

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC. and  
DR. REDDY'S LABORATORIES, INC.,  
Petitioners,

v.

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

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Cases

IPR2017-01995<sup>1,2</sup> (Patent 9,220,698 B2)  
IPR2018-00272 (Patent 9,393,208 B2)  
IPR2018-01341 (Patent 9,393,208 B2)<sup>3</sup>

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Before TONI R. SCHEINER, MICHELLE N. ANKENBRAND, and  
DEBRA L. DENNETT, *Administrative Patent Judges*.

DENNETT, *Administrative Patent Judge*.

ORDER

Denying Patent Owners' Motions to Terminate  
*37 C.F.R. §§ 42.71(a), 42.72*

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<sup>1</sup> On March 27, 2019, we vacated institution and terminated IPR2017-01995 (Paper 71), making this motion moot with respect to that case.

<sup>2</sup> Petitioner Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's"), from IPR2018-00894, was joined as a Petitioner to IPR2017-01995.

<sup>3</sup> We exercise our discretion to issue one Order to be filed in all three cases. The parties are not authorized to use this style heading for subsequent papers without Board preapproval.

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## I. INTRODUCTION

On February 10, 2019, pursuant to our prior authorization, Patent Owners filed a motion to terminate in each of the above-referenced proceedings. IPR2017-01995 (“the 1995 IPR”), Paper 66; IPR2018-00272 (“the 272 IPR”), Paper 25; IPR2018-01341 (“the 1341 IPR”), Paper 17.<sup>4</sup> Petitioners filed oppositions to each motion on February 22, 2019. 1995 IPR, Paper 68 (“Opp.”).<sup>5</sup>

## II. BACKGROUND

According to Patent Owners, litigation involving U.S. Patent No. 9,220,698 (“the ’698 patent”) commenced in February 2016, and litigation involving U.S. Patent No. 9,393,208 (“the ’208 patent”) commenced in December 2016, in the U.S. District Court for the District of New Jersey (collectively, the “New Jersey Action”). Mot. 2. Petitioner Mylan Pharmaceuticals Inc. (“Mylan”) filed a Petition requesting an *inter partes* review of the ’698 patent in August 2017, and filed a Petition requesting an *inter partes* review of the ’208 patent in December 2017. 1995 IPR, Paper 2; 272 IPR, Paper 2. Between these filings, the court in the New Jersey

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<sup>4</sup> The parties filed substantively similar papers in each proceeding. We refer to Patent Owners’ motions collectively as the “Motion” or “Mot.” and Petitioners’ oppositions collectively as the “Opposition” or “Opp.” We also cite to the Papers and Exhibits filed in the 1995 IPR, unless otherwise specified.

<sup>5</sup> Petitioner Dr. Reddy’s Laboratories, Inc. (“Dr. Reddy’s”), who filed in the 1341 IPR a motion to join the 272 IPR as a petitioner, did not respond to the motion to terminate the 1341 IPR, presumably because we have not yet determined whether to institute the 1341 IPR or whether to grant Dr. Reddy’s joinder motion.

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Action issued a *Markman* order construing the term “target,” which is recited in the independent claims of both patents, to mean “set as a goal.” Ex. 2073, 11.

We instituted review of the ’698 patent on March 8, 2018, and we instituted review of the ’208 patent on June 14, 2018. 1995 IPR, Paper 18; 272 IPR, Paper 9. In our Institution Decision (“Dec.”), we construed the term “target,” as recited in the ’698 and ’208 patents, to mean “have or set the goal of obtaining.” Dec. 11–12.<sup>6</sup>

On July 2, 2018, Dr. Reddy’s filed its Petition in the 1341 IPR and a motion to join the 272 IPR. 1341 IPR, Papers 2, 3. On August 14, 2018, we joined Dr. Reddy’s as a Petitioner to the 1995 IPR. Paper 47.

