Sterne Kessler
STERNE KESSLER GOLDSTEIN & FOX

2024

PTAB Year in Review

ANALYSIS & TRENDS | 5TH EDITION

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Introduction

The Patent Trial and Appeal Board (PTAB) continues to play a pivotal role in shaping the intellectual property landscape. In 2024, several developments affecting PTAB practice emerged, from new rulemaking at the USPTO to key Director Review decisions and ongoing issues at the interface between the PTAB and district courts. Our 2024 PTAB Year in Review report provides an in-depth exploration of these key developments and more, offering insights into the evolving dynamics at the PTAB and their broader implications for practitioners, patent holders, and challengers alike.

This year, we analyze case highlights from the past year, review the latest USPTO rulemaking efforts at the PTAB, and explore newly codified procedures, such as the Director Review process. Key topics also include the delineation of permissible arguments in replies, signature requirements at the PTAB, and significant shifts at the Federal Circuit. Additionally, the report takes a closer look at strategic challenges in PTAB practice, such as navigating IPR estoppel, leveraging experimental data in proceedings, and addressing genus claims. Complemented by statistical overviews and analyses, our comprehensive review serves as a guide to understanding the PTAB's trajectory and being prepared for what lies ahead.

We encourage you to not simply read the articles, but also to critically challenge our analysis and consider the impact of these issues on your patent litigation and portfolio development strategies. We thank our authors and our entire PTAB Trials 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 topics you would like to see us cover in 2025, please do not hesitate to contact us directly to start the conversation.

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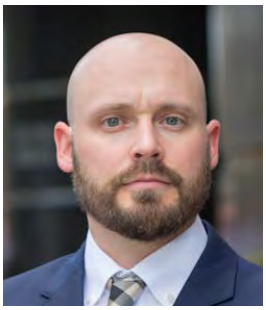

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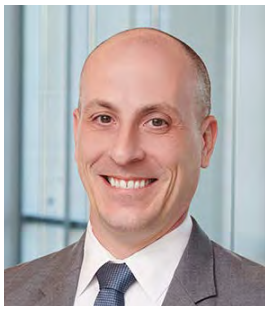

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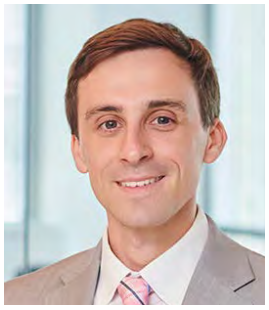

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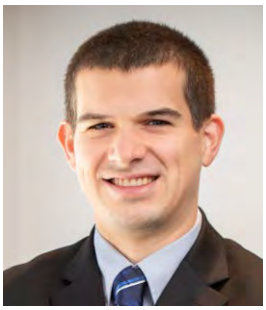

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2024 PTAB Case Highlights

BY JOSEPH K. VENIER AND JASON A. FITZSIMMONS

Abuse of Process and/or Sanctions - 37 C.F.R. § 42.12

Spectrum Solutions LLC v. Longhorn Vaccines & Diagnostics, LLC, IPR2021-00847, IPR2021-00850, IPR2021-00854, IPR2021-00857 & IPR2021-00860

Decision modifying-in-part order granting petitioner's motion for sanctions - Paper 143 (public version of confidential Paper 142) (Vidal July 26, 2024)

> The Director ordered review *sua sponte* in several proceedings where the Board sanctioned patent owner for deliberately withholding and concealing factual evidence relevant to patentability. The review addressed the questions of what regulations are implicated when a party withholds factual evidence during an AIA proceeding, whether an adverse final written decision deeming claims unpatentable is an appropriate sanction for such withholding, and whether any other sanctions may be appropriate. The Director determined that 37 C.F.R. Part 11 (concerning representation of others before the USPTO) and Part 42 (concerning PTAB trial practice) were implicated, but 37 C.F.R. § 1.56 (duty to disclose information material to patentability) was not. The Director further determined that the Board had the authority to hold claims unpatentable as a sanction, and that holding seven claims unpatentable as a sanction - out of 183 claims at issue, the rest of which were unpatentable on the merits - was proportionate to patent owner's "egregious conduct [that] included serious violations of multiple regulations,"[1] referring to patent owner's withholding of material evidence that was inconsistent with its arguments in favor of patentability of the challenged claims. Finally, the Director held that lesser sanctions such as additional opportunity for discovery, compensatory expenses, and attorney fees would be insufficient for the case at hand without ruling them out for less egregious misconduct. The Director accordingly affirmed the Board's sanction of entry of adverse judgment as to all challenged claims.

OpenSky Industries, LLC v. VLSI Technology LLC, IPR2021-01064

Order granting motion for fees – Paper 147 (public version of confidential Paper 141) (Vidal January 22, 2024)

> The Director issued an order granting a motion for fees after the Federal Circuit resolved both parties' appeals and remanded the case back to the USPTO to resolve remaining sanctions issues. In the order, the Director drew a distinction between patent owner's billing statement, created from patent owner's counsel's time records made contemporaneously with work done earlier in the proceeding, and "after-the-fact reconstructions"[2] of time found insufficient to support attorneys' fee awards in other cases. The Director accordingly found patent owner's billing statement to be acceptable evidence for the purpose of calculating an attorneys' fee award as a sanction for petitioner's misconduct, including discovery misconduct, disregard for the Director's prior orders, and other unethical conduct. The Director also rejected petitioner's argument that patent owner should not be awarded attorney's fees under the doctrine of unclean hands. Petitioner alleged that patent owner had unclean hands from misrepresenting fact and law, but the Director determined that the alleged misrepresentations had been addressed separately in an earlier Director order and therefore had no bearing on the sanctions for petitioner's conduct.

Decision granting-in-part petitioner's request on rehearing of order granting motion for fees – Paper 149 (Vidal March 11, 2024)

> In response to petitioner's request to modify the order granting the motion for fees, the Director agreed to modify the order to require payment of the awarded fees after the conclusion of all related appeals, rather than 30 days after the date of the order. However, the Director rejected petitioner's argument that the fee award was improperly calculated. Petitioner argued that the order granting the motion for fees did not show a "but for" link between specific misconduct and the awarded fees. The Director

determined that petitioner's "but for" causation argument was unduly narrow. The Director concluded that the order set forth a sufficient link between petitioner's misconduct and the subsequent work for which patent owner was awarded fees, noting that the relevant authority grants the fact-finder "discretion and judgment"[3] in assessing such a link. Subsequently, patent owner filed an amended notice of appeal[4] and petitioner filed a second notice of appeal[5], both for the purpose of challenging the Director's decision.

Bar Due to Patent Owner's Action – 35 U.S.C. § 315(b)

Luminex International Co., Ltd. v. Signify Holdings B.V., IPR2024-00101

Order vacating decision denying institution, and remanding for further proceedings – Paper 12 (Vidal August 20, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board determined Menard was a real party in interest that petitioner failed to identify in the petition, and that 35 U.S.C. § 315(b) barred institution because Menard had been served with a complaint alleging infringement of the challenged patent more than one year before the petition was filed. The Board panel's basis for finding Menard to be a real party in interest was that, in its answer to the complaint, Menard asserted as a defense that "Menard's suppliers will indemnify and defend Menard in this action,"[6] and then filed a third-party complaint against petitioner asserting entitlement to indemnification. Petitioner filed the petition for *inter partes* review less than one year later. The Director vacated the panel's decision, finding that the record evidence did not establish that Menard was the real party in interest. The Director also determined that the record evidence did not establish that Menard was a "privy of the petitioner,"[7] which the Board panel did not consider but which would also have resulted in the petition being time barred under 35 U.S.C. § 315(b). The Director also stated that she would issue a subsequent opinion detailing her reasoning for her determinations. On remand, the Board granted institution of *inter partes* review.[8]

Director Review supplemental opinion – Paper 20 (Vidal November 21, 2024)

In her subsequent opinion, the Director stated that the "heart of the real party in interest inquiry is focused on whether a petition has been filed at a party's behest."[9] The Director then characterized the indemnity agreement at issue as evidencing a "fairly standard customer-manufacturer relationship regarding the accused product" that "does not support an inference that the Agreement gives Menard the opportunity or ability to control this IPR proceeding or Petitioner's filing of the Petition."[10] The Director relied on these same characteristics of the indemnity agreement to support the conclusion that the agreement did not create the kind of pre-existing legal relationship that would have made Menard a privy of petitioner. The Director found that these facts distinguished *Ventex Co., Ltd. v. Columbia Sportswear North America, Inc.*, IPR2017-00651, Paper 152 (PTAB Jan 24, 2019) (precedential), where the Board found that an indemnification agreement *coupled with* an exclusive manufacturer-customer relationship between the petitioner and a third party supported a conclusion that the third party was a real party in interest. The Director found this distinction appropriate as a matter of policy to avoid encouraging patent owners to file complaints against indemnified resellers with the intent to avoid IPR challenges by indemnifying manufacturers.

Claim Construction

PLR Worldwide Sales Ltd. v. Flip Phone Games Inc., IPR2024-00133

Decision vacating decision denying institution, and remanding for further proceedings – Paper 12 (Vidal August 22, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board

determined that the record did not show a reasonable likelihood that petitioner would prevail with respect to any claim. The panel's determination was based on a finding that the prior art in the petition failed to disclose a "non-promotional background object"[11] in a mobile video game as recited in the challenged claims. The panel nonetheless found that the alleged "non-promotional background object" in petitioner's prior art failed to meet the definition of that claim term because it was not "unexpectedly interactive."[12] Because the panel's analysis hinged on assumptions about what a user would or would not expect, the Director determined that the decision not to institute involved a claim construction that "was improperly based on the subjective perspective of the user."[13] The Director accordingly vacated and remanded the decision with instructions to resolve the proper construction of the term "non-promotional background object." On remand, the Board referred to intrinsic and extrinsic evidence, including a dictionary definition of the word "background," to construe the claim term "background" as meaning "the part of a pictorial representation that is not in the foreground."[14] Based on that construction, the Board granted institution of *inter partes* review.[15]

Samsung Electronics Co., Ltd. v. Slyde Analytics, LLC, IPR2024-00040

Decision vacating decision denying institution, and remanding for further proceedings – Paper 14 (Vidal August 2, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board determined that the record did not show a reasonable likelihood that petitioner would prevail with respect to any claim. After observing that neither party provided a construction for the claim term "processor," nor did the specification of the challenged patent set forth a definition for that term, the Board turned to the definition for "processor" in The Authoritative Dictionary of IEEE Standards Terms (7th e. 2000).[16] Based on that definition, the Board construed "processor" to be something that executes code, a program, or instructions. The Board then concluded that the alleged "processor" in petitioner's prior art failed to meet that construction. The Director determined that the Board had failed to adequately consider two pieces of intrinsic evidence: (1) that the Board's construction of "processor" would have rendered one of the limitations in challenged claim 14 redundant to another, and (2) that the specification's mention of "a processor or other processing means for executing programmable software code" implied that the term "processor" as used in the challenged patent does not necessarily refer to something capable of "executing programmable software code."[17] The Director accordingly vacated and remanded the decision with instructions to resolve the proper construction of the term "processor." On remand, the Board relied on the same passage of the specification to again construe "processor" as something configured to execute programmable code and denied institution of *inter partes* review.[18]

ASSA ABLOY AB v. CPC Patent Technologies Pty, Ltd., IPR2022-01006, IPR2022-01045 & IPR2022-01089

Decision vacating Final Written Decision and remanding for further proceedings – Paper 49 (Vidal March 15, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's final written decision that petitioner had failed to show any claim in multiple related patents to be unpatentable. The Board panel's decision was based on a construction of a claim term that did not match either party's proposed construction. The Board gave the same claim term its plain and ordinary meaning in a preliminary construction in its institution decision, but adopted a new construction in its final written decision. The Director stated that "under the APA, the Board may not change theories midstream by adopting a different claim construction in the final written decision than that adopted in the institution decision without giving respondents reasonable notice of the change and the opportunity to present argument under the new theory."[19] The Director accordingly vacated the final written decision in each proceeding and remanded the proceedings with instructions to authorize petitioner and patent owner to

file briefs addressing the Board's new construction for the term in question. On remand, the Board arrived at a different construction of the claim term in view of briefing from the parties, but again found that petitioner had failed to show any claim unpatentable.[20]

Expert Testimony

MAHLE Behr Charleston Inc. v. Frank Amidio Catalano, IPR2023-00861

Decision vacating decision on institution and remanding for further proceedings – Paper 15 (Vidal April 5, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board found that a drawing in one of petitioner's prior art references failed to teach a sacrificial anode placed within 10 inches of a hot liquid inlet to a radiator because the prior art reference was silent as to the scale of the drawing. The Board also dismissed petitioner's expert's testimony that a skilled person would have interpreted the drawing in question as showing the sacrificial anode and hot liquid inlet at the same place, and therefore necessarily less than 10 inches apart, as an attempt "to back-fill with opinion testimony a prior art disclosure that does not suggest a required feature of the claimed invention."[21] The Director agreed that back-filling a prior art reference with opinion testimony would be improper, but disagreed with the Board's finding that petitioner had attempted to do so since the relevant expert testimony had not been provided without "additional supporting evidence or … technical reasoning."[22] Instead, petitioner's expert testimony related to how a skilled person would have interpreted elements that were shown on the face of the relied upon prior art drawing, and "[t]he Board should have thoroughly evaluated this argument and evidence."[23] The Director accordingly vacated the decision and remanded the case with instructions to the Board to consider whether petitioner's expert testimony provides sufficient "technical detail, explanation, or statements supporting"[24] the expert's determination. On remand, the Board considered, but ultimately disagreed with, the expert's determination and denied institution again.[25]

Institution/Multiple Petitions

Videndum Production Solutions, Inc. v. Rotolight Limited, IPR2023-01218

Decision vacating decision on institution and remanding for further proceedings – Paper 12 (Vidal April 19, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying decision, the Board weighed the *General Plastic* factors to determine whether to exercise discretion to deny institution in view of an earlier *inter partes* review that had been instituted on similar grounds to those raised in the present petition, but had been voluntarily terminated due to a settlement before the present petition was filed. The panel majority and the dissent agreed that petitioner had no significant relationship with the filer of the earlier petition. However, the panel majority "plac[ed] particular relevance on the third factor"[26] ("whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or… the Board's decision on whether to institute review in the first petition") and determined that the circumstances weighed in favor of denying institution, while the dissent found the opposite. On review, the Director determined that "where… the first and second petitioners are neither the same party, nor possess a significant relationship under *Valve*, *General Plastic* factor one *necessarily outweighs* the other *General Plastic* factors."[27] Noting that *General Plastic* concerned two petitions filed by the same petitioner and *Valve* extended the *General Plastic* framework to petitioners having a "significant relationship," the Director observed that *General Plastic* had never been extended to denying a second petition filed by an entity having no relationship to the filer of the first petition. The Director accordingly vacated the Board's decision and remanded with instructions to issue a decision on institution based on the merits of the petition. On remand, the

Board considered the merits of the petition and granted *inter partes* review.[28]

Ford Motor Company v. Neo Wireless LLC, IPR2023-00763[29]

Decision vacating decision on institution and remanding for further proceedings – Paper 28 (Vidal March 22, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board weighed the *General Plastic* factors and decided to exercise discretion to deny institution. The Board's decision was based in part on a determination that petitioner had a "significant relationship" (which petitioner disputed) under *Valve* with the filer of an earlier petition (Volkswagen) because petitioner and Volkswagen were co-defendants in related litigation, and because petitioner had used the earlier petition as a roadmap for its own. The Director found no such significant relationship between petitioner and Volkswagen on the basis that the parties found to be related in *Valve* were both co-defendants in litigation *and* were accused of infringement based on the same product, for which the parties had an ongoing licensing relationship. Without expressly deciding the accuracy of the Board's characterization of petitioner and Volkswagen as a co-defendants, the Director distinguished the facts in *Valve* on the basis that petitioner and Volkswagen had not cooperated in any relevant matter except in court-ordered pretrial coordination in the related litigation. The Director also noted that petitioner and Volkswagen were accused of infringement based on different products, and therefore had relatively little alignment in their interests. The Director accordingly vacated the Board's decision and remanded with instructions to issue a decision on institution based on the merits of the petition. On remand, the Board considered the merits of the petition and granted *inter partes* review.[30]

Multiple Proceedings - 35 U.S.C. § 325(d)

Nokia of America Corporation v. Alexander Soto and Walter Soto, IPR2023-00680, IPR2023-00681 & IPR2023-00682

Decision vacating decision on institution and remanding for further proceedings – Paper 18 (Vidal March 28, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board applied the *Advanced Bionics* framework to determine whether to deny institution under 35 U.S.C. § 325(d). Finding in the first part of the framework that substantially the same art and substantially the same arguments previously were presented to the Office and in the second part of the framework that petitioner had not demonstrated that the Office erred in a material manner, the Board exercised discretion to deny institution. On review, the Director determined that the Board had not sufficiently addressed petitioner's arguments related to the first part of the *Advanced Bionics* framework. The Director observed that the petition first pointed out differences between its prior art and the prior art cited by the Examiner, and second explained how those differences led to a different proposed combination and motivation to combine argument than that raised by the Examiner. The Director found that the Board failed to address petitioner's arguments as to either aspect of the first part of the *Advanced Bionics* framework by "simply stat[ing] that it was unpersuaded"[31] without explaining which of petitioner's relevant points it disagreed with. The Director also found that the Board's analysis, which reduced both the ground in the petition and the Examiner's rejection to "a first reference cited for electrical signal processing components combined with a second reference cited for pluggable form factors,"[32] improperly focused on the claim limitations rather than the underlying art and arguments. Accordingly, the Director vacated the Board's decision and remanded with instructions to reassess whether discretionary denial was appropriate. On remand, the Board again determined that petitioner presented substantially the same art and arguments as

previously presented to the Office without demonstrating that the Office erred, and denied institution.[33]

Decision vacating decision on institution and remanding for further proceedings – Paper 30 (Vidal December 3, 2024)

On remand, the Board denied institution again. Petitioner filed a second request for Director Review, and the Director again vacated the Board panel's decision denying institution. This time, in the underlying panel decision, the Board explained that it considered the petitions to present substantially the same art and arguments that were overcome during prosecution in part because both petitioner's and the Examiner's prior art references lacked a "pluggable optical transceiver." The Director found the Board's analysis insufficient for failing to address the fact that Applicant had distinguished the Examiner's primary reference by arguing that it lacked an optical transceiver at all, pluggable or otherwise, whereas it had not been disputed that petitioner's primary references disclosed an optical transceiver. The Director also addressed patent owner's arguments that discretion should be exercised to deny institution under § 314(a) because of the state of parallel district court proceedings, which had not been resolved in the previous Board decisions or Director Review. The Director found that three of the six *Fintiv* factors were neutral, but on balance the factors weighed against denying institution. While factor 2 ("proximity of the court's trial date to the Board's projected statutory deadline for a final written decision") weighed slightly in favor of denial because the Board's final written decision would be "likely to issue a few months after the currently scheduled district court trial date," the Director found that factor 3 ("investment in the parallel proceeding by the court and the parties") and factor 4 ("overlap between issues raised in the petition and in the parallel proceeding") together weighed more heavily against denial. Factor 3 weighed against denial because fact discovery, expert discovery, and claim construction briefing had not concluded, and factor 4 weighed "marginally" against denial because petitioner had submitted a *Sand Revolution* stipulation, agreeing not to "pursue invalidity against the asserted claims in the district court proceeding using the specific combination of prior art references set forth" in the petitions. Accordingly, the Director vacated the Board's decision and remanded with instructions to reassess whether denial was appropriate.

Obviousness - 35 U.S.C. § 103

Hesai Technology Co. Ltd. v. Ouster, Inc., IPR2023-01458

Decision vacating decision on institution and remanding for further proceedings – Paper 14 (Vidal July 25, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's decision denying institution. In the underlying panel decision, the Board determined that petitioner had not shown that a prior art reference disclosed an arrangement of detectors because petitioner had relied on an arrangement of 36 elements shown in one of the reference's drawings, but the reference's specification described the illustrated device as including 32 detectors. The Board concluded it could not assume the cited elements in the drawing were detectors because of that discrepancy. The Director disagreed, noting that "where a prior art reference includes an obvious error of a typographical or similar nature… the errant information cannot be said to disclose subject matter,"[34] but "the remainder of the reference would remain pertinent prior art disclosure."[35] The Director determined that the Board had erred by relying on an apparent typographical error in the prior art reference to disregard the disclosure of the relied upon drawing. The Director further found that the Board had erred by disregarding the drawing because the discrepancy in the specification related to the quantity of detectors, but petitioner had relied on the drawing for the arrangement of detectors it plainly showed. Accordingly, the Director vacated the Board's decision and remanded with instructions to consider the non-errant portions of the relied upon drawing.

