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Spotlight on Objective Evidence of Nonobviousnes in AIA Post-Grant Proceedings

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SPOTLIGHT ON OBJECTIVE EVIDENCE OF NONOBVIOUSNESS IN AIA POST-GRANT PROCEEDINGS

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I. OBJECTIVE EVIDENCE OF NONOBVIOUSNESS IN AIA POST-GRANT PROCEEDINGS

Obviousness may be raised by a Petitioner as a ground of unpatentability in both *inter partes* review (IPR) and post-grant review (PGR) proceedings.⁶ The Patent Trial and Appeal Board (PTAB) may institute an IPR or PGR if “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition” (IPR) or “it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable” (PGR).⁷ In making a decision to institute an IPR, PTAB may consider a Patent Owner’s Preliminary Response (POPR), if one was filed, arguing why the proceeding should not be instituted.⁸ For a PGR, the statutory language for the institution threshold is a little different (if the information in the petition is “not rebutted”),⁹ but it is reasonable to expect that the only way the information could be rebutted is in a Patent Owner’s Preliminary Response.¹⁰ The

⁶ 35 U.S.C. § 311(b) (2013); 35 U.S.C. §321(b) (2012).

⁷ 35 U.S.C. § 314(a) (2012) (“Institution of *inter partes* review (a) THRESHOLD.—The Director may not authorize an *inter partes* review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”).

35 U.S.C. § 324(a) (2012) (“Institution of post-grant review (a) THRESHOLD.—The Director may not authorize a post-grant review to be instituted unless the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.”).

⁸ 35 U.S.C. § 314(a) (2012).

⁹ 35 U.S.C. § 324(a) (2012). *See also*, Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,763 (Aug. 14, 2012) (“The Board expects that most petitions will raise issues of obviousness. In determining whether the subject matter of a claim would have been obvious over the prior art, the Board will review any objective evidence of nonobviousness proffered by the patent owner where appropriate.”).

¹⁰ In addition, the Office Patent Trial Practice Guide treats POPRs in IPRs and PGRs the same. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,764 (Aug. 14, 2012) (“The preliminary response may present evidence other than new

POPR is the only filing available to the Patent Owner prior to PTAB's decision to institute.

Objective evidence of nonobviousness may be raised by the Patent Owner in its POPR to convince PTAB that the petition should be denied, although the Patent Owner currently cannot generate new declarations or factual evidence for use in the POPR.¹¹ On Aug. 20, 2015, the United States Patent & Trademark Office (USPTO) released proposed rules that may change the use of new evidence in POPRs. The proposed rule showing the proposed amendment in italics reads:

§ 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 § 42.24.¹²

After institution, objective evidence of nonobviousness may be raised in the Patent Owner's Response (POR),¹³ this time with newly-generated declarations and additional factual evidence.

In IPRs so far, Patent Owners have experienced significant disappointment before PTAB with arguments based on objective evidence of nonobviousness. This article will examine the types of objective evidence that may be raised and examples of objective

testimonial evidence to demonstrate that no review should be instituted. §§ 42.107(c) and 42.207(c).")

¹⁰ 37 C.F.R. § 42.107(c) (2012); 37 C.F.R. § 42.207(c) (2012).

¹¹ *Id.*

¹² Same proposed change for 37 C.F.R. § 42.207 relating to POPRs in PGRs. Also, there is a proposed change to 37 C.F.R. § 42.108 to provide an opportunity for the Petitioner to respond to new testimony generated for the POPR prior to the institution decision:

37 C.F.R. § 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).

¹³ 35 U.S.C. § 316(a)(8) (2012); 35 U.S.C. § 326(a)(8) (2012).

evidence arguments in IPRs. We will also discuss why Patent Owners have experienced failure relying on objective evidence of nonobviousness, as well as suggest possible courses of action to obtain better results.

A. Same Types of Objective Evidence Can Be Raised in USPTO Proceeding or District Court Litigation or International Trade Commission Litigation

The types of objective evidence in any proceeding, whether judicial or administrative, are the same. Objective evidence of nonobviousness has been an integral part of a court's obviousness inquiry since at least *Graham v. John Deere*, 383 U.S. 1, 17-18 (U.S. 1966).¹⁴ The Manual of Patent Examining Procedure (MPEP) expressly relies on *Graham v. John Deere* in its Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103.¹⁵ MPEP § 2145 outlines examples of objective evidence: commercial success, long-felt but unsolved needs, failure of others, industry praise/skepticism, unexpected properties, unexpected results, and copying.

B. Objective, Real World Evidence May Be Strongest Possible Evidence of Nonobviousness

The Federal Circuit has acknowledged that objective evidence of nonobviousness may be the strongest evidence of nonobviousness.¹⁶ The MPEP instructs that examiners "should consider all rebuttal arguments and evidence presented by applicants [which] may include evidence of 'secondary considerations,' such as 'commercial success, long felt but unsolved needs, [and] failure of others.' *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 4459, 467."¹⁷ In fact, if present, such objective evidence must be considered fully and not merely for its

¹⁴ *Graham v. John Deere*, 383 U.S. 1, 17-18 (U.S. 1966) ("Under s 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.").

¹⁵ Manual of Patent Examining Procedure §2141 (2014).

¹⁶ *See Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (noting objective indicia "can be the most probative evidence of nonobviousness in the record, and enable[] the . . . court to avert the trap of hindsight.").

¹⁷ Manual of Patent Examining Procedure § 2145 (2014).

“knockdown” value, and the examiner must reweigh all evidence to determine whether the claims are nonobvious.¹⁸

C. When Can Objective Evidence Be Raised?

Objective evidence of nonobviousness may be submitted by the Patent Owner in the POPR if such evidence already exists, such as in the file history of the challenged patent or otherwise not “taken specifically for the purpose of the *inter partes* review.”¹⁹ Objective evidence of nonobviousness may also be submitted with the POR, whether or not the objective evidence is newly-generated.²⁰

1. Examples of Petitioner Pre-Emptively Raising in Petition to Try to Cut Off at the Pass the Effect of Any Such Evidence That Might Later Be Raised by the Patent Owner

a. *Conopco, Inc. v. Procter & Gamble Co.*, No. IPR2013-00505, -00510

In *Conopco, Inc. v. Procter & Gamble Co.*, No. IPR2013-00505, Petitioner raised objective evidence of nonobviousness in the Petition. After detailing all of its unpatentability arguments, the Petition closed on a section entitled “Objective Indicia of Nonobviousness,” and proceeded to challenge Patent Owner’s possible objective evidence of nonobviousness, in this case, unexpected results. Petitioner argued that any assertions of unexpected results must fail because the prior art discloses those same results; “[u]nexpected results must be “different in kind and not merely in degree from the results of the prior art.” citing *In re Aller*, 220 F.2d 454, 456 (C.C.P.A. 1955).²¹

Patent Owner responded in the POPR by indicating that it would submit objective evidence of nonobviousness in the form of

¹⁸ See *id.* (noting “Evidence pertaining to secondary considerations must be taken into account whenever present; however, it does not necessarily control the obviousness conclusion. . . . Office personnel should not evaluate rebuttal evidence for its ‘knockdown’ value against the *prima facie* case. . . . Rather, all evidence must be reweighed to determine whether the claims are nonobvious.”).

¹⁹ See 37 C.F.R. §§ 42.107 (2012); see also, *Anova Food, LLC v. Sandau*, No. IPR2013-00114, Paper 11, at 3 (P.T.A.B. June 25, 2013) (noting “The Board responded that 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.”).

²⁰ 35 U.S.C. §316(a)(8) (2012) and 35 U.S.C. §326(a)(8) (2012).

