

#### Webinar--Appeals to the Federal Circuit: Mid-Year Review June 7, 2022, 12 pm - 1 pm EST

Presented by the Appeals from the PTAB Committee and the Young Lawyers and Agents Committee, PTAB Bar Association

## Introduction to our Panelists

- Melissa Brand, Intellectual Property Counsel at Radius Health, Inc.
- Pauline Pelletier, Director in Sterne Kessler's Trial & Appellate Practice

Group.

- Jim Glass, Chair of Quinn Emanuel's Post-Grant patent practice.
- Rachel Elsby, Partner in Akin Gump's IP Litigation group.

# Auris Health, Inc. v. Intuitive Surgical Operations, Inc., No. 21-1732 (Fed. Cir. April 29, 2022):

- "Because the Board impermissibly rested its motivation-to-combine finding on evidence of general skepticism about the field of invention, we vacate and remand." Id. at 2.
- "It follows that generic industry skepticism cannot, standing alone, preclude a finding of motivation to combine." *Id*. at 5.
- "To be sure, evidence of industry skepticism may play a role in an obviousness inquiry—but as a secondary consideration in a significantly different context." *Id*. at 5.
- "...the evidence of skepticism must be specific to the invention, not generic to the field." *Id*. at 6.
- Dissent, J. Reyna: "I am also concerned that the majority opinion may reasonably be understood to announce an inflexible and rigid rule, namely that it is "impermissible" for the Board to consider evidence of artisans' skepticism toward robotic surgery in determining motivation to combine. I find no authority for this assertion, and indeed it appears in tension, at a minimum, with the central thrust of KSR." *Id*. at 3.

# Almirall, LLC v. Amneal Pharmaceuticals, LLC, No. 20-2331 (Fed. Cir. Mar. 14, 2022):

1. A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:

about 7.5% w/w dapsone;

about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;

about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the topical pharmaceutical composition does not comprise adapalene.

| Reference      | Thickening<br>Agent | Range                                      |
|----------------|---------------------|--|
| Garrett        | Carbopol            | 0.2%-4% (preferred<br>.5%-2% for Carbopol) |
| Nadau-Fourcade | Sepineo             | .01%-5%                                    |
| Bonacucina     | Sepineo             | .5%-5%                                     |

# Almirall, LLC v. Amneal Pharmaceuticals, LLC, No. 20-2331 (Fed. Cir. Mar. 14, 2022):

- "[I]n the absence of evidence indicating that there is something special or critical about the claimed range, an overlap suffices to show that the claimed range was disclosed in—and therefore obvious in light of—the prior art." *Id.* at 10.
- "We agree with Amneal that the Board did not err in applying a presumption of obviousness of overlapping ranges." *Id*. at 11.
- "[I]t was reasonable for the Board to find that, in the context of Garrett, a skilled artisan would recognize that the reference discloses a complete formulation— excluding the possibility of an additional active ingredient." *Id.* at 12.
- "The Board did not rely on a conclusory rationale of 'design choice' as sufficient to find that a skilled artisan would have combined the references; on the contrary, it reviewed the context-specific evidence for the soundness of Amneal's rationale." *Id.* at 13.
- "A finding of a reasonable expectation of success does not require absolute predictability of success." *Id.* at 15.

*Quanergy Systems, Inc. v. Velodyne Lidar USA, Inc.,* Case Nos. 20-2070; -2072 (Fed. Cir. Feb. 4, 2022):

- "To accord substantial weight to [evidence of objective indicia of nonobviousness], it must have a nexus to the claims, i.e., there must be 'a legally and factually sufficient connection' between the evidence and the patented invention." *Id.* at 17 (citation omitted).
- "We presume a nexus when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them." *Id.* at 17 (citation omitted).

*Quanergy Systems, Inc. v. Velodyne Lidar USA, Inc.,* Case Nos. 20-2070; -2072 (Fed. Cir. Feb. 4, 2022):

- "A patent challenger may not rebut the presumption of nexus with argument alone." *Id*. at 18.
- "There is no dispute that the Board must consider unclaimed features as part of its presumption analysis when they are raised. Here, Quanergy, at best, presented only a skeletal, undeveloped argument to the Board. *Id*. at 19-20.
- "Second, we disagree with Quanergy's assertion that the Board failed to provide an adequate factual basis or reasoned explanation when it dismissed the unclaimed features Quanergy identified to rebut a presumption of nexus. The Board's analysis of those unclaimed features is commensurate with Quanergy's presentation of the issue." *Id.* at 20.