Obviousness/Secondary Considerations

Nearmap US, Inc. v. Eagle View Technologies, Inc., IPR2022-00734

Decision vacating Final Written Decision and remanding for further proceedings – Paper 43 (Vidal February 20, 2024)

In response to petitioner's request for Director Review, the Director vacated the Board panel's final written decision that no claims were shown unpatentable. In the underlying panel decision, the Board determined that patent owner's evidence concerning secondary considerations of nonobviousness under the fourth *Graham* factor outweighed the strength of petitioner's grounds of invalidity. In making this determination, the Board did not resolve the construction of a claim term for which the parties advanced two different interpretations. The Director found that the Board had failed to conduct all necessary analysis because the final written decision's treatment of the petition's grounds of invalidity amounted to "present[ing] a summary of petitioner's contentions and indicat[ing] that the Board considered petitioner's contentions and evidence in reaching the ultimate conclusion of nonobviousness. However, the Board did so without providing any analysis or explanation to convey its reasoning."[36] Based on that finding, the Director concluded that the Board had not sufficiently explained why the fourth *Graham* factor should outweigh the other three. The Director also found that the claim construction issue bore on the weight of patent owner's evidence relating to secondary considerations of nonobviousness such that the proper construction should have been resolved before balancing the *Graham* factors. Accordingly, the Director vacated the Board's decision and remanded with instructions to set forth a claim construction and a full analysis of all *Graham* factors. On remand, the Board reconsidered petitioner's arguments and found all challenged claims unpatentable.[37]

1 IPR2021-00847, IPR2021-00850, IPR2021-00854, IPR2021-00857 & IPR2021-00860, Paper 143 at pg. 54 (P.T.A.B. July 26, 2024).
2 IPR2021-01064, Paper 147 at pg. 6 (P.T.A.B. January 22, 2024).
3 IPR2021-01064, Paper 149 at pg. 6 (P.T.A.B. March 11, 2024).
4 IPR2021-01064, Paper 150.
5 IPR2021-01064, Paper 151.
6 IPR2024-00101, Paper 12 at pg. 3 (P.T.A.B. August 20, 2024).
7 *Id.* at pg. 4.
8 IPR2024-00101, Paper 14 (P.T.A.B. September 9, 2024).
9 IPR2024-00101, Paper 20 at pg. 8 (P.T.A.B. November 21, 2024) (quoting *Uniloc 2017 LLC v. Facebook Inc.*, 989 F.3d 1018, 1028 (Fed. Cir. 2021) (internal quotation marks omitted)).
10 *Id.* at pg. 12.
11 IPR2024-00133, Paper 12 at pg. 2 (P.T.A.B. August 22, 2024).
12 *Id.* at pg. 6.
13 *Id.* at pg. 7.
14 IPR2024-00133, Paper 14 at pg. 16 (P.T.A.B. November 29, 2024).
15 *Id.* at pg. 55.
16 IPR2024-00040, Paper 14 at pg. 6 (P.T.A.B. August 2, 2024).
17 *Id.* at pg. 10.
18 IPR2024-00040, Paper 17 at pg. 17 and 30 (P.T.A.B. October 10, 2024).
19 IPR2022-01006, IPR2022-01045 & IPR2022-01089, Paper 49 at pg. 5 (P.T.A.B. March 15, 2024) (Quoting Axonics, Inc. v. Medtronic, Inc., 75 F.4th 1374, 1381-82 (Fed. Circ. 2023) (internal quotation marks omitted)).
20 IPR2022-01006, Paper 64 at pg. 81 and 100 (P.T.A.B. August 13, 2024); IPR2022-01045 & IPR2022-01089, Paper 59 at pg. 83 and 105 (P.T.A.B. August 13, 2024).
21 IPR2023-00861, Paper 15 at pg. 8 (P.T.A.B. April 5, 2024).
22 *Id.*
23 *Id.* at pg. 8–9.
24 *Id.* at pg. 9.
25 IPR2023-00861, Paper 18 at pg. 7-12 and 19-20 (P.T.A.B. May 24, 2024)
26 IPR2023-01218, Paper 12 at pg. 5 (P.T.A.B. April 19, 2024).
27 *Id.* at pg. 6 (Emphasis added, with "factor one" referring to the question of "whether the same petitioner previously filed a petition directed to the same claims of the same patent").
28 IPR2023-01218, Paper 15 (P.T.A.B. October 16, 2024).
29 *See also American Honda Motor Co., Inc. v. Neo Wireless LLC*, IPR2023-00797, Paper 27 (P.T.A.B. March 22, 2024) and *General Motors LLC and Nissan North America, Inc. v. Neo Wireless LLC*, IPR2023-00962, Paper 16 (P.T.A.B. March 22, 2024).
30 IPR2023-00763, Paper 30 (P.T.A.B. September 11, 2024).
31 IPR2023-00680, IPR2023-00681 & IPR2023-00682, Paper 18 at pg. 6 (P.T.A.B. March 28, 2024).
32 *Id.* at pg. 7.
33 IPR2023-00680, Paper 26 at pg. 36 (P.T.A.B. July 31 2024); IPR2023-00681, Paper 28 at pg. 34 (P.T.A.B. July 31 2024); IPR2023-00682, Paper 26 at pg. 34 (P.T.A.B. July 31 2024).
34 IPR2023-01458, Paper 14 at pg. 7 (P.T.A.B. July 25, 2024).
35 *Id.* at pg. 8.
36 IPR2022-00734, Paper 43 at pg. 7-8 (P.T.A.B. February 20, 2024).
37 IPR2022-00734, Paper 51 at pg. 28 (P.T.A.B. July 15, 2024).

USPTO Rulemaking in 2024 Related to PTAB Practice and Procedures

BY JENNIFER MEYER CHAGNON

The final year of Director Vidal's tenure as the Director of the U.S. Patent and Trademark Office was a busy year for rulemaking at the Office. Since late 2023, five Notices of Proposed Rulemaking (NPRMs) directly related to Patent Trial and Appeal Board (PTAB) practice were published for public comment. Of those, four have issued as final rules as of December 31, 2024. The fifth, the NPRM on *Patent Trial and Appeal Board Rules of Practice for Briefing Discretionary Denial Issues, and Rules for 325(d) Considerations, Instituting Parallel and Serial Petitions, and Termination Due to Settlement Agreement*,[1] is still awaiting a final rule after the public comment period closed in June 2024. 89 Fed. Reg. 28,693.

The following is an overview of the four PTAB related final rules that became effective in 2024. Also included is an identification of noteworthy fiscal year 2025 fee changes that affect PTAB practice.

Expanding Opportunities to Appear Before the Patent Trial and Appeal Board[2]

This final rule, which published on October 10, 2024, and became effective November 12, 2024, relates to access to practice before the PTAB. 89 Fed. Reg. 82,172. This rule change simplifies and streamlines the *pro hac vice* recognition process, as well as permits a party to forego appointing backup counsel with a showing of good cause.

In particular, Rule 42.10(a) was revised to permit a party to proceed without separate back-up counsel, upon a showing of good cause, such as lack of financial resources. In the Office comments accompanying the final rule, the Office indicated that a party is unlikely to be able to show lack of financial resources if also pursuing litigation in other forums involving the challenged patent. The comments further note that the inquiry focuses on the needs of the *party* requesting the relief, and not the needs or preferences of *counsel*.

Rule 42.10(c) was revised to establish a streamlined procedure for *pro hac vice* recognition for counsel who have been previously recognized as such in a prior PTAB proceeding. § 42.10(c)(2). No fee is required for this streamlined process, however a person seeking recognition must still file a declaration (or affidavit) affirming all requirements for admission are met. The rule also allows the opposing party to filed objections within five business days, but unless the Board orders otherwise within 10 business days, the person is deemed admitted upon filing of updated mandatory notices.

Rule 42.10(c) also was revised to clarify the requirement that any non-registered counsel that has been recognized *pro hac vice* must inform the Board of any updates relevant to the completeness of accuracy of information provided in connection with a prior *pro hac vice* request. § 42.10(c)(3). Another clarifying amendment to Rule 42.10(c) was that a party must establish *legal* familiarity with the subject matter (as opposed to *technical* familiarity) to support a *pro hac vice* request. § 42.10(c)(1).

In response to public comment on the proposed rule, the final rule did *not* include a proposed amendment to permit non-registered counsel to serve as lead counsel.

Rules Governing Director Review of Patent Trial and Appeal Board Decisions[3]

This final rule, which published on October 1, 2024, and became effective October 31, 2024, relates to the process and procedures by which the USPTO Director has review authority over PTAB decisions. 89 Fed. Reg. 79,744.

New Rule 42.75 was added, codifying much of the prior interim process for Director Review that was implemented (and subsequently revised) after the U.S. Supreme Court's decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1986 (2021).

Additional details regarding this new rule are in the article titled: **Process and Procedures for Director Review of PTAB Decisions Codified in 2024**

Rules Governing Motion to Amend Practice and Procedures in Trial Proceedings under the America Invents Act before the PTAB[4]

This final rule, which published on September 18, 2024, and became effective October 18, 2024, addresses motions to amend at the PTAB. 89 Fed. Reg. 76,421.

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continued

A major highlight of the rule changes implemented in this final rule is the option for patent owners to request non-binding preliminary guidance from the Board on their motion to amend, and file a revised motion to amend if desired. These rules makes permanent much of the PTAB's motion to amend pilot program, which was implemented in March 2019 and expired as of the effective date of this new rule.

Rule 42.121(a) was amended to reflect the allowance of requests for preliminary guidance on an original motion to amend. Note, for each of the IPR-specific motion to amend rules, there is a corresponding PGR-specific motion to amend rule, e.g., Rule 42.221(a) here.

Rule 42.121(e) was newly added, and provides additional details regarding the preliminary guidance process, as well as for subsequent briefing by the parties. The patent owner may request, and the Board will provide, non-binding preliminary guidance on the motion to amend. § 42.121(e)(1)-(2). In response, patent owners may file either a patent owner reply or a revised motion to amend in response. § 42.121(e)(3). Petitioners may file a sur-reply to the reply (or reply to the preliminary guidance if patent owner does not respond, to which patent owner can file a sur-reply). § 42.121(e)(4). These rules also set out at which stage(s) new evidence can be submitted.

Rule 42.121(f), also new, authorizes one revised motion to amend as of right in response to petitioner's opposition or the Board's preliminary guidance that is responsive to issues in those papers. The revised motion *replaces* the original motion to amend.

Other clarifying amendments were incorporated into the Motion to Amend rules, including:

Rule 42.121(b) was clarified to reflect that support in the original disclosure must be included *in the motion* for *each* proposed substitute claim.

Rule 42.121(d) was amended to include reference to the types of evidence that the Board may consider in exercising its discretion to grant or deny a motion to amend or to raise a new ground of unpatentability of a proposed substitute claim, 42.121(d)(3). This can include all evidence of record, and the Board also may make of record any evidence from related proceedings, may judicially notice evidence, or may request examination assistance from the examining corps. If the Board raises a new ground, patentability is determined based on a preponderance of evidence in the record, 42.121(d)(4). These revisions do not change the parties' burdens as previously set out in 42.121(d)(1)-(2).

Rules 42.121(e)(1) and 42.121(f)(1) also expressly state that the Board may request the Chief Judge to extend the final written decision deadline in accordance with Rule 42.100(c).

Rules Governing Pre-Issuance Internal Circulation and Review of Decisions Within the Patent Trial and Appeal Board[5]

This final rule, which published on June 12, 2024, and became effective July 12, 2024, addresses the process for decision circulation at the PTAB. 89 Fed. Reg. 49,808. This rule sets forth processes and procedures for PTAB decision circulation and internal PTAB review, with a goal to promote consistent, clear, and open decision-making processes.

New Rules 43.1-6 were added, codifying much of the prior interim process, originally put into place in May 2022, and subsequently modified and memorialized in PTAB SOP4 in October 2023.

Rules 43.1 and 43.2 provide relevant definitions.

Rule 43.3 specifies that the Director and other high-level officers of the USPTO are not involved in panel decisions prior to their issuance. § 43.3(a). In particular, unless sitting as a member of the panel, the Director or other high-level officers will not communicate with panel members regarding the merits of a decision prior to issuance or otherwise attempt to influence or direct the outcome thereof. § 43.3(b)-(c). Paneling authority is delegated, without interference in individual proceedings, to the Chief Judge. § 43.3(d).

Rule 43.4 ensures independent decision making by individual Board panels. PTAB management may not communicate with a panel regarding the merits of a decision prior to issuance, unless (1) a member of the panel specifically

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continued

requests input, or (2) the management judge is sitting as a member of the panel. § 43.4(a)-(b), (d)-(e). Acceptance of any suggested edits or feedback from management or otherwise is at the sole discretion of the panel. § 43.4(c).

Rule 43.5 sets out a procedure for pre-issuance circulation to and review by a designated group of non-management judges, with a goal of ensuring consistent, clear, and open decision-making. By rule, PTAB management may not be involved in this pre-issuance review process, § 43.5(a), and acceptance of any suggested edits or feedback is at the sole discretion of the panel, § 43.5(b). This rule makes clear that the panel has final authority and responsibility for the content of a decision. § 43.5(b).

Rule 43.6 specifies that all Board decisions must comply with all applicable statutes, regulations, binding case law, and written Office policy and guidance applicable to Board proceedings, expressly confirms there is no unwritten Office or Board policy or guidance binding on any panel, and requires that any binding guidance must be written and public.

Setting and Adjusting Patent Fees During Fiscal Year 2025[6]

This final rule, which published on November 20, 2024, and becomes effective January 19, 2025, sets and adjusts fees. 89 Fed. Reg. 91,898. Of most relevance to PTAB practice and procedure, fees for AIA trial proceedings are increasing by 25% across the board. § 42.15. Further, a new fee of $452 for requesting Director Review is to be added. § 42.15(f).

1 https://www.federalregister.gov/documents/2024/04/19/2024-08362/patent-trial-and-appeal-board-rules-of-practice-for-briefing-discretionary-denial-issues-and-rules

2 https://www.federalregister.gov/public-inspection/2024-23319/expanding-opportunities-to-appear-before-the-patent-trial-and-appeal-board

3 https://www.federalregister.gov/public-inspection/2024-22194/director-review-of-patent-trial-and-appeal-board-decisions

4 https://www.federalregister.gov/documents/2024/09/18/2024-21134/rules-governing-motion-to-amend-practice-and-procedures-in-trial-proceedings-under-the-america

5 https://www.federalregister.gov/public-inspection/2024-12823/rules-governing-pre-issuance-internal-circulation-and-review-of-decisions-within-the-patent-trial

6 https://www.federalregister.gov/documents/2024/11/20/2024-26821/setting-and-adjusting-patent-fees-during-fiscal-year-2025

Process and Procedures for Director Review of PTAB Decisions Codified in 2024

BY JENNIFER MEYER CHAGNON

On October 1, 2024, the USPTO published a new final rule, Rules Governing Director Review of Patent Trial and Appeal Board Decisions.[1] The final rule codifies many aspects of the PTAB's revised Interim Director Review process (effective July 24, 2023), and largely tracks the proposed rule that published on April 16, 2024.[2] The final rule became effective October 31, 2024.

The final rule adds a new rule—37 C.F.R. § 42.75—that addresses the following topics:

Scope of Director Review: Subsection (a) defines the scope of Director Review. Director Review is available for any institution decision or final decision in *inter partes* reviews (IPRs), post-grant reviews (PGRs), and derivation proceedings, as well as any decision granting rehearing of such a decision. This is consistent with prior practice under the revised interim Director Review process, and clarifies that derivation proceedings are within the scope of Director Review. The final rule also provides that Director Review is available for "any other decision concluding [an AIA] proceeding" (e.g., a grant of adverse judgment, or a dismissal of the proceeding).

Sua Sponte Director Review: Subsection (b) provides that the Director may *sua sponte* order Director Review. This is consistent with prior practice under the revised interim Director Review process. The new rule adds a deadline for initiating a *sua sponte* review "within 21 days after the expiration of the period for filing a request for rehearing" "absent exceptional circumstances." The rule does not, however, include a specific deadline for the Office to issue any decision on Director Review.

Requests for Director Review: Subsection (c) details the timing and format of the request, which are generally consistent with prior practice under the revised interim Director Review process. A party may file one request for Director Review, as an alternative to requesting panel rehearing. The deadline is the same as the deadline for requesting rehearing (per § 42.71(d)), with extensions available for good cause. The request must follow all format requirements of § 42.6(a) and is limited to 15 pages (per § 42.24(a)(1)(v)). No new evidence is permitted, and there is no responsive briefing by the opposing party. The Director may authorize modifications to these length, response, and evidence limitations in a particular proceeding.

Process: Subsection (e) provides information on the Director Review process. When granting Director Review, the Director will issue an order or decision setting out the scope of review, and a review will conclude with an order or decision providing the Director's reasons for disposition of the case. By default, a request for or initiation of Director Review does not stay any deadlines in the underlying proceeding. However, a request for or initiation of Director Review of an appealable Board decision does reset the time for appeal to the Federal Circuit, which then starts after all issues on Director Review are resolved. This is consistent with prior practice under the revised interim Director Review process. Of note, the rule does not include any specific deadline for the Office to issue any decision on Director Review.

Other Aspects: Subsections (d), (f), and (g) respectively address when an agency decision is considered "final" vis-à-vis a Director Review request, the Director's authority to delegate their review, and the general prohibition against ex parte communications related to specific requests or proceedings.

Many specific details regarding practice and procedures are not expressly included in the final rule. Instead, these details are addressed on the USPTO's Director Review web page,[3] which also was updated for consistency with the updated rule on the October 31, 2024 effective date thereof. The Director Review web page includes, for example, the applicable standards of review, information about precedential designation, possible issues to address in a Director Review request, details of the decision-making process and the Advisory Committee, conflicts of interest, and step-by-step instructions on how to file and perfect a request.

As compared to the prior practice under the revised interim Director Review process, the process instructions in the new Director Review website no longer require a party

Process and Procedures for Director Review of PTAB Decisions Codified in 2024 *continued*

requesting review to separately email the Director Review email address after filing their request in P-TACTS. Another change, effective January 19, 2025 as part of the Fiscal Year 2025 Fee Setting Rule Package, is a new fee of $452 for requesting Director Review.[4]

Notably, Director Review is only applicable to AIA trial proceedings. Director Review is not available for ex parte appeals (including appeals from reexamination or reissue applications). The Appeals Review Panel may be convened by the Director *sua sponte* to review PTAB ex parte appeals decisions, but parties may not request such review.[5]

The new rule regarding Director Review in AIA trial proceedings provides some certainty for parties as to the process, while still maintaining flexibility for the Director in reviewing and deciding Director Review requests.

1 89 Fed. Reg. 79,744.

2 89 Fed. Reg. 26,807.

3 Available at: https://www.uspto.gov/patents/ptab/decisions/director-review-process

4 89 Fed. Reg. 91,898 (November 20, 2024), adding new rule 37 C.F.R. § 42.15(f).

5 See www.uspto.gov/patents/ptab/appeals-review-panel.

Scope of Reply: The Line Between Presenting Permissible Responsive Arguments and Raising Impermissible New Arguments Continues to Take Shape

BY KRISTINA CAGGIANO KELLY, RICHARD BEMBEN, MARC-ANTHONY ARMAND

The PTAB had been historically strict in prohibiting a petitioner from raising new arguments for the first time in its reply brief. All arguments must be adequately presented in a Petition for *inter partes* or post-grant review in order to receive the Board's consideration. Recently, however, the Federal Circuit reversed the Board for failing to allow petitioners to fully address patent-owner arguments—especially claim construction—in their replies.[1]

In *Axonics, Inc. v. Medtronic, Inc.*,[2] the Board adopted a claim construction first presented in the patent owner's response after the institution decision and declined to consider *Axonic's* reply arguments under the new claim construction.[3] The Federal Circuit reversed that aspect of the decision, and remanded with instructions to the Board to consider the petitioner's arguments under the new claim construction.[4] The Court left open the issue of whether a petitioner could rely on a new embodiment from the prior art references relied on in the petition, when presented with new claim construction.[5] Since *Axonics*, the Board has issued several decisions providing guidance on where to draw the line between a fulsome reply and improper new arguments, especially in the context of claim constructions advanced in the patent owner response.

