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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,
ARGENTUM PHARMACEUTICALS LLC, ACTAVIS ELIZABETH LLC,
TEVA PHARMACEUTICALS USA, INC., SUN PHARMACEUTICAL
INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC.,
and SUN PHARMA GLOBAL FZE,
Petitioners,

v.

NOVARTIS AG,
Patent Owner.

Case IPR2017-00854[1]
Patent US 9,187,405 B2

Before CHRISTOPHER M. KAISER, ROBERT A. POLLOCK, and KRISTI L. R. SAWERT,[2] *Administrative Patent Judges.*

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Claims 1–6 Not Shown to Be Unpatentable
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

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[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.
[2] Replacing Judge Lora M. Green, who has left the Board.

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–6 of U.S. Patent No. US 9,187,405 B2 (Ex. 1001, "the '405 patent"). We have jurisdiction under 35 U.S.C. § 6.

For the reasons that follow, we determine that Petitioners have failed to show, by a preponderance of the evidence, that claims 1–6 of the '405 patent are unpatentable.

A. Procedural History

Apotex Inc. and Apotex Corp. ("Apotex") filed a Petition requesting an *inter partes* review of claims 1–6 the '405 patent. Paper 2 ("Pet."). Novartis AG[3] ("Novartis"), filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp."). We instituted *inter partes* review of each of the challenged claims. Paper 11, 27 ("Dec.").

Three parties filed Petitions substantially the same as Apotex's Petition along with requests for joinder: 1) Argentum Pharmaceuticals LLC ("Argentum") (IPR2017-01550, Papers 1 and 3); 2) Actavis Elizabeth LLC and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") (IPR2017-01946, Papers 2 and 3); and 3) Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE (collectively, "Sun") (IPR2017-01929, Papers 2 and 3). We granted each Petition and

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[3] According to Patent Owner, "Novartis AG has assigned its rights in U.S. Patent 9,187,405 to Novartis Pharmaceuticals Corporation (*see* Assignment at Reel 043314/Frame 0800). The real party in interest is Novartis Pharmaceuticals Corporation. Novartis AG and other Novartis subsidiaries may also have an interest." Paper 22.

associated requests for joinder to IPR2017-00854. *See* IPR2017-01550, Paper 10; IPR2017-01946, Paper 9; IPR2017-01929, Paper 7, respectively. Because our grants of joinder were conditioned on Apotex taking the lead role in the joined proceeding, we refer to Apotex, Argentum, Teva, and Sun, collectively, as "Petitioners."

After institution of trial and our grants of joinder, Patent Owner filed a Patent Owner Response (Paper 26, "PO Resp."); Petitioners filed a responsive Reply (Paper 49, "Pet. Reply"); and Patent Owner filed an authorized Sur-Reply (Paper 63, "PO Sur-Reply").

Patent Owner also filed a Corrected Contingent Motion to Amend. Paper 61. Petitioners opposed (Paper 51), and Patent Owner responded with a Reply in support of its motion (Paper 64).

Petitioners rely on the declaration of Dr. Barbara S. Giesser (Ex. 1002), first submitted with Apotex's Petition, and on the later-submitted Reply Declaration of Leslie Z. Benet, Ph.D. (Ex. 1047).

Patent Owner relies on the declarations of Fred D. Lublin, M.D. (Exs. 2003, 2025, 2107, 2097), William J. Jusko, Ph.D. (Exs. 2005, 2024, 2095), Lawrence Steinman, M.D. (Exs. 2022, 2096), and Jerold Chun, M.D., Ph.D, (Ex. 2098). Patent Owner further relies on the declaration of named inventor Christian Schnell. Ex. 2026.

Petitioners filed motions for observations on depositions of Drs. Lublin, Jusko, Steinman, and Chun (Papers 77, 79, 76, and 78, respectively); Patent Owner filed responses to each of those motions (Papers 90, 93, 91, 92, respectively).

We heard oral argument on May 11, 2018. A transcript of that proceeding is entered as Paper 108 ("Tr.").

The parties filed the following motions. Petitioners filed a motion to exclude evidence (Paper 82); Patent Owner opposed (Paper 89); and Petitioners submitted a reply in support of its first motion to exclude (Paper 98). Patent Owner filed a first motion to exclude evidence (Paper 80); Petitioners opposed (Paper 94); and Patent Owner submitted a reply in support of its first motion to exclude (Paper 97). Patent Owner filed a supplemental motion to exclude evidence (Paper 102); Petitioners opposed (Paper 101); and Patent Owner submitted a reply in support of its supplemental motion to exclude (Paper 103). The parties have also filed six motions to seal. (Papers 36, 50, 83, 99 (by Petitioners); Papers 29, 37 (by Patent Owner)).

B. Related Proceedings

According to Patent Owner, there are no other judicial or administrative matters that would affect, or be affected by, a decision in this proceeding. Paper 4, 2. Petitioners note that in IPR2014-00784, the Board issued a Final Written Decision relating to U.S. Patent No. 8,324,283 B2, and that "[a]lthough not from the same patent family as the '405 patent, the '283 patent included claims to pharmaceutical compositions of fingolimod, or a pharmaceutically acceptable salt thereof, that is suitable for oral administration, as well as claims directed to the treatment of multiple sclerosis using S1P receptor agonists." Pet. 20; *see id.* at 13–14; Paper 49, 7. We are not persuaded, however, that the Board's prior decision with respect to the '283 patent is probative of the instant proceeding.

C. The '405 Patent and Relevant Background

The '405 patent, titled "S1P Receptor Modulators for Treating Relapsing-Remitting Multiple Sclerosis," issued to Peter C. Hiestand and

Christian Schnell from U.S. Application No. 14/257,342 ("the '342 application"), filed April 21, 2014. Ex. 1001, at [21], [60], [71], [72]. The '342 application is a divisional of Application No. 13/149,468 ("the '468 application") (now U.S. Pat. No. 8,741,963). *Id.* at [60]. The '468 application, in turn, is a continuation of Application No. 12/303,765 ("the '765 application."), which is the U.S. entry of PCT/EP2007/005597, filed June 25, 2007. *Id.*; Ex. 1009, 21, 40. PCT/EP2007/005597 claims priority to foreign application GB0612721.1 (Ex. 1012), filed on June 27, 2006. Ex. 1001, at [30]; *see* Ex. 1009, 57–58.

The instant "invention relates to the use of an S1P[4] receptor modulator in the treatment or prevention of neo-angiogenesis associated with a demyelinating disease, e.g. multiple sclerosis." Ex. 1001, 1:5-8. "Characteristic pathological features of demyelinating diseases include inflammation, demyelination and axonal and oligodendrocyte loss. In addition[,] lesions can also have a significant vascular component. A firm link has recently been established between chronic inflammation and angiogenesis and neovascularization seems to have a significant role in the progression of disease." *Id.* at 9:6–12. According to the inventors, "[i]t has now been found that S1P receptor modulators have an inhibitory effect on neo-angiogenesis associated with demyelinating diseases, e.g. MS." *Id.* at 9:13–15.

"Multiple sclerosis (MS) is an immune-mediated disease of the central nervous system with chronic inflammatory demyelination leading to progressive decline of motor and sensory functions and permanent

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[4] S1P refers to sphingosine-1 phosphate, a natural serum lipid. Ex. 1001, 1:13–14.

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