

Objective Evidence in IPRs: Demonstrating Sufficient Nexus

Linking Evidence and Merits of Claimed Invention, Leveraging Prosecution Declarations

THURSDAY, NOVEMBER 5, 2015

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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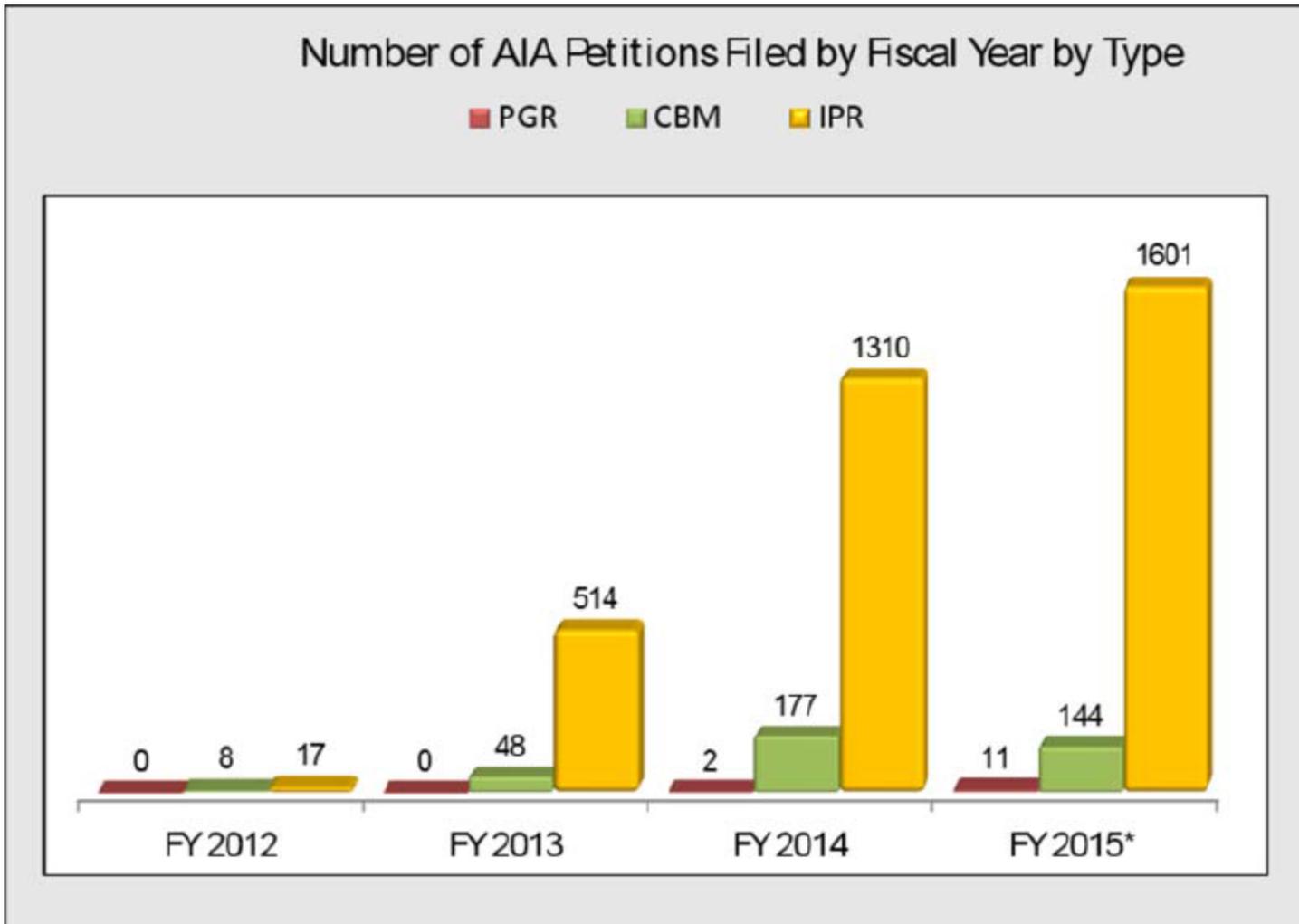
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IPR Filings Have Risen Quickly

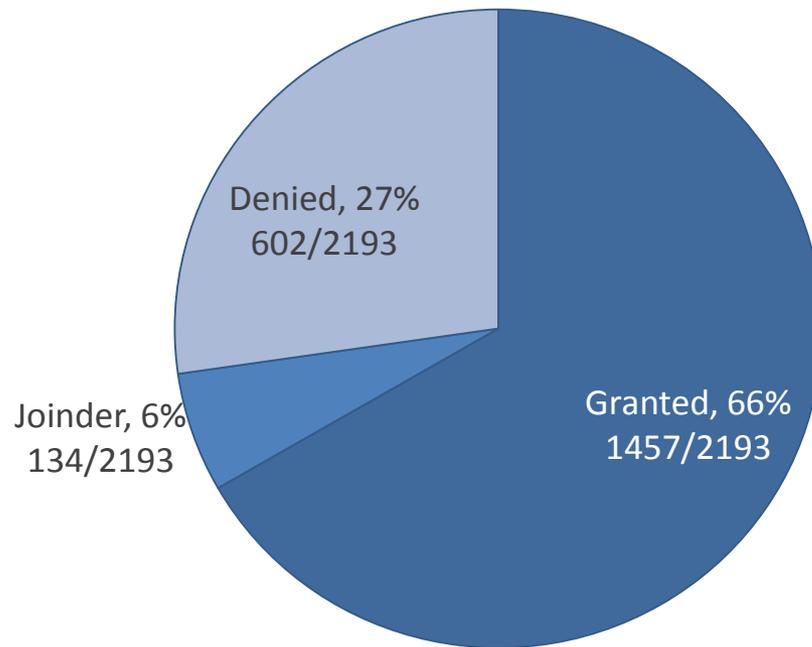


As of Aug. 31, 2015. Total IPR petitions filed since Sept. 16, 2012 is 3442.

Source: <http://www.uspto.gov/sites/default/files/documents/2015-08-31%20PTAB.pdf>

Petition Grant Rate is High!