The general rule that has emerged at the Board from its post-*Axonics* case law is that petitioners may cite new portions of prior art references and make new arguments in response to claim construction raised in the patent owner's response—provided the petitioner relies on the same prior-art embodiments to satisfy the same limitations as those relied upon in the petition.[6]

For example, in *DraftKings Inc. - DE v. AG 18, LLC d/b/a Arrow Gaming,*[7] the Board found that a petitioner's reliance on a new teaching within a previously cited embodiment was a proper reply.[8] Even though the petitioner invoked a definition from an embodiment that was not discussed in the petition, the petitioner's argument centered on how the embodiment cited in the petition satisfied the claim limitations.[9] Similarly in *Life Spine, Inc. v. Globus Medical, Inc.,*[10] the Board denied the patent owner's motion to strike new obviousness theories offered by a petitioner in its reply.[11] The Board specifically observed that the petitioner's reply arguments relied on the same embodiment from the same prior art reference that it discussed in the petition to support the same legal argument.[12] To be fair, however, the Board permitted the patent owner to file a sur-reply brief and supplemental expert declaration that addressed petitioner's reply obviousness theories.[13] Accordingly, both parties had notice and an opportunity to brief their positions under the Board's claim construction.

The Board has also allowed the reliance on new evidence in response to claim constructions. This includes citations to new portions of prior art references, new data or calculations, and the submission of new exhibits or declarant testimony. In *Guardant Health, Inc. v. University of Washington,*[14] for example, the petitioner cited a new paragraph from the prior art for the first time in its reply.[15] The Board held that even though the petition did not explicitly cite the paragraph, it was a proper response to the patent owner's newly proposed claim construction.[16]

Pioneer Pet Products, LLC v. Oil-Dri Corporation of America,[17] went even further. There, the Board allowed new calculations and test data to be submitted in reply.[18] The Board found that this new evidence did not exceed the proper scope of a reply because it was consistent with the arguments raised in the petition, and used to rebut the arguments patent owner raised in response.[19] It also helped that the new calculations and test data related to the same embodiments of the same prior art relied upon in the petition.[20]

In *Envirotainer AB v. DoubleDay Acquisitions LLC d/b/a CSafe Global*,[21] the Board allowed the petitioner to rely on new exhibits in its reply in support of its claim construction argument, even though the exhibits were available and relevant at the time the petition was filed, but were not submitted.[22] The Board held that any exhibits or declarant testi-

Scope of Reply: The Line Between Presenting Permissible Responsive Arguments and Raising Impermissible New Arguments Continues to Take Shape *continued*

mony filed in connection with a disputed claim construction did not exceed the proper scope of reply because the institution decision and patent owner's proposed construction in response opened the door to such submissions.[23]

Importantly, petitioners have been allowed to present new replies to claim construction arguments even where the petition does not offer any claim construction in the first instance.[24]

Where a petition does offer claim construction, the Board has allowed petitioners to revise those claim constructions in reply to a patent owner's response. In *Arthrex, Inc. v. P Tech, LLC,*[25] the Board allowed a petitioner to revise its claim construction from that presented in the petition, in response to patent owner's arguments.[26] The Board allowed this revision, finding that the changes to the claim construction amounted to deletions of a few words, and the resulting construction, though revised, was largely consistent with the construction in the petition.[27] The petitioner was then entitled to explain how the prior art satisfied the claim limitations under this new construction.[28]

Outside of claim construction, a petitioner may also raise new arguments when those arguments are in direct reply to points raised in the patent owner response. In *Amazon.com, Inc. et al v. WAG Acquisition, LLC,*[29] for example, the petitioner's reply extended a rationale used to challenge one claim limitation in the petition to a different claim limitation in the reply.[30] The Board found that this argument was permitted under *Axonics* because it countered the patent owner's response arguments.[31]

In view of this strong trend following *Axonics,* patent owners should be cautious about saving claim construction arguments for their patent owner response. Where new claim constructions are raised, and the petitioner is allowed to reply with new arguments, evidence, or even claim construction positions, the patent owner should ensure that they are permitted a sur-reply that includes a fulsome response to those new positions, including supplemental evidence if necessary. Additionally, patent owners should be on the lookout for petitioners who mischaracterize patent-owner arguments as new claim constructions in order to improperly change their invalidity theories during trial. The issue of what constitutes a "new" claim construction that entitles a petitioner to respond with new arguments is not well developed, but we expect this issue to receive some attention as parties continue to test the boundaries of the proper scope of reply.

1 See, e.g., *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1383 (Fed. Cir. 2023).
2 *Id.*
3 *Id.* at 1379.
4 *Id.* at 1384-85.
5 *Id.* at 1383-84.
6 See, e.g., *Unified Patents, LLC v. VL Collective IP, LLC*, IPR2022-01086 (PTAB); *Assa Abloy AB et al v. CPC Patent Technologies Pty Ltd.*, IPR2022-01045 (PTAB).
7 IPR2022-01447, Paper No. 33 (P.T.A.B. Mar. 13, 2024).
8 *Id.* at 56
9 *Id.*
10 IPR2022-01434, Paper No. 49 (P.T.A.B. Mar. 20, 2024).
11 *Id.* at 124.
12 *Id.*
13 *Id.*
14 IPR2022-01158, Paper No. 47 (P.T.A.B. Jan. 11, 2024).
15 *Id.* at 28.
16 *Id.* at 31.
17 IPR2022-01138, Paper No. 36 (P.T.A.B. Dec. 19, 2023).
18 *Id.* at 29.
19 *Id.*
20 *Id.* at 30.
21 IPR2022-00293, Paper No. 83 (P.T.A.B. Feb. 1, 2024).
22 *Id.* at 104.
23 *Id.*
24 See *Syngenta Crop Protection AG v. UPL Ltd.*, PGR2023-00017 (P.T.A.B. Jul.26, 2024) (allowing petitioner to counter the patent owner's claim construction and apply those constructions to the prior art in reply); *The Walt Disney Company et al v. WAG Acquisition, LLC Walt Disney*, IPR2023-00813 (P.T.A.B. Feb. 27, 2024) (allowing the petitioner to reply to patent owner's arguments about the preamble of a challenged claim being limiting, where the petition took no position on whether the preamble was limiting).
25 IPR2022-01043, Paper No. 22 (P.T.A.B. Nov. 21, 2023).
26 *Id.* at 28-29.
27 *Id.*
28 *Id.*
29 IPR2022-01433, Paper No. 26 (P.T.A.B. Feb. 15, 2024).
30 *Id.* at 93.
31 *Id.*

From the GC: Signature Requirements at the PTAB

BY JON WRIGHT, GENERAL COUNSEL

Introduction

"*A lawyer, as a member of the legal profession, is a representative of clients, an officer of the legal system and a public citizen having special responsibility for the quality of justice.*" This is the opening sentence from the preamble of the ABA Model Rules of Professional Conduct, which the U.S. Patent and Trademark Office (USPTO) adopted in 2013. When a lawyer signs a document that is submitted to a tribunal, that signature carries a certain weight. The USPTO takes its signature requirements very seriously. It explains (1) exactly what the signer is certifying with their signature, (2) exactly what is required to correctly sign a document, and (3) exactly what the possible repercussions are for failing to comply with both (1) and (2).

The USPTO signature requirements unambiguously apply to all post-grant patent challenges. This includes reexamination and reissue proceedings before the Central Reexamination Unit (CRU). 37 C.F.R. § 11.18. And it includes proceedings before the Patent Trial and Appeal Board (PTAB) for both inter partes review (IPR) and post-grant review (PGR) proceedings. 37 C.F.R. § 42.11(b)-(c).

Because many IPR and PGR practitioners have litigation backgrounds or are admitted *pro hac vice*, it is worth review-ing the USPTO's (and thus the PTAB's) strict signature certifications and requirements. Failure to understand and adhere to these certifications and requirements can have severe consequences for both the lawyer and their client.

What is a practitioner certifying when they sign a paper at the PTAB?

When a lawyer signs a paper that will be filed at the PTAB, they certify, first and foremost, that "all statements made therein of the party's own knowledge are true, all statements made therein on information and belief are believed to be true" and with the understanding that knowing or willful misrepresentation or deceit "shall be subject to the penalties set forth under 18 U.S.C. 1001," which include a fine and imprisonment up to 5 years. 37 C.F.R. § 11.18(b)(1).

The lawyer also certifies, "after an inquiry reasonable under the circumstances," the following four things:

(i) the paper is not being presented for any improper purpose, such as to harass someone or to cause unnecessary delay or needless increase in the cost of any proceeding before the Office;

(ii) the other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;

(iii) the allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and

(iv) the denials of factual contentions are warranted on the evidence, or if specifically so identified, are reasonably based on a lack of information or belief.

37 C.F.R. § 11.18(b)(2)(i)-(iv).

The USPTO is thus quite explicit in what a lawyer or agent's signature is certifying for each and every paper signed and submitted to USPTO. And it applies equally to every paper signed and submitted at the PTAB since Rule 42.11 references the "duty of candor and good faith" that each individual and party involved in an IPR or PGR proceeding owes to the Office, expressly referencing Rule 11.18(a)-(b).

How does one correctly sign a document at the USPTO?

Now that we understand what a lawyer is certifying when they sign a paper to be submitted to the PTAB, it is equally important to understand the formal signature requirements.

Signing in a representative capacity

Rule 1.34 allows a patent practitioner to act "in a representative capacity." That means that when a practitioner "signs a paper in practice before the [USPTO] in a patent case, his or her ... signature shall constitute a representation to the [USPTO] that under the provisions of this subchapter and the law, he or she is authorized to represent the particular party on whose behalf he or she acts." 37 C.F.R. § 1.34. If the practitioner is registered to practice before the Office, then the patent practitioner must

From the GC: Signature Requirements at the PTAB *continued*

set forth their registration number along with their name and signature. If the practitioner is not registered to practice before the Office, then they must be admitted *pro hac vice* before the Board and so indicate when filing.

Signatures must be personally inserted into the document

A signature must be personally inserted/applied by the individual identified as the signer, regardless of the manner of making the signature. 37 C.F.R. § 1.14(d). Most practitioners at the PTAB use what the Office refers to an "S-signature." In that instance, the requirement to personally apply one's signature means just that – "*the person signing the correspondence must insert his or her own S-signature with a first single forward slash mark before, and a second single forward slash mark after, the S-signature (*e.g.,*/Dr. James T. Jones, Jr./).*" 37 C.F.R. § 1.4(d)(2)(i). Of course, the USPTO permits old-fashioned handwritten signatures, as well as the insertion of graphic representations of handwritten or S-signatures. But, again, those must be personally inserted by the signer.

A secretary or paralegal, etc., is *NOT* permitted to sign or insert another's person's signature. To properly sign a document, the person signing must *actually type* their own name for an S-signature, or *personally insert* the graphic representation of their signature. The only exception to the personal insertion requirement is where the signer is physically unable to use a keyboard or to carry out the personal insertion of a graphical representation. In that narrow circumstance only, the signer "may, while simultaneously reviewing the document for signature, direct another person to press the appropriate keys to form the S-signature."

Violations of the certification as to the signature of another or a person's own signature may result in the imposition of sanctions under Rule 11.18(c) and (d).

What are the consequences of violating the signature requirements?

There are two ways one can violate the USPTO (and PTAB) signature requirements. *First*, a signer can violate the formal signature requirements set forth in Rule 11.18(a). For example, they could improperly direct a paralegal to insert their signature on a document that is then submitted to the PTAB. *Second*, they can violate the certification's substantive requirements set forth in Rule 11.18(b)(1)-(2). For example, the signer could violate their duty of candor and good faith to the PTAB, or submit a paper for an improper purpose, such as to harass or cause unnecessary delay in the proceeding.

The consequences of violating the certification requirements before the PTAB—i.e., violating the duty of candor and good faith—are highly fact dependent and subject to sanctions. Sanctions include entry of one or more of the following: (1) an order holding facts to have been established in the proceeding; (2) an order expunging or precluding a party from filing a paper; (3) an order precluding a party from presenting or contesting a particular issue; (4) an order precluding a party from requesting, obtaining, or opposing discovery; (5) an order excluding evidence; (6) an order providing for compensatory expenses, including attorney fees; (7) an order requiring terminal disclaimer of patent term; or (8) judgment in the trial or dismissal of the petition. 37 C.F.R. § 42.12(b).

Key Takeaways

- PTAB practitioners, especially those who have not previously and regularly practiced before the USPTO, should review and understand the signature requirements.
- Signatures must be *personally entered* onto each paper to be filed at the PTAB. That authority *cannot be delegated* to an assistant, secretary, or paralegal.
- A signature is a certification that the practitioner's representations in the paper comply with their general duty of candor and good faith to the tribunal.
- Violation of the signature certification can have severe consequences.

Developments at the PTAB and Federal Circuit in § 102(e) Jurisprudence

BY RICHARD A. CRUDO & KRISTINA CAGGIANO KELLY

Establishing that a reference qualifies as prior art is a crucial threshold inquiry in inter partes review (IPR) practice. In addition to the common tasks of establishing an earlier date and public accessibility, a developing body of case law has recently challenged what it means for U.S. published patent applications and issued patents to be filed "by another" under pre-AIA 35 U.S.C. § 102(e), and whether § 102(e)(1) art can even be used in IPRs in the first place.

In *Hopewell Pharma Ventures, Inc. v. Merck Serono S.A.*,[1] the Patent Trial and Appeal Board (PTAB) addressed § 102(e)'s "by another" requirement and articulated a framework for patent owners seeking to disqualify art as representing the work of a "common inventive entity." Meanwhile, the Federal Circuit recently answered a more fundamental question as to whether § 102(e)(1) art may be used in IPRs in the first place. In *Lynk Labs, Inc. v. Samsung Electronics Co.*[2] the court answered in the affirmative, holding that such art can in fact be considered by the PTAB in assessing patentability challenges.

Examining the "by Another" Requirement

Hopewell addressed the patentability of two of Merck's multiple-sclerosis treatment patents based on a patent application publication that Hopewell argued qualified as prior art under pre-AIA §§ 102(a) and (e). Merck tried to show that the relevant disclosure from the prior-art reference represented work from the inventors of the challenged patent such that the reference was not truly "by another."

The Board articulated a burden-shifting framework for making that assessment. First, the petitioner must make an initial showing that there is no facial overlap in the named inventors or assignees of the prior-art reference and the challenged patent. The PTAB found that Hopewell satisfied that burden since the listed inventors of the challenged patent were different from those listed on the prior-art reference.

Second, the burden of production shifts to the patent owner to come forward with evidence showing that all named inventors—and only the named inventors—of the challenged patent provided an inventive contribution to the relevant disclosure in the prior-art reference. The PTAB held that Merck failed to make such a showing. Merck argued that, through a collaboration agreement, the challenged-patent inventors were responsible for the dosing regimen disclosed in the prior-art reference, which was the basis for Hopewell's obviousness challenge. The PTAB disagreed, finding that Merck failed to produce evidence showing that all of the inventors of the challenged patent in fact made an inventive contribution to the relevant disclosure. In so holding, the PTAB rejected Merck's argument that there need not be complete overlap in inventorship for the reference to be disqualified. The Board also determined that, even if all inventors had made an inventive contribution to the dosing regimen disclosed in the prior-art reference, Merck failed to show that the inventors contributed to other portions of the reference on which Hopewell relied.

Hopewell thus highlights the stringency of the "by another" requirement and the importance that patent owners proffer evidence as to the inventive contribution of all inventors to the entirety of the prior-art disclosure relied upon by a petitioner.

Applicability of § 102(e) Art in PTAB Challenges

In *Lynk Labs*, the Federal Circuit addressed whether a published patent application that has been subsequently abandoned, and which qualifies as art under § 102(e)(1), may be used in an IPR.

Enacted in 1999, § 102(e)(1) creates so-called "secret springing" prior art—i.e., patent applications that, although *published after* the challenged patent, were *filed before* the patent.[3] Such applications are "secret" until they are published, at which time they "spring" into existence as prior art, back-dated to the time of their filing.[4] For nearly thirty years, it has been well understood that such patent applications could serve as invalidating prior art. For the past decade, moreover, nobody questioned whether such art could be used in IPRs.

Developments at the PTAB and Federal Circuit in § 102(e) Jurisprudence

continued

Until now. Lynk argued that, under § 311(b), IPRs may only be based on "prior art consisting of patents or printed publications."[5] And the Federal Circuit has long held that, to qualify as a "printed publication," a reference must be "sufficiently accessible to the public interested in the art before" the challenged patent's critical date.[6] Indeed, "public accessibility" before the critical date is the "touchstone" of the "printed publication" inquiry.[7] According to Lynk, it is unclear whether § 102(e)(1) patent applications so qualify because, even though such applications indisputably qualify as prior art, they are not publicly accessible before the challenged patent's critical date. Other provisions of pre-AIA § 102 (sub-sections (a) and (b)) expressly refer to "printed publications," thus reinforcing the notion that patent applications falling under sub-section (e)(1) do ***not*** qualify as printed publications. Accordingly, Lynk argued, such art cannot be used in IPRs.

The court rejected those arguments. Published patent applications, the court noted, indisputably qualify as "printed publications" in the literal sense of that phrase—they are "printed" and "published." They are not published until after the challenged patent's critical date, to be sure, but that is irrelevant because the meaning of "printed publication" is "temporally agnostic"—any temporal requirement as to when a reference must be published "is drawn from other language" in § 102.[8] Here, published patent applications are prior art as of their filing date by virtue of § 102(e)(1), which the court noted creates "a special rule for published patent applications."[9] Consequently, such applications fall within the scope of § 311(b). In so holding, the court rejected Lynk's distinction between § 102(e)(1)'s use of the phrase "applications for patent" and sub-sections (a)'s and (b)'s use of the phrase "printed publications," noting that the former is simply a specific instance of the latter.

The court also rejected Lynk's legislative history arguments based on longstanding precedent emphasizing the importance of public accessibility for determining whether a reference qualifies as a printed publication. Those "older cases," the court noted, focused on non-patent application publications (e.g., books, articles, and the like) which, before 1999, were the ***only*** forms of printed publications that qualified as prior art.[10] In the context of ***those*** references, the requirement that a reference be publicly accessible before the challenged patent's critical date makes sense. But in the context of published patent applications, the court held, that requirement is inapposite. In short, "Congress chose to afford published patent applications a prior-art effect different from the effect given to" other types of printed publications.[11]

Finally, the court noted that under Lynk's theory, an IPR petitioner would have to carve § 102(e)(1) invalidity grounds out of a petition and pursue such grounds in district court, which would undermine some of the efficiencies that it appears Congress may have intended to achieve with IPRs. While Congress may have intended for ***some*** invalidity challenges to be adjudicated in district court—e.g., public-use-based defenses, which typically involve difficult evidentiary issues—§ 102(e)(1) art does not fall within the scope of such challenges.

The court thus upheld the Patent Office's practice of treating so-called secret springing art as assertable in IPRs. This decision thus brings certainty to a longstanding but hotly contested practice.

1 IPR2023-00480, Paper 62 (PTAB Sept. 18, 2024); IPR2023-00481, Paper 63 (PTAB Sept. 18, 2024). Sterne Kessler represented the petitioner, Hopewell.

2 Appeal No. 23-2346 (Fed. Cir. Jan. 14, 2025).

3 Post-AIA § 102(a)(2) has a similar provision, but this Article focuses on pre-AIA § 102(e)(1).

4 If the patent applications are published *before* the challenged patent's critical date, then they qualify as prior art under pre-AIA §§ 102(a) or (b).

5 35 U.S.C. § 311(b).

6 *Voter Verified, Inc. v. Premier Elections Sols., Inc.*, 698 F.3d 1374, 1380 (Fed. Cir. 2012) (cleaned up).

7 *Samsung Elecs. Co. v. Infobridge Pte.*, 929 F.3d 1363, 1369 (Fed. Cir. 2019).

8 Appeal No. No. 23-2346, slip op. at 16-17.

9 *Id.* at 8.

10 *Id.* at 14.

11 *Id.* at 18-19.

Splitting Hairs – IPR Estoppel as Applied to Product Art

BY ANDREW Z. BARNETT AND RICHARD A. CRUDO

Introduction

The possibility of being estopped from asserting prior art in district court is a risk that must be considered when filing an IPR petition. 35 U.S.C. § 315(e)(2) prevents a petitioner, following a final written decision, from asserting invalidity grounds that the petitioner "raised or reasonably could have raised" in the petition.[1] As applied to printed publications, the estoppel inquiry is fairly straightforward. As applied to product art, the inquiry is anything but.

