

Paper No. \_\_\_\_

Date Filed: February 6, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMERIGEN PHARMACEUTICALS LIMITED,  
ARGENTUM PHARMACEUTICALS LLC,

Petitioner

v.

JANSSEN ONCOLOGY, INC.,  
Patent Owner

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Case IPR2016-00286<sup>1</sup>

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Patent No. 8,822,438 B2

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

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<sup>1</sup> Case IPR2016-01317 has been joined with this proceeding.

Patent Owner, Janssen Oncology, Inc., set forth four independent grounds for excluding evidence relied upon by Petitioners. (Paper 70). As discussed below, Petitioners have failed to refute those grounds. The exhibits should be excluded.

**A. Petitioners Offer No Legitimate Basis for Ignoring the Statutory Limitations on the Grounds for Cancellation**

Petitioners do not dispute that the governing statute, § 311(b), clearly and unambiguously states that IPRs may seek cancellation of a claim “only on the basis of prior art consisting of patents or printed publications.” Nor do Petitioners dispute that the declaration of their economist Dr. McDuff (Exh. 1017) offers opinions on “commercial success,” which are outside the ambit of “patents or printed publications.” Instead, Petitioners make several arguments, but none justifies ignoring the statute, which Petitioners do not even mention.

First, Petitioners point out that Patent Owner relied on commercial success in its Patent Owner’s Response, as if that had any bearing on what was permissible as grounds for seeking cancellation in the petition. (Paper 76 at 2). On the contrary, whether a patent owner chooses to rely on evidence of commercial success in its *response* to an IPR is completely irrelevant to what the explicit statute permits in an IPR petition in the first instance. Second, Petitioners criticize Patent Owner for not citing to regulations or case law on the issue at hand. (Paper 76 at 2). But this amounts to nothing more than misdirection by Petitioners, since

the basis of the instant motion is the governing *statute*. Petitioners' position is akin to requiring case law as a condition precedent to enforcing any statute, which is clearly not correct. Third, Petitioners urge that "commercial success" belonged in their petition, because the issue played a part in the course of the '438 patent prosecution. (Paper 76 at 2-3). However, Petitioners provide no authority for even suggesting that the prosecution history is a legitimate reason for departing from clear limits placed by § 311(b) on the grounds that can be raised in an IPR petition.

As for Dr. McDuff's second declaration (Exh. 1152), Petitioners concede that it was not cited anywhere in their reply brief. (Paper 76 at 3). Thus, even if Dr. McDuff's second declaration on "commercial success" were regarded as proper rebuttal, it is not connected to anything in Petitioners' reply. Petitioners' excuse that this was an inadvertent clerical error is unpersuasive. Petitioners do not explain how Patent Owner was supposed to know that Exhibit 1096 in the reply was in reality Exhibit 1152. Nor is there any merit to Petitioners' illogical argument that Patent Owner should have objected to its own deposition of Dr. McDuff. (Paper 76 at 3-4). Both declarations of Dr. McDuff should be stricken.

**B. Petitioners' Attempts to Excuse Their Failure to File Reply Exhibits on Time are Unavailing**

Petitioners claim that their failure to file and serve their reply exhibits on time was due to "technical problems" during the filing. (Paper 76 at 5). But that is

the same excuse that the Board rejected in *Teva*. See Patent Owner Motion to Exclude (Paper 70) at 6. Petitioner tries to distinguish *Teva* on the grounds that Petitioners here are not faced with a statutory deadline. (Paper 76 at 5). Yet that only weakens Petitioners' position. In *Teva*, the penalty for filing late (by just a few hours) was denial of the petition, while here Petitioners face a less draconian loss of only the late filed exhibits.

Like the petitioner in *Teva*, Petitioners here offer no explanation whatsoever as to why they waited so long (until 11:59 pm on January 16, 2017) to file and serve their reply and expert declarations.

Petitioners also argue that the Patent Office was officially closed on the January 16, 2017 deadline (a date chosen by Petitioners). But the date on which the Patent Office had access to the exhibits is utterly irrelevant to the issue here. Petitioners' resort to arguments based on prior extensions of time and the length of depositions taken by Patent Owner in the days after the January 16, 2017 deadline (Paper 76 at 4-5) are likewise irrelevant.

**C. Petitioners Have Not Shown that the Materials Omitted from Their Reply Meet the Standards for Relevance**

Petitioners do not dispute that the subject matter in entire portions of their expert reply declarations of Drs. Ratain and Dorin (and the entirety of Dr. McDuff's reply declaration) are not cited anywhere in Petitioners' reply brief.

(Paper 76 at 5-6). Without any support, Petitioners contend that their practice of including topics in expert declarations but not citing those portions of their expert reports is “extremely common.” (Paper 76 at 6). True or not, this essentially amounts to a defense of “everyone does it,” which does not address the issue of relevance under the governing Federal Rules of Evidence. *See* FRE 401-402.

In addition, even accepting Petitioners’ explanation that the failure to cite Dr. McDuff’s second declaration was a clerical error, Petitioners only cited to one page (page 21) of “Exhibit 1096,” his supposed declaration. (Paper 60 at 23). Thus, in any event, the remaining pages of his second declaration should be stricken, along with the uncited portions of the reply declarations of Drs. Ratain and Dorin.

**D. Petitioners Have Not Shown that the Challenged Exhibits Meet the Requirements for Authenticity and Hearsay**

Petitioners concede that many of their exhibits have not been authenticated, but pledge to provide supplemental declarations for that purpose in the future. But even for those exhibits that Petitioners contend have already been authenticated, the showing is still lacking. For example, for the website documents, Petitioners offer conclusory statements that the document was downloaded from a particular website, without providing any information about the source of the underlying information contained in the document. In this regard, Exhibit 1056, a document apparently taken from [www.barrons.com](http://www.barrons.com), can no longer be accessed at the

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