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Paper 11
Entered: July 18, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,
Petitioner,
v.
NOVARTIS AG,
Patent Owner.

Case IPR2017-00854
Patent US 9,187,405 B2

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

POLLOCK, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Apotex Inc. and Apotex Corp. ("Apotex" or "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–6 of U.S. Patent No. US 9,187,405 B2 (Ex. 1001, "the '405 patent"). Paper 2 ("Pet."). Novartis AG, ("Novartis" or "Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we institute an *inter partes* review of claims 1–6 of the '405 patent.

A. 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. Petitioner, however, notes 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.

B. *The '405 Patent and Relevant Background*

The '405 Patent, entitled "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[1] 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. [multiple sclerosis]." *Id.* at 9:13–15.

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

"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 disability." Ex. 1001, 8:61–64. The inventors state that S1P receptor agonists or modulators may be useful in the treatment of MS, including the Relapsing-Remitting MS (RR-MS) form, which accounts for 85% of patients' initial experience with the disease and is the precursor to the more debilitating Secondary-Progressive form (SPMS). *Id.* at 9:64–10:21; *see also id*. at 10:3–5 (noting that within 10 years of onset about half of RR-MS patients will develop SPMS); Ex. 1005,[2] 159–60, Fig. 1 (discussing the pathophysiology, classification, and clinical course of MS).

"S1P receptor agonists or modulators are known as having immunosuppressive properties or anti-angiogenic properties in the treatment of tumors. . . ." Ex. 1001, 8:56–60. Preferred compounds stimulate lymphocyte homing, thereby "elicit[ing] a lymphopenia resulting from a re-distribution, preferably reversible, of lymphocytes from circulation to secondary lymphatic tissue, without evoking a generalized immunosuppression." *Id.* at 2:17–23. "A particularly preferred S1P receptor agonist . . . is FTY720, i.e., 2-amino-2-[2-(4-octyphenyl)ethyl] propane-1,3-diol. . . ." *Id.* at 8:17–30. This compound, also known as fingolimod, is the active ingredient in Novartis's Gilenya product (fingolimod hydrochloride) approved for the treatment of RR-MS. *See id.* at 9:64– 10:16; Pet. 62; Prelim. Resp. 1.

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[2] Thomson, "*FTY720 in Multiple Sclerosis: The Emerging Evidence of its Therapeutic Value,*" 1(3) CORE EVIDENCE 157-167 (2006). Ex. 1005.

C. Challenged Claims

Illustrative claim 3 recites (paragraphing added):

> 3. A method for treating Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising
>
> orally administering to said subject 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form,
>
> at a daily dosage of 0.5 mg,
>
> absent an immediately preceding loading dose regimen.

The remaining independent claims differ only in the language of the preamble, such that the "treating" language of claim 3 is replaced with "reducing or preventing or alleviating relapses" (claim 1) or "slowing progression" of RR-MS (claim 5).

Depending from claims 1, 3, and 5, respectively, claims 2, 4, and 6 specify that the 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol is the hydrochloride salt form—i.e., fingolimod hydrochloride.

D. The Asserted Prior art and Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 21):

Ground	Claims	References	Basis
1	1–6	Kovarik[3] and Thomson	§ 103

[3] Kovarik and Appel-Dingemanse, WO 2006/058316, published June 1, 2006. Ex. 1004.

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