During this time, the New Jersey Action continued in parallel to our proceedings. On August 10, 2018, Mylan and Dr. Reddy’s moved for summary judgment in the New Jersey Action, arguing that the claims of the ’698 and ’208 patents are invalid as indefinite under the district court’s claim construction. Ex. 2074.

On August 28, 2018, then-Patent Owner Pozen Inc. filed a Suggestion of Bankruptcy in the 1995 IPR and the 272 IPR. Paper 50. We acknowledged the automatic stay under 11 U.S.C. § 362 and suspended all deadlines in our proceedings until the bankruptcy court lifted the stay. Paper 51. The New Jersey Action, however, continued.

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<sup>6</sup> The claims of the ’698 and ’208 patents use the terms “target” as follows: “the AM and PM unit dose forms *target*” or “further *target*” specified pharmacokinetic and pharmacodynamics profiles. *See, e.g.*, Ex. 1001, 52:26–38 (’698 patent claim 1).

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On November 19, 2018, the court in the New Jersey Action granted Mylan's and Dr. Reddy's motion for summary judgment of invalidity, holding the claims of the '698 and '208 patents invalid as indefinite when applying the court's construction of the term "target." *See* Ex. 2075, 10 ("Because . . . this Court concluded that 'target' means 'set as a goal,' it is not possible to discern what the target clauses are telling you to do or not do."). Patent Owners filed a notice of appeal of that decision to the United States Court of Appeals for the Federal Circuit on February 21, 2019. Ex. 1056.

After we lifted the stay of these proceedings, we authorized Patent Owners to file a motion to terminate as a result of the district court's granting summary judgment of invalidity.

### III. DISCUSSION

Patent Owners make essentially two arguments in support of termination: (1) Petitioners cannot meet their burden of demonstrating, by a preponderance of the evidence, that the challenged claims are unpatentable because the court in the New Jersey Action found the claims indefinite; and (2) proceeding with the *inter partes* reviews would not be an effective use of the Board's resources in light of Patent Owners' appeal of the district court decisions to the Federal Circuit. Mot. 1.

Petitioners respond that the Board has already construed the claims and applied the prior art in the decisions to institute (1995 IPR, Paper 18; 272 IPR, Paper 9). Opp. 5–9. Petitioners also argue that efficiency does not weigh in favor of terminating these proceedings. *Id.* at 9–10.

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For the reasons discussed below, we deny Patent Owners’ motions to terminate.

*A. Effect of District Court’s Indefiniteness Determination*

In an *inter partes* review, we are tasked with considering whether issued claims are unpatentable only under 35 U.S.C. §§ 102 or 103 on the basis of prior art consisting of patents or printed publications. 35 U.S.C. § 311(b). In other words, consideration of indefiniteness under 35 U.S.C. § 112 of issued claims is outside our statutory limits. *Id.*; *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141–42 (2016) (characterizing canceling an issued patent claim for indefiniteness under § 112 in an *inter partes* review proceeding as “shenanigans”).

In its order granting summary judgment of invalidity on the ground of indefiniteness, the court in the New Jersey Action determined that the target clauses limit the claims, and focused on the difficulty *a potential infringer* might have in determining what acts constitute *infringement*. Ex. 2075, 5, 9 (questioning how a physician would determine the boundary for what he or she may legally do without infringing the claims), 10 (explaining that applying its construction of the term “target,” there is no discernable standard for drawing the line that distinguishes infringing acts from non-infringing acts), 14 (holding that the patents fail to teach how to draw the line to determine what to do to avoid infringing).

Our purview is different. *See* 35 U.S.C. § 311(b). We interpret the issued claims and determine whether prior art patents and printed publications anticipate the claims or render them obvious. *Id.* What a prior art reference discloses is a question of fact. *In re Beattie*, 974 F.2d 1309, 1311 (Fed. Cir. 1992). In determining whether a petitioner has carried its

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burden of establishing unpatentability, we need not necessarily determine the outer boundaries of a claim in reaching a conclusion as to whether the asserted prior art anticipates a claim or renders it obvious. Further, unlike a U.S. district court, we do not determine whether the claims comply with § 112, ¶ 2, for *infringement* purposes. We maintain our focus on the issue of *patentability* based on the evidence before us. And we do not apply our claim constructions with a focus on what a potential infringer may or may not be able to discern as to whether its actions infringe the challenged claims.