Institution Decisions

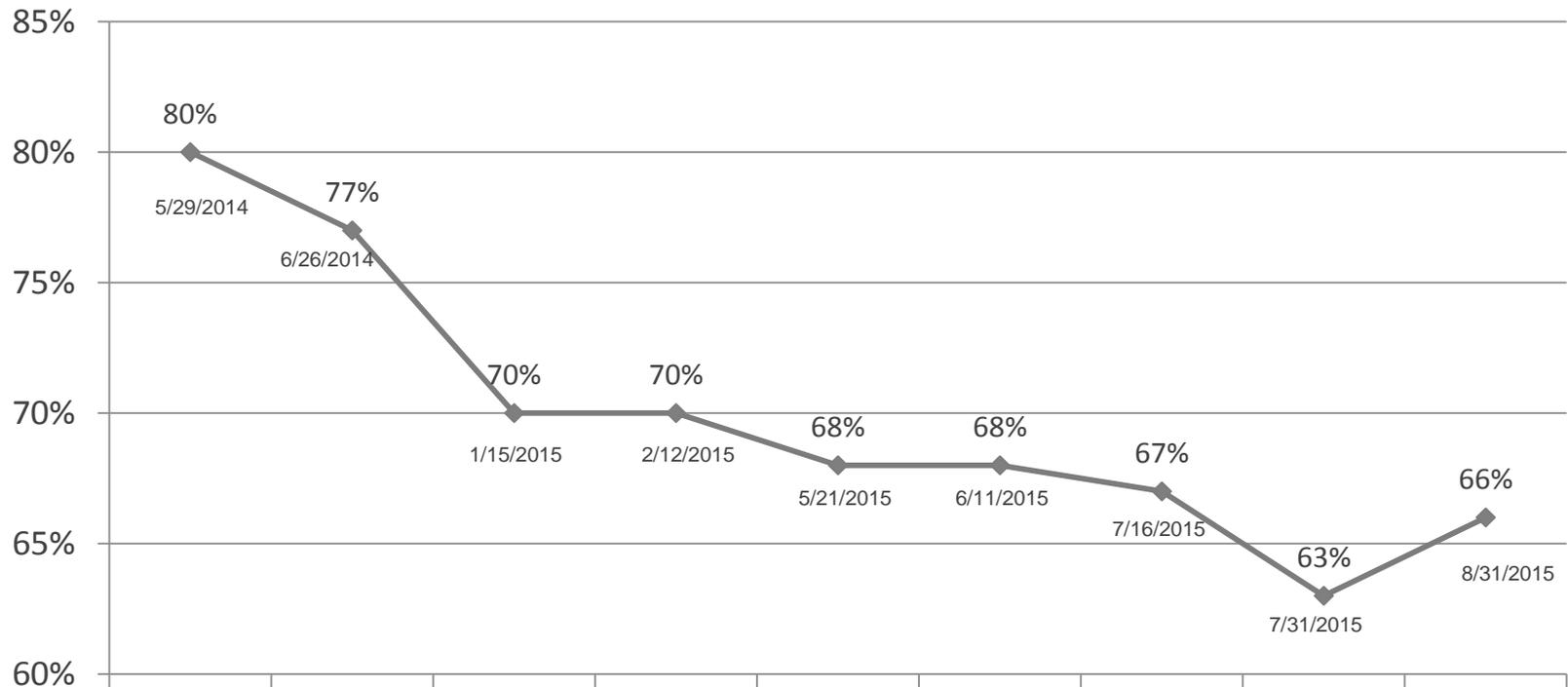


Granted +
joinder = 72%

PTAB IPR Institution Decisions, Sept. 16, 2012 – Aug. 31, 2015. Adding institutions to joinder grants means that 72% of petitions have resulted in an IPR. Source: <http://www.uspto.gov/sites/default/files/documents/2015-08-31%20PTAB.pdf>

But Petition Grant Rate Has Dropped in Last 18 Months

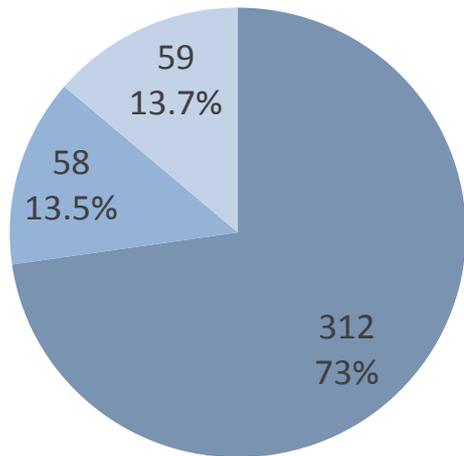
Institution rate



Number of petitions granted as the nominator and petitions granted + petitions denied + decisions granting joinder as the denominator. Source: <http://www.uspto.gov/sites/default/files/documents/2015-08-31%20PTAB.pdf>

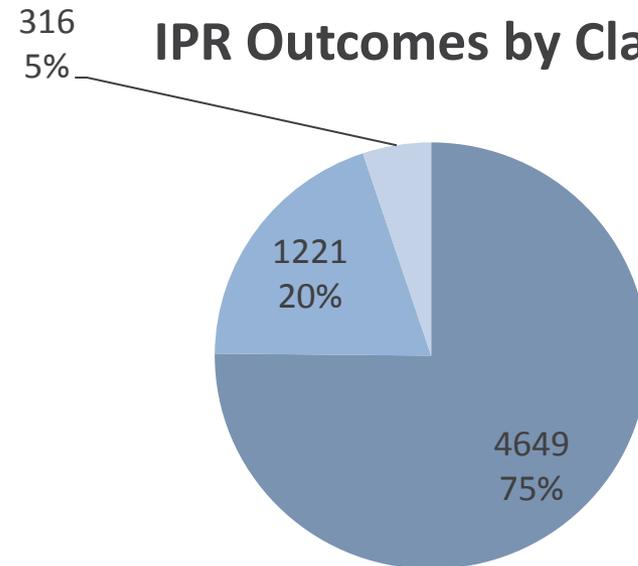
If IPR Instituted, Cancellation Rate is High!

