

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
Petitioner,

v.

ALLERGAN, INC.,
Patent Owner.

Case IPR2018-00608
Patent 9,161,926 B2

Before SHERIDAN K. SNEDDEN, TINA E. HULSE, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, “Petitioner”), filed a Petition requesting an *inter partes* review of claims 1–6 of U.S. Patent No. 9,161,926 B2 (Ex. 1001, “the ’926 patent”). Paper 2 (“Pet.”). Biogen, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”). We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the petition “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.” *See also* 37 C.F.R. § 42.4 (a).

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has established a reasonable likelihood that it would prevail with respect to at least one challenged claim. We thus institute an *inter partes* review of the challenged claims on all grounds set forth in the Petition.

A. *Related Matters*

The parties represent that they are not aware of any other judicial or administrative matter involving the ’926 patent. Pet. 6: Paper 4.

B. *The ’926 patent*

The ’926 patent describes compositions containing the drug dapsone, which are useful for treating a variety of dermatological conditions. Ex. 1001, Abst. The ’926 patent discloses that “[u]se of the polymeric viscosity builder provides compositions with increased concentrations of diethylene

glycol monoethyl ether relative to compositions without the polymeric viscosity builder.” *Id.* at Abst.

The ’926 patent describes the invention as follows:

it has been found that use of a polymeric viscosity builder minimizes the intensity of yellowing of the composition caused by the increased solubility of dapsone in diethylene glycol monoethyl ether. In addition, the polymeric viscosity builder influences dapsone crystallization. This, in turn, results in compositions with improved aesthetics (i.e., reduction in particle size which minimizes “gritty” feeling upon application).

Id. at 2:46–53.

According to one embodiment, the compositions include about 5% w/w to about 10% w/w dapsone, a first solubilizing agent (i.e., diethylene glycol monoethyl ether), optionally at least one second solubilizing agent, a polymeric viscosity builder, and water. *Id.* at 2:54–59.

Example 1 of the ’926 patent “show[s] the impact of acrylamide/sodium acryloyldimethyltaurate copolymer based thickener on dapsone particle size.” *Id.* at 12:23–26. The results disclosed in that example show that larger crystals were observed in the sample with carbomer homopolymer type C, as compared to an acrylamide/sodium acryloyldimethyltaurate copolymer based thickener. *Id.* at 12:23–35.

C. Illustrative Claims

Independent claims 1 and 5, reproduced below, are illustrative:

1. A topical pharmaceutical composition comprising:
 - about 7.5% w/w dapsone;
 - about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;

about 2% w/w to about 6% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the composition does not comprise adapalene.

5. A topical pharmaceutical composition comprising:

about 7.5% w/w dapsone;

about 30% w/w diethylene glycol monoethyl ether;

about 4% w/w of a polymeric viscosity builder consisting of acrylamide/sodium acryloyldimethyl taurate copolymer; and

water;

wherein the composition does not comprise adapalene.

Ex. 1001, 15:21–16:14–21.

D. Evidence Relied Upon

Petitioner relies upon the following prior art references:

Ex. 1004, International Patent Application Publication No. WO 2009/061298 (“Garrett”).

Ex. 1005, International Application Publication No. WO 2010/072958, English Translation at pages 38–72 (“Nadau-Fourcade”).

Ex. 1015, Bonacucina, G., et al., *Characterization and Stability of Emulsion Gels Based on Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer*, 10 AAPS PHARMASCI TECH 368–75 (2009) (“Bonacucina”).

Petitioner also relies upon the Declarations of Bozena B. Michniak-Kohn, Ph.D. (Ex. 1002) and Dr. Elaine Gilmore, M.D., Ph.D (Ex. 1018) to support its contentions.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 20–21):

Ground	Claims	Basis	References
1	1–6	§ 103(a)	Garrett and Nadau-Fourcade
2	1–6	§ 103(a)	Garrett and Bonacucina

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We determine that no explicit construction of any claim term is necessary to determine whether to institute a trial in this case. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy.’”)

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