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Paper No. 10
Entered: May 8, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,
Petitioners,

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner.

Case IPR2018-00151
Patent 8,138,229 B2

Before JEFFREY N. FREDMAN, RAMA G. ELLURU, and SUSAN L. C. MITCHELL, *Administrative Patent Judges.*

FREDMAN, *Administrative Patent Judge*.

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

Dismissing Petitioners' Motion for Joinder
37 C.F.R. § 42.122(b)

I. INTRODUCTION

A. Background

Petitioners Apotex Inc. and Apotex Corp. ("Petitioners") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–48 (the "challenged claims") of U.S. Patent No. 8,138,229 B2 (Ex. 1001, "the '229 patent"). Patent Owner Abraxis Bioscience, LLC. ("Patent Owner") filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Concurrently with the Petition, Petitioners filed a Motion for Joinder (Paper 3, "Joinder Motion"). The Joinder Motion seeks to join this proceeding with *Actavis LLC v. Abraxis Biosciences*, IPR 2017-01104 ("2017-01104 IPR"). Joinder Motion 1.

At the time Petitioners filed the instant Petition and Joinder Motion, the Board had instituted *inter partes* review of the '229 patent in the 2017–01104 IPR. Subsequent to that institution, the parties in the 2017–01104 IPR submitted a Joint Motion to Terminate *Inter Partes* Review under 35 U.S.C. § 317(a) and 37 C.F.R. §§ 42.72 and 42.74. Because we granted the motion to terminate, there is no instituted *inter partes* review for Petitioners to join, and the Joinder Motion is moot. However, because the instant Petition is not statutorily barred, a separate *inter partes* review may be instituted. 35 U.S.C. § 315(b).

We have authority to determine whether to institute an *inter partes* review under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "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). For the reasons set forth below, we conclude that Petitioners have

not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the '229 patent. Therefore, we deny institution of an *inter partes* review for claims 1–48 of the '229 patent.

B. Related Proceedings

Petitioners indicate that the '229 patent was asserted in *Abraxis BioScience, LLC v. Actavis LLC, C.A.* No. 16-1925-JMV-MF; and *Abraxis BioScience, LLC v. Cipla Ltd.*, C.A. No. 16-9074-JMV-MF. Pet. 4. In addition to the 2017-01104 IPR, Actavis filed three additional requests for *inter partes* review of other patents owned by Abraxis that are related to the '229 patent: IPR2017-01100 (involving U.S. Patent No. 8,853,260); IPR2017-01101 (involving U.S. Patent No. 7,820,788); and IPR2017-01103 (involving U.S. Patent No. 7,923,536). *Id.*

Petitioners indicate they also filed petitions for *inter partes* review of related U.S. Patent Nos. 7,820,788 (IPR2018-00152), and 7,923,536 (IPR2018-00153). Pet. 4. The '229 patent and U.S. Patent 7,923,536 are both continuations of U.S. Patent No. 7,820,788.

C. The '229 Patent (Ex. 1001)

The '229 patent involves methods of formulating pharmaceuticals with carriers to "reduce one or more side effects." Ex. 1001, 3:57–62. Such methods specifically involve formulating taxol (paclitaxel), an agent active against carcinomas, (*id*. at 4:33–35), with albumin, a protein found in human plasma (*id*. at 5:7–18).

The '229 patent specifically prefers that the composition "have a particle or droplet size less than about 200 nanometers" (*id*. at 9:55) and a "ratio of albumin to pharmaceutical agent in the pharmaceutical composition

[that] is about 18:1 or less" (*id*. at 3:28–29). It is also stated in the '229 patent that:

> While the ratio of protein to pharmaceutical agent will have to be optimized for different protein and pharmaceutical agent combinations, generally the ratio of protein, e.g., albumin, to pharmaceutical agent is about 18:1 or less (e.g., about 15:1, about 10:1, about 5:1, or about 3:1). More preferably, the ratio is about 0.2:1 to about 12:1. Most preferably, the ratio is about 1:1 to about 9:1.

Id. at 11:64 to 12:3. The '229 patent also prefers a formulation "essentially free of cremophor" because "cremophor typically is used as a solvent for paclitaxel, and is associated with side effects that can be severe" (*id*. at 12:7–9).

D. Illustrative Claims

Of the challenged claims, claim 1 is the sole independent claim of the '229 patent. The remaining challenged claims 2–48 depend directly or indirectly from claim 1. Claim 1 is illustrative of the challenged claims and recites:

> 1. A liquid pharmaceutical composition for injection comprising paclitaxel and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin, wherein the albumin and the paclitaxel in the composition are formulated as particles, wherein the particles have a particle size of less than about 200 nm, wherein the weight ratio of albumin to paclitaxel in the composition is about 1:1 to about 9:1, wherein the liquid pharmaceutical composition comprises about 0.5% to about 5% by weight of albumin, and wherein the liquid pharmaceutical composition further comprises saline.

Ex. 1001, 37:19–29.

E. The Asserted Grounds of Unpatentability

Petitioners contend that the challenged claims are unpatentable based on the following grounds. Pet. 6.

References	Basis	Claims Challenged
Desai[1]	§ 102(b)	1–19 and 21–48
Desai	§ 103(a)	1–19 and 21–48
Desai, Kadima,[2] and Liversidge[3]	§ 103(a)	1–19 and 21–48
Desai and Taxol label[4]	§ 103(a)	20
Desai, Taxol label, Kadima, and Liversidge	§ 103(a)	20

Petitioners rely also on the Declaration of Cory Berkland, Ph.D. Pet. 1–83; *see* Ex. 1002.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their 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, 2144–46 (2016). Under this standard, we interpret claim terms using "the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the

[1] WO 99/00113 A1, published Jan. 7, 1999 (Ex. 1006, "Desai").
[2] WO 00/06152 A1, published Feb. 10, 2000 (Ex. 1004, "Kadima").
[3] US 5,399,363, issued Mar. 21, 1995 (Ex. 1005, "Liversidge").
[4] Physicians' Desk Reference® 309, 881–887 (54th ed. 2000) "Taxol® (paclitaxel) Injection" (Ex. 1008, "Taxol® label")

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