

Filed on behalf of: Abraxis Bioscience, LLC

Filed: October 24, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ACTAVIS LLC,  
*Petitioner*

v.

ABRAXIS BIOSCIENCE, LLC,  
*Patent Owner*

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Case IPR2017-01104  
U.S. Patent No. 8,138,229

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**PATENT OWNER OBJECTIONS TO EVIDENCE SERVED WITH  
PETITION FOR *INTER PARTES* REVIEW  
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1), Abraxis Bioscience, LLC (“Patent Owner”) hereby submits the following objections to exhibits served with Actavis LLC’s Petition for Inter Partes Review (“Petition”). These objections are timely filed and served within ten business days of the PTAB’s October 10, 2017 Institution Decision (Paper 7).

Pursuant to 37 C.F.R. § 42.62, Patent Owner’s objections apply the Federal Rules of Evidence. Patent Owner’s objections and the basis for each objection are as follows:

#### **I. OBJECTIONS TO EXHIBIT 1002**

Patent Owner objects to Exhibit 1002, “Declaration of Cory J. Berkland, Ph.D.” Specifically, Patent Owner objects to the following paragraphs and associated headings in Exhibit 1002 pursuant to Fed. R. Evid. 702, Fed. R. Evid. 703 (insufficient qualification or support for expert testimony), Fed. R. Evid. 602 (lack of personal knowledge, speculation) and 37 C.F.R. § 42.65 (expert testimony does not disclose the underlying facts or data): ¶¶ 4, 16–29, 37, 39, 40, 55–59, 71–81, 83–90, 95, 97, 99, 100, 102, 104–113, 115, 118, 122–137, 139–176, 179–182, 184–185, 187–189 and 193–221. Patent Owner further objects to ¶ 91 pursuant to Fed. R. Evid. 402 (relevance) and Fed. R. Evid. 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons).

## II. **OBJECTIONS TO EXHIBITS 1008–1013, 1015, 1016, 1019–1025 and 1027**

Patent Owner objects to Exhibits 1009–1010, pursuant to Fed. R. Evid. 402 (relevance) and Fed. R. Evid. 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons). Petitioner does not assert these documents as prior-art references that anticipate or combine to render obvious the challenged patent claims, and as such are not listed as specific grounds for challenging the patent claims. Because these documents are used improperly by Petitioner’s expert to attempt to fill in absent claim elements where the asserted art itself is silent, the prejudice they would cause outweighs any purported probative value.

Patent Owner also objects to Exhibits 1009–1010, pursuant to 37 C.F.R. § 42.6(a)(3) (improper incorporation by reference). “Arguments must not be incorporated by reference from one document into another document.” 37 C.F.R. § 42.6(a)(3). Petitioner does not cite to or discuss the content of Exhibits 1009–1010 in its Petition. However, Petitioner’s expert cites to and discusses these exhibits in his declaration in support of Petitioner’s argument that Desai would have motivated a skilled artisan as of December 2002 to formulate paclitaxel and albumin as particles with a size less than 200 nm (Exhibit 1002 ¶ 142, n.1). Accordingly, Exhibits 1009–1010 are improperly incorporated by reference.

Patent Owner also objects to Exhibits 1009–1013, 1015, 1016, 1019–1025 and 1027, pursuant to Fed. R. Evid. 402 (relevance) and Fed. R. Evid. 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons) to the extent Petitioner may intend to rely on these exhibits as prior art to the challenged patent claims. Each of these documents are either dated after the priority date of the challenged patent claims, or lack sufficient information to determine whether any publication occurred before or after the challenged patent claims.

Patent Owner further objects to the dates in Exhibits 1009, 1010, and 1016 pursuant to Fed. R. Evid. 802 (hearsay) as evidence of when those exhibits were allegedly published or would have been publicly available or accessible to an ordinarily skilled artisan.

Patent Owner further objects to Exhibits 1011–1013 pursuant to Fed. R. Evid. 402 (relevance), Fed. R. Evid. 403 (excluding relevant evidence for prejudice, confusion, waste of time, or other reasons) and Fed. R. Evid. 802 (hearsay). These documents are not relevant because they consist of judgments and proceedings on other patents that occurred after the priority date of the '229 patent and that are not commensurate in scope with the '229 patent. Patent Owner further objects to the extent that these documents and statements within these documents are being offered for the truth of the matter asserted therein.

Patent Owner further objects to Exhibits 1008, 1016, 1019-1025 and 1027 pursuant to Fed. R. Evid. 106, 1002 and 1006. These documents appear to be incomplete excerpts of larger documents.

Dated: October 24, 2017

/ J. Patrick Elsevier, Ph.D. /

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