

Paper No. \_\_\_\_

Date Filed: May 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC.,  
AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF  
NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S  
LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA  
PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL  
CORP., and HIKMA PHARMACEUTICALS, LLC,  
Petitioner

v.

JANSSEN ONCOLOGY, INC.,  
Patent Owner

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Case IPR2016-01332<sup>1</sup>

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Patent No. 8,822,438 B2

**PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64(C)**

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<sup>1</sup> Case IPR2016-00853 has been joined with this proceeding.

## **I. Introduction**

Patent Owner Janssen Oncology, Inc. moves pursuant to 37 C.F.R. § 42.64(c) to exclude three categories of evidence submitted by Petitioners in this matter. In particular, Patent Owner hereby moves to exclude:

1. Expert declarations and exhibits that are outside the scope of the “prior art consisting of patents or printed publications” permitted by 35 U.S.C. § 311(b);
2. Sections of Petitioners’ declarations (and related exhibits) that are not cited in any paper in this proceeding, including Petitioners’ petition or reply brief, since this disconnected evidence should be excluded as irrelevant and prejudicial under Fed. R. Evid. 401, 402 and 403; and
3. Exhibits that lack authenticity or violate the hearsay rule. Such exhibits should be excluded under Fed. R. Evid. 901(a) and Fed. R. Evid. 801 and 802.

These grounds for exclusion are discussed below. As a preliminary matter, the Federal Rules of Evidence govern the admissibility of evidence submitted in the context of *inter partes* review proceedings before the Patent Trial and Appeal Board (the “Board”). See 37 C.F.R. § 42.62(a) (“[e]xcept as otherwise provided in this subpart, the Federal Rules of Evidence shall apply to a proceeding”). A motion to exclude evidence before the board is a two-step process: (1) a party must timely serve written objections to the challenged evidence (37 C.F.R. § 42.64(b)(1) (“Any objection to evidence submitted during a preliminary

proceeding must be filed within ten business days of the institution of the trial. Once a trial has been instituted, any objection must be filed within five business days of service of evidence to which the evidence is directed. The objection must identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence.”)); and (2) a party must preserve its objection by filing a motion to exclude (37 C.F.R. § 42.64(c) (“A motion to exclude evidence must be filed to preserve any objection”)). As noted below, Patent Owner timely raised the objections underlying the basis for the present motion.

Under Fed. R. Evid. 401, evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action. Irrelevant evidence is not admissible. Fed. R. Evid. 402. In addition, relevant evidence may be excluded if its probative value is substantially outweighed by unfair prejudice. Fed. R. Evid. 403.

Rules 802-807 of the Federal Rules of Evidence govern the admissibility of hearsay, which Rule 801 defines as “a statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) the party offers in evidence to prove the truth of the matter asserted in the statement.” Fed. R. Evid.

801(c). Absent the applicability of an exception to the rule against hearsay, it is not admissible. Fed. R. Evid. 802.

Admissible evidence must also be authenticated. Fed. R. Evid. 901. “To satisfy the requirement of authenticating or identifying an item of evidence, the proponent must produce evidence to support a finding that the item is what the proponent claims it is.” Fed. R. Evid. 901(a).

As discussed below, exhibits filed by Petitioners fail to meet one or more of these evidentiary standards and should be excluded.

## **II. Petitioners’ Attempt to Cancel the ’438 Patent Claims on the Basis of Commercial Success Evidence Is Barred by Statute**

The grounds for requesting cancellation to patent claims in an IPR are clear and unambiguous. Under 35 U.S.C. § 311(b), a petitioner may request cancellation of a claim “only on the basis of prior art consisting of patents or printed publications.” Contrary to the statute, Petitioners seek to rely on declarations and related exhibits of Dr. Ivan Hofmann, an economist offering his opinions on “aspects of commercial success, from an economic perspective.” *See* Exh. 1017 (Decl. of Hofmann) at ¶ 6 (describing scope and content of declaration). Dr. Hofmann’s declaration in support of the petition (Exh. 1017) does not offer any discussion or analysis of invalidity based on “prior art consisting of patents or printed publications.” Similarly, exhibits he relies upon are not prior art, but instead pertain to commercial aspects of Zytiga and Dr. Hofmann’s economic

arguments. *See* Exhibits 1040, 1041, 1046-1051, 1053-1055, 1057, and 1064-1066. For example, Dr. Hofmann relies on websites for information concerning pharmaceutical product information and sales data (Exhs. 1049 and 1055). None of Dr. Hofmann’s economic analysis falls within the statutorily permissible scope for challenging patent claims “only on the basis of prior art.” 35 U.S.C. § 311(b).

Petitioners will no doubt argue that evidence of commercial success can be relevant to the issue of obviousness or non-obviousness of a patent claim. But that misses the point. Congress has by statute expressly limited the grounds upon which a petitioner can seek cancellation of patent claims in an IPR. 35 U.S.C. § 311(b). And those grounds do not include economic analysis going to commercial success of the patented invention. Accordingly, there is no permissible basis for the Hofmann Declaration (Exh. 1017) and related exhibits (Exhs. 1040, 1041, 1046-1051, 1053-1055, 1057, and 1064-1066). These exhibits should therefore be stricken as contrary to the governing statute and legally irrelevant under FRE 402.<sup>2</sup>

### **III. Petitioners’ Exhibits and Expert Declarations That Are Not Cited in Their Petition or Reply Brief Are Irrelevant**

Petitioners should not be permitted to rely on sections of their expert declarations that are not cited in their petition or reply brief. In particular,

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<sup>2</sup> Patent Owner has raised objections on these grounds in Patent Owner’s Objections to Evidence, Paper No. 23, at 1-2.

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