

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

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

Cases

IPR2017-01995^{1,2} (Patent 9,220,698 B2)
IPR2018-00272 (Patent 9,393,208 B2)
IPR2018-01341 (Patent 9,393,208 B2)³

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

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

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

³ 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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IPR2018-01341 (Patent 9,393,208 B2)

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 17.⁴ Petitioners filed oppositions to each motion on February 22, 2019. 1995 IPR, Paper 68 (“Opp.”).⁵

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

⁴ 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.

⁵ 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. 11–12.⁶

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.

⁶ 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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