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Paper No. 7
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner,

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner.

Case IPR2017-01100
Patent 8,853,260 B2

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

MITCHELL, *Administrative Patent Judge*.

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

I. INTRODUCTION

Actavis LLC ("Petitioner") requests an *inter partes* review of claims 1–27 of U.S. Patent No. 8,853,260 B2 ("the '260 patent," Ex. 1001). Paper 2 ("Pet."). Abraxis Bioscience, LLC ("Patent Owner") filed a Preliminary Response. Paper 6 ("Prelim. Resp.").

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). We may not institute an *inter partes* review "unless . . . there is 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). Applying that standard, and upon consideration of the information presented in the Petition and the Preliminary Response, we deny the Petition and do not institute an *inter partes* review.

II. BACKGROUND

A. Related Matters

The parties identify two district court litigations involving the '260 patent: *Abraxis Bioscience, LLC v. Actavis LLC*, 2:16-cv-01925-JMV-MF (D.N.J. April 6, 2016) and *Abraxis Bioscience, LLC v. Cipla Ltd.*,, 2:16-cv-09074-JMV-MF (D.N.J. Dec. 7, 2016). *See* Pet. 4; Paper 4, 1–2. Petitioner identifies three additional petitions for *inter partes* review challenging other patents owned by Abraxis: U.S. Patent No. 7,820,788 B2 in IPR2017-01101; U.S. Patent No. 7,923,536 B2 in IPR2017-01103; and U.S. Patent No. 8,138,229 B2 in IPR2017-01104. Pet. 4.

B. The '260 Patent (Ex. 1001)

The '260 patent, titled "Formulations of Pharmacological Agents, Methods for the Preparation thereof and Methods for the Use Thereof"

issued on October 7, 2014. Ex. 1001, [45], [54]. The '260 patent relates to "compositions and methods useful for the in vivo delivery of substantially water insoluble pharmacologically active agents (such as the anticancer drug paclitaxel) in which the pharmacologically active agent is delivered in the form of suspended particles coated with protein (which acts as a stabilizing agent)." *Id.* at Abst. Such compositions are suitable for parenteral administration in aqueous suspension, thereby obviating the need for use of an emulsion containing a polyethoxylated castor oil, such as cremaphor, that may produce an allergic reaction in a patient. *Id*. at 9:44–56, 3:3–22 (using cremaphor to solubilize Taxol linked to severe hypersensitivity reactions in humans requiring premedication with corticosteroids and antihistamines and large dilution resulting in large volumes for infusion and long infusion times). The '260 patent further describes a method for reproducibly forming unusually small nanoparticles (less than 200 nm diameter), which can be sterile-filtered to avoid heat coagulation of the protein (e.g. human serum albumin) from autoclaving. *Id*. at 10:3–14, 26–32.

The '260 patent further describes such compositions for *in vivo* delivery of a substantially water insoluble pharmacologically active agent such as paclitaxel as follows.

> Invention compositions comprise substantially water insoluble pharmacologically active agents (as a solid or liquid) contained within a polymeric shell. The polymeric shell is a crosslinked biocompatible polymer. The polymeric shell, containing substantially water insoluble pharmacologically active agents therein, can then be suspended in a biocompatible aqueous liquid for administration.

Id. at 10:15–25.

Human serum albumin is used in the polymeric shell to take advantage of its capability to bind Taxol to enhance Taxol's absorption on the surface of the particles. *Id*. at 10:52–55. The '260 patent states that "[s]ince albumin is present on the colloidal drug particles (formed upon removal of the organic solvent), formation of a colloidal dispersion which is stable for prolonged periods is facilitated, due to a combination of electrical repulsion and steric stabilization." *Id*. at 10:55–59.

> One variation of the formulations is described in the '260 patent as
>
> a polymeric shell containing a solid core of biologic produced by initially dissolving the biologic in a volatile organic solvent (e.g. benzene), forming the polymeric shell and evaporating the volatile solvent under vacuum, e.g., in an evaporator, spray drier or freeze-drying the entire suspension. This results in a structure having a solid core of biologic surrounded by a polymer coat. This latter method is particularly advantageous for delivering high doses of biologic in a relatively small volume.

Id. at 25:57–66.

C. Illustrative Claim

Of the challenged claims, claim 1 is independent. Claim 1 is illustrative of the claimed subject matter and recites:

> 1. A pharmaceutical formulation comprising:
>
> paclitaxel at a concentration between 5 mg/ml and 15 mg/ml,
>
> wherein the pharmaceutical formulation is an aqueous suspension that is stable for at least 3 days under at least one of room temperature or refrigerated conditions, wherein the pharmaceutical formulation comprises nanoparticles comprising a solid core of paclitaxel and an albumin coating,
>
> and wherein the size of the nanoparticles in the formulation is less than 400 nm.

Ex. 1001, 67:32–42.

D. The Asserted Ground of Unpatentability

Petitioner asserts that claims 1–27 of the '260 patent are unpatentable as obvious over the combination of Desai,[1] Shively,[2] Liversidge,[3] and Remington's Pharmaceutical Sciences.[4] Pet. 6. Petitioner supports its assertions with the testimony of Cory J. Berkland, Ph.D. (Ex. 1002) and Edmund J. Elder, Jr., Ph.D., R.Ph. (Ex. 1034).

III. ANALYSIS

A. Claim Construction

The Board interprets claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent." 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, claim terms are given their ordinary and customary meaning in view of the specification, as would be understood by one of ordinary skill in the art at the time of the invention. *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).

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[1] Neil P. Desai et al., U.S. Patent No. 5,439,686, issued August 8, 1995. (Exhibit 1003, "Desai").
[2] Merrick L. Shively, U.S. Patent No. 5,407,683, issued April 18, 1995. (Exhibit 1004, "Shively").
[3] Gary G. Liversidge et al., U.S. Patent No. 5,399,363, issued March 21, 1995. (Exhibit 1005, "Liversidge").
[4] George Zografi, Ph.D. et al., *Chapter 19: Disperse Systems in* REMINGTON'S PHARMACEUTICAL SCIENCES, 257–309 (18th ed. 1990); G. Briggs Phillips, Ph.D. et al., *Chapter 78: Sterilization in* REMINGTON'S PHARMACEUTICAL SCIENCES, 1470–1480 (18th ed. 1990) (collectively, Exhibit 1006, "Remington's Pharmaceutical Sciences").

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