On first blush, it would seem that a patent challenger cannot be estopped from asserting product art, standing alone, since IPRs may only be brought "on the basis of prior art consisting of patents or printed publications."[2] But the problem is that products are rarely asserted in district court standing alone. Rather, printed publications such as product manuals and the like are often used in district court to describe how the products operate. And, even when products are asserted standing alone, they may be cumulative of publications that were or reasonably could have been asserted in an IPR. So when does estoppel apply?

The answer to that question "has not been definitively resolved."[3] In fact, three distinct approaches to answering the question have emerged. One line of cases, based on a decision authored by Judge Stark while a district judge in Delaware, adopts a broad view of § 315(e), holding that estoppel extends to products that are cumulative of references that could have been raised in an IPR—i.e., "a printed publication invalidity theory in disguise."[4] Another line of cases, based on a decision authored by Judge Noreika and endorsed by Judge Bryson sitting by designation in Delaware, adopts a narrower view of § 315(e), holding that estoppel does *not* apply to *any* invalidity theory that relies even in part on product art. And still a third line of cases splits the difference, employing a burden-shifting framework requiring a plaintiff to prove cumulativeness on a limitation-by-limitation basis. This Article addresses each of these approaches.

Judge Stark's Broad Interpretation of § 315(e)

The broad view of § 315(e) was first articulated by Judge Stark (then Chief Judge of the District of Delaware) in *Wasica Finance GmbH v. Schrader International, Inc.*[5] There, the patent challenger asserted a single prior art reference in an IPR and asserted that same reference, along with a physical product, in district court. The challenger argued that, because the product could not have been asserted in the IPR, there could be no estoppel, notwithstanding that the product was cumulative of the art that was asserted.[6]

Judge Stark disagreed. In his view, the invalidity ground asserted in district court was the same "ground" asserted in the IPR even though the "evidence used to support" that ground—i.e., the product art—was different.[7] In so holding, Judge Stark pointed out that a contrary ruling would "gut the estoppel provision entirely" because a defendant could "simply swap out" estopped references with nearly identical product art so as to avoid estoppel altogether.[8]

This broad view of § 315(e), although currently the minority view, has found some currency inside and outside Delaware. For example, in *Wirtgen America, Inc. v. Caterpillar, Inc.*,[9] Judge Wolson, sitting by designation in Delaware, held that a patent challenger was estopped from asserting an obviousness combination including a physical device that was cumulative of a printed publication asserted in an IPR. The court reasoned that, "[b]ecause the printed publication and the physical device fill the same gap" in the obviousness combination, the combination is in effect "the same ground" as asserted in IPR.[10] To hold otherwise, the court observed, would create a "mammoth loophole" because patent challengers "would always add a physical device that is identical to patents or printed publications in the subsequent civil case just to evade estoppel."[11] Other courts (including those in California and Texas) have taken a similarly broad view.[12]

Splitting Hairs – IPR Estoppel as Applied to Product Art

continued

Judge Noreika's Narrow Interpretation of § 315(e)

On the other end of the spectrum is a line of cases taking a much narrower view of § 315(e). In *Chemours Co. v. Daikin Industries, Ltd.*,[13] for example, Judge Noreika—also in Delaware—rejected *Wasica*'s approach and held instead that invalidity grounds involving product art are *not* estopped under § 315(e). The court reasoned that, "[a]s a matter of statutory interpretation," estoppel applies only to "grounds"—i.e., "specific pieces of prior art that are the basis or bases on which a petitioner challenges a claim."[14] And, because product art cannot be used in an IPR "ground," estoppel does not preclude the challenger from asserting such art in district court.[15] Notably, *Chemours* did not ask whether the product art was cumulative of the estopped references—the answer to that question, in the court's view, was irrelevant.

A majority of courts (including in Delaware and Illinois) have followed the *Chemours* approach.[16] In fact, Judge Bryson (sitting by designation in the District of Delaware) recently endorsed this view in *Prolitec Inc. v. ScentAir Technologies, LLC*.[17] Noting that both *Wasica*'s and *Chemours*' interpretations of § 315(e) were "plausible," Judge Bryson ultimately agreed with Judge Noreika that "grounds" refers to "the specific pieces of prior art that are the bases on which a petitioner challenges a claim."[18] Accordingly, he held, "IPR estoppel does not apply to device art, even when that device art is cumulative of patents and printed publications that were or could have been asserted in a prior IPR."[19]

An Intermediate Approach: Collateral Estoppel Lite

Yet a third approach has also emerged that arguably attempts to bridge the gap between *Wasica* and *Chemours*. In *Boston Scientific Corp. v. Cook Group Inc.*,[20] the Southern District of Indiana rejected *Chemours*' categorical exclusion of product art from § 315(e), but articulated a clearer framework than announced in *Wasica* for deciding whether product art is indeed cumulative. The court applied a burden-shifting framework for evaluating whether estoppel applies:

> [A] plaintiff must show that each and every material limitation present in the physical device is disclosed in the estopped reference; the burden then shifts to the defendant. If the defendant, in response, points to a material limitation that is disclosed in the physical device that is not disclosed in the estopped reference, then the burden shifts back to the plaintiff to show why said limitation is (1) either not material or (2) is in fact specifically disclosed in the estopped reference.[21]

This framework fleshes out *Wasica*'s cumulativeness inquiry by requiring a particularized showing from the plaintiff that "each and every material limitation" in the product is in fact disclosed in the estopped reference. And, by employing a burden-shifting framework that allows both sides to argue why it is fair or unfair to allow the invalidity grounds to be asserted in district court, the *Boston Scientific* approach implicitly adopts equitable principles that are typically central to collateral estoppel.

Conclusion

The Federal Circuit has not yet weighed in on this issue, but as described above, two currently sitting Federal Circuit judges (Judge Stark and Judge Bryson) have taken opposing views. It is no wonder, then, that courts inside and outside of Delaware are split on the issue.

Chemours is arguably more faithful to the statutory text but seems to create a loophole that patent challengers can easily exploit. *Wasica*, on the other hand, seems to close the loophole but arguably strays from the statutory text. *Wasica* could also discourage patent challengers from filing IPR petitions if they face a significant risk of estoppel even as to product art. And, while *Boston Scientific*'s middle ground seeks to strike a balance between the two extremes, it is debatable whether the statutory text supports such a middle ground. As always, it is important to know your jurisdiction and judge, and to think strategically at the outset of an IPR about downstream estoppel issues.

Splitting Hairs – IPR Estoppel as Applied to Product Art

continued

1 35 U.S.C. § 315(e)(2).

2 35 U.S.C. § 311(b).

3 *Singular Computing LLC v. Google LLC*, 668 F. Supp. 3d 64, 70 (D. Mass. 2023).

4 *IOENGINE, LLC v. PayPal Holdings, Inc.*, 607 F. Supp. 3d 464, 513 (D. Del. 2022) (Bryson, J., sitting by designation).

5 432 F. Supp. 3d 448 (D. Del. 2020) (Stark, J., sitting by designation).

6 *Id.* at 453–54.

7 *Id.* at 454.

8 *Id.* at 455 n.7.

9 2024 WL 51010, at *9 (D. Del. Jan. 4, 2024). Sterne Kessler represented Wirtgen in this litigation.

10 *Id.*

11 *Id.*

12 See, e.g., *Singular Computing*, 668 F. Supp. 3d at 74; *Hafeman v. LG Elecs., Inc.*, 2023 WL 4362863, at *1 (W.D. Tex. Apr. 14, 2023); see also *California Inst. of Tech. v. Broadcom Ltd.*, 2019 WL 8192255, at *7 (C.D. Cal. Aug. 9, 2019), *aff'd*, 25 F.4th 976 (Fed. Cir. 2022); *Biscotti Inc. v. Microsoft Corp.*, 2017 WL 2526231, at *8 (E.D. Tex. May 11, 2017).

13 2022 WL 2643517 (D. Del. Jul. 8, 2022).

14 *Id.* (cleaned up).

15 *Id.*

16 See, e.g., *IPA Techs. Inc. v. Microsoft Corp.*, 2024 WL 1797394, at *5–7 (D. Del. Apr. 25, 2024); *EIS, Inc. v. IntiHealth Ger GmbH*, 2023 WL 6797905, at *5–6 (D. Del. Aug. 30, 2023); *Pact XPP Schweiz AG v. Intel Corp.*, 2023 WL 2631503, at *1 (D. Del. Mar. 24, 2023); *Willis Elec. Co. v. Polygroup Macau Ltd. (BVI)*, 649 F. Supp. 3d 780, 814–15 (D. Minn. 2023); *Medline Indus., Inc. v. C.R. Bard, Inc.*, 2020 WL 5512132, at *4 (N.D. Ill. Sept. 14, 2020); *Milwaukee Elec. Tool Corp. v. Snap-On Inc.*, 271 F. Supp. 3d 990, 1031 (E.D. Wis. 2017).

17 2023 WL 8697973, at *22–23 (D. Del. Dec. 13, 2023).

18 *Id.* at *23.

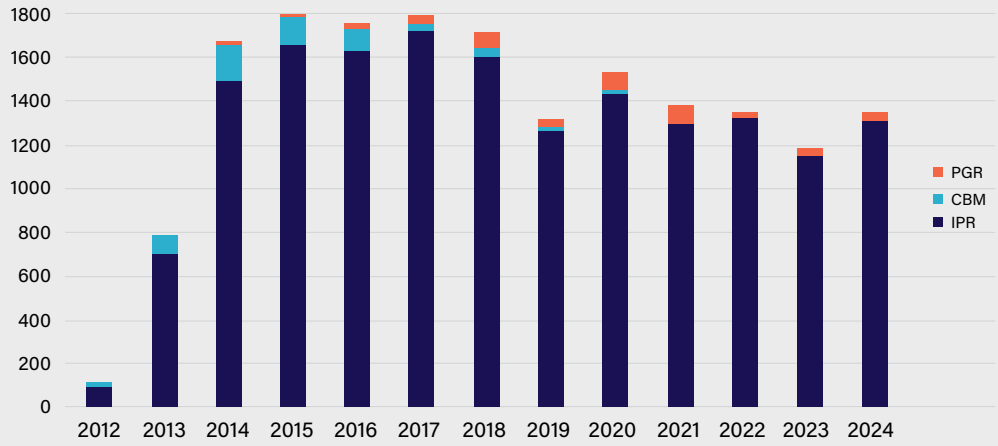
19 *Id.* But see *Wirtgen*, 2024 WL 51010, at *9 ("Respectfully, I disagree. Judge Bryson based his conclusion on a distinction between a 'ground' and the evidence supporting that ground. And I agree that there's a difference. But the physical device is not just a piece of evidence. It is part of the basis that animates the claim of invalidity.").

20 653 F. Supp. 3d 541 (S.D. Ind. 2023).

21 *Id.* at 594.

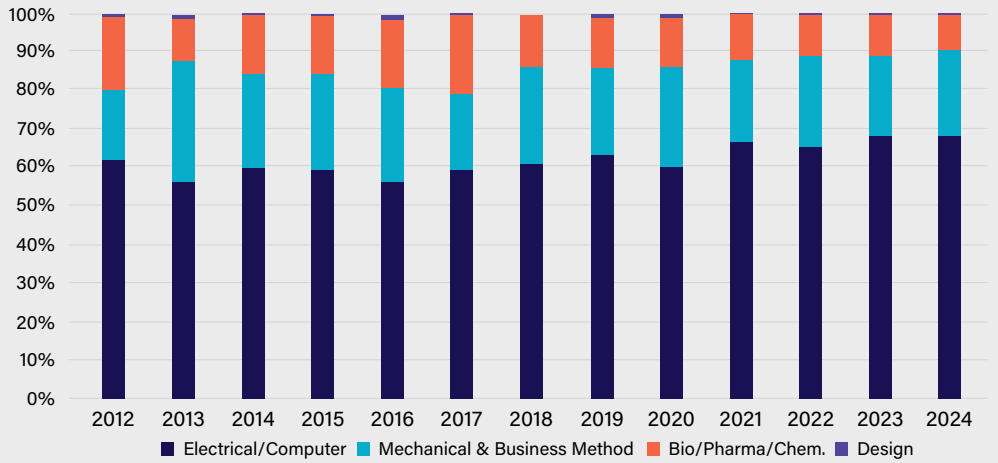
Key 2024 PTAB Statistics

Petitions Filed by Year



1,357 petitions were filed in 2024, exactly matching the total in 2022.

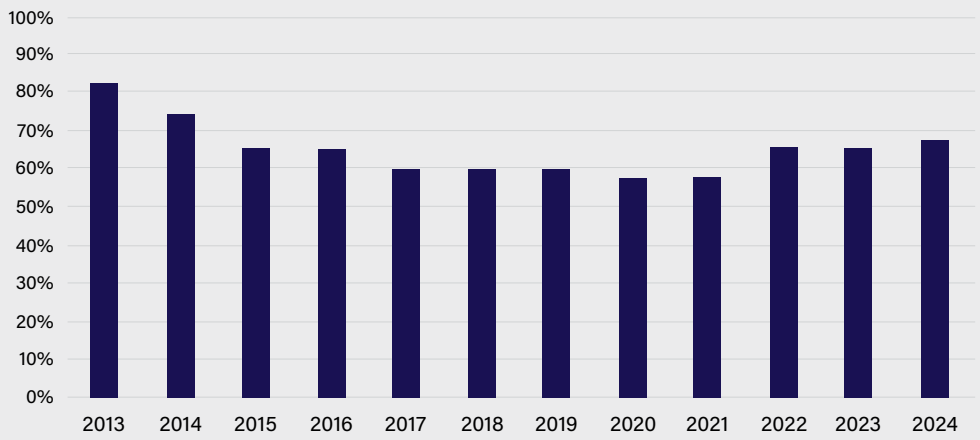
Challenged Patents by Technology



Petitions challenging bio/pharma and chemistry patents dipped below 10% of all petitions filed for the first year ever in 2024. This continued a multiyear decline from a peak in 2017, when more than 20% of petitions challenged patents in this technology space.

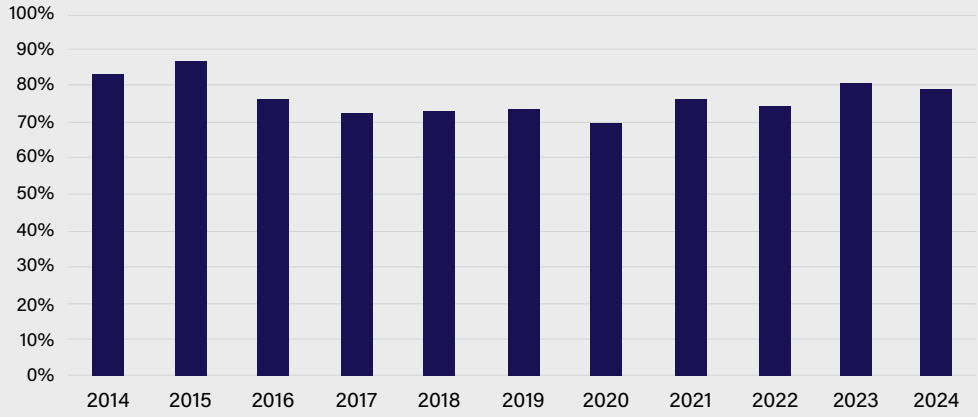
Key 2024 PTAB Statistics *continued*

Proceeding Institution Rate



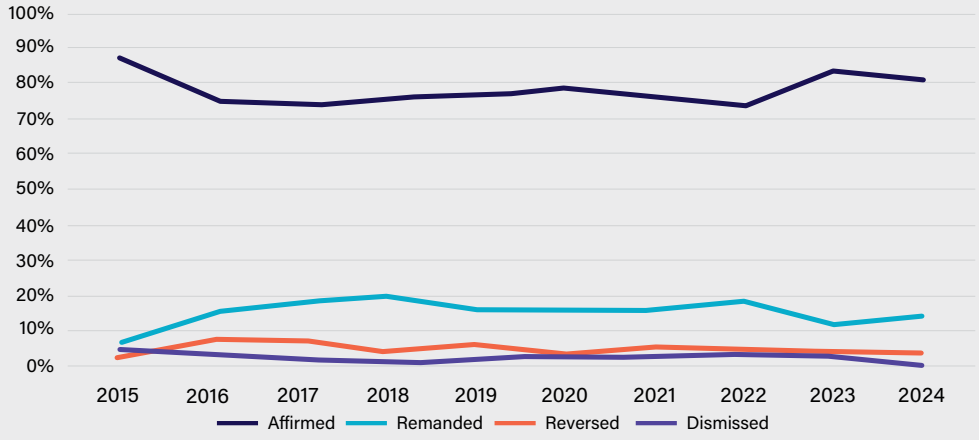
The institution rate held steady in 2024, exceeding 65% for the third straight year after hovering closer to 60% from 2017-21.

Claim Cancellation Rate in FWDs



In 2024, the Board cancelled 78% of the claims that it ruled on in Final Written Decisions. This was a slight decline from 2023, but still represented the second-highest claim cancellation rate over the last 9 years.

PTAB Trial Appeal Outcomes



The Federal Circuit affirmance rate of IPR and PGR appeals stayed above 80% for the second straight year.

Caveat Experimenter: Using Experimental Data in PTAB Proceedings Comes With Risks

BY ELDORA L ELLISON, PH.D., TREY POWERS, PH.D., AND MADELEINE BOND

Parties involved in Patent Trial and Appeal Board (PTAB) proceedings sometimes contemplate submitting experimental data to support their positions. Although such data can be useful, there also are risks. Several recent cases highlight the risks and benefits associated with submitting test data in PTAB proceedings.

Track the Art Closely

SNF S.A. v. Chevron USA, Inc., IPR2022-01534[1], highlights the strict standards the PTAB applies when assessing test results relied upon to show inherency. In *SNF*, the challenged claims recited a method for preparing an inverted polymer solution having a "filter ratio of 1.5 or less." *Id.* at 7. Notably, the claims did not recite a "dewatering" step. *Id.* To support the petition, petitioner's expert conducted experiments purporting to demonstrate that the prior art "Li" reference disclosed a method for preparing inverted polymer solutions inherently meeting the claimed filter ratio limitation. Petitioner's expert provided experimental data for the filter ratio obtained both before and after a "dewatering" step optionally included in the method used in several examples in *Li.*. *Id.* at 25. All of the exemplified "before dewatering" tests failed to meet the claimed filter ratio, which was met only after including a "dewatering" step. *Id.* at 27. In finding that the petitioner failed to prove inherent anticipation,[2] the PTAB noted:

> Neither Petitioner nor Dr. Barati provide any persuasive evidence supporting why Dr. Barati calculated filter ratios both "before dewatering" and "after dewatering," but relied only on the "after dewatering" data to support its argument that the challenged claims are anticipated by Li. Li's examples, however, provide no disclosure of a dewatering step. Moreover, we have not been directed to persuasive evidence that using a dewatering step in Li's examples was inherent in Li's disclosed procedures.

Id. at 26. Indeed, at his deposition, the petitioner's expert testified that he did not rely solely on Li for the dewatering step, but relied on other references also. *Id.* Ultimately, the PTAB concluded that petitioner failed to meet its burden to show inherency because there were "too many unanswered questions" about the variables petitioner's expert chose to test in attempting to show inherency using the Li reference. *Id.* at 27.

SNF serves as a reminder to practitioners that laboratory testing used to establish inherency should track the prior art disclosure with precision. Here, the petitioner relied upon the prior art's disclosure of various examples, but failed to establish that those examples included the dewatering step that was necessary for satisfying the claim limitations.

Petitioner's tests also faced additional avoidable criticisms from the patent owner, e.g., that petitioner's expert failed to disclose the source or verify the contents for nearly all of the starting materials he used, and he purported to have taken almost no written recordings or observations for his experiments. To this end, parties should be mindful of the requirements under 37 C.F.R. §42.65 to provide a fulsome explanation of their tests and data.[3]

Do the Right Test

It should go without saying that it is important to do the right test to establish inherency. But this is precisely the error that befell the petitioner in *Pioneer Pet Products, LLC v. Oil-Dri Corporation of America*, IPR2022-01138.[4] There, the patent claims were directed to:

> A [cat] litter comprising: 45% to 80% by weight of sodium bentonite, wherein the sodium bentonite comprises at least 47% of an external surface area of the litter [the "47% surface area limitation"]....