²¹ *Conopco, Inc. v. Procter & Gamble Co.*, No. IPR2013-00505, Paper 4 (P.T.A.B. Aug. 13, 2013).

unexpected results and commercial success if PTAB instituted an IPR on any obviousness ground of the Petition.²² Patent Owner also quoted the Examiner's Reasons for Allowance: "[t]he instant invention demonstrates an improvement over prior art formulations due to the surprising and beneficial results that are attained through these index criteria."²³

PTAB instituted trial on some of the challenged claims, but not all. It did not address the objective evidence issue in its institution decision.²⁴

Patent Owner proceeded to raise objective evidence in its POR, but it was not evidence of unexpected results as Petitioner had anticipated.²⁵ Instead, Patent Owner argued commercial success and long-felt but unmet need, supported by expert declarations prepared for the IPR, tipped the balance in favor of nonobviousness.²⁶ PTAB was not persuaded and held the instituted claims unpatentable.²⁷ In particular, PTAB found the expert declarations lacking in persuasive value and that Patent Owner failed to show sufficient nexus between the objective evidence and the claimed invention.²⁸

The same petitioner used the pre-emptive tactic again in the IPR2013-00510 Petition: "P&G may attempt to avoid a finding of obviousness by asserting that the shampoo compositions claimed in the '155 patent achieve unexpected results or by arguing the criticality of the recited ranges for the components of the shampoo compositions."²⁹ Patent Owner again responded in the POPR by indicating that it would submit objective evidence of nonobviousness in the form of unexpected results and commercial success if PTAB instituted an IPR on any obviousness ground of the Petition.³⁰ PTAB denied institution on all challenged claims, but did not address the

²² Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 8, at 50-51 (P.T.A.B. Nov. 15, 2013).

²³ *Id.* at 37.

²⁴ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 9 (P.T.A.B. Feb. 12, 2014).

²⁵ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 34 (P.T.A.B. July 25, 2014).

²⁶ *Id.* at 57-60.

²⁷ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 69 (P.T.A.B. Feb. 10, 2015).

²⁸ *Id.* at 25-28.

²⁹ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00510, Paper 2, at 59 (P.T.A.B. Aug. 14, 2013).

³⁰ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00510, Paper 7, at 45-46 (P.T.A.B. Nov. 18, 2013).

objective evidence issue.³¹

b. *Actavis, Inc. v. Research Corporation Technologies, Inc.*,
No. IPR2014-01126

Another petitioner employed a preemptive strike in *Actavis, Inc. v. Research Corporation Technologies, Inc.*, No. IPR2014-01126, closing the petition by stating that although the Patent Owner may try to argue unexpected properties, long-felt but unmet need, and copying, it would “preliminarily address these alleged secondary considerations[.]”³² According to Petitioner, the claimed compound did not have unexpected properties (“the R stereoisomer’s superior potency was not only expected—it was known”³³), there was no evidence of a long-felt but unmet need for an effective method of treating patients suffering from partial-onset seizures (“there were ‘many’ ‘well known anticonvulsants’ . . . ‘useful in the control of generalized seizures and all forms of partial seizures.’”³⁴), the fact that no one else had made and commercialized the claimed compound “is irrelevant,” and copying by generic producers is an FDA requirement, not proof of nonobviousness.³⁵

Patent Owner included arguments in its POPR as to why Petitioner’s assertions were incorrect, and noted that if an IPR was instituted on the obviousness ground asserted, it would present objective evidence of nonobviousness in its POR.³⁶ It argued that the properties of the racemate were not known and Petitioner failed to consider the absence of chronic toxicity.³⁷ Furthermore, there was a long-felt but “unmet need for antiepileptic treatments that were both effective and safe over both the short term *and* the long term.”³⁸ At the time of the invention, no one else thought that lacosamide was worth investigating.³⁹

PTAB denied institution because the Petitioner’s reference on

³¹ *Conopco, Inc. v. Procter & Gamble Co.*, No. IPR2013-00510, Paper 9 (P.T.A.B. Feb. 12, 2014).

³² *Actavis, Inc. v. Research Corporation Technologies, Inc.*, No. IPR2014-01126, Paper 6, at 50 (P.T.A.B. July 10, 2014).

³³ *Id.*

³⁴ *Id.* at 52.

³⁵ *Id.* at 52-53.

³⁶ *Actavis, Inc. v. Research Corporation Technologies, Inc.*, No. IPR2014-01126, Paper 19, at 56-57 (P.T.A.B. Oct. 23, 2014).

³⁷ *Id.* at 57.

³⁸ *Id.* at 58.

³⁹ *Id.* at 59.

which its unpatentability grounds were based was not prior art.⁴⁰ The objective evidence issue was not discussed.⁴¹

*c. Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.,
No. IPR2013-00247*

Petitioner in *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247, somewhat cursorily, stated that:

the patent owner may attempt to argue secondary considerations of nonobviousness, such as commercial success. However, there is no nexus between the patent claims and the success of the product marketed under the '105 Patent. So secondary considerations do not support patentability, and clearly do not overcome the strong showing of obviousness made herein.⁴²

Patent Owner answered the assertion in its POPR, noting that Petitioner was ignoring that the district court in the related litigation found the objective evidence supported nonobviousness.⁴³ Patent Owner provided the district court evidence of commercial success and copying as exhibits to its POPR.⁴⁴

PTAB instituted trial on all challenged claims on two of the 13 asserted grounds. It did not discuss the objective evidence of nonobviousness.⁴⁵

*d. St. Jude Med. v. Board of Regents of Univ. of Michigan,
No. IPR2013-00041*

In *St. Jude Med. v. Board of Regents of Univ. of Michigan*, No. IPR2013-00041, Petitioner argued in the Petition that, based on the

⁴⁰ *Actavis, Inc. v. Research Corporation Technologies, Inc.*, No. IPR2014-01126, Paper 21 (P.T.A.B. Jan. 9, 2015).

⁴¹ *Id.*

⁴² *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247, Paper 1, at 10 (P.T.A.B. April 11, 2013).

⁴³ *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247, Paper 10, at 1-2 (P.T.A.B. July 17, 2013).

⁴⁴ *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247, Paper 10 (P.T.A.B. July 17, 2013); *see also Amneal PharmaceuticalS, LLC v. Supernus Pharmaceuticals, LLC*, No. IPR2013-00368, Paper 6 (P.T.A.B. Sept. 23, 2013) (where Patent Owner submitted district court records as exhibits attached to the POPR).

⁴⁵ *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247, Paper 10 (P.T.A.B. July 17, 2013).

prior art asserted as the grounds for unpatentability, Patent Owner would not be able to show that any superior results were unexpected or that there was any commercial success or long-felt but unmet need tied to the merits of the claim invention.⁴⁶

Patent Owner did not file a POPR, and trial was instituted on all challenged claims based on 2 of the 7 asserted grounds.⁴⁷ No mention was made in the POPR of the suggested objective evidence the Patent Owner might raise.

After institution, Patent Owner filed a response that is confidential under a protective order. The Petitioner's Reply, however, indicates that Patent Owner argued commercial success and long-felt but unmet need.⁴⁸

PTAB found all instituted claims unpatentable.⁴⁹ PTAB discussed the objective evidence of nonobviousness, but found it unpersuasive. In particular, PTAB found that Michigan failed to sufficiently establish "that the St. Jude products enjoyed commercial success, or a nexus between any success and the invention claimed[.]"⁵⁰ In addition, arguments for long-felt but unmet need were undermined by a showing on the record that the need, if present, was met prior to the claimed invention.⁵¹

e. Scotts Company LLC v. Encap, LLC, No. IPR2013-00491

Scotts preemptively argued that Encap's prosecution evidence of long-felt need and copying was insufficient because at best the claims were broader than the product Encap asserted was copied and filled the long-felt need. According to Scotts, the "Examiner did not rely on these arguments in allowing the application."⁵²

⁴⁶ St. Jude Med. v. Board of Regents of Univ. of Michigan, No. IPR2013-00041, Paper 1, at 58-59 (P.T.A.B. Nov. 9, 2012).

