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Paper No. 57
Date: June 9, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC.,
Petitioner,

v.

UCB BIOPHARMA SPRL,
Patent Owner.

IPR2019-00400
Patent 8,633,194 B2

Before ROBERT A. POLLOCK, RYAN H. FLAX, and KRISTI L. R. SAWERT *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge.*

Final Written Decision

Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

Denying Patent Owner's Motion to Exclude Evidence
37 C.F.R. § 42.64

Denying Petitioner's Corrected Motion to Exclude Evidence
37 C.F.R. § 42.64

Decisions on Motions to Seal
37 C.F.R. §§ 42.1 and 42.54

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I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–11 of U.S. Patent No. 8,633,194 B2 ("the '194 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6.

Petitioner has the burden of proving unpatentability of a claim by a preponderance of the evidence. 35 U.S.C. § 316(e) (2018). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has not demonstrated by a preponderance of the evidence that claims 1–11 are unpatentable. For the reasons set forth below, we also deny the parties' motions to exclude evidence and grant, in-part, the proffered motions to seal.

A. Procedural History

Apotex Inc. ("Petitioner") filed a corrected Petition for an *inter partes* review of claims 1–11 of the '194 patent. Paper 4 ("Pet."). UCB Biopharma Sprl ("Patent Owner" or "UCB") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp."). The parties further submitted an authorized Reply and Sur-Reply to the Preliminary Response. Paper 13; Paper 16. In view of the then-available, preliminary record, we concluded that Petitioner satisfied the burden, under 35 U.S.C. § 314(a), to show that there was a reasonable likelihood that Petitioner would prevail with respect to at least one of the challenged claims. Accordingly, on behalf of the Director (37 C.F.R. § 42.4(a) (2018)), and in accordance with *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018) and the Office's Guidance on the Impact of SAS on AIA

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Trial Proceedings (Apr. 26, 2018),[1] we instituted an *inter partes* review of all the challenged claims, on all the asserted grounds. Paper 17 ("Inst. Dec."), 21.

After institution, Patent Owner filed a Response. Paper 22 ("PO Resp."). Petitioner filed a Reply. Paper 33 ("Reply"). Patent Owner filed a Sur-reply. Paper 38 ("Sur-reply").

Petitioner filed a Corrected Motion to Exclude Evidence directed to Exhibits 2024, 2030, 2031, and 2034. Paper 43. Patent Owner opposed that motion (Paper 48) and Petitioner filed a Reply (Paper 49). Patent Owner filed a Motion to Exclude Exhibits 1031–1038, 1040, 1041, and 1044. Paper 44. Petitioner opposed that motion (Paper 47) and Patent Owner filed a Reply (Paper 50). Also before us are three motions to seal pursuant to the default protective order. Papers 18, 28, 35.

On April 22, 2020, the parties presented arguments at oral hearing, the transcript of which is of record. Paper 56 ("Tr.").

B. Real Parties-in-Interest

Petitioner identifies itself, Apotex Corp., Apotex Holdings Inc., and Apotex Pharmaceuticals Holdings Inc. as real parties-in-interest. Pet. 3. Patent Owner asserts that its real parties-in-interest are UCB Biopharma Sprl, UCB, Inc., UCB Pharma S.A., UCB S.A., and UCB Manufacturing Inc. Paper 7, 2; Ex. 2008 (public version).

[1] https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

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C. Related Proceedings

The '194 patent is at issue in *UCB, Inc. v. Apotex Inc.*, No. 0-18-cv-60846 (S.D. Fla.). *See* Paper 7, 2; Paper 10, 2. On April 1, 2019, the district court in this related litigation issued an Order staying that case pending our review of the '194 patent. Ex. 3001 (order granting Apotex, Inc.'s motion to stay pending *inter partes* review and administratively closing the case); *see also* Paper 43, 6 (noting that the concurrent district court case remains stayed).

Patent Owner also notes the '194 patent was previously at issue in *UCB, Inc. v. Apotex Inc.*, 1:18-cv-03404 (S.D.N.Y.), which was voluntarily dismissed. Paper 7, 2.

D. Asserted Grounds of Unpatentability

Petitioner asserts two grounds of unpatentability (Pet. 7, 8):

Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–11	103(a)[2]	Handbook[3], WO '094[4]

[2] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '194 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. § 103 throughout this Decision.

[3] AMERICAN PHARMACEUTICAL ASSOCIATION, HANDBOOK OF PHARMACEUTICAL EXCIPIENTS (Arthur H. Kibbe, Ph.D. ed., 3d ed. 2000). Ex. 1006.

[4] International Patent Application Publication No. WO 2004/050094, published June 17, 2004. Ex. 1007.

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Ground	Claims Challenged	35 U.S.C. §	Reference(s)/Basis
2	1–11	103(a)	Handbook, EP '203,[5] US '558[6]

In support of its patentability challenges, Petitioner relies on, *inter alia*, the testimony of Dr. Paul A. Laskar, Ph.D. *See* Exs. 1002, 1050 (first and second Declarations, respectively); Ex. 1003 (curriculum vitae); Exs. 2010 and 2037 deposition transcripts). In opposition to these challenges, Patent Owner relies on, *inter alia*, the testimony of Dr. Sarfaraz K. Niazi, Ph.D. *See* Ex. 2014 (Declaration); Ex. 2098 (curriculum vitae); Ex. 1043 (deposition transcript).

E. The '194 Patent and Relevant Background

According to the '194 patent's specification, its "invention is based on the unexpected recognition that a pharmaceutical composition comprising an active substance belonging to the family of substituted benzhydryl piperazines and a reduced amount of preservatives is stable during a long period of time." Ex. 1001, 1:60–64; *see also id.* at 1:64–65 (defining stability as "the capacity to resist[] . . . microbial contamination"). Such combinations can be administered orally, by spray inhalation, and nasal installation and may be formulated as drops, nasal drops, eye drops, ear drops, and oral preparations such as a syrup. *Id.* at 5:8–29.

[5] European Patent Application Publication No. 0605203 A2, published July 6, 1994. Ex. 1004.
[6] U.S. Patent No. 5,698,558, issued Dec. 16, 1997. Ex. 1015.

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