Patent Owners argue that it is inappropriate for us to consider prior art challenges where claims are indefinite. Mot. 4–5 (citing *Blackberry Corp. v. MobileMedia Ideas, LLC*, Case IPR2013-00036 (PTAB Mar. 7, 2014) (Paper 65); *Microsoft Corp. v. IpLearn-Focus, LLC*, Case IPR2015-00097 (PTAB Mar. 26, 2015) (Paper 11)). As we note above, however, we did not conclude in the Institution Decisions that the term “target” was unclear or failed to delineate the scope of the ’698 and ’208 patent claims with reasonable certainty. Rather, we construed the term, applied the asserted references, and determined that Petitioner established a reasonable likelihood of prevailing on the merits of its patentability challenges. Dec. 11–12, 20–29.

The decisions Patent Owners cite in support of their argument, therefore, are inapposite. For example, in *Blackberry Corp. v. MobileMedia Ideas, LLC*, we instituted trial, then terminated the proceeding because the independent claims contained a computer-implemented means-plus-function element, but the specification failed to disclose a specific algorithm with

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which to program a microprocessor to achieve the claimed function. Case IPR2013-00036, slip op. 13, 20 (PTAB Mar. 7, 2014) (Paper 65). We rejected Patent Owner’s proposal to conduct the prior art analysis based on only the functional recitation of the means-plus-function element, finding that “an obviousness determination based on less than all of the claimed elements is speculative as to the meaning or scope of the claims.” *Id.* at 20. And in *Microsoft Corp. v. IpLearn-Focus, LLC*, we held a claim term was amenable to two plausible claim interpretations, and, therefore, failed to delineate the scope of the invention with reasonable certainty. Case IPR2015-00097, slip op. 9 (PTAB Mar. 26, 2015) (Paper 11). Although we agree that we have the authority to reconsider a decision to institute and subsequently terminate a proceeding, *see Medtronic, Inc. v. Robert Bosch Healthcare System, Inc.*, 839 F.3d 1382, 1386 (Fed. Cir. 2016), we find that the circumstances noted in Patent Owners’ cited decisions are markedly different from the circumstances in the present case.

Patent Owners contend that Petitioners cannot meet their burden of proof that the challenged claims are anticipated by or obvious over the cited prior art “because they rely on a construction, which has been accepted in this proceeding, that both they and the district court found to be indefinite.” Mot. 6. We disagree. Petitioners argue in this proceeding that the broadest reasonable interpretation of “target” as used in the challenged claims means “with the goal of obtaining,” but they also explain that they presented the alternative argument in parallel district court proceedings that the term “target” is indefinite. *See* Paper 2, 16 n.3. As we note above, the court in the New Jersey Action construed the term “target” to mean “set as a goal.”

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Ex. 2073, 11. The court, however, ultimately determined that although it could construe the term “target,” it could not apply that construction for purposes of determining infringement. *See* Ex. 2075, 9 (“This Court sees no way that defining the goals for a method can, without more, inform the public of how to act to avoid infringement.”), 10 (“Defendants are correct that the patent provides no discernable standard for drawing the line that distinguishes infringing acts from noninfringing ones.”).

Patent Owners’ argument suggests that we are required to agree with the district court’s determination that the “target” clauses are indefinite. But we are not required to reach the same determinations as the district court. *See Novartis AG v. Noven Pharms. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017) (explaining that, even on the same record, the Board properly may reach a different conclusion than that of a district court). Indeed, we cannot reach the same determination as the district court here, as the district court’s determination is based on applying its claim construction to determine infringement, and we are limited to addressing in an *inter partes* review whether the challenged claims are patentable “on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications.” 35 U.S.C. § 311(b). We determined that Petitioners established a reasonable likelihood that the prior art anticipates or renders the claims obvious.