IPR Outcomes by Case



- No instituted claims survived
- All instituted claims survived
- Mixed

IPR Outcomes by Claim



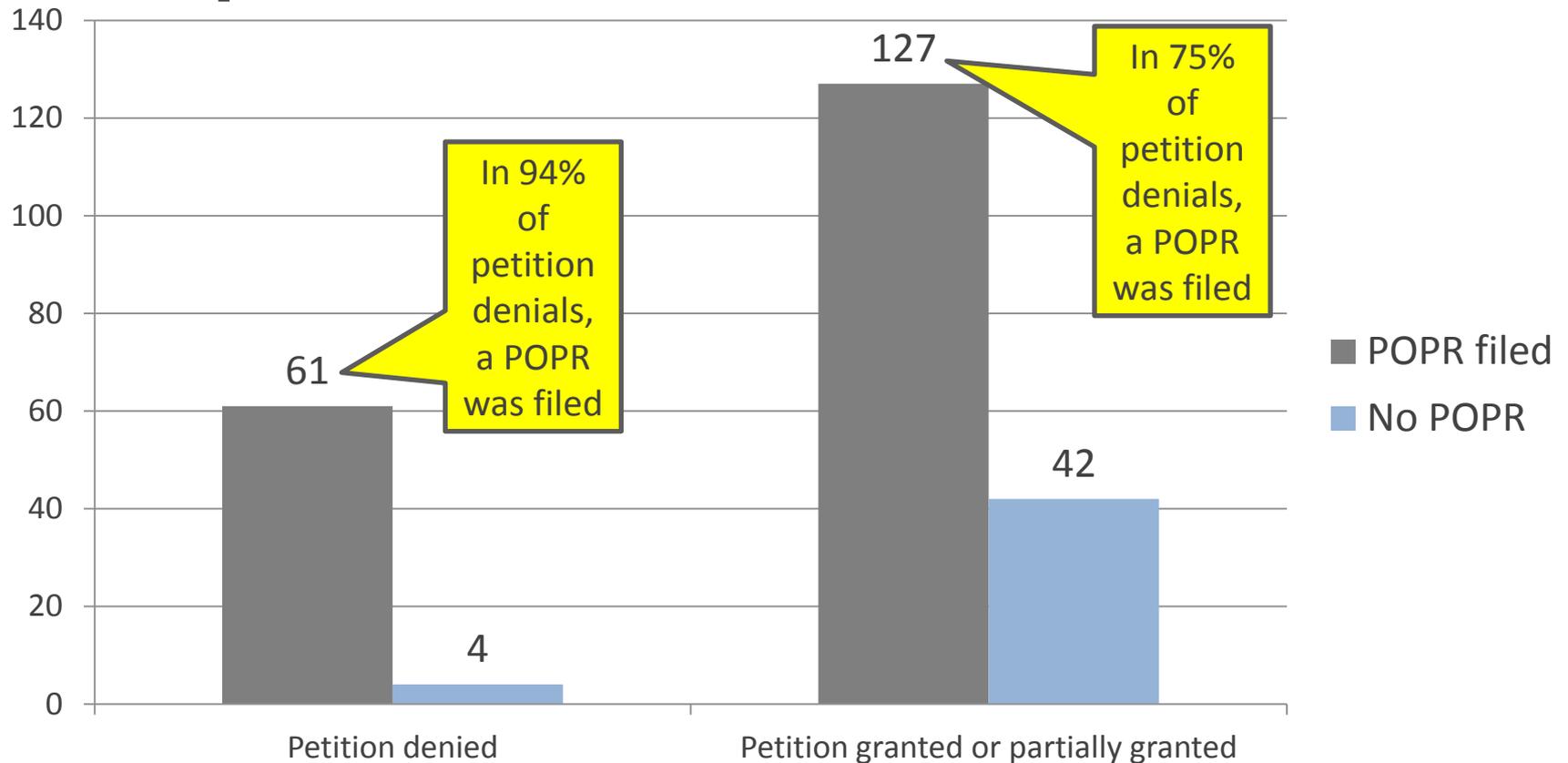
- All instituted claims unpatentable
- All instituted claims survived
- Instituted claims conceded

“Mixed outcome”: at least one instituted claims survived and at least one instituted claim was canceled.

As of Sept. 1, 2015. Source: Finnegan research, with thanks to Dan Klodowski, Kai Rajan, Elliot Cook, and Joe Schaffner.

Consider Filing Patent Owner Preliminary Response (POPR) – May Make A Difference!

(Sample from Bio/Pharma IPR Institution Decisions)



Source: Finnegan research; 234 institution decisions as of Sept. 30, 2015.

Currently, Patent Owner Cannot "Present New Testimony Evidence Beyond That Already Of Record" In POPR

37 C.F.R. §42.107(c): No new testimonial evidence. The preliminary response shall not present new testimony evidence beyond that already of record, except as authorized by the Board.

Significant tactical advantage for Petitioner.

But Specification, File History, Evidence From Other Proceedings Are Fair Game For Presenting In The POPR

- *Anova Food, LLC. v. Leo Sandau and William R. Kowalski*, IPR2013-00114, Paper 11 (PTAB June 25, 2014): “37 C.F. R § 42.107(c) applies only to ‘new’ testimony that was taken specifically for the purpose of the inter partes review proceeding at issue, as supported by the discussion and the comments that accompanied the rule. For example, a party submitting the prosecution history for the challenged patent may include a copy of the declarations contained therein.”

Proposed Rule Change

still
optional

§ 42.107 Preliminary response to petition.

- (a) The patent owner **may** file a preliminary response to the petition. The response may set forth the reasons why no inter partes review should be instituted under 35 U.S.C. 314 **and can include supporting evidence**. The preliminary response is subject to the word count under §42.24.

§ 42.108 Institution of inter partes review.

- (c) Sufficient grounds. Inter partes review shall not be instituted for a ground of unpatentability unless the Board decides that the petition supporting the ground would demonstrate that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable. **The Board's decision will take into account a patent owner preliminary response where such a response is filed, but supporting evidence concerning disputed material facts will be viewed in the light most favorable to the petitioner for purposes of deciding whether to institute an inter partes review. If the patent owner submits supporting evidence with its preliminary response, the petitioner may seek leave to file a reply to the preliminary response in accordance with § 42.24(c).**

Until Rule Changes, Consider Proactive Use of Substantive Declarations in Prosecution

Patent Owner can rely on **public records**. If there are good declarations in prosecution, those can be submitted by the Patent Owner before institution (Patent Owner's Preliminary Response) in an effort to persuade PTAB that there is not a substantial likelihood that at least one claim will be unpatentable.

Remember: **Patent Owner's goal is to avoid institution of an IPR/PGR.**

Load Up on Your Evidence During Prosecution!

The “objective evidence of nonobviousness” (also known as “secondary considerations,” as the term was coined in *Graham v. John Deere*) can, for example, include:

- Long-felt but unsolved need,
- Failure of others,
- Commercial success,
- Unexpected results created by the claimed invention, and
- Skepticism of skilled artisans before the invention.

See In re Rouffet, 149 F.3d 1q350, 1355 (Fed. Cir. 1998).

These objective considerations, when present, are important evidence, as they protect against the prejudice of hindsight bias, which frequently overlooks the fact that “[t]he genius of invention is often a combination of known elements which in hindsight seems preordained.”

McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351 (Fed. Cir. 2001).

Load Up on Your Evidence During Prosecution!