⁴⁷ St. Jude Med. v. Board of Regents of Univ. of Michigan, No. IPR2013-00041, Paper 12 (P.T.A.B. May 2, 2013). There is a POPR is listed after the Final Written Decision and indicated as entered on June 16, 2015, signed and served on Aug. 2, 2013; conversely, the institution decision clearly states, "[t]he Patent Owner, The Board of Regents of the University of Michigan ('University of Michigan'), did not file a preliminary response opposing institution of review." *Id.* at 2; St. Jude Med. v. Board of Regents of Univ. of Michigan, No. IPR2013-00041, Paper 1072, at 48 (P.T.A.B. June 16, 2014).

⁴⁸ St. Jude Med. v. Board of Regents of Univ. of Michigan, No. IPR2013-00041, Paper 29, at 11-14 (P.T.A.B. Nov. 1, 2013).

⁴⁹ St. Jude Med. v. Board of Regents of Univ. of Michigan, No. IPR2013-00041, Paper 69 (P.T.A.B. May 1, 2014).

⁵⁰ *Id.* at 25.

⁵¹ *Id.* at 28.

⁵² Scotts Company LLC v. Encap, LLC, No. IPR2013-00491, Paper 1, at 18 n. 8 (P.T.A.B. Aug. 2, 2013).

In response, Encap included objective evidence of nonobviousness in its POPR as additional reasons why *inter partes* review should be denied.⁵³ First, Encap noted that the Notice of Allowance said nothing about whether or not the Examiner relied on the secondary consideration arguments.⁵⁴ In addition, marketing literature, a Scotts video, and Scotts' failure to independently develop a product with a color indicator were all evidence of a long-felt but unmet need in the industry for a product that addressed the need to know when and how long to water.⁵⁵

According to Encap, Scotts copied Encap after Encap confidentially disclosed the color indicator technology in June 2002. Scotts was then successful at convincing the market that it was the innovator of this technology.⁵⁶

PTAB denied institution on all challenged claims without addressing the objective evidence of nonobviousness.⁵⁷

*f. Mylan Pharms. Inc. v. Gilead Sciences, Inc.,
No. IPR2014-00888*

Mylan's Petition addressed objective evidence of nonobviousness raised by Gilead in the reexamination of the patent claims at issue.⁵⁸ According to Mylan, Gilead's evidence of surprising and unexpected results, long-felt need, and commercial success did not outweigh the evidence of obviousness.⁵⁹ The prior art showed that the allegedly surprising results were known, and there was no nexus between the commercial success or long-felt need and the claimed compound (as opposed to the claimed compound in combination therapies).⁶⁰

Gilead countered in its POPR by both arguing that the examiner correctly evaluated the objective evidence of nonobviousness in the

⁵³ Scotts Company LLC v. Encap, LLC, No. IPR2013-00491, Paper 8, at 40-47 (P.T.A.B. Nov. 8, 2013).

⁵⁴ *Id.* at 40.

⁵⁵ *Id.* at 40-47.

⁵⁶ *Id.* at 44-47.

⁵⁷ Scotts Company LLC v. Encap, LLC, No. IPR2013-00491, Paper 9 (P.T.A.B. Feb. 5, 2014).

⁵⁸ A reexamination certificate was issued in 2008. *See also* Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00888, Paper 1, at 4 (P.T.A.B. Jun. 3, 2014); *see also*, Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00885 (P.T.A.B. Dec. 9, 2014); Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00886 (P.T.A.B. Dec. 17, 2014); Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00887 (P.T.A.B. Dec. 9, 2014).

⁵⁹ Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00888, Paper 4, at 49 (P.T.A.B. June 24, 2014).

⁶⁰ *Id.* at 49-52.

reexamination and the details supporting why the objective evidence of nonobviousness was persuasive.⁶¹ For example, the commercial success evidence of sales figures related to a drug in which the claimed compound was the sole active ingredient.⁶²

PTAB denied institution on all challenged claims without addressing the objective evidence of nonobviousness.⁶³

g. Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00720

The petitioner in *Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00720*, concluded its obviousness assertions in its Petition with a section noting that the Patent Owner did not submit any objective evidence of nonobviousness during prosecution.⁶⁴ Moreover, the objective evidence of nonobviousness submitted during prosecution of the parent application was insufficient in relation to the claims at issue because that evidence was not connected to the claim limitation at issue: “at least [a] two week period.”⁶⁵ A declaration supporting unexpected results was filed in the parent application, but there is nothing in the prosecution history indicating that the examiner relied on the declaration as a factor for issuing the parent claims.⁶⁶

Acorda filed a POPR, arguing that Petitioner bore the burden of showing invalidity and failed to counter Patent Owner’s evidence of commercial success, long-felt but unsolved needs, and failure of others, that was also submitted during the prosecution. Patent Owner attached as exhibits several declarations submitted during prosecution addressing objective evidence.⁶⁷

PTAB denied institution on all challenged claims without addressing the issue of objective evidence of nonobviousness.⁶⁸

⁶¹ *Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00888*, Paper 8, at 52-56 (P.T.A.B. Sept. 18, 2014).

⁶² *Id.* at 54-55.

⁶³ *Mylan Pharms. Inc. v. Gilead Sciences, Inc., No. IPR2014-00888*, Paper 15 (P.T.A.B. Dec. 9, 2014).

⁶⁴ *Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00720*, Paper 7, at 53 (P.T.A.B. March 5, 2015).

⁶⁵ *Id.* at 54.

⁶⁶ *Id.* at 55.

⁶⁷ *Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00720*, Paper 10 (P.T.A.B. May 26, 2015).

⁶⁸ *Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc., No. IPR2015-00720*, Paper 15 (P.T.A.B. Aug. 24, 2015).

2. *Examples of Patent Owner Raising Objective Evidence in Patent Owner Preliminary Response*

a. *Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073*

In its POPR, NuVasive argued, *inter alia*, that Medtronic's petition should be denied because it "failed to consider or even address objective indicia of nonobviousness."⁶⁹ Objective evidence which, according to NuVasive, Medtronic knew about, included commercial success, initial disbelief by experts, eventual praise by competitors, and copying by those same competitors. As evidence of Medtronic's knowledge, NuVasive submitted a Medtronic presentation showing "a chart of NuVasive's skyrocketing sales."⁷⁰ NuVasive argued that the Medtronic itself expressed initial skepticism and eventual praise and copying.⁷¹

PTAB instituted a trial on 7 of the 9 challenged claims.⁷² In doing so, it noted that it was not persuaded by the objective evidence presented by Patent Owner because there was no "clear or specific evidence explaining what . . . 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."⁷³

In the POR, the Patent Owner used 27 pages to discuss objective evidence of nonobviousness, including long-felt but unmet need, initial skepticism, praise and recognition by industry, superior results, commercial success, and copying.⁷⁴ Patent Owner submitted supporting expert declarations. Patent Owner also alleged that Petitioner knew of this evidence (again, based on Petitioner's internal documents), and that Petitioner withheld such evidence from its expert.⁷⁵

In its Reply, Petitioner argued that Patent Owner's evidence was faulty because it did not relate to claimed features but rather several

⁶⁹ *Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073, Paper 10, at 31 (P.T.A.B. Jan. 31, 2014).*

⁷⁰ *Id.* at 32.

⁷¹ *Id.* at 49-50.

