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Paper 94
Entered: December 9, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

SUPERNUS PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2013-00368
Patent 8,206,740 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, 2, 5–15, and 19–22 of U.S. Patent No. 8,206,740 B2 (Ex. 1001, "the '740 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.") 13–14.

After institution of trial, Patent Owner Supernus Pharmaceuticals, Inc. ("Supernus") filed a Patent Owner Response in redacted (Paper 40, "Resp.") and unredacted (Paper 39) forms. Amneal filed a Reply (Paper 57, "Reply"). Supernus did not file a Motion to Amend.

Amneal filed a Motion to Exclude certain of Supernus's evidence (Paper 70, "Pet. Motion to Exclude"). Supernus filed an Opposition in redacted (Paper 82) and unredacted (Paper 83) forms, and Amneal filed a Reply (Paper 86).

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 76, "Obs."), and Amneal filed a Response to the Observations (Paper 78, "Obs. Resp.").

Oral argument was conducted on August 12, 2014. A transcript is entered as Paper 92 ("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, 2, 5–15, and 19–22 are unpatentable.

Amneal's Motion to Exclude Evidence is dismissed as moot.

B. The '740 Patent

The '740 patent relates to once-daily, sub-antimicrobial formulations of doxycycline. Ex. 1001, 2:21–30. 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 2:64–67. 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 3:52–58, 10:2–8. The composition may be a pellet, a combination of pellets, a tablet, or a capsule. *Id*. at 5:41–55. The DR

[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.

portion may have an enteric polymer, such as hydroxypropyl methylcellulose phthalate. *Id*. at 7:14–21. The IR and/or DR portions may incorporate one or more excipients. *Id*. at 6:7–33. 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 6:11–22.

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

> 1. An oral pharmaceutical composition of doxycycline, which at a once-daily dosage will give steady state blood levels of doxycycline of a minimum of 0.1 µg/ml and a maximum of 1.0 µg/ml, the composition consisting of
>
> (i) an immediate release (IR) portion comprising 30 mg doxycycline;
>
> (ii) a delayed release (DR) portion comprising 10 mg doxycycline; and
>
> optionally, (iii) one or more pharmaceutically acceptable excipients.

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 '740 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 105 of Dr. Rudnic's Declaration (Ex. 2016). Tr. 70:19–71:20. Supernus cited column 7, lines 47–53 and Figures 2 and 3 of the '740 patent (Ex. 1001); paragraph 20 of Dr. Van Buskirk's Second Declaration; paragraph 176 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 addresses construction of "delayed release." Resp. 18 (citing Ex. 2015, 170:3–171:2).

Review of the evidence cited by the parties indicates their agreement, as well as that of their experts, that Exhibit 2058 correctly defines "delayed release" as "release of a drug at a time other than immediately following oral

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