Trials@uspto.gov
Tel: 571-272-7822

Paper 12
Entered: September 9, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,[1]
Petitioner

v.

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

Case IPR2018-00272
Patent 9,393,208 B2

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

DENNETT, *Administrative Patent Judge*.

FINAL WRITTEN DECISION

[1] We terminated the proceeding between Petitioner Mylan Pharmaceuticals Inc. and Patent Owners by Order on August 12, 2019. Paper 73. Petitioner Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") from IPR2018-01341 was joined as Petitioner to this proceeding on April 1, 2019. Paper 36. Dr. Reddy's remains as a Petitioner in this case.

Finding Claims 1–7 Unpatentable
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

Denying as Moot Petitioner's Motion to Exclude
and Dismissing-in-part as Moot and Denying-in-part
Patent Owners' Motion to Exclude
37 C.F.R. § 42.64(c)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–7 (collectively, the "challenged claims") of U.S. Patent No. 9,393,208 B2 (Ex. 1001, "the '208 patent"). We have jurisdiction under 35 U.S.C. § 6. For the reasons that follow, we determine that Petitioner Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's" or "Petitioner") demonstrates, by a preponderance of the evidence, that the challenged claims are unpatentable.

A. Procedural History

The procedural history of this proceeding is unusually complex, involving joinder; bankruptcy; change in ownership of the patent; settlement between the original Petitioner, Mylan Pharmaceuticals, Inc. ("Mylan") and Patent Owners; and a decision on the merits in the trial between the remaining Petitioner after joinder, Dr. Reddy's, and Patent Owners.

Mylan filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–7 of the '208 patent under 35 U.S.C. § 311. Mylan supported its Petition with the testimony of David C. Metz, M.D. (Ex. 1002) and Michael Mayersohn, Ph.D. (Ex. 1003). We instituted trial on June 14, 2018, to determine whether:

1. Claims 1–7 of the '208 patent are unpatentable under 35 U.S.C. § 102 as anticipated by the '285 patent[2];

2. Claims 1–7 of the '208 patent are unpatentable under 35 U.S.C. § 103 as obvious over the '285 patent; and

3. Claims 1–7 of the '208 patent are unpatentable under 35 U.S.C. § 103 as obvious over the combination of the '285 patent with the EC-Naprosyn label[3] and Howden 2005.[4]

Paper 9 ("Institution Decision" or "Inst. Dec."), 24.

On July 2, 2018, Dr. Reddy's filed a Petition requesting an *inter partes* review of claims 1–7 of the '208 patent in IPR2018-01341 ("1341 IPR") and filed a Motion for Joinder to this proceeding. 1341 IPR, Papers 2, 3. In its motion requesting joinder, Dr. Reddy's represented that it had filed substantively the same Petition as Mylan and agreed to take an "understudy" role to Mylan, accepting Mylan's arguments and experts, and agreeing to take an active role only if Mylan dropped out of the proceedings. 1341 IPR, Paper 3, 1, 7.

Shortly thereafter, on August 28, 2018, Patent Owner Pozen Inc. ("Pozen") filed a Suggestion of Bankruptcy in this case, the effect of which automatically stayed this proceeding pursuant to 11 U.S.C. § 362. Paper 12. We suspended all deadlines in this proceeding on August 31, 2018. Paper 13.

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[2] U.S. Patent 8,557,285 B2, filed Aug. 23, 2011, issued Oct. 15, 2013, to John R. Plachetka (Ex. 1005, "the '285 patent").

[3] Prescription Drug Label for EC-Naprosyn® and other Naprosyn® formulations (Ex. 1009, "EC-Naprosyn label").

[4] C.W. Howden, *Review article: immediate-release proton-pump inhibitor therapy–potential advantages*, 22 ALIMENT. PHARMACOL. THER. 25–30 (2005) (Ex. 1006, "Howden 2005").