Id. at 6. To establish that the "47% surface area limitation" was inherently disclosed in the prior art publication by House, petitioner argued that "[b]y virtue of House disclosing its litter contains a maximum of 80% by weight of sodium bentonite SCWEOS ["smectite clays which exhibit osmotic swelling"], a PHOSITA would have recognized that House at least inherently meets the claim limitation of 'at least 47% of the total external surface of the litter.'" *Id.* at 46. The PTAB noted

Caveat Experimenter: Using Experimental Data in PTAB Proceedings Comes With Risks

continued

that petitioner relies on declarant testimony that essentially repeated the arguments from the petition. *Id.* at 45.

The PTAB found that petitioner failed to prove by a preponderance of the evidence that House expressly or inherently discloses the 47% surface area limitation. *Id.* at 46. Noting that the petition "provides a single sentence of analysis of the limitation that contains several flaws," the PTAB found that "the argument improperly conflates weight percent and percent surface area by suggesting that a given weight percent alone will inherently disclose a certain percent surface area.... [T]he two measurements are not the same, and the Petition provides no argument or evidence linking the weight percent of sodium bentonite to any specific external surface area of that material." *Id.* The PTAB went on to state, "To make matters more confusing, the body of the argument in the Petition suggests that the 80% by weight of sodium bentonite leads to the 47% surface area limitation, but the claim chart summarizing the challenge suggests that litters having either 50% or 65% by weight of sodium bentonite leads to the 47% surface area limitation." *Id.* at 46–47. This case illustrates the PTAB's close attention to technical details and the need for parties and their counsel to do the same. In view of this and other flaws, the PTAB found the petition failed to meet the 47% surface area limitation. *Id.* at 49.

The petitioner also attempted to "fill the holes in the Petition by relying on new calculations and test data in its reply," but the PTAB did not view consideration of this new reply evidence as proper. *Id.* at 48. Rather, the PTAB found that the reply "introduces what amounts to new theories based on new portions of House never specifically identified in the Petition, as well as evidence that goes well beyond House's disclosure" and the PTAB declined to consider them. *Id.* at 49. The PTAB concluded that petitioner failed to prove anticipation. *Pioneer* underscores the importance of doing the proper test and analysis the first time, as the PTAB may disregard belatedly presented evidence.

Be Ready for Discovery

A party relying on test data may find that it is on the receiving end of a motion for additional discovery as the opposing party might probe for weaknesses. In *Syngenta v. UPL*, PGR2023-00017,[5] the petitioner conducted tests to support allegations regarding lack of synergy to refute non-obviousness and to show a lack of enablement. The petitioner originally produced data relating only to one of four assessed parameters. In response, the patent owner moved to compel disclosure of data relating to all parameters assessed in the same experiments, asserting that the information sought contradicts petitioner's arguments.[6] In ruling to compel such discovery, the PTAB stated:

> While petitioner contends that only some of the data from these tests, i.e., the severity data, is relevant, we do not agree that petitioner can effectively prevent patent owner from testing that assertion by withholding production of the rest of the data, [relating to other parameters,] from the same experiments.... That additional data is directly relevant to the factual allegations in this proceeding whether it supports patent owner's arguments regarding enablement and unexpected results or is simply consistent with the testimony . . . and petitioner's other factual assertions.

Id. at 3. Thus, a party seeking to rely on test results should be prepared for the possibility that they will have to disclose other, related tests even if that party deems such tests irrelevant. After obtaining the requested discovery in *Syngenta*, the patent owner and its expert asserted that the underlying test data demonstrated synergy for the claimed subject matter. However, at oral argument, counsel for patent owner acknowledged that the data its expert analyzed in forming his opinions on synergy did not fall within the scope of the challenged claim. As such, the PTAB found that there was no nexus between the data and the challenged claims and it therefore did not consider the patent owner's expert's opinions on synergy in determining obviousness.

Caveat Experimenter: Using Experimental Data in PTAB Proceedings Comes With Risks

continued

Don't Try to Hide

Parties considering conducting testing should familiarize themselves with *Spectrum Solutions v. Longhorn Vaccines and Diagnostics,* IPR2021-00847, including Director Vidal's *sua sponte* Director Review decision, lest they risk getting caught by the horns.[7] Director Vidal elected to review the PTAB panel's Final Written Decision so that she could address which regulations are implicated when a party withholds relevant factual evidence during an AIA proceeding. Director Review Decision, 3. In *Longhorn*, the patent owner submitted laboratory test data addressing whether the prior art taught certain claim limitations. *Id.* at 5. On cross-examination of the declarants, patent owner's counsel instructed its witnesses not to answer certain questions, asserting work product immunity. *Id.* The petitioner promptly sought—and was granted—additional deposition time after the parties briefed the PTAB on the applicability of work-product immunity regarding the unanswered deposition questions. *Id.* Additionally, the PTAB ordered the patent owner to serve petitioner with any relevant inconsistent information. *Id*; See 37 C.F.R. §42.51(b)(1)(iii). Upon obtaining the additional documents, petitioner found that patent owner had submitted data only for certain tested pathogens and assays, while withholding other, conflicting data. *Id.* at 6. And to make matters worse, the patent owner also withheld the conflicting data from its own expert. *Id.* at 19.

In *Longhorn*, the patent owner's efforts to hide behind the work-product doctrine were to no avail, because the PTAB held it "cannot be used to shield factual information from discovery that is inconsistent with positions taken by a party before the Board," because doing so violates the party's duty of candor and good faith to the Office. *Id.* at 23. Moreover, the PTAB found that the patent owner waived any immunity over the withheld data. *Id.* at 27. The PTAB noted that the patent owner could have filed the withheld test results under seal, requested *in camera* review, "provided a privilege log identifying the withheld [] Data," or "produc[ed] a redacted copy" so the petitioner and PTAB would be on notice of the existence of other test results. *Id.* at 30. The patent owner's strategic decisions and conduct in *Longhorn* led to serious repercussions: as a sanction, the PTAB entered adverse judgment against *all* challenged claim, including several claims that had otherwise survived on the merits. *Id.* at 51. And notably, the PTAB held that the patent owner could not avoid sanctions by pointing fingers at its counsel. *Id.* at 51–52.

The cases summarized in this article highlight some of the perils parties may face in relying upon test data in PTAB proceedings. Thus, it is important to develop a strategy that carefully balances such risks with the potential rewards.

1 The Final Written Decision issued on April 18, 2024 as Paper No. 46.

2 The PTAB also rejected petitioner's obviousness arguments based on the same reference for at least the same reasons.

3 § 42.65 Expert testimony; tests and data.

(a) Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. Testimony on United States patent law or patent examination practice will not be admitted.

(b) If a party relies on a technical test or data from such a test, the party must provide an affidavit explaining:

(1) Why the test or data is being used;

(2) How the test was performed and the data was generated;

(3) How the data is used to determine a value;

(4) How the test is regarded in the relevant art; and

(5) Any other information necessary for the Board to evaluate the test and data.

4 The Final Written Decision issued as Paper No. 36 on December 19, 2023.

5 The Final Written Decision was issued as Paper No. 58 on July 26, 2024.

6 PGR2023-00017, Papers 22, 27

7 The Final Written Decision was issued as Paper No. 114 on May 22, 2023, and the Director Review Decision was issued on July 11, 2024.

A Survey of AIA 35 U.S.C. § 102(b) Prior Art Exceptions at the PTAB

BY LOUIS PANZICA AND DAVID HOLMAN

Introduction

The Leahy-Smith America Invents Act ("AIA") redefined what constitutes prior art by making the U.S. patent system a "first-to-file" system instead of the pre-AIA "first-to-invent" system. Thus, under AIA 35 U.S.C. § 102(a), prior art is determined based on the effective filing date of the claimed invention, rather than the date of invention. But not all art preceding the effective filing date of a patent necessarily qualifies as prior art, due to certain exceptions under § 102(b).

Although the AIA has been in effect for well over 10 years, case law addressing AIA § 102(b) prior art exceptions remains relatively sparse. This is true both at the Federal Circuit and at the Patent Trial and Appeal Board ("PTAB"). However, earlier this year the Federal Circuit decided *Celanese Int'l Corp. v. Int's Trade Comm'n*[1] and *Sanho Corp. v. Kaijet Tech. Intl. Ltd., Inc.*[2], which each addressed §102(b) prior art exceptions. This prompted us to explore the PTAB's approach to assessing § 102(b) prior art exceptions. In particular, we examine the Board's analysis given certain fact patterns and evidence, and provide examples of evidence that could exclude an otherwise invalidating § 102(a) reference under a § 102(b) exception.

35 U.S.C. § 102(b) prior art exceptions

Under 35 U.S.C. § 102(a)(1), an invention is not patentable if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."[3] Section 102(b)(1) provides certain exceptions for § 102(a)(1) disclosures made one year or less before the filing date of the claimed invention if:

(A) the § 102(a)(1) disclosure was made by the inventor or a joint inventor or by another who obtained the subject matter directly or indirectly from the inventor or a joint inventor; or

(B) the §102(a)(1) disclosure had been previously publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter directly or indirectly from the inventor or a joint inventor.[4]

Under 35 U.S.C. § 102(a)(2), an invention is not patentable if the claimed invention was described in an issued patent, or a published patent application, that names another inventor and was effectively filed before the effective filing date of the claimed invention.[5] Section 102(b)(2) provides certain exceptions for § 102(a)(2) disclosures if:

(A) the § 102(a)(2) disclosure was obtained directly or indirectly from the inventor or a joint inventor;

(B) the § 102(a)(2) disclosure was, before the effective filing date of the § 102(a)(2) patent or application, publicly disclosed by the inventor or a joint inventor or another who obtained the disclosures directly or indirectly from the inventor or a joint inventor; or

(C) both the § 102(a)(2) disclosure and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.[6]

The Federal Circuit recently addressed § 102(b) prior art exceptions in *Celanese*[7] and *Sanho*.[8] In *Celanese*, the court addressed whether a prior sale of a product made using a secret process triggered the § 102(a)(1) on-sale bar to patentability of that process. There, the court declined to assess the possibility of a § 102(b)(1) prior art exception because the prior sale occurred more than one year before the effective filing date of the patent at issue.[9] *Sanho* (an IPR appeal), however, squarely addressed § 102(b) exceptions. In the IPR, Sanho argued that one of the asserted prior art patent references was not § 102(a)(2) prior art due to a prior non-confidential sale between the parties creating an exception under §102(b)(2)(B). The PTAB found, and the Federal Circuit affirmed, that the prior sale—although non-confidential—was nevertheless still a *private* sale and thus did not qualify as a *public* disclosure under § 102(b)(2)(B).[10]

These opinions from the Federal Circuit prompted us to examine cases in which the PTAB has assessed § 102(b) prior art exceptions. Below, we summarize these Board

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continued

decisions based on the types of evidence and arguments presented.

Prior inventor disclosure of § 102(a)(1) subject matter

A § 102(a)(1) disclosure may be disqualified as prior art under § 102(b)(1)(A) if (i) the disclosure is made one year or less before the effective filing date and (ii) the subject matter of the disclosure was previously disclosed by the inventor or a joint inventor. In January 2024, the PTAB addressed § 102(b)(1)(A) exceptions (prior inventor disclosures) in *Murray & Poole Enterprises Ltd. v. Institut de Cardiologie de Montreal.*[11] *In Murray*, the PTAB considered whether a published multi-author study qualified as an inventor disclosure under § 102(b)(1)(A) and (B). Murray's IPR petition asserted anticipation and obviousness grounds that included a reference called "Bouabdallaoui." Bouabdallaoui, an article discussing a clinical study, was co-authored by seven individuals, one of whom was the inventor of the challenged patent. Patent owner, "ICM," argued that the sole inventor of the challenged patent was also the corresponding author of Bouabdalloui, and lead investigator of the clinical study. Thus, according to ICM, Bouabdallaoui was excluded as prior art because it published less than one year before the challenged patent's effective filing date, and the relied-upon disclosures in Bouabdallaoui are those of the inventor.[12] In support of its argument, ICM submitted a declaration from the inventor explaining his role in the clinical study and his authorship of Bouabdallaoui.[13] Petitioner Murray argued that Bouabdallaoui had seven co-authors, and there was no evidence that the relied-upon disclosures in Bouabdallaoui were made "by the inventor" to satisfy §102(b)(1)(A).[14] Murray also argued that there was "no evidence from any other co-authors disclaiming contribution to the relevant subject matter."[15] In its decision on institution, the PTAB found that ICM's inventor declaration was insufficient to disqualify Bouabdallaoui as prior art because, *inter alia*, the declaration did not explain the inventor's relationship with all other co-authors, and thus, did not establish that the inventor was the *sole* inventor of the relied-upon disclosures in Bouabdallaoui.[16] The PTAB instituted trial, concluding that this issue "will benefit from development during trial."[17] A Final Written Decision in *Murray* is expected in January 2025.

The PTAB also addressed § 102(b)(1)(A) and (B) inventor disclosure exceptions in *Incyte Corp. v. Concert Pharms., Inc.*[18] Incyte's PGR petition asserted obviousness challenges that included a reference patent called "Silverman," which was Concert's own patent. Incyte argued that Silverman was prior art under § 102(a)(1) as of Silverman's 2016 issue date. In its obviousness arguments, Incyte alleged that Silverman's disclosure of a specific compound ("Compound I") provided a lead compound for a skilled artisan to select and further develop. Concert argued that the Compound I disclosures in Silverman were (i) a disclosure by the inventor of the challenged patent (§ 102(b)(1)(A)) and (ii) a public disclosure by the inventor (§ 102(b)(1)(B)).[19] As Concert explained, an inventor of the challenged patent had submitted a declaration ("Uttamsingh Declaration") during prosecution of the Silverman patent, disclosing Compound I and associated data.[20] According to Concert, the declaration became publicly available in the Silverman prosecution history before Silverman granted.

The PTAB considered Concert's arguments but instituted the PGR, finding that Concert's "evidence that the prior art exceptions . . . apply to Silverman [was] insufficiently persuasive at this stage and need[ed] to be tested at trial."[21] However, in its Final Written Decision, the PTAB found that the Uttamsingh Declaration is "a disclosure from an inventor of the challenged [] patent," which "result[s] in exclusion of the teachings a person of ordinary skill in the art would have gleaned from reading Silverman."[22] And without Silverman's Compound I disclosures, "[n]o other information or argument was presented in the Petition to support a motivation to use Compound (I) of the genus of Formula A of Silverman."[23]

Prior public use or sale of § 102(a)(1) subject matter

A § 102(a)(1) disclosure may be disqualified as prior art under § 102(b)(1)(B) if (i) the disclosure is made one year or less before the effective filing date and (ii) the subject matter of the disclosure was previously disclosed via a prior sale

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continued

or public use of the subject matter. For example, in *MerchSource LLC v. DODOCase VR, Inc.*, the PTAB considered whether a prior public sale excluded a prior art reference under § 102(b)(1)(B).[24] MerchSource's IPR grounds included a reference called "Tech#," which, according to MerchSource, was a Youtube video that published online before the effective filing date of the challenged patent. MerchSource argued that Tech# qualified as a printed publication under § 102(a)(1) because it was publicly available online. DODOCase argued that Tech# was not prior art because public sales of its products, which DODOCase argued were prior public disclosures by the inventor under § 102(b)(1)(B), occurred before the date of the Tech# video. To support its argument, DODOCase relied upon videos from the inventor; assembly instructions for the product; and a declaration from the inventor describing the prior disclosures. Notwithstanding DODOCase's evidence of prior sales, the PTAB decided the § 102(b) issue would benefit from further development at trial, and instituted the IPR.[25] In particular, the Board stated that "Petitioner will have an opportunity [during the IPR] to cross-examine the testimony of Patent Owner's declarant."[26] The proceeding was terminated prior to the PTAB issuing a Final Written Decision.

In *CQV Co. Ltd v. Merck Patent GmbH*, the PTAB considered whether a prior public use or sale of a product could exclude prior art under § 102(b)(1)(A).[27] Here, Petitioner CQV challenged Merck's patent claims as obvious over a product called "Xirallic," alleging that Xirallic was publicly available before the effective filing date of Merck's patent. CQV relied solely on fact witness testimony from two of its employees, who testified they had purchased and tested a sample of Xirallic before the effective filing date of the challenged patent. Merck argued that the Xirallic product was Merck's own product and any sale or offer for sale was not prior art under §102(b)(1)(A) because it was a disclosure made by the inventor. In its Final Written Decision, the PTAB concluded that CQV failed to meet its evidentiary burden of showing that Xirallic was in public use, on sale, or otherwise available to the public because CQV relied solely on fact witness testimony without additional corroborating evidence.[28]

Prior public use or public sale of § 102(a)(2) subject matter

Under § 102(b)(2)(B), a prior public sale or public use may constitute a "public disclosure" and disqualify a reference patent or patent application as § 102(a)(2) prior art. In *K/S HIMPP v. Bragi GmbH*, the Board addressed both § 102(b)(2)(B) exceptions (inventor public disclosures before prior art patents and applications) and § 102(b)(1)(B) exceptions (prior inventor public disclosures).[29] K/S HIMPP's petition relied on disclosures in a patent reference called the "Hensen Patent," which was filed on October 8, 2015, just before the challenged patent's effective filing date of November 13, 2015, along with a September 10, 2015 video from the inventor of the Hensen Patent that demonstrated the use of a product (the "Hensen Video").[30] In its preliminary response, Bragi asserted that—before the Hensen Patent's October 2015 filing date—the inventor publicly disclosed the relied-upon subject matter in the Hensen Patent through a series of published articles and website disclosures discussing the product (the "Kickstarter" disclosures), and published videos demonstrating the product's use.[31] Bragi asserted that the Kickstarter was published after February 2015, but before September 10, 2015. According to Bragi, the relied-upon disclosures in the Hensen Patent were excluded as prior art under § 102(b)(2)(B). But, Bragi did not address the prior art status of the Hensen Video.

Before its institution decision, the PTAB authorized additional briefing from the parties limited to the prior art status of the Hensen Patent. K/S HIMPP argued that the Hensen Patent was entitled to an earlier claimed priority date that pre-dated Bragi's §102(b)(2)(B) Kickstarter disclosures.[32] In its Decision on Institution, the PTAB focused on the § 102(a)(2) prior art status of the Hensen Patent. The PTAB agreed with K/S HIMPP, deciding at institution that while Bragi had effectively shown that its Kickstarter disclosures pre-dated the Hensen Patent's October 2015 filing date (and thus likely would have excluded the Hensen Patent as prior art as of that date), K/S HIMPP had effectively rebutted that showing with evidence that the Hensen Patent was entitled to an earlier effective filing date that pre-dated Bragi's Kickstarter disclosures.[33] The PTAB concluded that K/M HIMPP

has established that the Hensen Patent was prior art and accordingly instituted trial.[34] The PTAB also found that the Hensen Video was prior art under § 102(a)(1) because it was a printed publication and Bragi did not address the prior art status of the Hensen Video.[35]

During the IPR, Bragi asserted that the Hensen Video was not prior art because Bragi's Kickstarter disclosures were public disclosures by the inventor before the September 10, 2015 publication date of the Hensen Video.[36] According to Bragi, the Kickstarter disclosed the same subject matter as the Hensen Video, and thus, the Hensen Video was excluded from prior art under § 102(b)(2)(B). K/S HIMPP asserted that the Kickstarter did not disclose the same subject matter as the Hensen Video, and submitted a declaration that emphasized the differences in the visual representations of the products shown in the Kickstarter compared to the Hensen Video.[37] Thus, according to K/S HIMPP, the Hensen Video was prior art under § 102(a)(1) as a prior printed publication.