⁷² *Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073, Paper 14 (P.T.A.B. April 8, 2014).*

⁷³ *Id.* at 19.

⁷⁴ *Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073, Paper 26 (P.T.A.B. July 8, 2014).* This is one of the few cases where the Patent Owner argued objective evidence of nonobviousness before substantively countering the obviousness positions of the Petitioner.

⁷⁵ *Id.* at 2 and 34.

unclaimed features.⁷⁶

PTAB issued a final written decision holding the instituted claims unpatentable.⁷⁷ PTAB rejected the objective evidence of nonobviousness for insufficient nexus to the claimed invention:

In the instant case, Petitioner persuades us that the evidence of secondary considerations is not entitled to substantial weight, because Patent Owner has not established a sufficient nexus between the claimed subject matter and that evidence. Petitioner persuades us also that the evidence of secondary considerations is not reasonably commensurate in scope with the claimed subject matter.⁷⁸

b. Phigenix, Inc. v. Genentech, Inc., No. IPR2014-00842

According to Patent Owner Genentech, Phigenix's Petition should fail because, among other things, it (and the supporting expert declaration) failed to "challenge the merits of Patent Owner's secondary consideration evidence" raised during prosecution.⁷⁹ The prosecution history included data submitted to the examiner showing that the claimed methods for administering a trastuzumab-maytansinoid conjugate yielded unexpected results. In a related application, there was additional further evidence of unexpected results. The Patent Owner provided a detailed discussion of the unexpected results and submitted the prosecution declaration as a supporting exhibit.⁸⁰

Patent Owner also argued that Phigenix failed to address praise by others, including by Petitioner's expert prior to his retention for this case.⁸¹

PTAB denied the Petition with respect to all challenged claims,

⁷⁶ Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073, Paper 31, at 4 (P.T.A.B. Oct. 3, 2014), citing *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1346-47 (Fed. Cir. 2013).

⁷⁷ Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073, Paper 48 (P.T.A.B. Apr. 3, 2015).

⁷⁸ Medtronic, Inc. v. Nuvasive, Inc., No. IPR2014-00073, Paper 48, at 22 (P.T.A.B. Apr. 3, 2015).

⁷⁹ Phigenix, Inc. v. Genentech, Inc., No. IPR2014-00842, Paper 9, at 17 (P.T.A.B. Sept. 10, 2014).

⁸⁰ *Id.* at 18-21.

⁸¹ *Id.* at 21-22.

but did not discuss the objective evidence of nonobviousness.⁸²

3. *Examples of Patent Owner Raising Objective Evidence in Patent Owner Response*

a. *Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505*

The Patent Owner presented and argued objective evidence of nonobviousness in its Patent Owner Response (POR), including commercial success (evidence of sales of commercial embodiment of invention) and long-felt but unmet need (“prior art anti-dandruff conditioning shampoos existed but did not provide consumers with a superior combination of anti-dandruff efficacy and conditioning performance”).⁸³ In its Reply, Petitioner noted the absence of unexpected results, and attacked Patent Owner’s objective evidence as conclusory, unsupported, and lacking a nexus with the claimed invention.⁸⁴

In the Final Written Decision, PTAB held that Patent Owner’s objective evidence of nonobviousness did not overcome the strong showing of obviousness.⁸⁵ PTAB appeared to find Patent Owner’s assertions insufficiently supported:

Patent Owner avers, without further elaboration, that the Head & Shoulders® shampoo products “embody the claims of the ‘569 patent” and, further, “is due to the claimed features of the ‘569 patent.” ...The evidence upon which Patent Owner relies, but does not discuss in any detail in its brief, consists of a single sentence in the declaration of Dr. Lochhead: “Based on my training and nearly 40 years of experience, it is my opinion that the commercial success of [Patent Owner’s] Head & Shoulders® products that embody

⁸² Phigenix, Inc. v. Genentech, Inc., No. IPR2014-00842, Paper 10 (P.T.A.B. Dec. 9, 2014).

⁸³ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 34, at 57-60 (P.T.A.B. July 25, 2014).

⁸⁴ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 48, at 12-15 (P.T.A.B. Sept. 22, 2014).

⁸⁵ Conopco, Inc. v. Procter & Gamble Co., No. IPR2013-00505, Paper 69, at 27-28 (P.T.A.B. Feb. 10, 2015) (“[E]vidence of unexpected results and other secondary considerations will not necessarily overcome a strong prima facie showing of obviousness” quoting *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1009 (Fed. Cir. 2009)).

the claims of the '569 patent is due to the claimed features of the '569 patent, which represent the consumer desired properties of the superior combination of the anti-dandruff efficacy and conditioning performance.” We are not persuaded that Dr. Lochhead’s “training and nearly 40 years of experience” relate sufficiently to shampoo formulations; therefore, we find his testimony on that point is entitled to little weight.⁸⁶

According to PTAB, there was insufficient nexus shown between the claimed invention and the alleged commercial success of the Head & Shoulders® shampoo products.⁸⁷ Specifically, Patent Owner did not “explain adequately how the Head & Shoulders® products allegedly embody the challenged claims; nor does Patent Owner explain in any detail why it was the unique characteristics of the claimed shampoo composition that drove sales.”⁸⁸ There was similarly an insufficient showing that the Head & Shoulders® shampoo products embody the claimed invention and that those products satisfied a long-felt, but unmet need, among consumers.⁸⁹

PTAB also objected to Patent Owner presenting information only in a declaration without sufficient discussion in the POR:

We will not play archeologist with the record to discover evidentiary support for bare attorney argument made in such a response. *Id.* We decline to consider, moreover, information presented in a supporting declaration, but not discussed sufficiently in Patent Owner’s Response.⁹⁰

b. *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*,
No. IPR2013-00247

Patent Owner raised objective evidence of nonobviousness in its POR, specifically evidence of copying by the Petitioner.⁹¹ The district

⁸⁶ *Id.* at 26.

⁸⁷ *Id.*

⁸⁸ *Id.* at 26-27.

⁸⁹ *Id.* at 28.

⁹⁰ *Id.* at 27. See also 37 C.F.R. § 42.6(a)(3): “Incorporation by reference; combined documents. Arguments must not be incorporated by reference from one document into another document. Combined motions, oppositions, replies, or other combined documents are not permitted.”

⁹¹ *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247,

court had found this to be “strong” evidence of nonobviousness.⁹² Petitioner’s Reply only commented that copying was necessary for its product to work with Patent Owner’s machine, and anyway, “evidence of copying alone is insufficient.”⁹³

PTAB agreed with the Petitioner that the claims were unpatentable for obviousness and the objective evidence was insufficient because Patent Owner did not adequately show a “nexus” between the copying and the claimed subject matter.⁹⁴ “A nexus is required in order to establish that the evidence relied upon traces its basis to the claimed subject matter, not to another source.”⁹⁵ In particular, PTAB found that Pharmatech’s copying was “motivated by a desire to make Pharmatech’s test strips compatible with LifeScan’s machine”⁹⁶ and Patent Owner did “not show or explain credibly how this reason for copying relates to the claimed subject matter, as opposed to unclaimed features, or to considerations unrelated to the invention.”⁹⁷

*c. Permobil, Inc. v. Pride Mobility Products Corp.,
No. IPR2013-00407*

Pride Mobility raised objective evidence of nonobviousness for the first time in its POR by way of a declaration by the chairman of the company describing competitor copying and commercial success.⁹⁸ The evidence of copying was shown by a timeline comparing when the Patent Owner’s product, a 6-wheel wheelchair that had a low pivot axis, was introduced against the introduction of a competitive product by three other manufacturers starting about 2 years later.⁹⁹ Evidence of commercial success was shown through increase in sales and market share after the commercialization of the claimed invention.¹⁰⁰ The Patent Owner pointed out that the sales data were provided broken down by particular models so that it was clear that the

Paper 16, at 46-48 (P.T.A.B. Nov. 15, 2013).

