

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,
Petitioner,

v.

POZEN, INC. and HORIZON PHARMA USA, INC.
Patent Owners.

Case IPR2018-01341
Patent 9,393,208

**PATENT OWNERS' PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.120**

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EXHIBIT LIST

Exhibit No.	Description of Document
2001	Gabriel, S.E., et al., “Risk for Serious Gastrointestinal Complications Related to Use of Nonsteroidal Anti-inflammatory Drugs,” <i>Annals of Internal Medicine</i> , Vol. 115, No. 10, pp. 787-796 (1991) (“Gabriel”)
2002	Cryer, B. and Feldman, M., “Effects of Nonsteroidal Anti-inflammatory Drugs on Endogenous Gastrointestinal Prostaglandins and Therapeutic Strategies for Prevention and Treatment of Nonsteroidal Anti-inflammatory Drug-Induced Damage,” <i>Archives of Internal Medicine</i> , Vol. 152, pp. 1145-1155 (1992) (“Cryer”)
2003	Fries, J.F., et al., “Nonsteroidal Anti-Inflammatory Drug-Associated Gastropathy: Incidence and Risk Factor Models,” <i>The American Journal of Medicine</i> , Vol. 91, pp. 213-222 (1991) (“Fries”)
2004	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Response to Final Office Action Mailed March 26, 2015 (Sept. 25, 2015)
2005	U.S. Patent No. 9,220,698 Prosecution History Excerpt: Advisory Action (Oct. 9, 2015)
2006	<i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 2:15-cv-03324 (SRC), Opinion and Order (D.I. 82) (Nov. 14, 2017)
2007	<i>Horizon Pharma, Inc. v. Dr. Reddy's Laboratories, Inc.</i> , Case No. 2:15-cv-03324 (SRC), Opinion (D.I. 162) (Nov. 19, 2018)

Horizon Pharma USA, Inc. and Nuvo Pharmaceuticals (Ireland) Designated Activity Company, (hereinafter, "Patent Owner") respectfully submit this preliminary response under 35 U.S.C. § 313 to Dr. Reddy's Laboratories, Inc.'s (hereinafter, "Petitioner") request for inter partes review ("IPR") of claims 1-7 of U.S. Patent No. 9,393,208 ("the '208 patent"). Petitioner's Petition fails to demonstrate a reasonable likelihood that claims 1-7 of the '208 patent are unpatentable. While each of Petitioner's three proposed grounds relies upon U.S. Patent No. 8,557,285 ("the '285 patent"), Petitioner has failed to establish that the '285 patent qualifies as § 102(e) prior art to the '208 patent. Petitioner therefore has not carried its burden and shown that there is a reasonable likelihood that it would prevail with respect to any of the challenged claims. As such, institution should be denied.

I. INTRODUCTION

Non-steroidal anti-inflammatory drugs, or NSAIDs, have long been used for the management of inflammatory conditions including osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions. (Ex. 2001 at 787.) In fact, NSAIDs are one of the most widely used medicines in the world. (*Id.*) But NSAID use has long been known to increase the risk of serious damage to the gastrointestinal track, such as ulcers and bleeding. (*Id.*) This is believed to be the case because NSAIDs inhibit prostaglandin synthesis, which in turn, leads to reduced production of the

stomach's protective mucous coating. A loss or reduction in this mucosal coating leads to the stomach acid eroding the stomach lining. (Ex. 2002 at 1145.) The use of NSAIDs is recognized as causing the most prevalent serious drug toxicity in the United States, resulting in an estimated 2,600 deaths and 24,000 hospitalizations annually in rheumatoid arthritis patients alone. (Ex. 2003 at 213.) Over the years, pharmaceutical companies tried various approaches to develop safer NSAIDs, but were unsuccessful in reducing the risk of NSAID-associated GI injuries.