#### *B. Use of Judicial Resources*

Patent Owners argue that continuing a trial in these proceedings would be a waste of our resources. Mot. 8. Specifically, Patent Owners contend that an appeal of the court’s judgment of indefiniteness in the New Jersey Action will focus on the construction of the term “target” and the



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scope of the pharmacokinetic and pharmacodynamic elements of the claims, and that such issues are dispositive in this proceeding. *Id.* Patent Owners cite *Comtech Mobile Datacom Corp. v. Vehicle IP, LLC*, Case IPR2018-00531 (PTAB July 20, 2018) (Paper 9), as presenting a situation similar to that before us. Mot. 8–9.

In *Comtech Mobile*, we exercised discretion under 35 U.S.C. § 314(a) to deny institution of review. Case IPR2018-00531, Paper 9, 2. There, district court litigation on the challenged patent, ongoing for nine years at the time, was on its second appeal to the Federal Circuit over claim construction issues. *Id.* at 3. In particular, construction of a certain claim term was at issue in the pending Federal Circuit appeal and also potentially dispositive in the *inter partes* review, if instituted. *Id.* at 12. We determined that, were we to construe the term, we would be deciding (under the same standard) a disputed legal issue that was already before the Federal Circuit for resolution. *Id.* Also weighing in favor of denying an *inter partes* review, included the lengthy litigation history of the challenged patent against parties other than the petitioner, the patent owner’s offer of a covenant not to sue the petitioner or its customers for infringement of the challenged patent, and the lack of litigation (and, therefore, any time bar under 35 U.S.C. § 315(b)) against the petitioner. *Id.* at 13.

The proceedings before us are distinguishable from *Comtech Mobile*. First, we are not faced with similar circumstances regarding the litigation history of the challenged patents, the lack of copending district court litigation, or a patent owner’s covenant not to sue. Second, and more importantly, we already have instituted *inter partes* reviews in the 1995 IPR

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and the 272 IPR. *See, e.g.*, 1995 IPR, Paper 18; 272 IPR, Paper 9.<sup>7</sup> But for the stay of these cases during Patent Owner Pozen's bankruptcy proceeding, we would have issued our Final Written Decision in the 1995 IPR on or before March 8, 2019. *See* Paper 70. Now that the bankruptcy stay is lifted, we will convene an oral hearing for both cases on June 14, 2019 (if the parties request oral hearing), and we will issue our Final Written Decision in the both IPRs on or before September 8, 2019. Papers 67, 70. These proceedings, therefore, are not in their early stages and, contrary to Patent Owners' position, we find that terminating these *inter partes* reviews at this time would waste the significant resources that the parties and the Board already have expended on the proceedings. In addition, Patent Owners only recently filed a notice of appeal of the decision in the New Jersey Action (*see* Ex. 1056). Thus, the Federal Circuit's decision on the appeal is unlikely to issue until after we issue the Final Written Decisions in these proceedings.

#### IV. CONCLUSION

Having considered the Motions to Terminate and Oppositions, and the evidence of record, we deny the motions. We deny the motions without prejudice, however, should the Federal Circuit decide Patent Owners' appeal before we issue the Final Written Decisions in these proceedings.

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<sup>7</sup> Although we have not yet instituted review in the 1341 IPR, as we note above, Dr. Reddy's seeks to join the 272 IPR. Should we grant Dr. Reddy's motion for joinder, the 1314 IPR will proceed along the same schedule as the 272 IPR.

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V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Motion to Terminate IPR2017-01995 is dismissed as moot due to termination of the proceeding;

ORDERED that the Motions to Terminate IPR2018-00272 and IPR2018-01341 are *denied without prejudice* to reconsideration, should the Federal Circuit decide Patent Owners' appeal before we issue the Final Written Decisions in these proceedings.

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