In its November 4, 2024 Final Written Decision finding all claims unpatentable, the PTAB determined that the § 102(b)(1)(B) exception did not remove the Hensen Video as prior art. Interestingly, the PTAB noted that "there is no pertinent case law on th[e] issue" related to the § 102(b) prior art exceptions, and consulted the Manual for Patent Examining Procedure ("M.P.E.P.") for guidance.[38] The Board acknowledged that the M.P.E.P. is not a binding authority, but its guidance was "a persuasive interpretation of the [§ 102(b)] statute."[39] Ultimately, the PTAB determined that the Kickstarter did not disclose the same subject matter as the Hensen Video because the disclosures were "not identical, and the two subject matters at least embody different species of the" challenged patent.[40]

The PTAB similarly addressed § 102(b)(2)(B) exceptions in *Wilson Elecs. LLC v. Cellphone-Mate, Inc.*[41] Here, Wilson's IPR grounds included a reference patent called "Van Buren." In its preliminary response, Cellphone-Mate argued that it had publicly disclosed the invention before Van Buren's effective filing date by publicly displaying the device (called "Force5") at a trade show.[42] Cellphone-Mate also presented evidence of prior blog posts about the device, webinars and videos of the inventor discussing the Force5 product, as well as industry publications showing the device was on sale.[43] Unlike the cases above in which the PTAB instituted trial to better develop the record, in Wilson, the PTAB denied institution. In particular, the PTAB concluded that Cellphone-Mate presented evidence of publicly disclosing the relied-upon subject matter in Van Buren before Van Buren's filing date, while Wilson "has not explained its challenge of the claims over Van Buren with sufficient particularity to show Van Buren is prior art."[44]

Commonly owned § 102(a)(2) subject matter

Under § 102(b)(2)(C), a prior art disclosure may be disqualified as prior art if the subject matter disclosed and the claimed invention were commonly owned before the filing date of the claimed invention. For example, in *Sanofi Pasteur Inc. v. Pfizer Inc.*[45], Sanofi's IPR grounds included two PCT publications. In its preliminary response, Pfizer asserted that the PCT publications were not prior art because they were commonly owned and subject to an obligation of assignment at the time the challenged claims were filed. The PTAB agreed with Pfizer and denied institution, stating that Pfizer "provided evidence that these publications were subject to assignment to Patent Owner as of the effective filing date of the" challenged patent, and the assignments were recorded before the publication dates of the PCT applications.[46]

Similarly, in *Incyte Corp. v. Concert Pharms., Inc.* (discussed earlier in this article), Concert raised an alternative argument that the Silverman patent was not prior art under § 102(b)(2)(C) because both Silverman and the challenged patent were assigned to Concert.[47] In its pre-institution reply brief, Incyte argued that the assignment to Concert was executed by the inventors 18 months after the challenged patent's effective filing date.[48] Thus, according to Incyte, *the inventors* (not Concert) owned the challenged patent as of its effective filing date and there was no common ownership exception.[49] The PTAB instituted trial, finding Concert's later-executed assignment alone was insufficient to show

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continued

common ownership under § 102(b)(2)(C).[50] During trial, Concert argued that the inventors were under an obligation to assign the challenged patent to Concert before the effective filing date, and submitted as evidence the inventors' employment agreement.[51] The PTAB ultimately concluded that it did not need to reach the common ownership issue because Incyte had narrowed its trial arguments to whether Silverman qualified as § 102(a)(1) (not § 102(a)(2)) prior art.[52]

Conclusion

While this sample size of PTAB decisions is small, we note the following trends. At the institution stage, the PTAB may conclude that patent owner arguments attempting to disqualify art under § 102(b)(1) or (b)(2) are insufficient for purposes of denying institution. This is especially so when patent owners rely on bare inventor declarations without any corroborating evidence. However, patent owners may be able to maintain or even further develop those same arguments during trial, which can lead to successful disqualification of the prior art reference, so long as the inventor had disclosed the same subject matter as the prior art reference. Evidence of common ownership (e.g., such as recoded assignments) may have a higher likelihood of successfully disqualifying prior art under § 102(b)(2)(C) at the institution stage.

1 111 F.4th 1338 (Fed. Cir. 2024).
2 108 F.4th 1376 (Fed. Cir. 2024).
3 35 U.S.C. § 102(a)(1).
4 35 U.S.C. § 102(b)(1).
5 35 U.S.C. § 102(a)(2).
6 35 U.S.C. § 102(b)(2).
7 111 F.4th 1338 (Fed. Cir. 2024).
8 108 F.4th 1376 (Fed. Cir. 2024).
9 111 F.4th at 1347.
10 108 F.4th at 1385.
11 IPR2023-01064, Paper 9 (P.T.A.B., Jan. 16, 2024).
12 *Id.*, Paper 6 at 4–5.
13 *Id.*, Paper 9 at 52.
14 *Id.*, Paper 7 at 2–3.
15 *Id.*
16 *Id.* Paper 9 at 55.
17 *Id.*, Paper 9 at 56.
18 PGR2021-00006, Paper 68 (P.T.A.B., May 11, 2022).
19 *Id.*, Paper 68 at 17.
20 *Id.*
21 *Id.*, Paper 20 at 19.
22 *Id.*, Paper 68 at 42.
23 *Id.*, Paper 68 at 59.
24 IPR2018-00494, Paper 12 (P.T.A.B., Aug. 22, 2018); see also, *MerchSource LLC v. DODOCase VR, Inc.*, PGR2018-00019, Paper 11 (P.T.A.B., Aug. 29, 2019).
25 IPR2018-00494, Paper 12 at 20.
26 Id.
27 PGR2021-00054, Paper 56 (P.T.A.B. Aug. 11, 2022).
28 *Id.*, at 29.
29 IPR2023-00901, Paper 14 (P.T.A.B., Nov. 13, 2023).
30 *Id.*, Paper 3 at 6.
31 See *id.*, Paper 11 at 17–37.
32 See *id.*, Paper 12 at 1–4.
33 *Id.*, Paper 14 at 12.
34 *Id.*, Paper 14 at 12, 27.
35 *Id.*, Paper 14 at 15.
36 *Id.*, Paper 39 at 11.
37 *Id.*, Paper 39 at 15.
38 *Id.*, Paper 39 at 14 n.10.
39 *Id.*
40 *Id.*, Paper 39 at 16.
41 IPR2018-017798, Paper 10 (P.T.A.B., April 23, 2019).
42 *Id.*, Paper 8 at 28–29, 33–34.
43 See *id.*, Paper 8 at 28–36.
44 *Id.*, Paper 10 at 35.
45 IPR2018-00188, Paper 10 (P.T.A.B., June 5, 2018).
46 *Id.*, Paper 10 at 14.
47 PGR2021-00006, Paper 11 at 21.
48 *Id.*, Paper 17 at 2.
49 *Id.*
50 *Id.*, Paper 20 at 19.
51 *Id.*, Paper 37 at 18.
52 *Id.*, Paper 68 at 13 n.3.

The PTAB Continues to Shape Application of the Lead-Compound Analysis in Chemical Obviousness Cases

BY OLGA A. PARTINGTON, PH.D., TYLER LIU

The so-called "Lead Compound Analysis" is the primary legal framework for assessing chemical obviousness. For years, patent owners have enjoyed largely favorable outcomes in cases related to chemical obviousness due to the Patent Trial and Appeal Board's (PTAB) dutiful application of the lead compound analysis as the primary legal framework. But the decisions we have seen from the PTAB in 2023-2024 appear to continue the trend, started a few years ago, where the PTAB is willing to deviate from the lead compound framework, exposing vulnerability of chemical compound claims in AIA proceedings.

The Lead Compound Analysis (LCA) for assessing obviousness of a chemical compound was first articulated by the Federal Circuit 24 years ago.[1] Under this approach, there must be a reason for a POSA 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] A key distinction between the previous, "*Dillon*," approach and the LCA was that to qualify as a "lead," the compound must possess some beneficial property that somehow distinguish it from other prior art compounds.[3] Thus, by focusing on the most promising prior art compound(s) rather than the closest prior art compound (the practice under *Dillon*), the LCA imposed a much higher burden for showing obviousness in chemical arts.

While the PTAB was slow to adopt the LCA in ex parte appeals,[4] the PTAB's approach to chemical obviousness in inter partes post-grant proceedings was a surprising (and swift) deviation from its ex parte practice. 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.'"[5] As such, from the inception of AIA proceedings in 2012, the PTAB started to adhere to a strict LCA framework in post-grant proceedings, leading to a nearly universal survival of compound claims.[6]

After a nearly 10-year stretch[7] of the strict application of the lead compound framework, the PTAB surprised us in 2021 with an expressly-articulated refusal to rely on the LCA in *NOF Corporation v. Nektar Therapeutics*.[8] The *NOF* panel "decline[d] to apply the lead compound analysis as the exclusive test for obviousness," looking instead "to the general law of obviousness for guidance."[9] Similarly, in *Alzheon Inc. v. Risen (Suzhou) Pharma Tech Co.*, Ltd., the PTAB concluded that "the standard set forth in *In re Dillon* appears to be the closest applicable standard to apply in this case," which dealt with a question of whether a deuterated drug is *prima facie* obvious over its non-deuterated isotopolog.[10]

The PTAB's treatment of chemical obviousness cases since *NOF* and *Alzheon* appears to support the notion that the PTAB has become more selective about applying the LCA framework. Among the 2023-2024 chemical obviousness cases we surveyed, the PTAB applied the lead compound framework in two, and rejected it in two.

Cases where the PTAB applied the lead compound analysis:

Mylan Pharms et al. v. Bausch Health Ireland Ltd., IPR2022-00722, Paper 78 (P.T.A.B. Sep. 8, 2023)

Mylan petitioned the PTAB seeking review of U.S. Patent No. 7,041,786 ("the '786 patent") assigned to Bausch.[11] The '786 patent relates to new agonists of guanylate cyclase receptor that are analogs of uroguanylin, with the challenged claims directed to a peptide having SEQ ID NO: 20, compositions comprising the peptide, and a PEGylated version of the peptide.[12]

Mylan asserted multiple grounds of unpatentability based on obviousness.[13] In a straight-forward application of the LCA, the PTAB found that a POSA would have had a reason to select the identified lead compound, and to modify the lead to arrive at the claimed peptide agonist.[14] Bausch did successfully argue that the particular features of the claimed peptide provided unexpected and superior results compared to human uroguanylin.[15] While Mylan was ulti-

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continued

mately unsuccessful in invalidating the '786 patent claims in view of the strong evidence of unexpected results, this case is an example of the PTAB's adherence to the lead compound framework.

Mylan Pharms., Inc. v. Novo Nordisk A/S, IPR2023-00722, Paper 9 (P.T.A.B. Oct. 2, 2023)

This is another example of the PTAB's willingness to follow a straight-forward application of the lead compound framework. Mylan filed a petition challenging claims of U.S. Patent No. 8,536,122, directed to modified analogs of glucagon-like peptide 1 (GLP-1).[16] One such analog, known as semaglutide, is the active ingredient in Novo Nordisk's popular Ozempic®, Rybelsus®, and Wegovy® products.[17]

In this case, both parties agreed that the lead compound analysis should apply, and the PTAB readily accepted both parties' approach. In the petition, Mylan argued that a POSA would have selected liraglutide as a lead compound for further development.[18] The PTAB, in the Institution Decision, found that Mylan "has sufficiently established that liraglutide would have been, at a minimum, one of the best candidates for further development" in view of liraglutide's promising phase 2 trials and potentially other beneficial uses beyond the treatment of diabetes.[19] Ultimately, however, the PTAB denied institution and found that Mylan failed to adequately explain why a POSA would have opted to make three separate modifications with a reasonable expectation of success.[20]

Cases where the PTAB rejected the lead compound analysis:

Shanghai Hongene Biotech Corp. v. Chemgenes Corp., IPR2023-00490, Paper 35 (P.T.A.B. July 18, 2024)

Petitioner Shanghai Hongene Biotech Corp. challenged claims 1-5 of U.S. Patent No. 9,884,885 ("the '885 patent") directed to N-2 acetyl protected nucleosides and phorphoroamidites useful for synthesizing RNA oligonucleotides.[21] Petitioner used *Dillon's* "structural similarity" rather than the lead compound framework and argued that the challenged claims would have been obvious because the "only difference between" compound x of the prior art "and the molecule recited in challenged claim 2 of the '885 patent" is that compound x "has an isobutyryl group, while the latter [claimed compound] has an acetyl group."[22] Patent owner, in turn, insisted that petitioner had to explain the selection of compound x as "a lead," which it failed to do.[23]

The PTAB was "not persuaded that the lead compound analysis is an appropriate one for [this] case" because guanosine is "a natural, obvious starting place for any artisan seeking to build oligonucleotides."[24] During the oral argument, Judge John New questioned whether the lead compound analysis was appropriate because "swapping out one known protecting group from another" was a "fairly simple substitution, and in view of *KSR*" did not "seem to be a terribly big jump to get to obviousness."[25] Judge New also pointed out that unlike in *Takeda*,[26] petitioner was not "plucking this particular molecule, compound X, out of a long, long list of undifferentiated chemicals."[27] Rather, petitioner was "simply substituting one known substituent group for another known substituent group," which "generally lead[s] to obviousness."[28] The PTAB ultimately concluded that, "to a person of ordinary skill, Crooke's compound x would have been an obvious starting point for modification."[29]

Sarepta Therapeutics, Inc. v. The Trustees of the Univ. of Penn., IPR2024-00580, Paper 9, (P.T.A.B. Aug. 22, 2024)

Petitioner Sarepta Therapeutics filed a petition challenging claims 1, 3-6, and 8 of U.S. Patent No. 11,680,274, directed to a recombinant adeno-associated virus comprising an AAV capsid comprising various AAV proteins and amino acid sequences.[30] Without explaining the selection of the AAVrh.10 capsid as "a lead," petitioner argued that "it would have been obvious to a POSA to make substitutions from AAV8 into AAVrh.10, in an attempt to confer the uniquely favorable properties of AAV8 onto AAVrh.10."[31] Patent owner argued that petitioner had to apply the lead compound framework and "identify a motivation to modify

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continued

a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound."[32]

Without resorting to a strict application of the lead compound framework, the PTAB found that based on the disclosure of the prior art and the unrebutted testimony of petitioner's expert, "petitioner has sufficiently shown on the record before us that a POSA would have been motivated to select the promising AAVrh.10 as a starting point" to arrive at the claimed recombinant AAV.[33] In instituting trial, the PTAB also noted that "Petitioner has sufficiently shown that a POSA would be motivated to modify AAVrh.10 based on a comparison with AAV8" to improve efficiency of gene transfer to liver.[34] Indeed, the Board credited the opinion of Dr. Shaffer that a POSA would have been motivated to make "four variants of AAVrh.10, each containing a single substitution of a non-phosphorylatable amino acid for a phosphorylatable amino acid, and using those sequences to make rAAV vectors," including the claimed rAAV vector.[35] The PTAB concluded that "Petitioner has shown sufficiently for purposes of institution that a POSA would have been motivated to make the substitution at the 665 position with a reasonable expectation of success."[36]

Similar to *Shanghai v. Chemgenes*, the PTAB here opted to forgo a lead compound analysis for a simple, easy-to-understand, *KSR*-type obviousness argument.

Recently, the Federal Circuit in *Cytiva BioProcess R&D AB v. JSR Corp* provided additional clarity on the application of the lead-compound analysis in chemical compound cases.[37] In this case, Cytiva appealed the final written decisions of unpatentability from six *inter partes* reviews.[38] Cytiva argued that the Board "erred by failing to conduct this lead-compound analysis."[39]

The Federal Circuit held that "our case law has not suggested that lead compound analysis is *always* required. Instead, we have explained that the lead compound analysis is an ordinary or generally applicable test that assists courts in assessing obviousness for new compounds."[40] The Court further held that a "lead-compound analysis is not required where the prior-art references expressly suggest the proposed modification."[41]

The PTAB's recent decisions in both *Sarepta* and *Shanghai* seem to be in compliance with the reasoning from the Federal Circuit in *Cytiva.* The PTAB has been willing to forgo a strict application of the lead compound analysis in situations where the art provides "an obvious starting point for modification"[42] or a reason for a POSA to make a simple substitution to arrive at the claimed compound.[43]

With the Federal Circuit's most recent weigh-in, the PTAB is likely to continue with the trend of selectively applying the lead-compound analysis in the chemical obviousness space. The recent cases show that patent owners who rely heavily on the lead compound analysis have been unsuccessful in convincing the PTAB to confirm patentability. On the other hand, petitioners who are more flexible in their obviousness arguments have recently been successful at invalidating chemical claims. Both parties should consider these recent decisions in determining whether to insist on a strict application of the lead-compound analysis at the PTAB.

The PTAB Continues to Shape Application of the Lead-Compound Analysis in Chemical Obviousness Cases

continued

1 *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).

2 *Otsuka Pharm. Co. Ltd. v. Sandoz Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012).

3 *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990).

4 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)).

5 *Sawai Inc. v. Astellas Pharma Inc.*, IPR2018-00079 (PTAB May 4, 2018) (Paper 7).

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 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).

8 *NOF Corporation v. Nektar Therapeutics*, IPR2019-01397, 3 (PTAB Aug. 5, 2021) (Paper 70).

9 *Id.*

10 *Alzheon Inc. v. Risen (Suzhou) Pharma Tech Co., Ltd.*, IPR2021-00347, 65 (PTAB July 12, 2022) (Paper 53).

11 *Mylan Pharms et al. v. Bausch Health Ireland Ltd.*, IPR2022-00722, Paper 1 at 1 (PTAB Mar. 21, 2022).

12 *Id.* at 11-12.

13 *Id.* at 4.

14 IPR2022-00722, Paper 78 at 16-37.

15 *Id.* at 37-60.

16 *Mylan Pharms., Inc. v. Novo Nordisk A/S*, IPR2023-00722, Paper 1 at 10-15 (PTAB Mar. 16, 2023).

17 IPR2023-00722, Paper 9 at 7.

18 IPR2023-00722, Paper 1 at 6-7, 30-34.

19 IPR2023-00722, Paper 9 at 28.

20 *Id.* at 29-44.

21 *Shanghai Hongene Biotech Corp. v. Chemgenes Corp.*, IPR2023-00490, Paper 1 at 1-2 (PTAB Jan. 19, 2023).

22 *Id.* at 33-34.

23 IPR2023-00490, Paper 16 at 22-24.

24 IPR2023-00490, Paper 35 at 37.

25 IPR2023-00490, Paper 36 at 29:10-18.

26 *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007).

27 IPR2023-00490, Paper 36 at 30:15-20.

28 *Id.* at 30:20-24.

29 IPR2023-00490, Paper 35 at 37-38.

30 *Sarepta Therapeutics, Inc. v. The Trustees of the Univ. of Penn.*, IPR2024-00580, Paper 1 at 1-2, (PTAB Feb. 21, 2024).

31 *Id.* at 3.

32 IPR2024-00580, Paper 8 at 25.

33 IPR2024-00580, Paper 9 at 23-24.

34 *Id.* at 24-25.

35 *Id.* at 26-27.

36 *Id.* at 27.

37 *Cytiva Bioprocess R&D AB v. JSR Corp.*, No. 23-2074 (Fed. Cir. 2024).

38 *Id.* at 2.

39 *Id.*

40 *Id.* at 11.

41 *Id.* at 12.

42 IPR2023-00490, Paper 35 at 37.

43 IPR2024-00580, Paper 9 at 27.

PTAB Trends in 2024: Challenges to Genus Claims

BY CHRISTOPHER M. GALLO

In the biotechnology and chemical spaces, genus claims are often sought by patent applicants to protect not only a specific product of interest, but also as a means to protect against others making related products that incorporate the advance over the prior art made by the applicant. In 2024, the Patent Trial and Appeal Board (PTAB) issued several decisions in the biotechnology and chemical space where the written description and enablement requirements came into play in proceedings involving challenges to genus claims. As these patentability requirements are seemingly become stricter for biotechnological and chemical inventions, and the Supreme Court has recently weighed in with respect to enablement, it is worth assessing how the PTAB handled analysis of written description and enablement requirements in the biotechnology and chemical spaces in 2024.

