

Filed: February 8, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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DR. REDDY'S LABORATORIES, INC.,

Petitioner

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS  
(IRELAND) DESIGNATED ACTIVITY COMPANY.

Patent Owners

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Case No. IPR2018-01341

U.S. Patent No. 9,393,208

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**PATENT OWNERS' MOTION TO TERMINATE**

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Pursuant to the Board's Order dated January 25, 2019 (IPR2018-01341, Paper No. 14), Patent Owners, Horizon Pharma USA, Inc. and Nuvo Pharmaceuticals (Ireland) Designated Activity Company, submit this Motion to Terminate the *Inter Partes* Review of U.S. Patent No. 9,383,208 ("the '208 patent"). Corresponding motions will be filed concurrently in co-pending Case Nos. IPR2017-01995 involving U.S. Patent No. 9,220,698 ("the '698 patent") and IPR2018-00272 involving the '208 patent.

The Board should dismiss the Petition pursuant to 37 C.F.R. § 42.71(a) and terminate this *inter partes* review pursuant to 37 C.F.R. § 42.72 for two reasons. First, Petitioner cannot meet their burden of demonstrating by a preponderance of the evidence that the challenged claims are unpatentable because the district court has found that under Petitioner's own construction, the claims are indefinite. Second, because of the late stage of the district court litigation and pending appeal to the Federal Circuit, proceeding with this *inter partes* review would not be an effective use of the Board's resources.

## **I. Background**

The claims of the '208 patent require administering AM and PM unit dose forms that provide 500 mg of naproxen and 20 mg of esomeprazole and that

“target” particular pharmacokinetic (PK) and pharmacodynamic (PD) profiles for naproxen and esomeprazole. Ex. 1001 at 46:33-47 (claim 1).

The parties began litigating the '698 patent in February 2016 and the '208 patent in December 2016 in the District of New Jersey. In November 2017, the district court issued its Markman Order construing the claims of the '698 and '208 patents. Ex. 2073. The court adopted Petitioner's proposed construction of the term “target” as used in claim 1 of both patents to mean “set as a goal.” *Id.* at 11. Fact discovery closed in December 2017 and expert discovery closed in July 2018.

On August 10, 2018, Petitioner moved for summary judgment that the claims of the '698 and '208 patents are invalid as indefinite. Ex. 2074. Petitioner argued that under the court's construction of “target,” the claims of both patents are indefinite because “[n]othing in the claims, the specification, or the prosecution history allows those skilled in the art to discern with any reasonable certainty where the boundaries of the asserted claims lie.” *Id.* at 2. According to Petitioner, the claims are merely aspirational and “provide no discernable standard for how far a particular formulation administered to any given patient or group of patients can stray from the stated goals and still infringe the claims.” *Id.* at 10. Petitioner also argued that the claims are indefinite because they do not specify “who or what must ‘target’” the PK and PD profiles in the claims. *Id.* at 16-18.

The district court granted Petitioner's motion because it found the claims of the '698 and '208 patents to be "incomprehensible." Ex. 2075 at 10. The district court explained that because it construed "target" as "set as a goal," "it is not possible to discern what the target clauses are telling you to do or not do." *Id.* According to the court, "[i]t is not possible to comprehend what these phrases mean, because pills cannot be said to set goals." *Id.* at 8. The court went on to state that, even if it interpreted the claims as requiring that a physician set the goals, the claims are neither "comprehensible nor cognizable" because "it simply cannot be that the question of infringement of a method patent turns on the mental state of the accused infringer, or of a pill that does not have one." *Id.* at 10-11. On January 22, 2019, the court entered final judgment that "all claims of the '698 and '208 patents are invalid for indefiniteness." Exs. 2076 and 2077.

On July 2, 2018, Petitioner DRL filed the petition that led to this *inter partes* review. Petitioner identified only a single term for construction: the term "target" as used in claim 1. Petitioner contends that "target" should be construed to mean "with the goal of obtaining." Paper 2 at 15. According to Petitioner, "the patent drafters wrote the claims so that the recited PK values need only be 'targeted,' not necessarily achieved." *Id.* at 17. Petitioner relied on the same prior art and arguments presented during the district court litigation.

## **II. The Board Has Authority to Terminate These Proceedings**

The Board has found that applicable regulations grant the Board “broad authority” to dismiss petitions and terminate trial. *Facebook, Inc. v. EveryMD.com LLC*, Case IPR2017-02027, Paper 24 at 4-6 (P.T.A.B. Oct. 9, 2018) (dismissing petition and terminating trial where patent at issue was found to be invalid under 35 U.S.C. § 101 in other proceedings). Specifically, applicable regulations grant the Board authority to “dismiss any petition” and “terminate a trial . . . where appropriate . . . .” 37 C.F.R. §§ 42.71(a), 42.72.

## **III. Petitioner Cannot Meet their Burden of Showing that the Claims Are Unpatentable**

Where the claims at issue have been found to be indefinite, it is inappropriate for the Board to consider prior art challenges in an *inter partes* review. For example, in *Blackberry Corp. v. MobileMedia Ideas, LLC*, the Board terminated the proceedings after oral argument because the claims at issue were indefinite. IPR2013-00036, Paper 65 (Order, Termination of Proceeding) at 7-8 (P.T.A.B. Mar. 7, 2014). The Board stated that “[w]ithout 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.” *Id.* at 20. In addition, the Board has declined to institute review for similar reasons. *See, e.g., 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.”).