⁹² *Id.* at 48.

⁹³ Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd., No. IPR2013-00247, Paper 17, at 3-4 (P.T.A.B. Feb. 18, 2014).

⁹⁴ Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd., No. IPR2013-00247, Paper 27, at 22 (P.T.A.B. Aug. 6, 2014).

⁹⁵ *Id.* at 20-21.

⁹⁶ *Id.* at 21.

⁹⁷ *Id.*

⁹⁸ Permobil, Inc. v. Pride Mobility Products Corp., No. IPR2013-00407, Paper 23, at 53-55 (P.T.A.B. March 20, 2014).

⁹⁹ *Id.* at 54.

¹⁰⁰ *Id.* at 56-57.

patented invention was the reason for the commercial success.¹⁰¹

Petitioner argued against Patent Owner’s evidence of copying because it did not show “actual efforts to replicate a specific product.”¹⁰² It also considered the evidence of commercial success insufficient because no nexus was shown: “none of the key factors affecting market-share changes during the relevant time period (pricing, promotion, and reimbursement) are related to the structural feature of a wheelchair’s front-arm pivot location.”¹⁰³

PTAB held all the challenged claims unpatentable.¹⁰⁴ In part, this was because it agreed with Petitioner that Patent Owner did not provide sufficient evidence of copying—particularly “evidence of actual efforts to replicate a specific product.”¹⁰⁵ “None of the evidence submitted by Patent Owner demonstrated that Invacare, Sunrise Medical, or Petitioner was aware of the ‘598 patent prior to developing its product[.]”¹⁰⁶ PTAB also agreed that Patent Owner did not establish sufficient nexus that the increased market share was attributable to the claimed invention; evidence of increased sales did not “establish sufficiently that customers were buying the Q600 and Q6000 because of their low-pivot.”¹⁰⁷

d. *Captioncall, LLC v. Ultratec, Inc., No. IPR2013-00543*

Ultratec raised objective evidence of nonobviousness at the end of its POR.¹⁰⁸ Referring to the evidence as “strong” and “directly attributable to the claimed invention,” it directed PTAB to two supporting expert declarations describing substantial industry praise, long-felt but unresolved need, commercial success of the products and services embodying the invention, and the failure of others.¹⁰⁹ A third supporting expert declaration “explain[ed], on a feature by feature basis, the nexus between those secondary considerations and the claimed design.”¹¹⁰ No further analysis or argument was made.

¹⁰¹ *Id.* at 57.

¹⁰² *Permobil, Inc. v. Pride Mobility Products Corp., No. IPR2013-00407, Paper 26, at 14 (P.T.A.B. May 20, 2014).*

¹⁰³ *Id.* at 15.

¹⁰⁴ *Permobil, Inc. v. Pride Mobility Products Corp., No. IPR2013-00407, Paper 53 (P.T.A.B. Dec. 31, 2014).*

¹⁰⁵ *Id.* at 21.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 22.

¹⁰⁸ *Captioncall, LLC v. Ultratec, Inc., No. IPR2013-00543, Paper 20, at 55 (P.T.A.B. May 12, 2014) (stating Ultratec did not submit a POPR).*

¹⁰⁹ *Id.* at 56.

¹¹⁰ *Id.* at 56-57.

In its Reply, Petitioner attacked the evidence, but did not attack Patent Owner's tactic of effectively "incorporating by reference" the expert declarations.¹¹¹ According to Petitioner, there was "no evidence that skilled workers, with knowledge of the prior art, tried to solve any of the recounted problems and failed."¹¹² The praise was not from those of skill in the art, nothing supported the assertions of failure by others or copying, and none of the evidence showed sufficient nexus to the claimed invention.¹¹³

PTAB held all the instituted claims unpatentable.¹¹⁴ In discussing the objective evidence, PTAB faulted Patent Owner for only providing a list of secondary considerations evidence, without substantive argument or explanation.¹¹⁵ "This does not provide sufficient analysis for us to determine whether Patent Owner has provided adequate evidence of secondary considerations and a nexus between any such evidence and the merits of the claimed invention."¹¹⁶ PTAB also found Patent Owner's experts' declarations conclusory and unsupported.¹¹⁷ PTAB found that Petitioner's showing of obviousness was not outweighed by Patent Owner's asserted objective evidence.

*e. Ariosa Diagnostics v. Verinata Health, Inc.,
No. IPR2013-00276*

Verinata cited to Petitioner's past press releases and website announcements about Petitioner's (allegedly directly infringing) product as objective evidence of praise in the industry showing nonobviousness.¹¹⁸

Petitioner's Reply noted that Verinata provided only evidence of praise for the Ariosa product, and no evidence that the Ariosa product falls within the claims.¹¹⁹

¹¹¹ Captioncall, LLC v. Ultratec, Inc., No. IPR2013-00543, Paper 33, at 13-15 (P.T.A.B. July 7, 2014).

¹¹² *Id.* at 14.

¹¹³ *Id.* at 14-15.

¹¹⁴ Captioncall, LLC v. Ultratec, Inc., No. IPR2013-00543, Paper 66 (P.T.A.B. March 3, 2015).

¹¹⁵ *Id.* at 26.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 27-28.

¹¹⁸ Ariosa Diagnostics v. Verinata Health, Inc., No. IPR2013-00276, Paper 20, at 56-57 (P.T.A.B. Jan. 16, 2014) (noting the concurrent patent infringement litigation); Verinata Health, Inc. v. Ariosa Diagnostics, Inc., No. 3:12-cv-05501-SI, 2014 WL 7205108 (N.D. Cal. Dec. 17, 2014).

¹¹⁹ Ariosa Diagnostics v. Verinata Health, Inc., No. IPR2013-00276, Paper 26, at

PTAB's Final Written Decision held that Petitioner did not show that the challenged claims were unpatentable, but it was based on Patent Owner's substantive patentability arguments, not the objective evidence of nonobviousness.¹²⁰

4. *No PGR Decisions on Objective Evidence Yet*

As of Aug. 25, 2015, 13 post-grant review (PGR) petitions have been filed; three have been instituted (PGR2015-00003, PGR2015-00005, and PGR2015-00009).¹²¹ Two were settled before a decision on institution. In PGR2015-0003 and -0005, PTAB authorized Patent Owner to file a motion requesting additional discovery on "certain secondary indicia of non-obviousness," which it did.¹²² PTAB has not yet issued a decision on the motion (as of Aug. 25, 2015). In PGR2015-00009, Patent Owner waived the POPR.¹²³

II. AN ISSUE FOR PATENT OWNERS, WHETHER FOR INSTITUTION OR AT TRIAL, HAS BEEN WHETHER THE OBJECTIVE EVIDENCE, EVEN IF IMPRESSIVE, IS LINKED TO THE MERITS OF THE CLAIMED INVENTION

As can be seen from the above description of several cases, Patent Owners are not having much success with objective evidence persuading PTAB to either deny a petition or uphold the instituted claims. So far, no PTAB final written decision has articulated objective evidence of nonobviousness as its basis for finding in favor of the Patent Owner. One institution denial has,¹²⁴ which will be discussed in detail in Section III. An additional partial Patent Owner success will be discussed in Section IV.¹²⁵

12-13 (P.T.A.B. April 3, 2014).

¹²⁰ *Ariosa Diagnostics v. Verinata Health, Inc.*, No. IPR2013-00276, Paper 43 (P.T.A.B. Oct. 23, 2014).