Lack of Enablement for Sequence Identity Claims Having a Functional Element

As the Federal Circuit has recognized, generic claims reciting functional elements make such claims especially susceptible for attack by written description and enablement.[1] In *Inari Agriculture, Inc. v. Pioneer Hi-Bred International, Inc.*, claims challenged in a post-grant review (PGR) were directed to a transgenic plant comprising a recombinant polynucleotide encoding an enzyme having dual-substrate activity, wherein the enzyme comprised (1) amino acids having at least 85% sequence identity to a specific sequence and (2) a specific amino acid motif with specific spacing between fixed amino acid sequences in the motif.[2]

At institution, the Board found that it was more likely than not that at least one challenged claim of the challenged patent lacked written description and enablement.[3] That finding by the Board also involved a decision that the challenged patent was PGR-eligible because the challenged patent's pre-AIA priority application was also found to not provide written description and enablement support.[4]

In its Final Written Decision, the Board reaffirmed its findings with respect to lack of enablement in the priority application. In doing so, the Board stepped through the *Wands* factors and pointed to the Supreme Court's finding in *Amgen v. Sanofi* that analyzing enablement of genus claims involves determining if there is a common quality running through the genus that gives it a peculiar fitness for the claimed function.[5]

In short, the Board's analysis found that based on the claimed sequence's length and the requirement for it having at least 85% sequence identity to the recited sequence, the claim encompassed up to 2.4×10^{106} candidate species, whereas the specification disclosed two exemplary sequences.[6] The Board also found that it would not have been predictable which of the possible species encompassed by the claims would have the claimed dual-enzyme activity and which would not.[7] Additionally, the Board determined that (1) there was a lack of guidance and working examples in the specification that would indicate which of the candidate species would meet the claimed function, (2) a skilled artisan would not know from the art which amino acids could tolerate changes, and (3) unpredictability between *in vitro* and *in vivo* function would require making and testing each variant for its activity.[8]

Lastly, aiding in the Board's final determination of a lack of enablement were experiments performed by the patent owner previous to the filing of the PGR and submitted during the proceeding. Those experiments showed that having the claimed amino acid motif, claimed amino acid spacing, and claimed sequence identity did not constitute (1) a structure-function correlation sufficient enough to predict function; or (2) a common quality running through the genus.[9]

In view of the above, the Board concluded that "[w]hile it may have been possible for a skilled artisan to make certain polypeptides" with the claimed function "using the guidance provided in the [s]pecification and the methods known by an ordinarily skilled artisan, practicing the full scope of the claimed polypeptides would fall outside routine experimentation."[10]

This case is particularly instructive because many patent applicants seeking protection for a protein of interest typically include sequence identity claims as a standard practice. Such sequence identity claims tied to a functional

element should be assessed on both the petitioner's and patent owner's sides for the claimed genus's size, any unpredictability that would require making and testing each variant for whether it meets the claimed function, how sufficiently the claims are supported by a structure-function correlation or a representative number or species in the specification, and what was the knowledge in the art at the time of filing. This case also reaffirms that post-*Amgen* weighing the *Wands* factors remains an instructive tool in assessing enablement support.

A Single Working Example Not Sufficient to Support Broad Functional Claim

In *Forte Biosciences, Inc. v. University of Massachusetts*,[11] the Board found a lack of written description and enablement upon analogizing the facts at issue with those in *Juno v. Kite*[12] and *Amgen*. The Board determined that the challenged claims were "directed broadly to a method of treating vitiligo by administering an inhibitor of IL-15 or the IL-15 receptor in a therapeutically affective amount," which was "a functional description, requiring that the administered compound be both an inhibitor of IL-15 or IL-15 receptor and therapeutically effective."[13]

Regarding written description, the patent owner sought to frame the inquiry as to whether or not the challenged patent demonstrated possession of the claimed method of treating vitiligo with an IL-15 or IL-15 receptor inhibitor and not whether the inventors were in possession of the entire genus of IL-15 and IL-15 receptor inhibitors capable of functioning in the claimed method.[14] The Board disagreed that the analysis should be solely focused on the claimed method, but should also focus on the genus of inhibitors because the claimed method could not be practiced without them.[15]

The Board then analyzed the scope of the claimed genus and found it to be broad, encompassing at least small molecules, antibodies, nucleic acids, and peptides.[16] Yet, the specification only provided one working example, an antibody, and the art demonstrated unpredictability in which IL-15 and IL-15 receptor inhibitors would be effective.[17] Based on that, the Board likened the facts to *Juno*. There, the claims encompassed any single-chain antibody fragment ("scFv") capable of binding a target antigen and the specification only disclosed two exemplary scFvs in working examples. That led to a finding of a lack of written description because a skilled artisan would not have found the two disclosed examples sufficiently representative of the entire genus.[18] Applying that in *Forte*, the Board found a lack of written description. It determined that given the unpredictability in the art a skilled artisan would not have found the single working example using an antibody sufficiently representative of the different possible inhibitor types disclosed in the specification and the hundreds of known IL-15/IL-15 receptor inhibitors.[19] It also found a lack of structure-function correlation in the specification and the art given that the candidate species encompassed by the claims were not all a readily identifiable class, did not all target the same biological pathways, did not have any common structural features, and did not always function as inhibitors.[20]

Turning to enablement, the Board found the facts in *Forte* similar to those in *Amgen*.[21] The Board found that, as in *Amgen* where the claims encompassed the entire genus of antibodies capable of binding specific residues of their target and blocking its function and the specification provided a limited number of exemplary antibodies, the claims in *Forte* encompassed the entire genus of IL-15/IL-15 receptor inhibitors capable of treating vitiligo and only one working example.[22] Pointing again to the unpredictability as to which inhibitors would and would not function to treat vitiligo, the Board determined that a skilled artisan would have to painstakingly test every candidate compound to determine if it met the claimed function.[23] The Board thus found a lack of enablement. In doing so, it rejected the patent owner's argument that the claims being to a method absolved it of the need to disclose information about what inhibitors met the claimed function.[24]

The Board's decision in *Forte* provides another example of how broad functional claims can be particularly susceptible to written description and enablement challenges, whether they are directed to a product or a method. This decision

PTAB Trends in 2024: Challenges to Genus Claims

continued

also demonstrates how cases such as *Juno* and *Amgen* remain instructive when lodging and defending against § 112(a) challenges, as well as how extrinsic evidence of unpredictability and inoperability can be utilized.

Blaze Marks Would Not Have Directed a Skilled Artisan to Envisage a Claimed Subgenus

It is well-established that "the hallmark of written description is disclosure."[25] For genus claims, the Federal Circuit has held that sufficient disclosure can be established by showing that a specification discloses a representative number of species or features common to the claimed genus, such that a skilled artisan would be able to visualize or recognize the members of the genus.[26]

Throughout the years, the Federal Circuit has established different ways of determining whether a patent specification discloses either or those two factors sufficiently enough to support a genus claim: (1) searching for a precise definition, such as by structure, formula, chemical name, physical properties, or other properties sufficient to distinguish the species of the genus from others; (2) looking for structure-function correlations in the specification and/or known in the art when analyzing functional claims; (3) analogizing a claimed genus to a plot of land and seeing how much of that plot of land the species disclosed in a specification cover; and (4) looking for blaze marks that direct a skilled artisan to the claimed subject matter.[27]

In *Daiichi Sankyo, Inc. v. Seagen Inc.*, the Board analyzed the challenged claims in a PGR using a "blaze marks" analysis and found a lack of written description in both the patent and its priority applications.[28] There, the challenged claims were directed to an antibody-drug conjugate ("ADC") having a certain chemical formula comprising a "tetrapeptide" subunit and a "drug moiety."[29]

To make the patent PGR-eligible, the petitioner challenged patent's priority claim. At issue was a "W_w" element in the claims that required that the ADC comprises a tetrapeptide made up of four amino acids selected from combinations of glycine and phenylalanine ("gly/phe"), as well other requirements.[30] The petitioner argued that the W_w element encompasses 81 different species, none of which were specifically identified in the patent's priority applications, whose disclosure embodied over 47 million species.[31] The petitioner further stated that there were no blaze marks in the specifications of the priority applications that would have pointed a skilled artisan to the claimed gly/phe tetrapeptides, rather one would have been directed to a different subgenus.[32] In response, the patent owner pointed to three other tetrapeptides that had different combinations of amino acids, other than gly/phe, disclosed in the priority applications, which the patent owner asserted would have guided a skilled artisan to the claimed gly/phe tetrapeptides.[33]

Upon analysis of the parties' arguments, the Board found that the preponderance of the evidence showed that the priority applications lacked the requisite descriptive support for the W_w element. Applying a "blaze marks" analysis, the Board stated that the disclosure of the priority applications would not "allow a person of ordinary skill in the art to inherently, necessarily, or immediately envisage a tetrapeptide with only glycine or phenylalanine as the amino acids."[34] The Board, therefore, concluded that "the requisite description" for the claimed W_w element was "lacking in the priority applications as it is an 'undifferentiated description. . . [that] failed to provide sufficient 'blaze marks' to guide a reader through the forest of disclosed possibilities toward the claimed compound, which resided among the myriad others that also could have been made.'"[35]

The Board also found that, while the claimed gly/phe tetrapeptides might have been obvious in view of the other specifically disclosed tetrapeptides, "a description that merely renders the invention obvious does not satisfy the written description argument."[36] And because the challenged patent's specification also suffered from the same lack of blaze marks as the priority applications, the Board found that the challenged claims lacked written description support in the challenged patent as well.

The petitioner in *Daiichi* also challenged the challenged patent's written description support for the "drug moiety"

PTAB Trends in 2024: Challenges to Genus Claims

continued

element. The petitioner took the position that the challenged patent's specification failed to disclose a representative number of species or common structural features of drug moieties for use in the claimed ADC.[37] The Board disagreed, finding the facts similar to those in *Capon v. Eshhar*, because the art was "aware of a number of chemotherapeutic drug compounds and the use of antibody-drug conjugates."[38] The specification also disclosed a large number of drugs, incorporated by reference numerous references describing ADCs, and the structures of chemotherapeutic agents were known in the art.[39] The Board also found the facts different from those in *Juno* because the claims were focused on the particular linker selected, rather than the drug, and the specification-at-issue disclosed "dozens of different known chemotherapeutic agents in multiple different classes that would have been expected to kill cancer cells."[40] The Board, therefore, found the "drug moiety" element sufficiently supported in the challenged patent.

The decision in *Daiichi* demonstrates how claims to a specific subgenus or species can be susceptible to written description challenges when a skilled artisan would not have been directed to selection of the claimed subgenus or species by a patent's specification. The *Daiichi* decision also demonstrates how different facts can lead to different conclusions on written description. Unlike in *Forte*, where *Juno* was found applicable, here the claims did not recite any functional elements and the claimed "drug moiety" genus was well established. Thus, *Daiichi* shows how the outcome of a case can depend on how the written description issue is framed.

Future Considerations

In a world post-*Amgen*'s role in analyzing enablement and with increasingly tighter written description requirements being imposed on biotechnology and chemical patents, an array of possible invalidity §112 attacks and defenses become available for challenging and defending genus claims in the biotechnology and chemical spaces at the PTAB: assessing whether or not the challenged patent has disclosed a clear structure-function relationship for functional claims, demonstrating a lack of or presence of sufficient representative species, the presence or absence of blaze marks directing a skilled artisan to the claimed genus, the presence or absence of a sufficient number of working examples, and/or showing a lack of or presence of a common quality running through the genus that gives it a peculiar fitness for its particular purpose.

Also of note, the above decisions all involved PGRs, where challenges to written description and enablement are typically top-of-mind because PGR-eligible patents can be challenged under the provisions of § 112(a). Nonetheless, these decisions can also be instructive for inter partes reviews (IPRs), where unpatentability challenges are limited to grounds based on prior art patents and printed publications. Indeed, as discussed above, petitioners made use of written description and enablement arguments to attack the priority claim of the challenged claims. Such § 112-based priority attacks are also available in IPRs and can be a useful tool for bringing challenges based on intervening prior art.

PTAB Trends in 2024: Challenges to Genus Claims

continued

1 See, e.g., *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (discussing written description); *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021) (discussing enablement).

2 *Inari Agric., Inc. v. Pioneer Hi-Bred Int'l, Inc.*, PGR2023-00022, Paper 50, at *4–5 (PTAB Oct. 10, 2024).

3 *Id.* at *6.

4 *Id.*

5 *Id.* at *13–33 (citing *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988); *Amgen Inc. v. Sanofi*, 143 S.Ct. 1243 (2023)).

6 *Id.* at *13.

7 *Id.* at *19–21.

8 *Id.* at *22–29.

9 *Id.* at *20, 30–32.

10 *Id.* at *32 (the Board found that it did not need to reach the issue of written description given that it found a lack of enablement).

11 *Forte Biosciences, Inc. v. Univ. of Mass.*, PGR2023-00014, Paper 45 (PTAB June 24, 2024).

12 *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021).

13 *Forte* at *16.

14 *Id.*

15 *Id.* at *16–*17 (citing *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 925–26 (Fed. Cir. 2004)).

16 *Id.* at *17.

17 *Id.* at *17–*20.

18 *Juno*, 10 F.4th at 1338–39.

19 *Forte* at *20.

20 *Id.* at *21–*22.

21 *Id.* at *29–31.

22 *Id.* at *30.

23 *Id.* at *31–*33.

24 *Id.* at *36–*37.

25 *Ariad*, 598 F.3d at 1351.

26 *Id.* at 1350.

27 *Id.*; *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014); *Idenix Pharm. LLC v. Gilead Sci.*, 1149, 1164 (Fed. Cir. 2019) (citing *In re Ruschig*, 379 F.2d 990, 994–95 (CCPA 1967)).

28 *Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR2021-00030, Paper 57 (PTAB Jan. 16, 2024).

29 *Id.* at *8.

30 *Id.* at *15.

31 *Id.*

32 *Id.* at 16.

33 *Id.* at 18.

34 *Id.* at 25.

35 *Id.* at *28 (quoting *Novozymes A/S v. Dupont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013)).

36 *Id.* at *29 (cleaned up).

37 *Id.* at 31.

38 *Id.* (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005)).

39 *Id.* at 37–38.

40 *Id.* at 38–39.

Supplemental Examination: Five Takeaways from the Last Five Years

BY JASON D. EISENBERG, JESSICA HARRISON, AND THOMAS BARALDI

Supplemental Examination (SE) was created by 35 U.S.C. § 257 of the America Invents Act and is now over 12 years old. SE provides a patent owner with a mechanism to request that the Patent Office (Office) consider, reconsider, or correct information that may be relevant to patentability, and in some situations to cleanse the patent from inequitable conduct issues so long as they had not yet be raised in district court. But SE offers so much more to patent owners. Yet for many practitioners and patent owners, SE remains an unknown, misunderstood, or overlooked procedure.

Briefly, any patent owner may file a request for SE with up to 12 items of information for the Office to consider. The Office's Central Reexamination Unit (CRU) decides whether or not one or more of the submitted items raises a substantial new question of patentability (SNQ) to one or more of the patent's claims and issues a SE Certificate communicating their findings. When an SNQ is raised, the Office orders a § 257 Reexamination (SE-Rx), which is examined by a team of CRU examiners. An expanded reexamination of the patent ensues, ultimately culminating in a Reexamination Certificate summarizing the SE-Rx outcomes.

For this article, we reviewed almost all SE requests and the submitted items of information from 2019-2024. Focusing on cases where SE-Rx's were instituted, we considered the resultant SE-Rx's to understand how the CRU handled those proceedings. We included Patent Trial and Appeal Board (PTAB) outcomes to get a full picture of strategic risks and benefits of filing a SE request and the potential subsequent § 257 Reexamination.

In the first four sections of this article we provide four important takeaways that emerged from our findings: a gain in acceptance by patent owners, prevalent errors for non-compliant requests, a wide variety of "items of information" are raising SNQs, and once SNQ is found, how the CRU and PTAB examine SE-Rx with a broader scope of examination as compared to traditional Rx.

Based on these findings, we end by providing some strategic considerations for choosing between SE, RE, and RX.

1. SE has gained acceptance by the patent community

To determine acceptance, we looked at the overall number of SE requests filed from the procedure's first full year, 2013, to the last full year of available data, 2023. We then looked at the speed of the procedures.

First, as illustrated in Chart 1, initially PO's use of SE was low with only 30 requests for SE considered by the CRU during the procedure's first full year. The volume of SE requests steadily increased until 2017 when the CRU considered 161 SE requests. Beginning in 2018, SE request volume has remained relatively steady with 80-100 each year. We note 2021 as somewhat of a lower outlier, with 68 SE requests, and we suggest that this slight dip as likely related to Covid-19 impacts, noting that Office fiscal year 2021 numbers included October – December 2020 filings.

Chart 1: Overall Supplemental Examination Filing and Outcomes

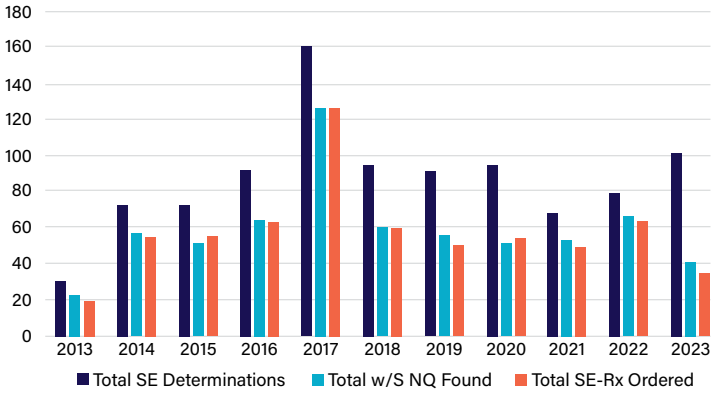
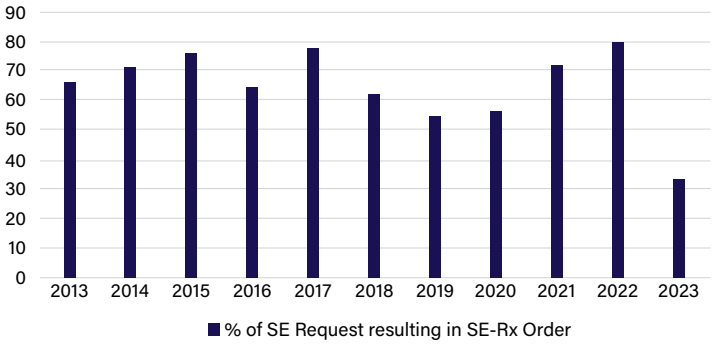


Chart 2: % of SE Request resulting in SE-Rx Order



Office statistics separately report the number of total SE requests with an SNQ found separately from the number

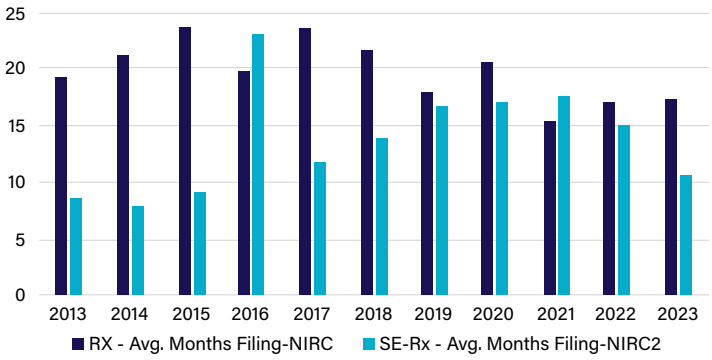
Supplemental Examination: Five Takeaways from the Last Five Years

continued

of SE-Rx's ordered, with most years having slightly less SE-Rx's ordered than SE requests with an SNQ found. We speculate this difference is caused by SE requests that raise an SNQ being determined in one Office fiscal year and then proceed to an SE-Rx Order in the subsequent fiscal year. This speculation would also account for 2021, where 54 SE-Rx's were ordered and only 51 SEs raised an SNQ. To discount our speculation, we considered the percentage of SE-Rxs ordered in relation to the total number of SE requests filed, illustrated in Chart 2. Consistently between 60 and 80% of SE requests result in an SE-Rx order, with three outlier years: 2019 at 54%, 2020 at 56%, and 2023 with 33%. (We also note that through the first three quarters of fiscal year 2024, only 31% of SE requests have resulted in an SE-Rx order, but it is too early to call this reduction in outcomes a "trend").

Second, timing is often an important consideration to those practitioners and owners considering SE as an alternative to Reissue (RE) or Ex Parte Reexamination (RX). SE is very fast – on average less than 2 months – when no SNQ is raised. This speed can be very attractive to certain owners with items of information that need to be considered, but are believed unlikely to raise an SNQ against patent claims. Moreover, as Chart 3 illustrates, SE-Rx proceedings proceed slightly faster through CRU prosecution than regular RX proceedings. We believe this may be due to a number of factors including 1) patent owner's willingness to cancel or amend claims in an SE-Rx (necessarily owner filed) contrasted with patent owner's fighting for patentability based on claim construction arguments usually found in third-party requested RXs, and 2) the relatively low number of SE-Rx appeals compared to the number of RX appeals, probably also based on amending versus arguing, given that a PTAB appeals adds, on average, 8-12 months to proceeding time.

Chart 3: Speed of Proceedings



2. Noncompliant SE requests remain a problem

With any new proceeding, a certain number of mistakes on initial filings are to be expected as practitioners seek boundaries and learn new rules. Yet even 10 years in for the review proceedings filed over the last five years a significant number of SE requests continue to be rejected by the CRU as noncompliant with one or more requirements of 37 C.F.R. §§ 1.605, 1.610 and/or 1.615.

A non-compliant request is not given a filing date and the owner is required, via a Notice of Noncompliant Supplemental Examination Request (NNSER) (37 C.F.R. § 1.610(d)), to correct the request within a specified time. The patent owner must submit a complete, corrected request because the Office expunges the entire originally-filed request once a corrected request is received. For this reason, a corrected request must contain all of the required information without reliance on any defective originally-filed request. If the patent owner does not cure the issues in the corrected filing, the SE is terminated and only the advance paid reexamination fee is refunded.