Indeed, secondary consideration evidence “may be the most probative and cogent evidence in the record.” *Apple Inc. v. ITC*, 725 F.3d 1356, 1366 (Fed. Cir. 2013) (internal quotation marks and citations omitted). Objective evidence of these secondary considerations can establish that “an invention appearing to have been obvious in light of the prior art was not.” *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Nexus Required For Objective Evidence Of Nonobviousness Is Not A New Concept

- CCPA, Federal Circuit, PTAB case law and MPEP:
 - All rely on *Graham v. John Deere Co.*, 383 U.S. 1 (1966):
 - (1) the scope and content of the prior art;
 - (2) differences between the prior art and the claims at issue;
 - (3) the level of ordinary skill in the pertinent art; and
 - (4) **evaluation of any relevant secondary considerations.**

“Nexus” Between Evidence and Claimed Invention

- **Manual of Patent Examining Procedure §716.01(b)**
 - “The term “nexus” designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988).”

PTAB Requires Nexus

- *Gnosis S.p.A. v. Merck & Cie*, IPR2013-00117, Paper 71 (P.T.A.B. June 20, 2014)
 - PTAB: Instituted claims held unpatentable (or canceled by Patent Owner)
 - “Merck argues, and Gnosis does not dispute, that administration of each of the above Pamlab products to a patient falls within the scope of the claims under review. ...**It is not sufficient, however, that a product or its use merely falls within the scope of a claim in order for objective evidence of nonobviousness tied to that product to be given substantial weight. There must also be a causal relationship, termed a “nexus,” between the evidence and the claimed invention. . . . A showing of sufficient nexus is required in order to establish that the evidence relied upon traces its basis to a novel element in the claim, not to something in the prior art. . . . Objective evidence that results from something that is not ‘both claimed and novel in the claim’ lacks a nexus to the merits of the invention.”** [citations omitted]

PTAB Requires Nexus (con't)

- *Gnosis* (con't)
 - PTAB rejected objective evidence
 - “Nexus must exist in relation to all types of objective evidence of nonobviousness. GPAC, 57 F.3d at 1580 (generally); In re Huang, 100 F.3d 135, 140 (Fed. Cir. 1996) (**commercial success**); In re Antor Media Corp., 689 F.3d 1282, 1293 (Fed. Cir. 2012) (**licensing**); Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (**copying**); Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1313 (Fed. Cir. 2006) (**failure of others**); Rambus Inc. v. Rea, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (**long-felt need**); Kao, 639 F.3d at 1069 (**unexpected results**); Stamps.com Inc. v. Endicia, Inc., 437 F. App'x 897, 905 (Fed. Cir. 2011) (**skepticism**); Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1328 (Fed. Cir. 2008) (**praise**).”

PTAB Requires Nexus (con't)

- *Gnosis* (con't)
 - PTAB rejected objective evidence
 - “Thus, for objective evidence to be accorded substantial weight, the record ‘must establish a nexus between the evidence and the merits of the claimed invention.’ Moreover, **establishing nexus involves a showing that novel elements in the claim, not prior-art elements, account for the objective evidence of nonobviousness.** . . . As the Federal Circuit explains, ‘[t]o the extent that the patentee demonstrates the required nexus, his objective evidence of nonobviousness will be accorded more or less weight.’ . . . Thus, the stronger the showing of nexus, the greater the weight accorded the objective evidence of nonobviousness.”
[citations omitted]

Objective Evidence of Nonobviousness: Use Evidence from Prosecution

- Strong patentability positions during drafting and prosecution.
 - Analyze carefully considered strong arguments and/or declarations supporting §112 positions (written description and enablement) and §103 positions (nonobviousness)
- Consider *Therasense*
 - Careful thought and planning.

Declarations

- Declarations need to be as solid as possible. PTAB has found that defective declarations relied on for patentability during prosecution can form an independent basis for instituting an IPR.
- *K-40 Electronics, LLC v. Escort, Inc.*, IPR2013-00203, Paper 6 (PTAB Aug. 29, 2013)
 - PTAB reviewed a § 1.131 **declaration from the prosecution**, found it deficient, and reapplied the prior art the declaration had antedated, instituting the IPR.
 - Case also had live testimony from inventor at oral hearing.
 - One might want declarations from the inventor during prosecution that can then be referred to by the Patent Owner in the optional Preliminary Response to try to ward off institution.

Sample Expert Declaration Dealing with Objective Evidence

These declarations establish that there would have been no reasonable expectation of success of the claimed subject matter by showing:

- 1) significant unexpected results in the teeth of strong skepticism by FDA experts and fulfillment of a long-felt need;
- 2) the claimed subject matter is reasonably commensurate in scope with commercial success, coupled with a nexus between that commercial success and the merits of the claimed invention;
- 3) the claimed subject matter relating to NMR chemical shifts and solvent used is neither necessarily present or inherently anticipated, nor in any way suggested by the claimed of the '699 patent relied on for the ODP rejection.

Sample Expert Declaration Dealing with Objective Evidence

In particular, the declaration of Dr. _____ supports the patentability of claims _____, as amended, by providing expert opinion establishing significant unexpected results for the claimed subject matter in the face of skepticism by experts in the field. To do so, the _____ declaration establishes that the drug product _____ capsules comprising _____ mg of _____ achieved results which were significant and unexpected, i.e., they could not have been expected (reasonably predicted), given the previous, but largely inadequate, treatments for the cutaneous manifestations of cutaneous _____ in patients who are refractory to at least one prior systemic therapy.

Sample Expert Declaration Dealing with Objective Evidence

- Commercial Success
 - “In other words, the commercial success would be expected for each mg amount across the mg range. That testimony of course, applies with equal force to new claim .”

Sample Expert Declaration Dealing with Objective Evidence

“And that is not all. The declaration of [redacted] provides factual testimony supporting the patentability of claims [redacted] by laying a foundation establishing significant commercial success of the [redacted] capsules comprising [redacted] mg of [redacted], [redacted] such as purchase of rights to those capsules by other pharmaceutical companies, copying of those capsules by generic manufacturers, and significant market share and sales growth for the capsules, even though competing FDA-approved products are available. Mr. [redacted] also lays the predicate for concluding that there is a nexus between the commercial success and the merits of the claimed inventions recited in claims [redacted]. That is especially because market share has remained stable even though promotional costs have declined. And those claims are reasonably commensurate in scope with the commercial success.”

Sample Expert Declaration Dealing with Objective Evidence

“As explained at the interview, Federal Circuit case law binding on the USPTO establishes that commercial success establishes the patentability of a claim broader in scope than the single embodiment of commercial success shown within the claim. See *In re Glatt*, 630 F.3d 1026, 1030 (Fed. Cir. 2011) and *Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996).”

