC
1100 New York Avenue, NW
Washington, DC 20005
202.371.2600