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Paper 112
Entered: September 24, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TORRENT PHARMACEUTICALS LIMITED
and
APOTEX, INC. AND MYLAN PHARMACEUTICALS INC.,
Petitioners,

v.

NOVARTIS AG AND MITSUBISHI PHARMA CORP.,
Patent Owners.

Case IPR2014-00784
Case IPR2015-00518
Patent 8,324,283 B2

Before LORA M. GREEN, CHRISTOPHER M. KAISER, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

KAISER, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

INTRODUCTION

Torrent Pharmaceuticals Limited ("Torrent") filed a Petition to institute an *inter partes* review of claims 1–32 of U.S. Patent No. 8,324,283 B2 ("the '283 patent," Ex. 1001). Paper 2 ("Pet.").[1] On December 1, 2014, the Board instituted trial to review patentability of the challenged claims. Paper 11 ("Dec. on Inst."). Apotex, Inc. and Mylan Pharmaceuticals Inc. ("Apotex," or, together with Torrent, "Petitioners") filed a separate Petition also seeking to institute an *inter partes* review of claims 1–32 of the '283 patent. IPR2015-00518, Paper 1 ("IPR-518 Pet."). This second Petition was accompanied by a motion seeking joinder with the trial that had been instituted in IPR2014-00784. IPR2015-00518, Paper 2 ("IPR-518 Joinder Mot."). On February 17, 2015, the Board instituted trial in IPR2015-00518 and joined the proceedings in IPR2014-00784 and IPR2015-00518. IPR2015-00518, Paper 8 ("IPR-518 Dec.").

Thereafter, Novartis AG and Mitsubishi Pharma Corp. ("Patent Owners") filed a Response (Paper 28 ("PO Resp.")), and Petitioners filed a Reply (Paper 55).[2] Patent Owners also filed a motion to amend the challenged claims by replacing them with proposed amended claims 33–64 (Paper 26 ("Mot. to Amend")), Petitioners filed an opposition to this motion (Paper 52 ("Mot. to Amend Opp.")), and Patent Owners filed a reply (Paper

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[1] This decision refers to papers and exhibits filed in both the joined proceedings (IPR2014-00784 and IPR2015-00518). Except where noted otherwise, citations are to the papers and exhibits filed in IPR2014-00784.

[2] Redacted versions of the Response and Reply were filed as Paper 30 and Paper 54, respectively.

62 ("Mot. to Amend Reply")).[3] Both Petitioners and Patent Owners requested oral argument, and an oral hearing was held July 31, 2015. A transcript of the oral argument is included in the record.[4] Paper 111 ("Tr.").[5] Each side filed a motion to exclude certain evidence submitted by the other side. Paper 73; Paper 78. The parties filed oppositions to these motions to exclude, Paper 80; Paper 83, as well as replies to the oppositions, Paper 91, Paper 94. In addition, there are multiple pending motions to seal various pleadings and exhibits.

We have jurisdiction under 35 U.S.C. § 6(c), and we issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. We conclude Petitioners have established by a preponderance of the evidence that claims 1–32 of the '283 patent are unpatentable. We also conclude that Patent Owners have failed to establish by a preponderance of the evidence that proposed amended claims 33–64 are patentable. In addition, we deny in

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[3] Redacted versions of the Motion to Amend, the Opposition to the Motion to Amend, and the Reply to the Opposition to the Motion to Amend were filed as Paper 27, Paper 53, and Paper 63, respectively.

[4] The parties are directed to file a redacted version of the transcript that will be publicly available. The redacted version of the transcript shall be filed no later than one week after the entry of the present decision.

[5] Patent Owner filed objections to the demonstrative exhibits used by Petitioners at the hearing. Paper 105. In reaching our decision on the merits, we have considered arguments and evidence that are presented in the demonstrative exhibits only where those arguments and evidence were presented previously and are supported by the record. We expunge all the demonstrative exhibits themselves from the record, because they constitute neither evidence nor, to the extent that they differ from the written briefing, argument allowable under our rules.

part and dismiss in part each side's motion to exclude evidence, we seal certain pleadings and exhibits, and we unseal several exhibits that we substantively rely on in reaching our decision.

The '283 Patent

The '283 patent relates to a solid pharmaceutical composition suitable for oral administration, wherein the composition comprises a sphingosine-1 phosphate (S1P) receptor agonist and a sugar alcohol. Ex. 1001, 1:11–14, 1:33–35. "The sugar alcohol may act as a diluent, carrier, filler or bulking agent, and may suitably be mannitol." *Id.* at 9:53–54. The '283 patent indicates that solid compositions comprising a sugar alcohol are "particularly well suited to the oral administration of S1P receptor agonists," "provide a convenient means of systemic administration of S1P receptor agonists, do not suffer from the disadvantages of liquid formulations for injection or oral use, and have good physicochemical and storage properties." *Id.* at 1:36–42. According to the '283 patent, a "particularly preferred S1P receptor agonist . . . is FTY720, i.e. 2-amino-[2-(4-octylphenyl)ethyl]propane-1,3-diol." *Id.* at 8:23–25. FTY720 is also known as fingolimod. Ex. 2007 ¶ 13; Tr. 31:13–15. The '283 patent further describes that solid compositions comprising a sugar alcohol "may show a high level of uniformity in the distribution of the S1P receptor agonist through the composition, as well as high stability" and "may be manufactured on high speed automated equipment." Ex. 1001, 1:42–48. S1P receptor agonists are immunomodulating compounds, and solid pharmaceutical compositions comprising S1P receptors may be useful for

treating and preventing organ/tissue transplant rejection, autoimmune disease/inflammatory conditions, or viral myocarditis and viral diseases caused by viral mycocarditis. *Id.* at 1:18–22, 12:19–37.

Claims 1 and 19 of the '283 patent are independent claims and are illustrative of the claimed subject matter. They are reproduced below.

> 1. A solid pharmaceutical composition suitable for oral administration, comprising:
>
> (a) a SIP receptor agonist which is selected from 2-amino-2-[4-(3-benzyloxyphenoxy)-2-chlorophenyl]propyl-1,3-propane-diol or 2-amino-2-[4-(3-benzyloxyphenylthio)-2-chlorophenyl]propyl-1,3-propane-diol, 2-amino-2-[4-(3-benzyloxyphenylthio)-2-chlorophenyl]-2-ethyl-1,3-propane-diol, and its phosphates or a pharmaceutically acceptable salt thereof; and
>
> (b) a sugar alcohol.
>
> 19. A solid pharmaceutical composition suitable for oral administration, comprising mannitol and 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol or a pharmaceutically acceptable salt thereof.

Id. at 17:2–11, 18:7–10.

Reviewed Ground of Unpatentability

The Board instituted trial to review the patentability of the challenged claims on the following ground:

Claim(s) Challenged	Basis	References
1–32	§ 103	Chiba[6] and Aulton[7]

[6] Chiba et al., US 6,004,565, issued Dec. 21, 1999 ("Chiba," Ex. 1006).

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