“In addition, *In re Hollingsworth*, 253 F.2d 238 (CCPA 1958), cited in MPEP 716.03(a)(II), also shows that one embodiment having commercial success within the scope of new claims can be sufficient to show non-obviousness over the claims of the patent.”

“If a particular range is claimed, applicant does not need to show commercial success at every point in the range....[W]here substantial commercial success is achieved at an apparently typical point within those ranges, and the affidavits definitely indicate that operation throughout the claimed ranges approximates that at the particular points involved in the commercial operation, we think the evidence as to commercial success is persuasive.”

So Far, Objective Evidence of Nonobviousness in IPRs Not Working Well

Objective evidence of nonobviousness must have nexus.

Patent Owners not much success so far with objective evidence of nonobviousness - not showing nexus (linking the objective evidence of obviousness to the merits of the claimed invention).

Unsuccessful Attempts To
Rely On Objective Evidence Of
Non-obviousness

“Nexus” Required

Tandus Flooring, Inc. v. Interface, Inc., IPR2013-00527, Paper 48 (PTAB Feb. 12, 2015)

– PTAB:

- “Before delving into the specific arguments and evidence of secondary considerations, we note that it is not sufficient that a product or its use merely be within the scope of a claim in order for objective evidence of nonobviousness tied to that product to be given substantial weight. **There must also be a causal relationship, termed a “nexus,” between the evidence and the claimed invention. ...A nexus is required in order to establish that the evidence relied upon traces its basis to a novel element in the claim, not to something in the prior art.** ...Objective evidence that results from something that is not “both claimed and novel in the claim,” lacks a nexus to the merits of the invention. ... **All types of objective evidence of nonobviousness must be shown to have nexus.** ...The stronger the showing of nexus, the greater the weight accorded the objective evidence of nonobviousness.”

No “Nexus”

Cardiocom, LLC v. Robert Bosch Healthcare Systems, Inc., IPR2013-00468. Paper 72 (PTAB Jan. 27, 2015)

- Patent Owner failed to establish nexus between the claimed invention and the objective evidence.
- PTAB:
 - “Any commercial success of the Health Buddy is only relevant if the Health Buddy actually was the claimed monitoring system or apparatus, or actually was used to practice the methods, recited in the challenged claims. Patent Owner has not provided sufficient evidence to show that was the case.”
 - “Patent Owner does not show sufficiently that the '192 patent actually satisfied the alleged need. ...Thus, Patent Owner's evidence of long-felt need is not persuasive.”
 - “evidence of industry praise is only relevant when it is directed to the merits of the invention claimed. ...Patent Owner has not established a sufficient nexus with the claimed methods, and industry praise of the Health Buddy does not support a conclusion of nonobviousness of the claims.”

No “Nexus”

Smith & Nephew, Inc. v. Convatec Tech., Inc., IPR2013-00102, Paper 87 (PTAB May 29, 2014)

- All challenged claims unpatentable.
- Patent Owner’s objective evidence insufficient.
 - “ConvaTec has not shown, however, that the sales of the AQUACEL® Ag product line are a result of the claimed invention.”
 - “no details of the manufacturing process for AQUACEL® Ag products as supporting evidence that the products are manufactured using the steps recited in the claims.”
 - No explanation:
 - “how such praise is directed to any particular feature of the method recited in the claims.”
 - “that advantages of the claimed invention are not met by silverized hydrogels of the prior art[.]”
 - “that the evidence of long-felt and unmet need is solved by the particular steps recited in the claims, or to the photostability of the product, to the extent they are distinguishable from the prior art of record.”

No “Nexus”

- *CustomPlay, LLC v. ClearPlay, Inc.*, IPR2014-00339, Paper 27, at 29-30 (P.T.A.B. July 21, 2015)
- PTAB: All instituted claims unpatentable; rejected Patent Owner's argument of objective evidence of nonobviousness.
 - Statements about gross sales were not sufficiently tied to the merits of the claimed invention so as to constitute evidence of commercial success.
 - “Patent Owner argues, without citation of any supporting evidence, that ‘secondary considerations [of commercial success] support the validity of the claims.’ ... The objective indicia, however, must establish a nexus with the claimed subject matter. Here, Patent Owner provides argument, but no evidence, of the alleged commercial success. *See, e.g.*, PO Resp. 54 (‘Since 2001, [Patent Owner] has had gross sales of \$21 million.’). Patent Owner also fails to provide any evidence that the alleged commercial success is due to the patented invention rather than other factors.”

No “Nexus”

- *LKQ Corporation v. Clearlamp, LLC*, IPR2013-00020, Paper 73, at 28 (P.T.A.B. March 27, 2014)
 - PTAB rejected objective evidence of copying:
 - “Neither is it apparent from the record that there is sufficient evidence that LKQ undertook to replicate the particular process of Mr. Paperi. Indeed, even assuming that LKQ does produce a product encompassed by the patent, ... the record suitably establishes that one of ordinary skill in the art would have been cognizant from the prior art of all the steps associated with those claims and which operate for their intended function. In that regard, Clearlamp has not shown persuasively that LKQ's refurbishing process is due only to an act of copying of the particular process practiced by Dr. Paperi, rather than simply through practice of the teachings of the prior art.”

No “Nexus”

- *Qualtrics Labs, Inc. v. OpinionLab, Inc.*, IPR2014-00421, Paper 41, at 30-31 (P.T.A.B. July 24, 2015)
 - PTAB held all instituted claims unpatentable.
 - PTAB described the level of detail required to show sufficient nexus between commercial success and the claimed invention:
 - “To show how commercial success supports non-obviousness, however, Patent Owner must prove that the sales were a direct result of the unique characteristics of the invention, and not a result of economic and commercial factors unrelated to the quality of the patented subject matter. Patent Owner has not so shown. **Even if Patent Owner’s product includes the limitations of claim 1, there is no explanation as to how these limitations are related to the alleged commercial success other than simply alleging that the limitations are present in its product.** Patent Owner provides examples of the database and reporting module features of its product and discusses use of various features by its customers, but does not attempt to tie any of these features to the alleged commercial success. Patent Owner’s specific discussion of “commercial success” does not cure this deficiency.
 - *Patent Owner’s arguments*: “utilized by an extensive list of customers” and “OpinionLab’s customer list has continued to grow”

No Nexus

- *Qualtrics Labs, Inc. v. OpinionLab, Inc.*, IPR2014-00421, Paper 41, at 31-32 (P.T.A.B. July 24, 2015)
 - PTAB : Industry praise evidence rejected.
 - “As with commercial success ... evidence of industry praise is only relevant when it is directed to the merits of the invention claimed. Patent Owner identifies various documents discussing features of its product... . Notably, these materials quoted in the Patent Owner Response praise [Patent Owner's] product in general. Patent Owner does not identify any praise due to specific features that are present in the claims. Patent Owner has not established a sufficient nexus with the claimed invention.