In the early 2000s, Dr. Plachetka—the inventor of U.S. Patent Nos. 6,926,907 (“the ’907 patent,” Ex. 1004) and 8,557,285 (“the ’285 patent,” Ex. 1005) (collectively, “the Plachetka patents”) and co-inventor of the ’208 patent—set out to create a better arthritis medicine with a lower risk of GI toxicity. While others in the field had tried to solve the GI toxicity problem by administering separate medicines to reduce gastric acidity or to replace gastroprotective prostaglandins, Dr. Plachetka approached the problem with an unorthodox solution: he combined a proton pump inhibitor (“PPI”) to inhibit the production of gastric acid with an NSAID to relieve pain and inflammation into a single dosage form. Significantly, Dr. Plachetka designed the dosage form to exhibit coordinated release of the active ingredients: the PPI would be released immediately into the stomach to elevate the gastric pH (i.e., lower the acidity) to reduce the toxic effects of the NSAID. The release of the NSAID would be delayed until the pH of the environment was higher,

such as in the small intestine. Prior to Dr. Plachetka's invention, no one had combined an immediate-release PPI with a delayed-release NSAID. This dosage form reduces the side effects previously associated with long-term, daily use of NSAIDs.

Subsequent to the invention claimed in the '907 and '285 patents, Dr. Plachetka collaborated with his employee Everardus Orlemans, and Brian Ault and Mark Sostek, scientists from AstraZeneca to improve upon the claimed inventions.¹ They selected esomeprazole as the immediate-release PPI and naproxen as the delayed release NSAID. They also chose the specific dosages of esomeprazole and naproxen to include in the formulation to facilitate the desired effect, and determined that this novel formulation should be administered twice a day (in an AM unit dose form and, ten hours later, in a PM unit dose form).

During prosecution of the related '698 patent,² the applicants were faced with and successfully overcame the very challenge now raised by Petitioner, namely

¹ In 2013, Horizon purchased rights to these and the related patents from AstraZeneca AB and is the current assignee of AstraZeneca's interest in these patents.

² The '208 patent is a continuation of the '698 patent. The '208 patent is also terminally disclaimed over the '698 patent.

inherent anticipation by, or obviousness over, an earlier related Plachetka patent. As applicants explained during prosecution of the parent '698 patent, Plachetka and his colleagues "unexpectedly discovered and demonstrated that, by practicing the recited method, they can achieve a [more beneficial] pharmacodynamic profile" in which the patient achieved a protective post-administration intragastric pH higher than 4.0 for a longer period of time. (Ex. 1013, 1/30/2013 Applicant Arguments at 7-8.)

Applicants argued that the '285 patent's parent failed to teach the claimed unexpected pharmacokinetic parameters.³ (Ex. 2004, 9/25/2015 Applicant Arguments at 5-7.) The Examiner subsequently withdrew the obviousness rejections made over the '907 patent and the '208 patent issued on July 19, 2016. (Ex. 2005, 10/9/2015 Advisory Action at 2.)

³ Although Petitioner failed to include relevant portions of the '698 prosecution history with this Petition, those materials were included in Petitioner's Petition targeting the '698 patent, IPR2017-01995. For ease of reference, they are included in Patent Owner's exhibits.

Petitioner, having lost an infringement suit on the '907 and '285 patents in district court,⁴ now brings this petition for *inter partes* review of the '208 patent. Each of the three combinations of art fail because they are all based on the '285 patent and Petitioner has not established that the '285 patent is § 102(e) prior art to the '208 patent. Moreover, the fact that, during prosecution of the parent '698 patent, the Patent Office considered and rejected the very arguments that Petitioner now re-raises demonstrates that the Petition does not support a conclusion of unpatentability.

Under these circumstances, as Petitioner is simply re-hashing arguments previously overcome, the Board should exercise its discretion to deny institution pursuant to 35 U.S.C. § 325(d). Moreover, considering the merits of its argument, Petitioner has not demonstrated a reasonable likelihood that it will prevail as it has failed to provide evidence that the '285 patent qualifies as prior art.

