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Paper 7
Entered: May 4, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAWAI USA, INC. and SAWAI PHARMACEUTICAL CO., LTD.,
Petitioner,

v.

ASTELLAS PHARMA INC.,
Patent Owner.

Case IPR2018-00079
Patent 6,346,532 B1
Reexamination 6,346,532 C1

Before JAMES T. MOORE, SUSAN L. C. MITCHELL, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. ("Petitioner") filed a Petition for an *inter partes* review of claims 1, 3–6, 9, 11, 12, 15, and 16 of U.S. Patent No. 6,346,532 C1 ("the '532 patent," Ex. 1001[1]). Paper 1 ("Pet."). Astellas Pharma Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . 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(a). Applying that standard, and upon consideration of the information presented in the Petition and the Preliminary Response, we deny the Petition and do not institute an *inter partes* review.

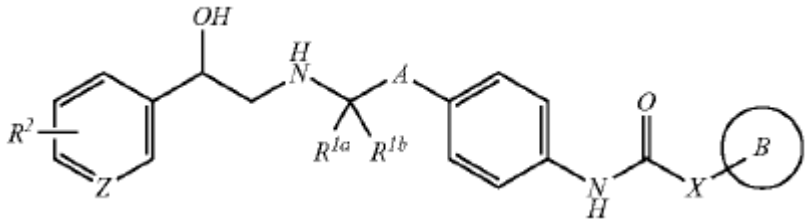
A. Related Proceedings

The parties identify *Astellas Pharma Inc. v. Sawai USA, Inc.*, No. 16-cv-954 (D. Del. 2016) and *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, No. 16-cv-905 (D. Del. 2016) as related matters under 37 C.F.R. § 42.8(b)(2). These cases have been consolidated in the district court. Pet. 55; Paper 4, 2.

[1] The '532 patent underwent a reexamination proceeding before the Office, and a reexamination certificate issued on February 24, 2015. Exhibit 1001 contains both the original patent and the reexamination certificate. For clarity, we use the term "Ex. 1001 B1" when citing to the original patent, and "Ex. 1001 C1" when citing to the reexamination certificate.

B. The '532 Patent

The '532 patent discloses amide derivatives or salts thereof. The amide derivatives have the following formula:



where ring B is a nitrogen-containing heteroaryl group which is unsubstituted or substituted and is optionally fused with a benzene ring; X is a lower alkylene or an alkenylene, both of which are unsubstituted or substituted with hydroxy or a lower alkyl group, or X is a carbonyl or a group represented by –NH–, and when X is a lower alkylene which is substituted with a lower alkyl group, a carbon atom of the ring B optionally bonds with the lower alkyl group so that a ring is formed; A is methylene, ethylene, or a group represented by $–CH_2O–$; R^{1a}, R^{1b} are the same or different and each is a hydrogen atom or a lower alkyl group; R^2 is a hydrogen atom or a halogen atom; and Z is a group represented by =CH–; or a salt thereof. Ex. 1001 C1, 1:25–62. According to the '532 patent, these compounds selectively stimulate β_3 receptor,[2] and are useful for treating diabetes. *Id.* (Abstract). The '532 patent specifically discloses the chemical compound (R)-2-(2-aminothiazol-4-yl)-4′-[2-(2-hydroxy-2-phenylethyl) amino]ethyl]acetanilide, now known as "mirabegron." Mirabegron is recited in claim 5 of the '532 patent. *Id.* at 2:24–47.

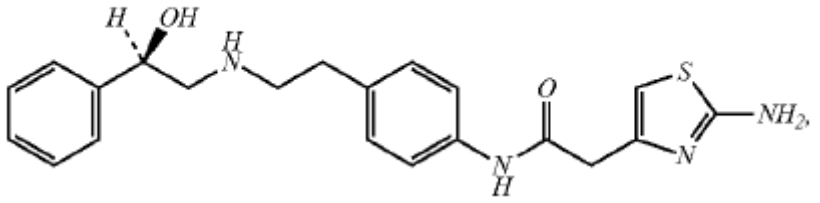
[2] Compounds that stimulate β_3 receptor go by various names known in the art, including: β_3 agonists, β_3 adrenoreceptor agonists, β_3 receptor agonists, and β_3 adrenergic agonists. *See* Prelim. Resp. 7 n.2.

C. Challenged Claims

Petitioner challenges claims 1, 3–6, 9, 11, 12, 15, and 16 of the '532 patent. Pet. 2. Claim 5 is illustrative of the claimed subject matter:

5. A compound of formula (Ia):

(Ia)



or a salt thereof.

Ex. 1001 C1, 2:24–47.

D. The Prior Art

Petitioner advances the following references as prior art on which it relies for the asserted grounds challenging claims 1, 3–6, 9, 11, 12, 15, and 16 of the '532 patent:

1. Nathalie Blin et al., *Structural and Conformational Features Determining Selective Signal Transduction in the β3-Adrenergic Receptor*, 44 MOL. PHARMACO. 1097–1104 (1993) ("Blin," Ex. 1006);

2. Michael H. Fisher et al., U.S. Patent No. 5,541,197 (Jul. 30, 1996) ("Merck '197," Ex. 1008);

3. Robert J. Mathvink et al., U.S. Patent No. 6,011,048 (Jan. 4, 2000) ("Merck '048," Ex. 1010);

4. Richard B. Silverman, THE ORGANIC CHEMISTRY OF DRUG DESIGN & DRUG ACTION 19–23 (1992) ("Silverman," Ex. 1016); and

5. C.W. Thornber, *Isosterism and Molecular Modification in Drug Design*, 8 CHEM. SOC. REV. 563–580 (1979) ("Thornber," Ex. 1017).

E. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 3–6, 9, 11, 12, 15, and 16 of the '532 patent on the following two grounds:

Claims	Basis	References
1, 3–6, 9, 11, 12, 15, and 16	35 U.S.C. § 103	Merck '197 in view of Blin, and Silverman or Thornber
1, 3–6, 9, 11, 12, 15, and 16	35 U.S.C. § 103	Merck '197 in view of Blin, and Merck '048 and Silverman or Thornber

Pet. 10. Petitioner also relies on the Declaration of Robert M. Williams, Ph.D. (Ex. 1002). *Id.* at 2 n.2.

II. ANALYSIS

We address below whether the Petition meets the threshold showing for institution of an *inter partes* review under 35 U.S.C. § 314(a). We consider each ground of unpatentability in view of the understanding of a person of ordinary skill in the art. For this Decision, we find that the prior art itself is sufficient to demonstrate the level of ordinary skill in the art at the time of the invention. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001). Further, based on the information presented at this stage of the proceeding, we consider Petitioner's declarant, Dr. Williams, qualified to opine from the perspective of an ordinary artisan at the time of the invention. *See* Ex. 1003 (curriculum vitae of Dr. Williams).

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