No Nexus

- *Qualtrics Labs, Inc. v. OpinionLab, Inc.*, IPR2014-00421, Paper 41, at 32-33 (P.T.A.B. July 24, 2015)
 - PTAB : Copying evidence rejected.
 - Merely showed “similarities between its products and those offered by Petitioner” without “any analysis or explanation of how other companies, such as Petitioner, allegedly copied its product that allegedly includes the features of the claimed invention.”

No Nexus

- *Seagate Technology (US) Holdings, Inc. v. Enova Technology Corp.*, IPR2014-00683, Paper 47 (P.T.A.B. Sept. 2, 2015)
 - PTAB: All instituted claims unpatentable.
 - Objective evidence of industry praise rejected for insufficient nexus.
 - “Although Exhibit 2018 discusses general features of Patent Owner’s X-Wall products, Patent Owner does not identify any praise due to specific elements that are recited in the challenged claims.”
 - Even if article is “praise,” relates to prior art feature.
 - Even if award is “praise,” not shown to relate to claimed element.
 - Unsubstantiated allegations cannot establish nexus.

No Nexus

- *Seagate Technology* (con't)
 - Objective evidence of commercial success rejected for insufficient nexus.
 - Patent Owner did not establish that the products included claimed features claimed.
 - Patent Owner did not establish that Petitioner's sales had any relationship to the merits of the claimed invention.
 - “even if the Petitioner's product sales are considered in the context of commercial success, “evidence related solely to the number of units sold provides a very weak showing of commercial success, if any.”
 - more probative evidence is whether the sales represent ‘a substantial quantity in th[e] market.’”
 - No evidence of the size of the market to which to compare Petitioner's sales.

No Nexus

- *Endo Pharmaceuticals, Inc. v. Depomed, Inc.*, IPR2014-00652, Paper 68 (P.T.A.B. Sept. 16, 2015)
 - PTAB: All instituted claims unpatentable.
 - Patent Owner: successfully commercialized patented invention in drug Gralise® (sales and market share data).
- PTAB: Insufficient nexus shown
 - Patent Owner did not sufficiently show that Gralise® embodies the claims of the '340 patent.
 - Cites declaration and claim charts.
 - “merely citing to a claim chart as support—without any explanation in the Patent Owner Response—is insufficient to demonstrate a nexus and violates our rule against incorporation by reference.”

No Nexus

- *Endo* (con't)
 - Patent Owner: licensing program establishes that the claims are not obvious.
 - PTAB: “without a showing of a nexus, ‘the mere existence of . . . licenses is insufficient to overcome the conclusion of obviousness.’” (citing Federal Circuit case law)
 - Patent Owner did little more than list the licenses and their respective sales revenue.
 - “[T]estimony of Dr. Nicholson only details the revenues for each license and does not establish whether the licensing program was successful because of the merits of the claimed invention or for other economic reasons, such as to avoid litigation or because of prior business relationships.”

No Nexus

- *Medtronic, Inc. v. Nuvasive, Inc.*, IPR2014-00074, Paper 15 (P.T.A.B. April 8, 2014)
 - Patent Owner raised objective evidence of nonobviousness in its POPR: faulted Petitioner's experts' declarations for not taking into account the documentation of industry praise and success submitted in earlier district court litigation between the parties.
 - Patent Owner also directed the PTAB's attention to Petitioner's internal documents indicating its knowledge of Patent Owner's commercial success, initial skepticism, industry praise and copying.
 - PTAB: Rejected objective evidence; no nexus.
 - “We have reviewed the evidence presented by Patent Owner. Although Patent Owner asserts that the “XLIF” system (“eXtreme Lateral Interbody Fusion”) is a commercial embodiment protected by the ’356 patent, on the current record, Patent Owner has not advanced any clear or specific evidence explaining what the XLIF system is precisely, such that it is clear which features, if any, of the challenged claims, are part of the XLIF system. It is, therefore, not clear, on the current record, that any of the alleged secondary indicia of non-obviousness relate to the surgical system recited in the challenged claims.

No Nexus Doomed Patent Owner

Patent Owner's failure to tie its objective evidence to the claimed invention doomed its objective evidence argument.

Patent Owner failed on a threshold issue of explaining how any objective evidence even relate to the product of the claimed invention, let alone provide a causal nexus to the objective evidence.

Objective Evidence Raised in POPR

- *Phigenix, Inc. v. Immunogen, Inc.*, IPR2014-00676, Paper 10, at 11-30 (P.T.A.B. July 30, 2014)
 - Patent Owner extensively detailed objective evidence of unexpected results, industry praise, long-felt need and commercial success, presented in two expert declarations during prosecution, and criticized the petition for not addressing this evidence.

Objective Evidence Rejected

- *Phigenix, Inc. v. Immunogen, Inc.*, IPR2014-00676, Paper 11, at 22 (P.T.A.B. Oct. 29, 2014)
 - PTAB instituted the IPR, partly because the references on which the IPR obviousness grounds were based were different than those in prosecution and partly because Patent Owner failed to establish (1) the objective evidence was reasonably commensurate in scope with the challenged claims, (2) the requisite nexus, and (3) even whether the results in fact were unexpected:
 - “Patent Owner's Preliminary Response and evidence of record at this time do not address adequately considerations such as whether evidence of objective indicia are reasonably commensurate with the scope of the challenged claims, whether a sufficient nexus exists between such evidence and the merits of the claimed invention, or whether evidence of unexpected results establishes a difference between the results obtained and those of the closest prior art.”

What Would Be Sufficient Nexus?

PTAB looking for causation of the commercial success by the merits of the claimed invention; mere correlation may not be enough.

Need to analyze and/or explain why the copying was driven by the merits of the claimed invention.

Successful Attempts To Rely
On Objective Evidence Of
Non-obviousness

Example Where Objective Evidence in “Record” Successfully Used by Patent Owner to Get IPR Petition Denied

Omron Oilfield & Marine, Inc. v. Md/Totco, A Division Of Varco, L.P., IPR2013-00265, Paper 11 (PTAB Oct. 31, 2013)

- Patent Owner requested PTAB exercise its discretion to deny the petition because of the same art/arguments before the Office during reexamination.
 - Patent Owner was able to rely on evidence in the record in a reexamination of the patent of commercial success.