⁴ See District Court Amended Memorandum Opinion, Public Version (D.I. 497 in Case No. 3:11-cv-02317-MCL-DEA) (lead case); District Court Final Judgment (D.I. 499 in Case No. 3:11-cv-02317-MLC-DEA); and District Court Final Judgment (D.I. 87 in Case No. 3:13-cv-04022-MLC-DEA).

II. THE PETITION SHOULD BE DENIED BECAUSE THE '208 PATENT HAS BEEN FOUND INDEFINITE IN RELATED DISTRICT COURT PROCEEDINGS⁵

As with IPR2018-00272, Petitioner maintains that the claim term “target” should be construed to mean “with the goal of obtaining.” Pet. at 14-17. In IPR2018-00272, the Panel adopted Petitioner’s construction. *Mylan Pharm. Inc. v. Horizon Pharma USA, Inc.*, IPR2018-00272, Paper 9, Institution Decision at 9-10 (P.T.A.B. Jun. 14, 2018) (“We are persuaded, for purposes of this decision, that Petitioner’s proposed construction reflects the broadest reasonable construction consistent with the specification of the ’208 patent and its file history. . . . We accept Petitioner’s construction generally, but alter the meaning for grammatical reasons such that ‘target’ means ‘have or set the goal of obtaining.’”).

In related district court proceedings, Petitioner argued that the claim term “target” was indefinite, or alternatively, should be construed to mean “set as a goal.” The district court adopted this construction, noting that it would not decide indefiniteness at the claim construction stage. Ex. 2006 (*Horizon Pharma, Inc. v. Dr. Reddy’s Labs., Inc.*, Case No. 2:15-cv-03324 (SRC), D.I. 82, Opinion and Order at 11, 13 (Nov. 14, 2017) (“*Markman* opinion”)). Petitioner subsequently moved

⁵ On January 25, 2018, the Board granted Patent Owners permission to file a motion to terminate proceedings in IPR2017-01995, IPR2018-00272, and IPR2018-01341. The deadline for that motion is February 8, 2019. Patent Owners incorporate the arguments raised in that briefing in this Preliminary Response.

for summary judgment of invalidity that the '208 patent is indefinite due to the "target" language. Specifically, Petitioner argued that given the court's construction of "target" to mean "set as a goal," the "patents provide no guidance regarding how often, if ever, the recited ranges must be met or how close one must come to those ranges to infringe the asserted claims." Ex. 2007 (*Horizon Pharma, Inc. v. Dr. Reddy's Labs., Inc.*, Case No. 2:15-cv-03324 (SRC), D.I. 162, Opinion at 7 (Nov. 19, 2018) (citing Petitioner's summary judgment brief) ("Summary judgment opinion")). The district court found Petitioner's argument persuasive, finding the '208 patent invalid as indefinite because the target clause "fails to inform with reasonable certainty about the scope of the invention." *Id.* at 9.

An *inter partes* review may be instituted only on prior art challenges under 35 U.S.C. §§ 102 and 103. 35 U.S.C. § 311(b). It is well settled that the Board may not institute an *inter partes* review based on indefiniteness. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141–42 (2016) ("[N]or does our interpretation enable the agency to act outside its statutory limits by, for example, canceling a patent claim for 'indefiniteness under § 112' in inter partes review.").

