

Paper No. ____

Date Filed: January 30, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
ARGENTUM PHARMACEUTICALS LLC,

Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR2016-00286¹

Patent No. 8,822,438 B2

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

¹ Case IPR2016-01317 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 four 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. Exhibits that Petitioners belatedly filed in connection with their reply brief and declarations after the January 16, 2016 deadline;
3. Sections of Petitioners’ reply declarations (and related exhibits) that are not cited in any paper in this proceeding, including Petitioners’ reply brief, since this disconnected evidence should be excluded as irrelevant and prejudicial under Fed. R. Evid. 401, 402 and 403; and
4. 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. Deforest McDuff, an economist offering his opinions on “aspects of commercial success, from an economic perspective.” *See* Exh. 1017 (Decl. of McDuff) at ¶ 6 (describing scope and content of declaration). Neither Dr. McDuff’s declaration in support of the petition (Exh. 1017) nor his reply

declaration (Exh. 1152) 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. McDuff’s economic arguments. *See* Exhibits 1040-1067 and 1149-1151 and 1190. For example, Dr. McDuff relies on various investment research reports commenting on the market for Zytiga (Exhs. 1042-1044, 1056, 1058-1061), an article on “Patent Valuation” (Exh. 1054), and various websites and industry sources for information on Zytiga sales and market share (Exhs. 1045 and 1067). None of Dr. McDuff’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 McDuff Declaration (Exh. 1017) and related exhibits (Exhs. 1040-1067). Further, any argument Petitioners may offer that the second McDuff Declaration,

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