On January 4, 2019, Mylan filed an order from the bankruptcy court approving the sale of certain of Pozen's assets, including the '208 patent, to Nuvo Pharmaceuticals (Ireland) Designated Activity Company ("Nuvo"), which lifted the automatic stay of this proceeding. Ex. 1051, 1, 19 (identifying Nuvo as the purchaser). On January 16, 2019, we received Mandatory Notices identifying Nuvo as a real party-in-interest in this proceeding. Paper 16. On January 25, 2019, we issued an order modifying the schedule and the case caption to reflect the change in ownership of the '208 patent to Horizon Pharma USA, Inc. ("Horizon") and Nuvo (collectively, "Patent Owners"). Paper 20.

Patent Owners filed a Response on March 1, 2019.[5] Paper 32 ("PO Resp."). We granted Dr. Reddy's motion to join this proceeding on April 1, 2019. Paper 36. Mylan and Dr. Reddy's filed a Reply on May 8, 2019 (Paper 49, "Pet. Reply"), and Patent Owners filed a Sur-reply on May 20, 2019 (Paper 52, "PO Sur-reply"). On June 3, 2019, pursuant to 37 C.F.R. § 42.100(c), we adjusted the one-year pendency of this proceeding due to joinder. Paper 60.

Patent Owners filed a motion to seal certain exhibits. Paper 31 ("PO Motion to Seal"). Both parties also filed motions to exclude, which have been fully briefed. *See* Papers 56, 57, 66 (briefing related to Petitioner's Motion to Exclude); Papers 55, 58, 65 (briefing related to Patent Owners' Motion to Exclude).

We held a hearing on June 14, 2019, and entered the transcript of the hearing into the record. Paper 70 ("Tr."). On July 29, 2019, Mylan and Patent Owners filed a Joint Motion to Terminate Petitioner Mylan from the proceeding. Paper 71.

[5] Patent Owners' rely on the expert testimony of Dr. David R. Taft (Ex. 2025) and Dr. David A. Johnson (Ex. 2026) to support the Response.

We granted the motion and terminated Mylan from this proceeding on August 12, 2019. Paper 73.

B. Related Matters

Mylan previously filed a petition requesting an *inter partes* review of U.S. Patent No. 9,220,698 ("the '698 patent"), case IPR2017-01995 ("1995 IPR"). 1995 IPR Petition 2. Mylan asserted that the '698 patent and '208 patent are "related" (*id.*), and Patent Owners acknowledged that the '208 patent "claims, or may claim, the benefit of priority" to the same application to which the '698 patent claims priority (1995 IPR Paper 4, 2). On March 8, 2018, we instituted an *inter partes* review of all claims challenged on all asserted grounds in the 1995 IPR. *See* 1995 IPR, Paper 18. On August 14, 2018, we joined Dr. Reddy's to the 1995 IPR. We terminated the 1995 IPR on March 27, 2019 (1995 IPR Paper 71), and denied Dr. Reddy's Request for Rehearing of our termination decision on August 12, 2019 (1995 IPR Paper 77).

C. The '208 Patent (Ex. 1001)

The '208 patent, titled "Method for Delivering a Pharmaceutical Composition to Patient in Need Thereof," issued July 19, 2016. Ex. 1001. The '208 patent relates to methods for delivering a pharmaceutical composition of naproxen and esomeprazole in a unit dose form. *Id.* at col. 1, ll. 13–18.

Nonsteroidal anti-inflammatory drugs (NSAIDs) such as naproxen are used widely to treat pain and inflammation, but many NSAIDs are associated with gastrointestinal complications. *Id.* at col. 1, ll. 19–24. The presence of acid in the stomach and upper small intestine is a major factor in development of gastrointestinal disease in patients taking NSAIDs. *Id.* at col. 1, ll. 24–26.

Esomeprazole is a proton pump inhibitor ("PPI"). PPIs inhibit gastric acid secretion, and thus raise the gastrointestinal tract pH. *Id.* at col. 1, ll. 30–33. PPIs

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