The Board’s decisions to terminate trial where claims have been found indefinite is proper because “the claims must be reasonably clearcut to enable courts to determine whether novelty and invention are genuine.” *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942). Indeed, “a claim cannot be both indefinite and anticipated.” *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010); *see also 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).

Petitioner cannot meet their burden of demonstrating by a preponderance of the evidence that the challenged claims are unpatentable because they rely on a construction, which has been accepted in this proceeding, that both they and the district court found to be indefinite. *See Microsoft Corp.*, IPR2015-00097, Paper 11 at 13-14 (determining that Petitioner has not shown a reasonable likelihood that it would prevail where claims were indefinite). As explained above, the district court accepted Petitioner’s argument and found that “target,” should be construed as “set as a goal.” Under that construction, the court held that the claims were



indefinite because “target” did not specify how closely one must match the claimed parameters to target them, it introduced a subjective element into the claims, and it did not specify who or what must set the goal. Ex. 2075 at 8-11.

Under the court’s construction of “target,” Petitioner cannot meet their burden of showing that the relevant limitations are disclosed by the prior art. Although Petitioner employs a construction that they and the district court contend is indefinite, they make no effort to explain how the prior art addresses the ambiguities they claim are inherent in their construction.

Instead, the Petition compounds the confusion. For example, after laying out their proposed construction, Petitioner makes no argument that the prior art discloses a “goal” of any sort in either of the first two grounds. Paper 2 at 33-48. Instead, Petitioner argues that, although the claimed PK and PD parameters were not disclosed in the cited art, they were “inherent.” *Id.* at 36-40. But Petitioner does not explain how the dosage forms of the prior art could “set as a goal of obtaining” the PK and PD parameters that were simply unknown in the art. Further, Petitioner contends that “Grounds 1 and 2 of this Petition do not depend on the Board adopting Petitioner’s proposed construction of ‘target.’” *Id.* at 36 n.10. Thus, it is unclear what construction of “target” Petitioner contends should be compared against the prior art in Grounds 1 and 2 or even if Petitioner

considered the “target” limitation at all. If Petitioner contends that different constructions of “target” apply to Grounds 1 and 2 than to Ground 3, this also favors termination of the proceedings. *See, e.g., Microsoft Corp.*, IPR2015-00097, Paper 11 at 7-10, 13-14 (declining to institute where Petitioner proposed alternative constructions for a claim term).

For Ground 3, Petitioner argues that “[t]he skilled artisan must therefore have the goal of obtaining the recited PK and PD elements.” Paper 2 at 49. But Petitioner’s definition of a skilled artisan includes both a medical doctor, who would treat patients, and a pharmacologist or pharmacokineticist, who would not. *Id.* at 8. And Petitioner does not explain which of the individuals within its definition would be responsible for setting a goal. Nor does Petitioner explain how their interpretation of the claims as requiring that a skilled artisan set a goal are consistent with the claim’s requirement that “the AM and PM unit dose forms” and not an artisan “target” the specified PK and PD profiles.

Because Petitioner relies on a construction of “target” that has been found indefinite, and because Petitioner does not apply a consistent interpretation of the term in its petition, they cannot meet their burden of demonstrating that the challenged claims are unpatentable. Accordingly, this *inter partes* review should be terminated.

#### IV. Proceeding Would be a Waste of the Board's Resources

Although Patent Owners do not concede that the claims of the '698 and '208 patents are indefinite, proceeding with this *inter partes* review would not be an efficient use of the Board's resources. This is because an appeal of the district court's judgment of indefiniteness will focus on the construction of the term "target" and the scope of the PK and PD elements of the claims, which are precisely the issues that are dispositive in this review.<sup>1</sup>

The Board was presented with a similar situation in *Comtech Mobile Datacom Corp. v. Vehicle IP, LLC*, Case 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 judgment of non-infringement, which was on appeal. The Board found the situation to "strongly warrant against institution of *inter partes* review because the construction of [the disputed term] is both pending on appeal before the Federal Circuit and potentially dispositive in this case." *Id.* at 12. As in *Comtech Mobile*, should trial proceed, the Board "would be deciding a disputed legal issue that is already currently before

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<sup>1</sup> A notice of appeal is due by February 21, 2019. Should Patent Owners decline to appeal the district court's judgment, proceeding with trial would also not be efficient because the issues raised in the petition would be moot.

our reviewing court for resolution.” *Id.* In such circumstance the Board has found that trial “would not be an efficient use of the Board’s resources.” *Id.* Indeed, the very act of proceeding with this review conflicts with and in fact undermines the district court’s determination regarding the definiteness of the claims at issue.

Other factors also weigh in favor of terminating these proceedings. The art and arguments presented by Petitioner here are the same as those in the district court litigation. The parties have completed fact and expert discovery and the cases are ready for trial. Should the appeals court reverse the finding of indefiniteness, then Petitioner would be able to assert the anticipation and obviousness challenges at issue here at the district court, but with the Federal Circuit’s guidance as to the scope of the claims.

Further, this and the co-pending IPRs are at a relatively early stage. An institution decision has not been made in the IPR2018-01341, Patent Owners have not filed a response in IPR2018-00272, and Petitioner has not filed a reply in the IPR2017-01995. Oral Argument will not occur until mid-June 2019. Thus, termination of these proceedings would save considerable resources while not depriving Petitioner of the ability to make their anticipation and obviousness arguments at the district court should it be necessary following an appeal.

Case No. IPR2018-01341  
Patent No. 9,393,208

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Respectfully submitted,

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**CERTIFICATE OF SERVICE UNDER 37 C.F.R. § 42.6(e)**

I, Thomas A. Blinka, hereby certify that on this 8th day of February 2019,  
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