Petitioner has argued—and the district court has found—that the claim term "target" does not inform those skilled in the art about the scope of the '208 patent with reasonable certainty. As the district court has ruled the term indefinite, the Board cannot compare the '208 claims to the prior art to assess the claims for

obviousness or anticipation as to do so would contravene the district court's determination. In *Microsoft Corp. v. IpLearn-Focus, LLC*, the Board declined to institute an *inter partes* review because it found the challenged claims to be indefinite. See *Microsoft Corp. v. IpLearn-Focus, LLC*, IPR2015-00097, Paper 11, Decision at 13-14 (P.T.A.B. Mar. 26, 2015) ("As claim 1 fails to indicate the scope of the claimed invention, we do not attempt to apply claim 1 to the asserted prior art."). See also *Blackberry Corp. v. MobileMedia Ideas, LLC*, IPR2013-00036, Paper 65, Order, Termination of Proceeding at 20 (P.T.A.B. Mar. 7, 2014) ("Without ascertaining the proper claim scope, we cannot conduct a necessary factual inquiry for determining obviousness—ascertaining differences between the claimed subject matter and the prior art."). See also *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236–37 (1942) (holding that "the claims must be reasonably clearcut to enable courts to determine whether novelty and invention are genuine"); *In re Steele*, 305 F.2d 859, 862–63 (C.C.P.A. 1962) (holding that where a claim's meaning is indefinite under 35 U.S.C. § 112, ¶ 2, any rejection based on prior art is improperly based on speculation).

As it currently stands, the claims of the '208 patent have been held invalid as indefinite by the district court. As the Board cannot properly assess whether or not the claims of the '208 patent are anticipated or obvious under this scenario, the Board should decline to institute the Petition.

In addition, institution of this petition should be denied for the same reasons it was denied in *Comtech Mobile Datacom Corp v. Vehicle IP, LLC*, IPR2018-00531, Paper 9 (P.T.A.B. July 20, 2018). There the Board determined that *inter partes* review would not be an efficient use of the Board's resources because the district court had already construed a potentially dispositive claim term and entered summary judgment of non-infringement. The Board stated, "Petitioner's claim construction contentions strongly warrant against institution of *inter partes* review because the construction of "dispatch" is both pending on appeal before the Federal Circuit and potentially dispositive in this case." *Id.* at 12. As in *Comtech Mobile*, the district court has already construed the term "target" in the '208 patent and found that under its construction the claims are indefinite. Upon an appeal by Patent Owners of the district court's determination, should the Board institute this IPR, the Board "would be deciding a disputed legal issue that is already currently before our reviewing court for resolution." *Id.* Accordingly, DRL's petition should be denied because is not an efficient use of the Board's resources.

III. PETITIONER HAS NOT ESTABLISHED THAT THE '285 PATENT IS § 102(e) PRIOR ART

Petitioner raises three potential grounds of unpatentability, all based on a Plachetka patent: anticipation by the '285 patent, obviousness in light of the '285 patent, and obviousness in light of the combination of the '285 patent, the EC-

Naprosyn label, and Howden. (Paper 2 at 3.) Petitioner's arguments, however, incorrectly assume that the '285 patent is prior art under § 102(e).

The '285 patent was filed on August 23, 2011 with Plachetka as the sole inventor. The '285 patent claims priority to Provisional Application No. 60/294,588, which was filed on June 1, 2001. The '208 patent was filed on December 28, 2015 and claims priority to Provisional Application No. 61/095,584 (filed on September 9, 2008) and Application No. 12/553,107 (filed on September 3, 2009)—two years before the '285 patent—with Plachetka, Ault, Sostek, and Orlemans as co-inventors.

Petitioner asserts that the '285 patent is § 102(e)(2) prior art simply because the named inventors on the '285 and '208 patents overlap but are not identical. (Paper 2 at 20-21 n.4.) Petitioner sets forth no further support or analysis as to why the '285 patent should be treated as prior art under § 102(e)(2). The fact that one patent has named a different inventive entity on its face than another does not necessarily make the first patent prior art. *Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279, 281 (Fed. Cir. 1988). Indeed, it is not Patent Owner's burden to prove that the '285 patent is not § 102(e)(2) art. Rather Petitioner bears the burden of establishing that the portions of the '285 patent on which it relies as prior art and the subject matter of the '208 claims in question represent the work of different inventive entities. Petitioner has provided no evidence and indeed has made no attempt to make such a showing here.