Example Where Objective Evidence in “Record” Successfully Used by Patent Owner to Get IPR Petition Denied

Omron (con’t)

- PTAB: Petition denied.
 - Found Petitioner established a prima facie case of obviousness, and then reviewed the objective evidence of nonobviousness provided to the examiner during a reexamination, and agreed that it was persuasive.
 - “we determine that Patent Owner has presented sufficient evidence to establish a prima facie case of nexus.”
 - No rebuttal by Petitioner.
 - “We find that the ’142 Patent had significant commercial success, which, here, overcomes the prima facie case of obviousness.”

Example Where Objective Evidence Successfully Used by Patent Owner Avoid Unpatentability Determination in FWD

Intri-Plex Technologies, Inc. v. Saint-Gobain Performance Plastics Rencol Ltd., IPR2014-00309, Paper 83 (PTAB March 23, 2014)

- Patent Owner submitted objective evidence of nonobviousness via a declaration (prepared for the IPR) supporting the Patent Owner Response.
- PTAB: Final Written Decision that Intri-Plex did not meet its burden of showing challenged claims unpatentable.
 - “we determine that the first three Graham factors favor a determination that the challenged claims are obvious. However, a proper obviousness determination requires a consideration of all factors, and we determine that **Saint-Gobain’s case for nonobviousness based on secondary considerations is particularly strong, and outweighs the other three factors**. In particular, we are persuaded that our finding of commercial success is particularly strong, Indeed, we determine that commercial success alone sufficiently outweighs the other three factors, and that our finding of copying merely strengthens further our finding that secondary considerations weigh in favor of Saint-Gobain.”

Objective Evidence Accepted, But Did Not Outweigh

- *Unverferth Manufacturing Co., Inc. v. J&M Manufacturing Co., Inc.*, IPR2014-00758, Paper 26 (P.T.A.B. Aug. 31, 2015)
 - Evidence of long-felt need - neutral
 - Evidence of Petitioner's efforts - insufficient nexus.
 - Evidence of Patent Owner's efforts - PTAB gave "some weight."
 - "However, this evidence, when compared to the evidence of Exhibits . . . does not overcome the evidence of obviousness of the claimed subject matter. Each of the claimed elements were known in the art, and utilized for their known purpose to give predictable results."
 - PTAB: Claim unpatentable.

Requests For Additional Discovery Of Objective Evidence

So Far, PTAB Showing Strict Standards Around Objective Evidence of Nonobviousness

- If objective evidence of nonobviousness requires additional discovery, have to request authorization to file a motion requesting additional discovery.
- *Garmin Factors*
 - More than a possibility and mere allegation.
 - Litigation position and underlying basis.
 - Ability to generate equivalent information by other means.
 - Easily understandable instructions.
 - Requests not overly burdensome to answer.
 - *Garmin Int'l, Inc. v. Cuozzo Speed Techs., LLC*, IPR2012-00001, Paper No. 26 (P.T.A.B. Mar. 5, 2013).

Additional Discovery on Objective Evidence

Kamada, Ltd. v. Grifols Therapeutics Inc., IPR2014-00899, Paper 22 (PTAB March 4, 2015)

- Patent Owner requested additional discovery on copying: “the existence and timing of Petitioner’s ‘800 Patent and the competing commercial product... and the unprovoked filing of the Petition, make clear that this allegation of copying is much higher than a ‘possibility or mere allegation.’”

Additional Discovery on Objective Evidence

Kamada (con't)

- PTAB: Authorized motion but then denied Patent Owner's request for additional discovery relating to objective evidence of copying.
 - “Patent Owner has not provided any authority to support its argument that copying claims into another patent application constitutes proof of copying for purposes of secondary considerations of nonobviousness. Nor are we aware of any such authority. Patent Owner has also failed to present any evidence or reasoning tending to show beyond speculation that, even if there were evidence of copying, a nexus exists between Petitioner's alleged copying and the claimed invention [.]”

Additional Discovery on Objective Evidence

Shire Development LLC v. LCS Group, LLC, IPR2014-00739, Paper 23 (PTAB March 12, 2015)

- Patent Owner filed motion to submit supplemental information.
 - FDA and Petitioner information released after it had filed its Patent Owner Response relevant to objective evidence of nonobviousness, particularly long-felt but unmet need.
 - Petitioner statements in media contradict position in IPR, contradict Petitioner’s argument that other, non-pharmacological treatments were available and sufficient
 - FDA announcement of first FDA-approved medication for the treatment of BED.
- PTAB: “the interests of justice are served by permitting entry of [the FDA approval announcement only] as supplemental information.”
 - Could not have been earlier submitted because the press release was issued by the FDA after the filing of the Patent Owner Response.

Additional Discovery on Objective Evidence

- *MasterImage 3D Asia, LLC v. RealD, Inc.*, IPR2015-00035, Paper 28 (P.T.A.B. June 23, 2015).
 - Patent Owner sought authorization to file a motion for additional discovery of documents relevant to objective evidence of copying and commercial success.
 - Documents produced by Petitioner in an ITC proceeding, but the rules of the ITC precluded use of such documents in another proceeding, such as the PTAB.
 - PTAB denied: Patent Owner had not satisfied the *Garmin* factors.
 - Patent Owner only made allegations without any support that there was more than a “mere possibility” of evidence of copying in the documents.
 - “Patent Owner has not presented a threshold showing of nexus” between the documents allegedly containing evidence of commercial success and the claims.”

PTAB Strict Application of Nexus Requirement To Request For Additional Discovery

- *Microsoft Corp. v. Proxyconn, Inc.*, IPR2012-00026, Paper 32 (P.T.A.B. March 8, 2013)
 - PTAB denied Patent Owner's motion for additional discovery related to objective evidence.
 - “As Patent Owner recognizes, the nexus requirement for proving commercial success is well established by the case law and is strictly observed. ... The interest of justice standard for granting additional discovery and its legislative history require that a showing of relevance be made by the party seeking additional discovery before the request is granted.

PTAB Strict Application of Nexus Requirement To Request For Additional Discovery

- *Microsoft Corp. v. Proxyconn* (con't)
 - PTAB denied Patent Owner's motion for additional discovery related to objective evidence.
 - “As the cases surveyed demonstrate, this puts a heavy burden on Patent Owner. The Board will not allow Patent Owner additional discovery with no indication that the information sought will be relevant.”
 - “Patent Owner failed to provide a sufficient showing that might establish the relevance of the additional discovery requested, much less demonstrating that the interest of justice standard has been met.”