¹²¹ *Larose Industries, LLC v. Choon's Design Inc.*, No. PGR2014-00008, filed Aug. 5, 2014; *Accord Healthcare, Inc. v. Helsinn Healthcare S.A. and Roche Palo Alto LLC*, No. PGR2014-00010, filed Sept. 2, 2014 (showing one of the co-authors represented Helsinn Healthcare); *American Simmental Assn. v. Leachman Cattle of Colorado, LLC*, No. PGR2015-00003, filed Nov. 21, 2014; *American Simmental Assn. v. Leachman Cattle of Colorado, LLC*, No. PGR2015-00005, filed Jan. 30, 2015.

¹²² *American Simmental Assn. v. Leachman Cattle of Colorado, LLC*, No. PGR2015-00003, Paper 28 (P.T.A.B. Aug. 12, 2015).

¹²³ *See Netsirv v. Boxbee, Inc.*, No. PGR2015-00009, Paper 8 (P.T.A.B. May 6, 2015).

¹²⁴ *See Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division Of Varco, L.P.*, No. IPR2013-00265 (P.T.A.B. Dec. 12, 1995).

¹²⁵ *Lupin Ltd. v. Vertex Pharms. Inc.*, No. IPR2015-00405, Paper 13 (P.T.A.B. July 9, 2015) (showing IPR instituted, but on fewer than all challenged claims).

If objective evidence of nonobviousness is “the most probative and cogent evidence of nonobviousness” and a “powerful tool[] for courts faced with the difficult task of avoiding subconscious reliance on hindsight,”¹²⁶ why aren’t Patent Owners winning with objective evidence? Perhaps, in cases where claims have survived a challenge, PTAB has made that decision based on no prima facie case of obviousness. In that situation, PTAB may well feel that objective evidence of obviousness does not need to be articulated as a basis for holding in favor of the Patent Owner.

So far, when PTAB does mention objective evidence, it tends to show that PTAB is underwhelmed by the objective evidence of nonobviousness presented, particularly focusing on a lack of nexus shown between the objective evidence and the merits of the claimed invention. For example, in *Toyota Motor Corp. v. Leroy G. Hagenbuch*, No. IPR2013-00638, PTAB found the objective evidence arguments relating to commercial success significantly lacking:

Patent Owner simply cites to the sales price of Toyota’s subscription service as commercial success. ...That does not establish “commercial success” as objective evidence of nonobviousness. Patent Owner does not provide information regarding sales volume or market share information as compared to providers of competing products. ...Furthermore, Patent Owner has not even attempted to show a nexus between any sales and the merits of the claimed invention. Although Patent Owner references several claim limitations, there is no explanation as to how these limitations are related to the alleged commercial success of the claimed invention other than simply alleging that the limitations are present[.]¹²⁷

In *Zodiac Pool Systems, Inc. v. Aqua Products, Inc.*, No. IPR2013-00159, the same complaint was made about tying the limitations to the asserted long-felt but unmet need:

Patent Owner fails to demonstrate that the recitations of the challenged claims solve the other problems

¹²⁶ *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012); *see also* *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325 (Fed. Cir. 2013).

¹²⁷ *Toyota Motor Corp. v. Leroy G. Hagenbuch*, No. IPR2013-00638, Paper 42, at 23 (P.T.A.B. Jan. 30, 2015).

which Patent Owner contends are the subject of long-felt need. . . . Consequently, to the extent that Patent Owner may have shown that these problems represent a long-felt need, Patent Owner fails to show a nexus between that need and limitations recited in the challenged claims of the '183 Patent.¹²⁸

Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd., No. IPR2013-00247, provides an example with respect to copying:

Because LifeScan has not shown nexus convincingly, the objective evidence does not persuade us that the apparent copying of its test strips can be traced to the claimed subject matter.¹²⁹

Failure to tie the objective evidence to the merits of the claimed invention seems to be a major reason why Patent Owners have been disappointed by reliance on such evidence.¹³⁰

PTAB is consistently citing to Federal Circuit cases for the standard of nexus that is required for objective evidence of nonobviousness to be considered persuasive. For example:

[A]s the Federal Circuit held in *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006), “[e]vidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.” *Id.* ...In order to establish a proper nexus, the patent owner must offer “proof that the sales were a direct result of the unique characteristics of the claimed invention -- as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter.” *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996) (citation omitted) (concluding that the patentee failed to establish nexus). In *In re DBC*,

¹²⁸ *Zodiac Pool Systems, Inc. v. Aqua Products, Inc.*, No. IPR2013-00159, Paper 71, at 36 (P.T.A.B. Aug. 22, 2014)

¹²⁹ *Pharmatech Solutions, Inc. v. Lifescan Scotland, Ltd.*, No. IPR2013-00247, Paper 27, at 22 (P.T.A.B. Aug. 6, 2014).

¹³⁰ See *Cardiocom, LLC v. Robert Bosch Healthcare Systems, Inc.*, No. IPR2013-00468, Paper 72 (P.T.A.B. Jan. 27, 2015) (explaining PTAB found nexus lacking between each of evidence of commercial success, long-felt need, industry praise, teaching away by others, and copying).

545 F.3d 1373 (Fed. Cir. 2008), the Federal Circuit observed that “[Patentee] has done little more than submit evidence of sales,” concluding that “[h]owever substantial those sales, that evidence does not reveal in any way that the driving force behind those sales was the claimed [invention].” *Id.* at 1384 (Emphasis added).

Where, as here, the patent is said to cover a feature or component of a product, the patent owner has the additional burden of showing that the commercial success derives from the feature. *Tokai Corp. v. Easton Enters.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011). Further, especially where the feature is found in the product of another, there must be proof that it falls within the claims. E.g., *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (infringer’s counsel stated at trial that the patent had been copied); *Hughes Tool Co. v. Dresser Industries, Inc.*, 816 F.2d 1549, 1552 (Fed. Cir. 1987) (patented O-ring seal copied by defendant).¹³¹

These are familiar standards to patent practitioners.

A challenge for Patent Owners facing IPRs and PGRs to adequately address objective evidence arguments is the page limit on POPRs and PORs. In addition, the current restriction on no declaration testimony specifically generated for the IPR with the POPR is a challenge for Patent Owners.¹³² Furthermore, PTAB has

¹³¹ See *Microsoft Corp. v. Proxyconn, Inc.*, No. IPR2012-00026, Paper 32, at 4-5 (P.T.A.B. March 8, 2013) (Denying Proxyconn’s motion for additional discovery to obtain evidence of “secondary considerations of non-obviousness.” In authorizing the motion, PTAB had expressly ordered Patent Owner to address nexus: “Patent Owner’s motion will specifically identify the information sought and address the relevance of that information, *including the nexus between the information sought and the allegation of commercial success* (Emphasis added).” (Emphasis in original). See also *MasterImage 3D Asia, LLC v. RealD, Inc.*, No. IPR2015-00035, Paper 28, at 3 (P.T.A.B. June 23, 2015) (denying Patent Owner’s request for authorization to file a motion for additional discovery: “allegations that Petitioner may have discussed Patent Owner’s product does not, in and of themselves, reflect more than a “mere possibility” or “mere allegation that something useful [to the proceeding] will be found” on the issue of copying With respect to commercial success, Patent Owner has not presented a threshold showing of nexus with respect to the claims”).

¹³² 37 C.F.R. § 42.107(3) (2014); 37 C.F.R. § 42.207(3) (2014) (explaining on Aug. 20, 2015, the United States Patent & Trademark Office (USPTO) released proposed rules that may change the use of new evidence in POPRs).

made it clear that assertions made only in declarations and not developed in the attorney argument will not be considered.¹³³

This means that the Patent Owner possibly faces a difficult decision as to how many pages to devote to addressing the asserted unpatentability grounds and how many pages to devote to objective evidence of nonobviousness and the nexus between that evidence and the merits of the claimed invention.