A. Legal Standard

“The question of whether the asserted prior art is ‘by another’ is not . . . dependent on the inventors listed on the face page of a patent, but dependent on who the inventor of the underlying subject matter asserted as prior art is, as compared to the claimed subject matter at issue.” *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01750, Paper 15 at 20 (P.T.A.B. Apr. 3, 2017) (quoting *Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279, 281 (Fed. Cir. 1987) (“the fact that an application has named a different inventive entity than a patent does not necessarily make that patent prior art.”)); *see also Riverwood Int’l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003) (“To fully answer the question before us—whether the ’806 patent is prior art as to the ’789 and ’361 patents—the district court must look beyond the superficial fact that the references were issued to different inventive entities.”). “What is significant is not merely the differences in the listed inventors, but whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity.” *Riverwood Int’l*, 324 F.3d 1356 (emphasis added). If the subject matter relied on as prior art and the subject matter of the claims at issue have the same inventor, then the prior art cannot be used to invalidate the claims absent a statutory bar. *In re DeBaun*, 687 F.2d 459, 462 (C.C.P.A. 1982) (“[W]e have reaffirmed that an applicant’s own work, even though publicly disclosed prior to his application,

may not be used against him as a reference, absent the existence of a time bar . . .
.”).

B. Petitioner Has Not Met Its Burden to Show That the '285 Patent Is § 102(e) Prior Art

Petitioner's sole analysis of how the '285 patent allegedly qualifies as § 102(e) prior art is contained in a footnote. The Petition states: “Therefore, even though both the '285 and '208 patents list John Plachetka as an inventor, the '285 has a different inventive entity because the '208 lists three other inventors in addition to John Plachetka.” (Paper 2 at 20-21 n.4.)

It is Petitioner's burden, however, to establish by a preponderance of the evidence, that the '285 patent qualifies as § 102(e) prior art. *Ariosa Diagnostics, Inc. v. Illumina, Inc.*, IPR2014-01093, Paper 69 at 9 (P.T.A.B. Jan. 7, 2016). Petitioner has utterly failed to meet its burden here—it has provided no analysis comparing the subject matter of the two sets of claims to determine whether the inventive entities are truly different. Petitioner also failed to provide any shred of evidence to support its argument.

Because Petitioner has failed to meet its burden to establish that the '285 patent is § 102(e) prior art, it cannot demonstrate there is a reasonable likelihood of success with respect to any of the challenged claims. The Board should therefore decline to institute this *inter partes* review.

IV. THE PTO HAS PREVIOUSLY REJECTED SUBSTANTIALLY THE SAME ARGUMENTS DURING PROSECUTION OF THE PARENT '698 PATENT

As described above, during prosecution, the Examiner entered an obviousness-type double patenting rejections to the pending claims based on the parent '698 patent. In turn, during examination of the '698 patent, the Examiner made obviousness and obviousness-type double patenting rejections over the '907 Plachetka patent, which is a grandparent to the '285 patent. As applicants successfully argued during prosecution of the '698 patent, the claimed pharmacokinetic parameters were unexpected and non-obvious over the dosage forms disclosed in the '907 patent. This reasoning, which the Examiner ultimately agreed with, applies equally to the '285 patent.

Petitioner, however, provided no explanation how its arguments made in the Petition are any different than what was presented during prosecution. Since the Patent Office has already considered this argument, it would be appropriate to exercise its discretion and deny institution.