#### PTAB Proceedings – Original Claims:

- Petitioner argued claims unpatentable based on anticipation and obviousness theories (Schacherer).
- PO argued that Schacherer did not disclose the "wireless" features of the original claims; and filed conditional motion to amend (MTA) specifically directed to those limitations.
- Board agreed with Petitioner that original claims were unpatentable for *anticipation* by Schacherer. (FWD at 25).

#### PTAB Proceedings – MTA:

- Petitioner opposed the MTA and argued that the amended claims were *obvious* stated at a hearing that focusing on obviousness and not anticipation was an intentional "tactical decision, to focus our arguments in the limited space we had." (POP at 17).
- Board denied the MTA, finding that Petitioner "ha[d] carried its burden in showing that [PO's] proposed amendments d[id] not overcome the *anticipatory* nature of Schacherer's disclosure." (FWD at 29).
- **Anticipation** was not raised by Petitioner in connection with the amended claims only with the original non-amended claims.

#### **POP Proceedings:**

- PO sought rehearing and POP review (*Boalick,* Hirshfeld, Iancu).
- Issue: "We authorized supplemental briefing from the parties to address the impact of *Nike* on this proceeding." (POP at 4).
  - *Nike v. Adidas,* 955 F.3d 45, 51 (Fed. Cir. 2020): "[T]he Board may sua sponte identify a patentability issue for a proposed substitute claim based on the prior art of record."
- "We conclude that the Board *may*, in certain *rare circumstances*, raise a ground of unpatentability that a petitioner did not advance, or insufficiently developed, against substitute claims proposed in a motion to amend. We hold, however, that such circumstances are not present in this case and the Board should not have raised its own ground of unpatentability." (POP at 4).
- Emphasis on the adversarial nature of IPR proceedings.

#### **POP Proceedings – "rare circumstances":**

- Challenger ceases to participate in an IPR proceeding,
- Challenger choses not to oppose the motion to amend, and:
- "[A] situation could arise where the record *readily and persuasively establishes that substitute claims are unpatentable for the same reasons that corresponding original claims are unpatentable*." (POP at 12-13).
- But later on in the decision:
  - "Accordingly, the anticipation ground based on Schacherer, which was raised only in the Petition with respect to the original claims, was not advanced, much less sufficiently developed, by Petitioner against the proposed substitute claims." (POP at 17).
  - "We conclude that, as a policy matter, the Board should not have raised the Schacherer anticipation ground. We do not find the circumstances of this case to qualify as one of the rare circumstances necessitating the Board to advance a ground of unpatentability that Petitioner did not advance or sufficiently develop." (POP at 19).

Federal Circuit (Prost, Reyna, Hughes) (Hughes, J.):

- "[W]e do find problematic the Panel's reasoning behind its decision to confine the Board's discretion to sua sponte raise patentability issues to only rare circumstances."
- "Yet, on appeal, Hunting Titan *did not challenge* the Panel's decision as an abuse of discretion. That is, Hunting Titan failed to argue that the Panel misapplied the readily identifiable evidence exception. Because Hunting Titan raised no such argument, it is forfeited."
- Footnote: "It does strike us as odd, however, that the [POP] determined that the Schacherer anticipation ground was not readily identifiable and persuasive such that the Board should have sua sponte raised this ground of unpatentability against [the substitute claims]."

#### Federal Circuit:

- "We are not determining the patentability of the proposed substitute claims."
- "[N]or are we deciding whether the [POP] abused its discretion in determining that the Schacherer anticipation ground was not readily identifiable and persuasive such that the Board should have sua sponte raised this ground of unpatentability."
- "Likewise, we are not opining on the other limitations that the [POP] placed on the Board."
- "Finally, we do not decide whether the Board has an independent obligation to determine patentability of proposed substitute claims. These questions need not be answered to resolve the appeal before us."
- Concurrence (Prost, J.): "I write separately to explain why, had that challenge [to the Board's ruling under the abuse of discretion standard] been preserved, it likely would have succeeded and why I'm troubled by how the PTO is handling this issue."