III. MAKING THE NECESSARY LINK (NEXUS) BETWEEN OBJECTIVE EVIDENCE OF NONOBVIOUSNESS AND THE CLAIMED INVENTION

PTAB's instructions are clear: "To show how commercial success supports nonobviousness, 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."¹³⁴ This "nexus" between the evidence and the claimed invention "is a legally and factually sufficient connection."¹³⁵

Looking to the Federal Circuit case law, a few more guiding principles can be found:

If the feature that created the commercial success was known in the prior art, the success is not pertinent to the issue of obviousness.¹³⁶

Information solely on numbers of units sold is insufficient to establish commercial success.¹³⁷

[S]elf-referential commendation fall[s] well short of demonstrating true industry praise.¹³⁸

¹³³ *Conopco, Inc. v. Procter & Gamble Co.*, No. IPR2013-00505, Paper 69, at 27 (P.T.A.B. Feb. 10, 2015) ("We decline to consider, moreover, information presented in a supporting declaration, but not discussed sufficiently in Patent Owner's Response."); 37 C.F.R. § 42.6(a)(3) (2014).

¹³⁴ *Toyota Motor Corp. v. Leroy G. Hagenbuch*, No. IPR2013-00638, Paper 42, at 24 (P.T.A.B. Jan. 30, 2015).

¹³⁵ *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988).

¹³⁶ *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013).

¹³⁷ *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

¹³⁸ *Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013).

Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division Of Varco, L.P., No. IPR2013-00265, provides an example of a case where the Patent Owner raised objective evidence of nonobviousness presented during a reexamination, and, after finding a prima facie case of obviousness was made out by Petitioner, PTAB analyzed the objective evidence, balanced it against the evidence of obviousness, and found the objective evidence of nonobviousness persuasive.

Petitioner noted that Patent Owner raised objective evidence of nonobviousness in the reexamination of the patent.¹³⁹ According to Petitioner, the examiner “never retreated from his position that the claims are prima facie obvious ...[but] found that the Patent Owner’s showing of secondary considerations overcame the obviousness rejection.”¹⁴⁰ Petitioner argued that since it was raising prior art not considered during prosecution or reexamination, the Patent Owner’s objective evidence of nonobviousness “will be unable to overcome the strong showing of obviousness set forth in this Petition.”¹⁴¹

Patent Owner filed a POPR, arguing that the petition should be denied because the USPTO “already determined the overpowering evidence of secondary considerations of non-obviousness overcomes even a prima facie case”¹⁴² and attached the expert declarations from prosecution containing objective evidence of nonobviousness and linking that evidence to the claimed invention.¹⁴³ Patent Owner then compared the prior art disclosures examined in the initial prosecution, two reexaminations, and the Petition, and argued that the Petitioner’s art and arguments “for obviousness in its petition are identical to the disclosures already considered by the PTO in analyzing obviousness.”¹⁴⁴

PTAB denied institution on all challenged claims.¹⁴⁵ PTAB found Petitioner had established a prima facie case of obviousness. PTAB then turned to the objective evidence of nonobviousness, reviewed the examiner’s findings with respect to it, and agreed that “patent owner’s evidence of secondary considerations is

¹³⁹ *Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division of Varco, L.P.*, No. IPR2013-00265, Paper 1, at 9-10 (P.T.A.B. May 3, 2013).

¹⁴⁰ *Id.* at 9.

¹⁴¹ *Id.* at 10.

¹⁴² *Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division of Varco, L.P.*, No. IPR2013-00265, Paper 10, at 42 (P.T.A.B. Aug. 6, 2013).

¹⁴³ *Id.* at 9 n.12.

¹⁴⁴ *Id.* at 44.

¹⁴⁵ *Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division of Varco, L.P.*, No. IPR2013-00265, Paper 11 (P.T.A.B. Oct. 31, 2013).

persuasive.”¹⁴⁶

The objective evidence included commercial success, long-felt but unmet need, failure of others, and unexpected results.

Patent Owner’s evidence of commercial success was a brochure featuring the invention and trial testimony that the product was successful due to the patented features. “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.”¹⁴⁷ PTAB found that “[b]ased on the record cited above, we determine that Patent Owner has presented sufficient evidence to establish a prima facie case of nexus.”¹⁴⁸ Patent Owner presented evidence that the claimed invention was successful, including sales growth and evidence of the growth of a product later judged infringing.¹⁴⁹

Petitioner did not submit rebuttal evidence, and PTAB concluded that the Patent Owner presented sufficient evidence to establish that the claimed invention was “a significant commercial success.”¹⁵⁰

Patent Owner did not provide sufficient evidence supporting long-felt but unmet need or unexpected results. The evidence of significant commercial success, however, overcame the prima facie case of obviousness.¹⁵¹

Petitioner requested rehearing, arguing that PTAB abused its discretion by denying trial “based solely on evidence of purported commercial success that Patent Owner developed through direct testimony in a civil litigation that did not involve Petitioner in any way.”¹⁵² Petitioner attacked the objective evidence and argued that PTAB “misapprehended the strength of petitioner’s prior art.”¹⁵³

PTAB denied Petitioner’s request for rehearing.¹⁵⁴ First, it cited 35 U.S.C. § 325(d), noting that the references relied upon in the Petition were “not substantially different from the references before the Office in a prior ex parte reexamination in which the patentability

¹⁴⁶ *Id.* at 13.

¹⁴⁷ *Id.* at 14.

¹⁴⁸ *Id.* at 15.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 16.

¹⁵¹ *Id.*

¹⁵² *Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division of Varco, L.P.*, No. IPR2013-00265, Paper 12, at 1 (P.T.A.B. Dec. 2, 2013).

¹⁵³ *Id.* at 10.

¹⁵⁴ *Omron Oilfield & Marine, Inc. v. MD/TOTCO, A Division of Varco, L.P.*, No. IPR2013-00265, Paper 14 (P.T.A.B. Feb. 13, 2014).

of the challenged claims was confirmed” based on the evidence of commercial success.¹⁵⁵ “In other words, we concluded that the Petition presented the same, or substantially the same, prior art and arguments to the Office as those overcome in the reexamination.¹⁵⁶ Petitioner knew of the evidence presented in the reexamination, and could have addressed it in the Petition, but did not.¹⁵⁷ Addressing the objective evidence in the rehearing request was too late: “we are not persuaded by Petitioner’s new arguments regarding the merits or admissibility of the evidence of secondary considerations.”¹⁵⁸

Sufficient nexus to a request for additional discovery of objective evidence was shown in *John’s Lone Star Distribution, Inc. v. Thermolife Int’l, LLC*, No. IPR2014-01201.¹⁵⁹ 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, such as a nitrate and at least one amino acid, and as increasing vasodilation and nutrient absorption In addition, Patent Owner is not required to provide “comparative sales information” or its own sales data in a motion for additional discovery, even if such information and evidence would be appropriately cited in a Patent Owner Response. 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

¹⁵⁵ *Id.* at 3.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 4.

