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Paper 7
Entered: October 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner,

v.

ABRAXIS BIOSCIENCE LLC,
Patent Owner.

Case IPR2017-01103
Patent 7,923,536 B2

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

FREDMAN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. Background

Petitioner Actavis LLC ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1–16 (the "challenged claims") of U.S. Patent No. 7,923,536 B2 (Ex. 1001, "the '536 patent"). Patent Owner Abraxis Bioscience, Inc. ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

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 Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the '536 patent. Therefore, we institute an *inter partes* review for claims 1–16 of the '536 patent.

B. Related Proceedings

Petitioner indicates that the '536 patent was asserted in *Abraxis BioScience, LLC v. Actavis LLC,* C.A. No. 16-1925-JMV-MF (D.N.J. April 6, 2016), and in *Abraxis BioScience, LLC v. Cipla Ltd.*, C.A. No. 16-9074-JMV-MF (D.N.J. Dec. 7, 2016). Pet. 4–5. Petitioner has also filed three additional requests for *inter partes* review of other patents owned by Abraxis, two of which are related to the '536 patent: IPR2017-01100 (involving U.S. Patent No. 8,853,260); IPR2017-01101 (involving U.S.

Patent No. 7,820,788); and IPR2017-01104 (involving U.S. Patent No. 8,138,229). Pet. 5.

C. The '536 Patent (Ex. 1001)

The '536 patent involves methods of formulating pharmaceuticals with carriers to "reduce one or more side effects." Ex. 1001 at 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 '536 patent specifically prefers that the composition "have a particle or droplet size less than about 200 nanometers" (*id*. at 9:52). The '536 patent states 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. 11:61–67. The '536 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 12:1–6).

D. Illustrative Claims

Of the challenged claims, claim 1 is the sole independent claim of the '536 patent. The remaining challenged claims 2–16 depend directly or indirectly from claim 1. Claim 1 is illustrative of the challenged claims and recites:

> 1. A method of treating cancer in a human individual, comprising injecting into the individual an effective amount of a pharmaceutical composition 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 in the composition have a particle size of less than about 200 nm, and wherein the weight ratio of albumin to paclitaxel in the composition is about 1:1 to about 9:1.

Ex. 1001, 37:20–29.

E. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following grounds and asserted references. Pet. 1–3.

References	Basis	Claims Challenged
Desai[1]	§ 102(b)	1–16
Desai	§ 103(a)	1–16
Desai, Kadima,[2] and Liversidge[3]	§ 103(a)	1–16

Petitioner relies also on the Declaration of Cory Berkland, Ph.D. Pet. 1–73; *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.*,

[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").

LLC v. Lee, 136 S. Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation approach, 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). We determine that the following claim language needs to be discussed.

1. *"the weight ratio of albumin to paclitaxel in the composition"*

Petitioner offers an interpretation of the claim phrase "the weight ratio of albumin to paclitaxel in the composition" as "at least the albumin-paclitaxel ratio in the starting ingredients used to make the composition." Pet. 18 (citing Ex. 1002 ¶¶ 36, 48). Petitioner states a "skilled artisan reading [the '536 patent's] examples would understand that the 'ratio of albumin to paclitaxel' was based on the amounts used to make the composition." Pet. 19 (citing Ex. 1002 ¶ 37).

Patent Owner disagrees, and offers an interpretation that the "claimed ratio term should be construed to mean the weight ratio of albumin-to-paclitaxel in the *finished* pharmaceutical composition for injection." Prelim. Resp. 10 (emphasis added). Patent Owner states

> the claim requires that the ratio be of the albumin to paclitaxel "in the composition," and that "composition" is plainly the "pharmaceutical composition" to be "inject[ed] into the individual"—*i.e.*, the finished pharmaceutical product. (*Id.*, claim 1.) . . . Thus, based on the plain claim language, the ratio refers to the claimed finished pharmaceutical product, not the albumin and paclitaxel starting materials prior to the formation of the nanoparticles.

Prelim. Resp. 11. Patent Owner notes "the prosecution history confirms this construction . . . The Examiner . . . understood that the 9:1 ratio was

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