# Fleming v. Cirrus Design Corp., No. 21-1561 (Fed. Cir. Mar. 10, 2022) (Lourie, Hughes, Stoll) (Stoll, J.):

- Board found original claims obvious and proposed amended claims *unpatentable* for lack of written description.
- Fed. Cir. affirmed: "We need not consider Mr. Fleming's proposed construction, however, because substantial evidence supports the Board's finding of lack of written description under either Mr. Fleming's or the Board's construction." Slip Op. at 18.

# *ClearOne, Inc. v. Shure Acquisition Holdings, Inc.,* No. 21-1517 (Fed. Cir. June 1, 2022) (Moore, Newman, Hughes) (Moore, CJ.):

- Board found proposed amended claims *patentable* and not indefinite.
- Fed. Cir. affirmed: "The phrases 'self-similar or fractal-like' and 'self-similar or repeating' are not juxtapositions; they equate self-similar to fractal-like or repeating patterns. And even if self-similar is broader than these examples, that does not make the term indefinite." Slip Op. at 7.
- "Just because a term is susceptible to more than one meaning does not render it indefinite." *Id.* at 8.

# *Qualcomm Inc. v. Apple Inc.,* No. 20-1561 (Fed. Cir. Feb. 1, 2022):

- "The parties' main argument on appeal focuses on whether AAPA constitutes "prior art consisting of patents or printed publications" under § 311(b) such that it may form "the basis" of a ground in inter partes review. We hold that it does not." *Id*. at 10.
- "In other words, § 311(b) does not permit AAPA in this case to be the basis of a ground in an inter partes review, because it is not contained in a document that is a prior art patent or prior art printed publication." Id. at 13.
- "...it does not follow that AAPA is categorically excluded from an inter partes review...We have held that 'it is appropriate to rely on admissions in a patent's specification when assessing whether that patent's claims would have been obvious' in an inter partes review proceeding." *Id*. at 13.
- "...AAPA may not form the 'basis' of a ground in an inter partes review, and it is therefore impermissible for a petition to challenge a patent relying on solely AAPA without also relying on a prior art patent or printed publication." *Id*. at 16.

# Intuitive Surgical, Inc. v. Ethicon LLC, No. 20-1480 (Fed. Cir. Feb. 11, 2022):

- "The plain language of § 315(e)(1) is clear that estoppel is triggered when an IPR proceeding results in a final written decision, compelling the conclusion that Intuitive was estopped as to the Prisco/Cooper IPR once the Giordano/Wallace and Timm/Anderson IPRs concluded with final written decisions. We cannot ignore this statutory language simply because the petitions were filed on the same day and were instituted within days of each other." *Id.* at 8.
- "It follows, therefore, that Intuitive actually knew of the Prisco prior art at the time it filed the other two petitions and knew which claims it wanted to challenge based on that art. Certainly, Intuitive reasonably could have raised its grounds from the Prisco/Cooper IPR in either the Giordano/Wallace or Timm/Anderson IPRs...We reject the proposition that the three petitions could not have been more concisely written to fit in only two petitions." *Id.* at 8-9.
- "Thus, only parties to an IPR fall within the zone of interests protected by the law invoked—i.e., the right to appeal a final written decision of the Board." Id. at 12.

Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc., No. 21-1759 (Fed. Cir. May 13, 2022):

- "We conclude that we lack jurisdiction to review the Board's decision to vacate its institution decision, a decision it made based in part on its evaluation of the time bar and changed Patent and Trademark Office policy." Id. at 2.
- "The Board's 'termination' decision was multifaceted...the Board's substantive discussion of time-bar considerations was central to its decision...Thus, we cannot conclude that the Board's decision was purely a sanctions decision over which we ordinarily would have jurisdiction." Id. at 7.
- "The fact that the Board's termination decision occurred on remand from our court does not change our conclusion that we lack jurisdiction. The Board retains the inherent authority to reconsider its decisions." *Id*. at 8-9.

# Atlanta Gas Light Co. v. Bennett Regulator Guards, Inc., No. 21-1759 (Fed. Cir. May 13, 2022):

- <u>Dissent, Newman</u>: "The PTAB's sanctions order is not excluded from the appellate jurisdiction of the Federal Circuit, as the panel majority holds. Our appellate jurisdiction of PTAB decisions is set by statute; **no exception excludes the appeal of a sanctions order.**" *Id*. at 1.
- "The Sanctions Order is the only issue on appeal." Id. at 2.
- "Here the agency imposed the sanction of cancellation of extensive administrative proceedings and their final decisions of patent invalidity, which final decisions had been appeald to the Federal Circuit and affirmed with issueance of a mandate on patent invalidity." *Id*. at 3.
- "No statute, no precedent, removes sanctions issues from appealability." *Id*. at 7.