¹⁵⁹ *John’s Lone Star Distribution, Inc. v. Thermolife Int’l, LLC*, No. IPR2014-01201, Paper 30 (P.T.A.B. May 13, 2015), in addition to meeting the *Garmin* factors for additional discovery requests (see *Garmin Int’l, Inc. v. Cuzzo Speed Technologies, LLC*, No. IPR2012-00001, Paper 26, at 6-7 (P.T.A.B. March 5, 2013)).

certain requested documents is necessary in the interest of justice. Specifically, we authorize additional discovery from Petitioner in relation Patent Owner's Request (2)[.]¹⁶⁰

IV. SHOWING THAT THE OBJECTIVE EVIDENCE OF NONOBVIOUSNESS IS COMMENSURATE IN SCOPE WITH THE BREADTH OF THE CLAIMED INVENTION

As in all other obviousness determinations, whether they are in litigation or in prosecution, the objective evidence of nonobviousness has to be evaluated in the context of the scope of the claimed invention.¹⁶¹ In *Zodiac Pool Systems, Inc. v. Aqua Products, Inc.*, IPR2013-00159, Patent Owner argued that the long-felt but unmet need was for an efficient, automated cleaning device. In particular, “[c]ontrolling the movement of the cleaner was critical to avoiding the twisting of the electric cable which would seriously impede the cleaner's operation.”¹⁶² Petitioner attacked that argument by pointing out that the claim did not require or describe controlled movement or solve the other problems making up the long-felt need (“susceptibility of parts to wear and breakdown and elimination of power supply cables”).¹⁶³ PTAB rejected Patent Owner's objective evidence for not demonstrating “adequately that the challenged claims represent a solution to the alleged long-felt need.”¹⁶⁴

An IPR was instituted in *Lupin Ltd. v. Vertex Pharms. Inc.*, IPR2015-00405,¹⁶⁵ but it was instituted on fewer than all challenged claims and fewer than all asserted grounds based on the objective evidence of nonobviousness the Patent Owner was able to point to in its POPR. In particular, Patent Owner argued that evidence of unexpected results, long-felt need, copying of others, failure of others, and commercial success rebutted any prima facie case of obviousness. The evidence came from articles, clinical studies, deposition transcript from another IPR of patent owner's expert, and labels. Petitioner

¹⁶⁰ *Id.* at 4-5.

¹⁶¹ *Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, No. IPR2013-00159, Paper 71, at 34 (P.T.A.B. Aug. 22, 2014), citing *In re Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (citing *In re Tiffin*, 448 F.2d 791, 792 (CCPA 1971)); *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998).

¹⁶² *Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, No. IPR2013-00159, Paper 28, at 17 (P.T.A.B. Nov. 25, 2013).

¹⁶³ *Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, No. IPR2013-00159, Paper 44, at 9-11 (P.T.A.B. Mar. 10, 2014).

¹⁶⁴ *Zodiac Pool Sys., Inc. v. Aqua Prods., Inc.*, No. IPR2013-00159, Paper 71, at 36 (P.T.A.B. Aug. 22, 2014).

¹⁶⁵ *Lupin Ltd. v. Vertex Pharms. Inc.*, No. IPR2015-00405, Paper 13 (P.T.A.B. July 9, 2015).

knew of this evidence and addressed it briefly in its petition.

PTAB found the objective evidence of nonobviousness persuasive with respect to claims directed to specific compounds and compositions.¹⁶⁶ However, the evidence was not “commensurate in scope” with broader claims, and the IPR petition was granted with respect to those claims.¹⁶⁷

Federal Circuit precedent provides guidance for showing the objective evidence of nonobviousness is commensurate in scope with the claims. For example, the case law holds that evidence of commercial success is relevant if the item sold was within the scope of the claims, even if not all possible embodiments within the claims were successfully commercialized.¹⁶⁸

V. PROSECUTION DECLARATIONS TO SUPPORT NONOBVIOUSNESS POSITIONS MAY BE EFFECTIVE TO OBTAIN DENIAL OF IPR PETITION

A. In The POPR, Currently Patent Owner Cannot Rely On Evidence “Taken Specifically for the Purpose of the Inter Partes Review”¹⁶⁹ But, to Defeat Institution, the Patent Owner Should Be Able to Rely on Declarations Setting Forth Objective Evidence of Nonobviousness and Originating from the Prosecution¹⁷⁰

Depending on the particular circumstances and objectives of each patent application, the Patent Owner may consider developing and submitting declarations during the original prosecution or prosecution of related cases providing objective evidence of nonobviousness. Such declarations may be useful later in a POPR in an effort to persuade PTAB to deny institution. A denial of a petition

¹⁶⁶ *Id.* at 22-23.

¹⁶⁷ *Id.* at 23.

¹⁶⁸ See *In re Glatt Air Techniques*, 630 F.3d 1026, 1030 (Fed. Cir. 2011); *Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996); *In re Hollingsworth*, 253 F.2d 238, 240-41 (C.C.P.A. 1958).

¹⁶⁹ See 37 C.F.R. § 42.107; see also *Anova Food, LLC v. Sandau*, No. IPR2013-00114, Paper 11, at 3 (P.T.A.B. June 25, 2013) (noting “The Board responded that 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”).

¹⁷⁰ On Aug. 20, 2015, the United States Patent & Trademark Office (USPTO) released proposed rules that may change the use of new evidence in POPRs. See 80 Fed. Reg. 50,720 (Aug. 20, 2015).

in full is a “win” for the Patent Owner because all of the challenged claims remain intact, and the institution decision is not appealable.¹⁷¹

B. Requires Careful Thought and Planning

Any declaration, of course, should be considered and planned carefully. PTAB has found that defective declarations relied on for patentability during prosecution can form an independent basis for instituting an IPR.¹⁷² Moreover, the declaration testimony proffered during prosecution to establish objective evidence of nonobviousness may be subject to intense scrutiny in any eventual litigation. In particular, the doctrine of inequitable conduct is alive and well post-*Therasense*.¹⁷³ Although inequitable conduct cannot be raised during an IPR or PGR, there is apparently no estoppel precluding a losing IPR or PGR petitioner from raising inequitable conduct in a subsequent litigation, based perhaps on the prosecution declaration providing the objective evidence of nonobviousness.

VI. CONCLUSION

Objective evidence of nonobviousness may be raised by the Patent Owner in its POPR or POR to rebut a prima facie case of obviousness. In IPRs so far, Patent Owners have mostly experienced disappointment before PTAB with arguments based on objective evidence of nonobviousness. Based on examples of objective evidence arguments made in such IPRs so far, it appears that Patent Owners are not sufficiently linking the objective evidence of nonobviousness to the merits of the claimed invention. More attention to this linking may lead to more Patent Owner success with these arguments, particularly since “objective evidence” may be the strongest evidence of nonobviousness.¹⁷⁴ Declarations supporting nonobviousness positions, prepared prior to and for a reason other than the IPR, may provide a useful tool for Patent Owners to then leverage in POPRs of future IPRs. If the USPTO’s proposed rule

¹⁷¹ 35 U.S.C. §314(d) and 35 U.S.C. §324(e).

¹⁷² *K-40 Electronics, LLC v. Escort, Inc.*, No. IPR2013-00203, Paper 6 (P.T.A.B. Aug. 29, 2013).

¹⁷³ *See, e.g., Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324 (Fed. Cir. 2012); *Apotex Inc. v. Cephalon, Inc.*, No. 2:06-CV-2768, 2011 WL 6090696, at *1 (E.D. Pa. Nov. 7, 2011) *aff’d without opinion*, 500 F.App’x 959 (Fed. Cir. 2013); *Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339 (Fed. Cir. 2013); *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333 (Fed. Cir. 2013); *Apotex, Inc. v. UCB, Inc.*, 763 F.3d 1354 (Fed. Cir. 2014); *American Calcar, Inc. v. American Honda Motor Co.*, 768 F.3d 1185 (Fed. Cir. 2014).

¹⁷⁴ *See supra* section IB.

amendment allowing declaration evidence to be prepared to support a POPR becomes a final rule, Patent Owners may have more resources at their disposal to support arguments of objective evidence.