

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

SUPERNUS PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2013-00372
Patent 8,394,406 B2

Before LORA M. GREEN, SCOTT E. KAMHOLZ, and
GEORGIANNA W. BRADEN, *Administrative Patent Judges*.

KAMHOLZ, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Amneal Pharmaceuticals, LLC (“Amneal”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–12 and 16–21 of U.S. Patent No. 8,394,406 B2 (Ex. 1009, “the ’406 patent”). The Board instituted trial for the challenged claims on the ground, asserted by Amneal, of obviousness over WO 02/080932 A1 (Ex. 1002, “Ashley ’932”), which incorporates by reference provisional patent application serial No. 60/281,854 (Ex. 1003, “Ashley ’854”) and U.S. Patent No. 5,348,748 (Ex. 1005, “Sheth”). Decision to Institute (Paper 8, “Dec.”) 14.

After institution of trial, Patent Owner Supernus Pharmaceuticals, Inc. (“Supernus”) filed a Patent Owner Response in redacted (Paper 39, “Resp.”) and unredacted (Paper 38) forms. Amneal filed a Reply (Paper 56, “Reply”). Supernus did not file a Motion to Amend.

Amneal filed a Motion to Exclude certain of Supernus’s evidence (Paper 69, “Pet. Motion to Exclude”). Supernus filed an Opposition in redacted (Paper 80) and unredacted (Paper 81) forms, and Amneal filed a Reply (Paper 84).

Amneal relies upon declarations from Dr. Glenn A. Van Buskirk in support of its Petition (Ex. 1022) and its Reply (Ex. 1066). Supernus relies upon a declaration from Dr. Edward M. Rudnic in support of its Response (Ex. 2016), as well as deposition testimony from Dr. Van Buskirk

(Exs. 2015, 2193).¹ Amneal relies upon deposition testimony from Dr. Rudnic in its Reply (Ex. 1052). Supernus filed a Motion for Observations on Cross-Examination of Amneal's Reply witnesses (Paper 74, "Obs."), and Amneal filed a Response to the Observations (Paper 76, "Obs. Resp.").

Oral argument was conducted on August 12, 2014. A transcript is entered as Paper 90 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Amneal has not proved that claims 1–12 and 16–21 are unpatentable. Amneal's Motion to Exclude Evidence is dismissed as moot.

B. The '406 Patent

The '406 patent relates to once-daily, sub-antimicrobial formulations of doxycycline. Ex. 1009, 2:38–46. Such formulations can be used to inhibit activity of collagen destruction enzymes, which are associated with human diseases, such as rosacea, without provoking undesired side effects attendant to an antibacterial dose. *Id.* at 3:6–9. A combination of an immediate-release ("IR") portion, with 30 mg doxycycline, and a delayed-release ("DR") portion, with 10 mg doxycycline, facilitates once-daily dosing by providing a steady-state blood level of 0.1 to 1.0 µg/ml or 0.3 to 0.8 µg/ml. *Id.* at 3:61–68; 10:14–20. The composition may be a pellet, a combination of pellets, a tablet, or a capsule. *Id.* at 5:50–64. The DR portion may have an enteric polymer, such as hydroxypropyl

¹ The parties rely on the testimony of other witnesses, but that evidence is not listed here because it is not cited in this decision.

methylcellulose phthalate. *Id.* at 7:24–30. The IR and/or DR portions may incorporate one or more excipients. *Id.* at 6:16–42. Examples of excipients include binders, such as hydroxypropyl methylcellulose (HPMC); disintegration agents, such as cross-linked polyvinylpyrrolidone; and filling agents, such as lactose. *Id.* at 6:20–31.

Claim 1 is illustrative of the claimed subject matter and is reproduced below, with line breaks added for clarity.

1. An oral pharmaceutical composition comprising less than 50 mg of total doxycycline, which at a once-daily dosage will give steady state blood levels of the doxycycline between 0.1 µg/ml and 1.0 µg/ml, and a C_{max} of the doxycycline between 0.4 µg/ml and 0.8 µg/ml, the composition consisting of
 - (i) an immediate release (IR) formulation of the doxycycline,
 - (ii) a delayed release (DR) formulation of the doxycycline comprising at least one enteric polymer, and
 - (iii) one or more pharmaceutically acceptable excipients,wherein the doxycycline in the IR and DR formulations is in a ratio of 75:25.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms are given their ordinary and customary meaning, as

would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

The only term requiring construction for purposes of this decision is “delayed release.” Neither party proposed a construction of this term in its principal brief. The ’406 patent, too, does not provide an express definition of this term. Tr. 42:7–9.

In response to a request during oral argument, Tr. 48:7–21, the parties identified the record evidence they rely on concerning construction of “delayed release.” Amneal cited paragraphs 19 and 20 of Dr. Van Buskirk’s Second Declaration (Ex. 1066) and paragraph 110 of Dr. Rudnic’s Declaration (Ex. 2016). Tr. 70:19–71:20.² Supernus cited column 7, lines 47–53 and Figures 2 and 3 of related U.S. Patent No. 8,206,740 (Ex. 1001); paragraph 20 of Dr. Van Buskirk’s Second Declaration; paragraph 177 of Dr. Rudnic’s Declaration; the definition of “delayed release” on page 7 of Exhibit 2047; the definition of “delayed release” on page 30 of Exhibit 2058; the definition of “enteric coated” on page 32 of Exhibit 2058; and passages from the transcript of Dr. Van Buskirk’s second deposition at page 11, line 7, to page 13, line 6 and at page 16, line 14, to page 17, line 2 (Ex. 2193). Tr. 80:11–81:20. Supernus also cited a passage from the transcript of Dr. Van Buskirk’s first deposition in argument that indirectly

² Citations to the record given during oral argument were made with respect to the record in case IPR2013-00368, which involves U.S. Patent No. 8,206,740, of which the ’406 patent is a continuation. *See* Tr. 14:8–9; Resp. 4. The citations here are adjusted as needed to refer to the same material cited during the oral argument.

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