# *California Inst. of Tech. v. Broadcom Ltd.,* 25 F.4th 976, 979 (Fed. Cir. 2022) (Lourie, Linn, Dyk) (Linn, J.)

- "In the district court proceedings, [Apple and Broadcom] challenged ... invalidity, relying on grounds the PTAB did not address in its earlier instituted IPR decisions. The district court nonetheless held that these challenges were barred by estoppel because Apple and Broadcom were aware of the prior art references at the time they filed their IPR petitions and reasonably could have raised them in those petitions even if they could not have been raised in the proceedings post-institution."
- "After Shaw, in SAS Institute, Inc. v. Iancu, ... the Supreme Court made clear both that there is no partial institution authority conferred on the Board by the America Invents Act and that it is the petition, not the institution decision, that defines the scope of the IPR. See id. at 1357–58 ("[T]he statute tells us that the petitioner's contentions, not the Director's discretion, define the scope of the litigation ... There is no room in this scheme for a wholly unmentioned 'partial institution' power that lets the Director select only some challenged claims for decision.").
- "Given the statutory interpretation in SAS, any ground that could have been raised in a petition is a ground that could have been reasonably raised 'during inter partes review.' Thus, the Supreme Court's later decision in SAS makes clear that Shaw, while perhaps correct at the time in light of our pre-SAS interpretation of the statute cannot be sustained under the Supreme Court's interpretation of related statutory provisions in SAS."

# *California Inst. of Tech. v. Broadcom Ltd.,* 25 F.4th 976, 979 (Fed. Cir. 2022) (Lourie, Linn, Dyk) (Linn, J.)

"Accordingly, we take this opportunity to overrule *Shaw* and clarify that estoppel applies not just to claims and grounds asserted in the petition and instituted for consideration by the Board, but to all claims and grounds not <u>stated</u> in the <del>IPR</del> petition but which reasonably could have been <del>included in the petition</del> asserted. In a regime in which the Board must institute on all <del>grounds asserted</del> challenged claims and the petition defines the IPR litigation, this interpretation is the only plausible reading of 'reasonably could have been raised' and 'in the IPR' that gives any meaning to those words."

ERRATA to Precedential Opinion, ECF No. 67 (Feb. 22, 2022)

# Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., 25 F.4th 998 (Fed. Cir. 2022) (Newman, Lourie, Stoll) (Lourie)

- In its breach of contract claim, Nippon alleged that Sarepta breached the MCA by filing the seven IPR
  petitions, arguing that it "directly contravenes the MCA's forum selection clause, which requires that Sarepta
  and Nippon Shinyaku bring any such patent challenges in the United States District Court for the District of
  Delaware." Nippon filed a motion for a preliminary injunction asking the court to enjoin Sarepta from
  proceeding with its IPR petitions and to require that Sarepta withdraw the petitions.
- "[T]his appeal presents 'a question of contract interpretation under Delaware law, which we review de novo.' In this case, the plain language of the forum selection clause in Section 10 of the MCA resolves the dispute. Section 10 states clearly that 'all Potential Actions arising under U.S. law relating to patent infringement or invalidity, and filed within two (2) years of the end of the Covenant Term, shall be filed in the United States District Court for the District of Delaware.' J.A. 513–14. The express definition of 'Potential Actions' includes 'patent or other intellectual property disputes ... filed with a court or administrative agency,' J.A. 509 (emphasis added), and the district court acknowledged that the 'definition of "Potential Actions" in Section 1 literally encompasses IPRs.' Decision, 2021 WL 4989489, at \*3. Sarepta does not contend otherwise. The MCA's forum selection clause is thus unambiguous, and we must 'give effect to the plain meaning of [its] terms.' *Estate of Osborn*, 991 A.2d at 1159–60."
- "Under the plain language of Section 10, Sarepta was required to bring all disputes regarding the invalidity of Nippon Shinyaku's patents—including the allegations and contentions contained in Sarepta's IPR petitions—in the District of Delaware. Sarepta instead brought those disputes in the form of IPR petitions at the Board, which contravened the plain language of the forum selection clause in Section 10 of the MCA."

# Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., 25 F.4th 998 (Fed. Cir. 2022) (Newman, Lourie, Stoll) (Lourie)

"As a general principle, this court has recognized that parties are entitled to bargain away their rights to file IPR petitions, including through the use of forum selection clauses. For example, in *Dodocase VR, Inc. v. MerchSource, LLC,* 767 F. App'x 930, 935 (Fed. Cir. 2019) (non-precedential), we affirmed a district court's grant of a preliminary injunction on the basis that a defendant had likely violated a forum selection clause by filing IPR petitions, even though the forum selection clause did not explicitly mention IPRs. Even in *Kannuu Pty Ltd. v. Samsung Electronics Co.,* 15 F.4th 1101, 1106–10 (Fed. Cir. 2021), where we determined that the parties' forum selection clause did not extend to IPRs, that determination was based on the specific language in the forum selection clause at issue in that case. Inherent in our holding in Kannuu was an understanding that a differently worded forum selection clause, which uses a defined term that the district court acknowledged 'literally encompasses IPRs.'" (emphasis added)

• See lead case IPR2021-01134, Papers 28 and 29 (granting stipulated suspensions pending issuance of the Federal Circuit's mandate and a decision on remand); after the district court issued an order granting Nippon the injunctive relief it sought, on May 25, 2022, Sarepta filed a "Compelled Motion in Compliance with Court Order" (Paper 30) with the PTAB, requesting that its seven petitions be withdrawn (motion is still pending).

Alarm.com Inc. v. Hirshfeld, 26 F.4th 1348, 1350 (Fed. Cir. 2022) (Taranto, Chen, Cunningham) (Taranto, J.)

- "[W]e conclude, Alarm.com's APA challenge to the Director's vacatur decisions based on estoppel is not precluded. The text, statutory scheme, and legislative history pertaining to ex parte reexamination do not evince a fairly discernable intent to preclude judicial review of these decisions."
- "We have no reason to think that any such anomalies, if more than theoretical at all, are sufficiently substantial to meet the high standard of justifying a conclusion that, with no review-precluding text, Congress nevertheless clearly intended to preclude review in these circumstances."
- "In these circumstances, we conclude, the legislative history evidence, like the statutory scheme evidence, is too weak to supplant the text and the accompanying presumption of judicial review for the estoppel determination in question."



#### Webinar--Appeals to the Federal Circuit: Mid-Year Review June 7, 2022, 12 pm - 1 pm EST

Presented by the Appeals from the PTAB Committee and the Young Lawyers and Agents Committee, PTAB Bar Association Arthrex, Inc. v. Smith & Nephew, Inc., No. 2018-2140, 2022 WL 1696322 (Fed. Cir. May 27, 2022) (Moore, Reyna, Chen) (Moore, J.)

- "Although an inferior officer generally cannot issue a final agency decision, he may perform the functions and duties of an absent PAS officer on a temporary, acting basis...This further supports that an inferior officer may temporarily perform an absent PAS officer's duties without violating the Appointments Clause." Id. at 5-6.
- "We therefore conclude that the Commissioner's exercise of the Director's authority while that office was
  vacant did not violate the Appointments Clause...Because the FVRA applies only to non-delegable duties,
  and because deciding rehearing requests is a delegable duty, we hold that the FVRA does not apply here." Id.
  at 9.
- "adopting Arthrex's position would have significant consequences...potentially encompassing every Executive agency." *Id.* at 13.
- "That the Appointments Clause requires that a PAS have review authority does not mean that a principal officer, once bestowed with such authority, cannot delegate it to other agency officers." *Id.* at 16.
- "The government argues that there are no non-delegable duties of the Director. This decision is limited to a determination that the Director's authority to review re- hearing requests is a delegable duty. As that is the only power at issue in this case, we go no broader." *Id.* at 17, N. 5.
- "Arthrex does not persuade us that the Commissioner violated the Appointments Clause, the FVRA, or the Constitution's separation of powers in denying Arthrex's re-hearing request. Nor does it identify reversible error in the Board's decision that ElAttrache anticipated the challenged claims of the '907 patent. Accordingly, we affirm." *Id.* at 27.

# Thank you!