A. Institution of an *Inter Partes* Review Is Discretionary

The Board has discretionary power to authorize an IPR to proceed, or to deny some or all of the grounds. 37 C.F.R. § 42.108(a), (b). This discretionary power to determine whether or not to institute trial is guided, in part, by 35 U.S.C. § 325(d). Under 35 U.S.C. § 325(d), the Board may deny institution if “the same or

substantially the same prior art or arguments previously were presented to the Office.” *See id.* (denying institution where petition raised the “same or substantially the same prior art or arguments previously were presented to the Office”); *Apple Inc. v. Papst Licensing GmbH & Co. KG*, IPR2016-01841, Paper 10 at 20-22 (P.T.A.B. Apr. 17, 2017) (denying institution of petition that presented “substantially the same arguments regarding the unpatentability of the claimed subject matter over [the prior art]” that were considered during prosecution). Indeed, the PTAB has provided guidance as to when institution is appropriate over previously considered arguments, articulating a six factor analysis. *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01587, Decision (Dec. 15, 2017). The recycled arguments raised by Petitioner, however, are not sufficient under any of these factors to warrant institution.

Likewise, in *Unified Patents Inc. v. Berman*, IPR2016-01571, Paper 10 at 12 (P.T.A.B. Dec. 14, 2016), the PTAB denied institution, in part, because the prior reference cited in the Petition had been previously considered during prosecution. Noting that the Petitioner failed to “present any argument distinguishing the Examiner’s prior consideration of [the reference] or . . . provide a compelling reason why [the Panel] should readjudicate substantially the same prior art and arguments as those presented during prosecution and considered by the Examiner.” *Id.* The PTAB noted that it was the Petitioner’s burden to either explain why the prior art

was being applied in a different manner in the petition or to provide another compelling reason as to why the Panel should reconsider the art and arguments. Because the petitioner had failed to do so, the Panel exercised its discretion under § 325(d) to deny institution. That same outcome is appropriate here.

B. Petitioner Has Failed to Explain Why the Board Should Reconsider Obviousness Over a Plachetka Patent

The purpose of these *inter partes* review proceedings is to allow parties to present novel issues and art not considered during prosecution. It would be a waste of administrative resources to institute this petition in order to address an issue that was already considered and decided during prosecution. Further, the Petition is glaringly silent as to why the Board should revisit the Examiner's non-obviousness determination over a Plachetka patent.

As described above, during prosecution, the Examiner raised the same arguments with respect to the '907 patent that Petitioner now raises with respect to the '285 patent. The '907 and '285 patents share a common specification and claim priority to the same provisional application. The Petition fails to describe the relevant prosecution history of the parent '698 patent. In particular, the Petition does not disclose that the '285 patent it relies on has the same disclosure as the '907 patent addressed during prosecution. Nor does the Petition address arguments made during

prosecution that convinced the examiner that the claims of both the '698 and '208 patents were valid in view of the shared disclosure of the '907 and '285 patents.

The Petition fails to identify any new issue or evidence that would merit revisiting the Examiner's non-obviousness determination. Accordingly, the Board in its discretion should deny institution pursuant to 35 U.S.C. § 325(d).

V. CONCLUSION

For the reasons discussed above, Patent Owner respectfully requests that the Board deny institution for Petitioner's Petition. In the event that this *inter partes* review is instituted, however, Patent Owner reserves the right to challenge Petitioner's Grounds for other reasons.

DATED: January 31, 2019

Respectfully submitted,

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USPTO Reg. No. 44,541

CERTIFICATE OF COMPLIANCE WITH WORD COUNT LIMITS

Pursuant to 37 C.F.R. § 42.24(d), I certify that this Petition complies with the type-volume limits of 37 C.F.R. § 42.24(b)(1). According to the word processing system used to prepare it, this Response contains 3661 words, excluding parts that are exempted by 37 C.F.R. § 42.24(a).

Date: January 31, 2019

BY: /Thomas A. Blinka/
Thomas A. Blinka, Ph.D.
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CERTIFICATION OF SERVICE UNDER 37 C.F.R. § 42.6(e)

I, Thomas A. Blinka, hereby certify that on this 31st day of January 2019, the foregoing **PATENT OWNER'S PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.120** was served electronically via email on the following:

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