There appear to be two flavors of issues that result in non-compliance: insufficient application of each item of information to the patent claims and procedural errors, e.g., improper counting of items, excessive number of items, and improper fee calculations.

Supplemental Examination: Five Takeaways from the Last Five Years

continued

a) Insufficient application of each item of information to the patent claims

MPEP § 2802(a) notes that the "patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent." A patent owner must provide this information in their list of items of items of information submitted to the Office. MPEP § 2809(a) states that "[e]ach request for supplemental examination may include no more than twelve items of information believed to be relevant to the patent" (emphasis added). A patent owner must, among other requirements, identify the one or more claims to which each item is relevant to and have a "**separate, detailed explanation of the relevance and manner of applying**" each item to the one or more claims. (emphasis added). *See* MPEP § 2811(b)(5).

In our analysis of supplemental examination requests since 2019, 33 out of approximately 150 supplemental examination requests, or 22% of all initial filings, were not compliant with Office regulations. Nearly every noncompliant request failed to provide a "separate, detailed explanation of relevance and manner of applying" the item of information to at least one claim of the patent. The Office regularly noted that such noncompliant requests simply provided a general statement of relevance and had no direct citations to the relevant portions of the item. Another common scenario involved the submission of prior art and an expert declaration espousing opinion about the operation of the prior art. While the request may or may not have applied the prior art to the claims of the patent, commonly the declaration was applied to the prior art and not applied to the claims at issue in the request. Such expert declarations, and their incorporated background materials, are generally inappropriate for inclusion as an item of information in an SE request and should be reserved for submission and consideration of their probative weight after an SE-Rx has been granted and prior art actually applied to reject the claims.

b) Procedural issues: Improper counting of items, excessive number of items, and improper fee calculations

Some patent owners inadvertently cited to more than 12 items of information in their original and supplemental examination requests. While the requests themselves listed 12 or fewer items of information, many of the items and their corresponding descriptions contained references to additional materials outside of the listed items. In these instances, the Office classifies such items and any references to outside materials as separate items. For example, a declaration from a company sales executive attesting to facts surrounding a potential offer of sale of the claimed article may be entirely appropriate for submission as an item of information. However, if that declaration refers to multiple exhibits such as email communications and references sales contracts or receipts, each of those referenced exhibit materials must be separately submitted and each will separately count as one of the 12 total items of information. Similarly, the patent owner may not avoid the 12 item limit by not submitting something that is fully described within the body of the request.

Additionally, a handful of requests were noncompliant based on adding items of information which were illegible, too cumulative, and required translations.

Some requests failed to properly include appropriate fees or improperly calculate document size fees as set forth in 37 C.F.R. § 1.20(k)(3). Each item of information may be subject to document size fees, and blank pages are counted.

A summary of all these issues is found in Charts 4 and 5. Chart 4 illustrates our analysis of noncompliant requests over the past 5 years and Chart 5 illustrates the total number of noncompliant requests and the reasons for noncompliance.

Supplemental Examination: Five Takeaways from the Last Five Years

continued

Chart 4: Noncompliant SE Request Instances

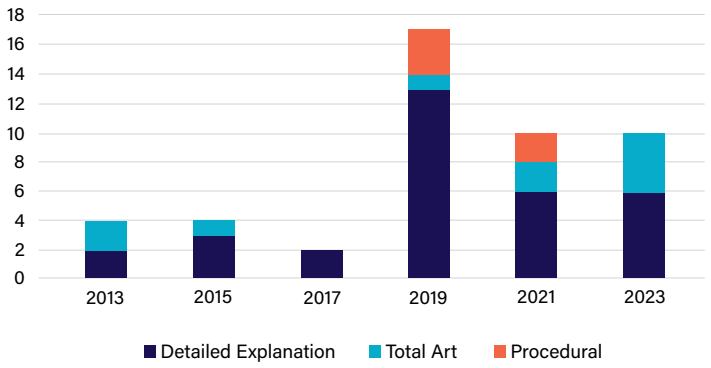
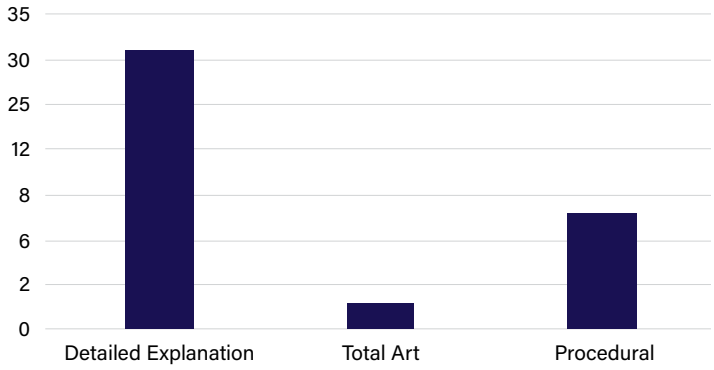


Chart 5: Total Noncompliant Requests 2019-2023



As Chart 5 indicates, there has been a noticeable increase in noncompliant requests since 2019, with the Office becoming more focused on highlighting insufficient detailed explanations. The Office has emphasized that it does not want to be inundated with too many items of information in a single supplemental examination request. Nor does the Office want to guess on how the item is specifically related to the one or more claims of a patent.

Patent owners who avoid these common pitfalls can put themselves in the best position to receive a filing date for their supplemental examination request and avoiding excess legal fees in an already expensive post-issue legal procedure.

3. A wide variety of "items of information" are raising SNQs

a) Patents and printed publications

Patents and printed patent publications are perhaps the most common form in which items of information are presented. Our analysis analyzed how many times such references raised an SNQ and where the items originated from. Of course, many patent owners referred to U.S. patents and publications in their list of items of information. Additionally, patent owners also included patents and publications from outside the United States. Such patents often originated from European governing bodies and procedures, such as the EPO and Germany, potentially from prosecution, opposition, litigation, and now Unified Patent Court (UPC) proceedings. Asia also played an important role in the supplemental examination landscape, as many items were patents originating from Korea, Japan, and China and their respective proceedings.

Our analysis shows that there were 63 instances of one or more U.S. patents and patent publications cited in an owner's list of items of information. Out of these instances, U.S. patents and printed patent publications raised an SNQ 46 times. Further, one or more non-U.S. patents and publications were cited in 49 supplemental examination requests. We noted 29 SNQs followed these requests.

b) Non-Patent Literature (NPL) and "other information"

Non-patent literature (NPL) encompasses a wide variety of materials. It can range from PTAB decisions, research articles, technical standards, declarations, and "other information." There has been an increased focus on "other information" including declarations, internal corporate documents, adjudicative decisions, on sale bar information, etc. The Office has grouped this kind of information into the NPL landscape, despite taking an untraditional form. Nonetheless, both forms of NPL can present a significant obstacle towards patentability and, in turn, has serious implications as to whether a supplemental examination request raises an SNQ.

Supplemental Examination: Five Takeaways from the Last Five Years

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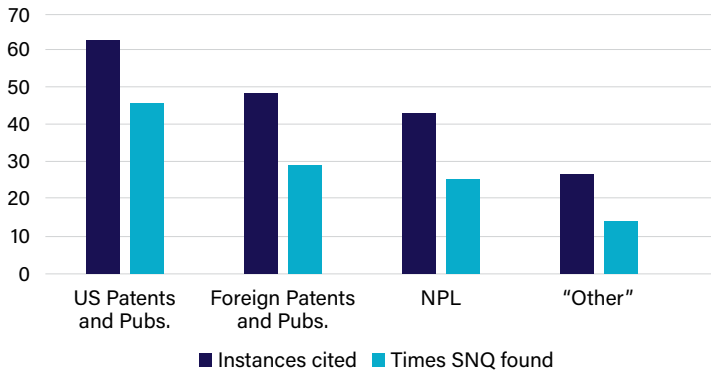
Our analysis shows that one or more NPL documents, in the traditional sense, were cited 43 times in a patent owner's list of items of information. Out of these instances, traditional NPL was involved in generating a SNQ 25 times. Further, "other" forms of NPL were cited one or more times in 27 supplemental examination requests. 14 SNQs were associated with such requests.

Chart 6 below compares the number of instances in which one or more forms of prior art were presented in supplemental examination requests with the number of times SNQs resulted from the request. While our analytical process focused on the raw numbers of the types of art cited, each type of art appeared to be cited a consistent amount over the past 5 years.

Chart 6: Citation Instances vs. SNQs Found



4. Once an SNQ is found, the CRU and PTAB examine SE-Rx with a broader scope of examination as compared to traditional Rx

Reexamination proceedings have existed for more than 40 years. Requests for Reexamination and subsequent RX proceedings under 35 U.S.C. §§ 301-305 are limited to prior art consisting of patents or printed publications. This limitation therefore limits questions of patentability to those raised under 35 U.S.C. §§ 102 and 103. As prescribed in 37 C.F.R. § 1.552(a), "claims in an ex parte reexamination proceeding will be examined on the basis of patents or printed publications and, with respect to subject matter added or deleted in the reexamination proceeding, on the basis of the requirements of 35 U.S.C. 112."

In contrast, SE-Rx proceedings ordered under 35 U.S.C. § 257 as a result of a SE request are not so limited. SE's "other information" is much broader than "patent and printed publications." If the SE-Rx is ordered, and rejections under all statutory requirements of patentability are available to CRU examiners. Another distinction is that for SE-Rx, a new prior art search is performed by CRU examiners whereas in RX, a new prior art search is generally not performed. Thus, the subsequent SE-Rx proceeding's broader scope and implications must be considered when deciding to file an SE request as compared to a reissue or patent owner ex parte reexamination.

In our look at SE-Rx proceedings over the last five years, we noted the statutory basis of rejections entered by the CRU and took a look at appeals of SE-Rx rejections to assist patent owners considering filing SE requests.

a. Statutory basis for rejections entered by CRU

Our review indicates that the CRU examiners are extremely thorough in their examination during SE-Rx proceedings. All proceedings contained new prior art searches performed by the CRU examiner. We observed many instances of the CRU examiner supplementing the "other information" with additional prior art discovered during these new searches. We also observed at least two instances of the CRU examiner not utilizing any "other information" that was found to raise an SNQ in the SE determination, and instead relied wholly on new prior art discovered by their search.

From an in-depth analysis of over 100 SE-Rx proceedings, we found the following distribution of rejections illustrated in Chart 7.

Supplemental Examination: Five Takeaways from the Last Five Years

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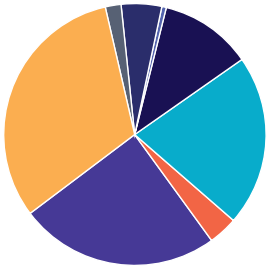
Chart 7: Distribution of Statuatory Rejections



103 102 112(d) 112(b) 112(a) 305 101-DP 101-elig.

While a few SE-Rx proceedings contained only one statutory type of rejection, most contained two types and some contained as many as six different statutory types of rejections. Unsurprisingly, 35 U.S.C § 103 rejections were the most common, followed closely by 35 U.S.C § 102 rejections and 35 U.S.C § 112(b) rejections. We noted a surprising number of 35 U.S.C. § 112(a) (written description/enablement) rejections were applied, particularly upon claim amendment. For example, in attempting to narrow the claims in response to other rejections, applicant's often utilized language that was deemed outside the boundaries or scope of possession demonstrated by the original disclosure. Here, we noted that patent owners should pay careful attention to the terms and phrases utilized in the disclosure and amend claims precisely to avoid these rejections.

We were surprised to see 35 U.S.C. § 112(d) rejections applied on multiple occasions, indicating that the CRU Examiners pay close attention to the format and language of dependent claims. Also surprising were newly applied double patenting rejections, indicating the CRU Examiner's thorough review of related files of the underlying patent's extended patent family. And we noted that in at least nine proceedings, 35 U.S.C. § 112(f) (means plus function) analysis was applied during claim interpretation.

b. A quick look at SE-Rx PTAB and CAFC Appeals

As part of our analysis, we looked at all SE-Rx PTAB and Court of Appeals for the Federal Circuit (CAFC) appeals filed and decided since the inception of the proceeding.

The numbers show that the PTAB judges find little fault in the CRU's work product and determinations. For 24 appeals, 16 were fully affirmed or affirmed-in-part. Only five appeals resulted in the Examiner's rejection(s) being fully reversed. In three additional reversals, the PTAB entered new grounds of rejection at their own initiative.

There are few CAFC appeals, so they may not show much new information. In one appeal, the CAFC vacated the prior PTAB affirmance of an obviousness rejection comprising more than five references and remanded the SE-Rx proceeding to the PTAB for reconsideration. Upon reconsideration, the PTAB reversed the prior § 103 rejections and entered new § 103 rejections based upon applicant's admissions from the oral hearing, and new § 112(b) rejections, before returning the file to the CRU for further prosecution. Ultimately, in that file, the Reexamination Certificate shows numerous cancelled claims, narrowing amended claims, and new narrow claim were found patentable.

We summarize some of our finding in Charts 8, 9, and 10.

Chart 8 illustrates common types of rejections being appealed from SE-Rx rejections included § 112(a) (both enablement and written description bases), § 112(b); § 102, and § 103. We also saw § 101 rejections, § 305 rejections (improper broadening), § 112(d) (improper dependent claim) rejections affirmed by the PTAB. In several instances, a decision on one or more appealed rejections was not reached as the PTAB fully affirmed the rejections of all claims based upon § 112(a) or § 112(b).

Charts 9 and 10 illustrate what technologies are being appealed and the success of these appeals. Applicants have been most dissatisfied with the examinations in CRU Art Unit 3992, which handles all electrical technologies. With 18 appeals decided, the PTAB has affirmed one or more AU 3992 Examiner rejections in 15 proceedings, or 83% of the time. The mechanical technology art unit 3993 has been affirmed in three of four appeals (75%). Only two applicants have appealed AU 3991 Examiner's rejections. In both cases, the rejections were fully affirmed (100% affirmance rate).

Supplemental Examination: Five Takeaways from the Last Five Years

continued

Chart 8: Appealed Rejection Types and Affirmances

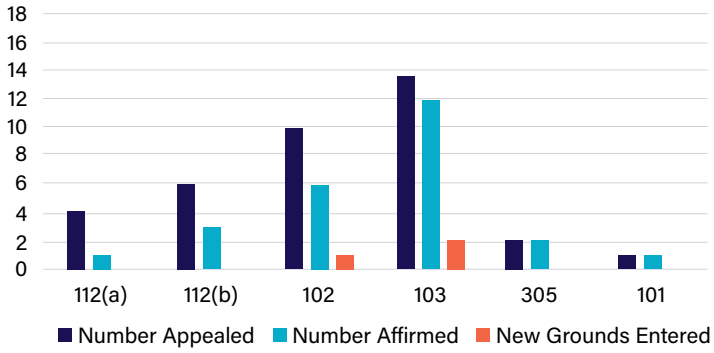


Chart 9: Total Number of SE-Rx Appeals by CRU Art Unit

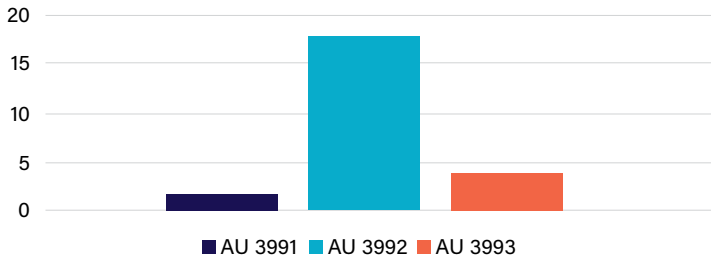
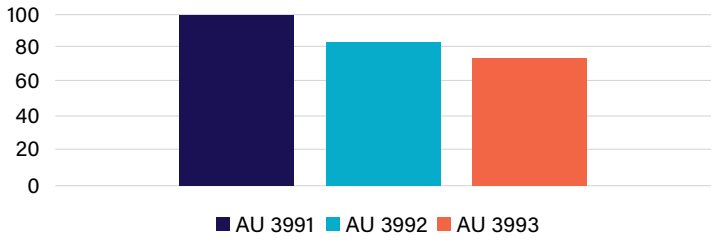


Chart 10: PTAB Affirmance Rate by CRU Art Unit



5. Strategic consideration for choosing between SE, RE, and RX

Patent owners have three distinct procedures available for corrective action post-patent grant: reissue, reexamination, and supplemental examination. Each procedure has distinct requirements, timelines, advantages, and risks. Each can be used to have additional prior art or "other information" considered by the Office. Careful consideration must be given to each by assessing the risks and advantages of each procedure.

A reissue application is the only post-grant proceeding that potentially allows claim broadening when applied for within two years of patent grant. Reissue applications can be controlled by a patent owner – that is they may be abandoned and they may support the filing of a continuation or a continued examination reissues. Additional prior art or "other information" may be filed on an information disclosure statement during reissue prosecution. However, for a reissue to be proper, the patent owner must correct an "error" in the original patent and admit that the error is one that renders the patent "wholly or partly inoperative or invalid." This may be a difficult statement for some patent owners. Reissues may not recapture subject matter surrendered during the original prosecution, including during prosecution of related applications (the patent family). Reissue may be lengthy, and the patent claims are subject to a wholly new prosecution, including a new prior art search. Reissues cannot cure inequitable conduct.

A patent owner may request a reexamination of their patent, if there is a "patent or printed publication" that raises an SNQ against at least one claim of the patent. In the request, the patent owner must detail how the patent or printed publication raises an SNQ of patentability against at least one of the patent's claims, and usually provide narrowing amendments to overcome the SNQs. And while an SNQ of patentability is a lower threshold than a rejection's preponderance of evidence standard, some patent owners may have discomfort admitting to patentability questions and proving proposed rejections of their claims. RX proceedings, when granted, are generally limited to the issues of the reexamination request and not subjected to additional prior art search. Potential rejections are limited to those based solely in prior art, unless the claims are amended. And like Reissues, additional prior art or "other information" may be filed on an IDS during the RX proceeding. However, once an RX proceeding is ordered, the RX proceeding must conclude with the issuance of a reexamination certificate. That is, a patent owner cannot stop the RX proceeding from

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going forward without giving up all the claims present in the proceedings. And like reissues, RX proceedings may be lengthy. Claims can only be narrowed during RX proceedings, and the patent owner has no right of continuation.

SE requests provide patent owners with a path for having "other information" reviewed by the Office without admission of an underlying error in the patent or assertion that the information raises an SNQ of patentability. And SEs are the only proceeding that can cleanse the patent from inequitable conduct. Because "other information" is broad, the patent owner is not restricted as to the type of information that may be cited to the Office in an SE request. This alone offers advantages over RX proceedings as it allows consideration of information that is not restricted to prior art. Another clear advantage of an SE request is speed. The Office must render a decision on an SE request within three months. When the goal is simply to have the information considered by the Office, and when the patent owner is reasonably confident that the information does not raise an SNQ of patentability or rise to the level of supporting a rejection against the claims, SE is highly advantageous. Even when SE-Rx is ordered, these proceedings move through the CRU at a slightly faster rate than RX proceedings. The patent owner must balance these advantages against the risk of an SE-Rx being ordered by the Office, because an SE-Rx has a broader scope of rejections that can be applied compared to regular RX. For the right fact pattern, SE clearly has advantages that must be acknowledged.

About Sterne, Kessler, Goldstein & Fox

Based in Washington, D.C., Sterne Kessler is one of the world's leading intellectual property law firms, specializing in the full range of IP services globally for more than four decades. We are passionate about IP law, with a unique combination of legal acumen and technical expertise in both prosecution and litigation. This enables us to offer unparalleled insights and forward thinking strategies to protect and enforce our clients' valuable IP assets.

Our team of experienced litigators have the trial skills and technical depth to deliver results across any venue, from district court to the Federal Circuit and International Trade Commission. Sterne Kessler is also recognized as a leading firm for patent prosecution and strategic counseling, trademarks, and post-grant proceedings at the Patent Trial and Appeal Board. With over 400 dedicated professionals, the firm is committed to delivering exceptional service to clients. The world's most innovative companies, including Fortune 500 companies, entrepreneurs, start-ups, inventors, venture capital firms, and universities trust Sterne Kessler with their most complex IP matters. For more information about the firm and our services, visit sternekessler.com or follow us on LinkedIn to stay up-to-date on our latest news and updates.

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