Sufficient Nexus for Request for Additional Discovery

John's Lone Star Distribution, Inc. v. Thermolife International, LLC, IPR2014-01201, Paper 30 (P.T.A.B. May 13, 2015)

- Patent Owner requested additional discovery of documents relating to evidence of commercial success.
- PTAB partially granted the request, finding sufficient nexus between the request for certain sales information and the claim limitations:
 - “Patent Owner points us to evidence indicating that potentially relevant products have enjoyed at least some commercial success, after being advertised as containing components recited in challenged claims. ... Here, prior to filing its Response, Patent Owner seeks discovery on the issue of commercial sales of three products by a competitor, most likely to bolster evidence Patent Owner may already have in its possession relating to the issue of commercial success generally. In view of contentions of both parties, as well as evidence before us, we are persuaded that Patent Owner has set forth a threshold amount of evidence sufficient to deem that the discovery of certain requested documents is necessary in the interest of justice.”

Sufficient Nexus for Request for Additional Discovery

- *Kingston Tech. Co. v. CATR Co.*, IPR2015-00149, Paper 24 (P.T.A.B. June 10, 2015)
 - *Garmin* factor analysis.
 - Patent Owner's Request 1: financial results for product - GRANTED
 - Patent Owner submitted claim chart allegedly showing product met limitations of claims.
 - Patent Owner's Request 2: consumer feedback received by Petitioner concerning product - GRANTED
 - Patent Owner's Request 3: other feedback received by Petitioner concerning product - DENIED
 - Patent Owner's Request 4: documents evidencing Petitioner's "initial decision to commercialize a product" - DENIED

Evidence Commensurate In Scope

Commensurate in Scope Analyzed on Claim-by-Claim Basis

- *Lupin Ltd. v. Vertex Pharm. Inc.*, IPR2015-00405, Paper 13, at 22-23 (P.T.A.B. July 9, 2015)
 - PTAB determined that Patent Owner's objective evidence of nonobviousness was only commensurate in scope with the patent's narrower claims.
 - PTAB accepted Patent Owner's evidence of nonobviousness only for the subject matter of the narrower claims 68 and granted the petition with respect to the broader claims.

Not Commensurate in Scope

- *Torrent Pharmaceuticals Ltd. v. Novartis Ag*, IPR2014-00784, Paper 112 (P.T.A.B. Sept. 24, 2015)
 - Objective evidence: claimed combination of fingolimod and mannitol shows unexpected results.
 - Patent Owner: claimed combination unexpected stability at low doses of fingolimod, even though combinations of fingolimod and other excipients were unstable at those same low doses.
 - But claim did not have stability or dosage limitation.
 - PTAB: “The evidence of unexpected results made of record is not commensurate in scope with claim[.]”

Not Commensurate in Scope

- *FLIR Systems, Inc. v. Leak Surveys, Inc.*, IPR2014-00411, Paper 114 (P.T.A.B. Sept. 3, 2015)
 - Patent Owner: inventor modified a camera and achieved unexpected results in variable ambient conditions , such as variable atmospheric temperatures and wind conditions.
 - But claims do not recite or require any specific conditions.
 - PTAB: “there is no nexus that is tied to the novel elements of the claims at issue or that are reasonably commensurate with the scope of the claims.”
 - Also, Patent Owner’s evidence of skepticism of others not commensurate in scope - does not show evidence based on the claimed limitations of the challenged patents.

Take Aways

- Strategic use of prosecution or litigation declarations.
- Best practices for establishing nexus between the objective evidence and the merits of the claimed invention.

Take Aways

- It may suffice for Patent Owners to simply cite Federal Circuit case law about a presumption of nexus when the marketed product is the claimed invention.
- “A prima facie case of nexus is established when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent. *In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995).

Take Aways

- But, may be more prudent for Patent Owner to provide detailed explanation linking the objective evidence with the claimed invention.
- If objective evidence of nonobviousness arises late in the IPR proceeding, it may still be possible for Patent Owner to get that evidence before the PTAB.

Take Aways

- Currently, in the POPR, Patent Owner cannot “present new testimony evidence beyond that already of record.”
- This may change in the future, but for now, to defeat institution, Patent Owner should be able, in the POPR, to rely on declarations setting forth objective evidence of nonobviousness originating from the prosecution or even from other publicly available documents, such as from reexamination and litigation that are not “new testimony evidence.”

Take Aways

- But note that even if the declarations are prepared for related litigation, they must still be executed prior to the filing of the IPR petition, otherwise they are not “new.” See *FLIR Sys., Inc. v. Leak Surveys, Inc.*, IPR2014-00608, Paper 10, at 33-34 (P.T.A.B. Sept. 5, 2014), and *C&D Zodiac, Inc. v. B/E Aerospace, Inc.*, IPR2014-00727, Paper 15, at 18 (P.T.A.B. Oct. 29, 2014).

Take Aways

- Best case scenario for a Patent Owner is to have the petition denied and avoid an IPR, particularly since denial cannot be judicially reviewed.
- Even if this is not achieved, the POPR may lead to the trial being instituted on fewer grounds and/or fewer claims than challenged in the petition -> still a positive development for a Patent Owner now faced with a trial narrower in scope.
- Patent Owner consider loading evidence into her prosecution, along with crisp and compelling arguments to show no prima facie case of obviousness, at least in applications likely to end up in litigation or a post-grant proceedings, such as IPR.

Take Aways

- Solid evidentiary showings and/or possibly declarations, in addition to on-point legal arguments, may help to develop strong patentability records.
- Prudently establishing such records during prosecution could support Patent Owner's efforts to persuade the PTAB that Petitioner does not have a “reasonable likelihood” of success and thus achieve denial of institution.

Take Aways

- The PTAB desires to have cases front-loaded to make the most efficient use of its resources by allowing it to make the institution decision based on the most information possible.
- If Patent Owner has relevant and compelling information in the prosecution history, or in related proceedings, such as reexamination or litigation, that could well help Patent Owner convince the PTAB to deny the petition. In particular, in the POPR, Patent Owner can tell the PTAB in a concise, compelling argument why the petition should be denied.
- Such concise and compelling arguments can help the PTAB achieve both the policy objective that IPR proceedings be “just, speedy, and inexpensive” and the statutory objective of resolution 12-18 months from institution.

Thank You!



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Thanks.

Please join us for our next conference, “Leveraging Experts for USPTO Prosecution and PTAB - Developing Strong Patentability Records to Strengthen Claims Against IPR and PGR Challenges” scheduled on Thursday, November 12, 2015 at 1 pm EDT.

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