

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2018-01403
Patent No. 8,399,514 B2

Before SHERIDAN K. SNEDDEN, JENNIFER MEYER CHAGNON, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

SNEDDEN, *Administrative Patent Judge*.

ORDER

Patent Owner's Motion for Additional Discovery
37 C.F.R. §§ 42.5, 42.51

I. INTRODUCTION

With our authorization, Patent Owner filed a Motion for Additional Discovery (Paper 24, “Motion” or “Mot.”) in the instant proceedings, and Petitioner filed an Opposition (Paper 28, “Opp.”). For the reasons stated below, Patent Owner’s Motion is denied.

II. DISCUSSION

A. *The Parties’ Dispute*

The dispute between the parties concerns the admissibility of the originally filed ClinicalTrials.gov exhibit, Exhibit 1010. With its Petition, Petitioner submitted a declaration of Robert Mihail. Ex. 1054 (“Mihail Declaration”). The Mihail Declaration is an identical copy of the declaration previously submitted in IPR2015-01993. Opp. 1–2. The Mihail Declaration describes the process in which the content of the ClinicalTrials.gov exhibit (Ex. 1010) was obtained. *Id.* Petitioner submitted the same Mihail Declaration into this proceeding for the purposes of describing how the same ClinicalTrials.gov information was collected. *Id.*

In response to Patent Owner’s objections related to the authenticity of Exhibit 1010 (Paper 14, 1), Petitioner served supplemental evidence in the form of a “Declaration of Emily J. Greb” (“Greb Declaration”)¹ and a “Replacement Exhibit 1010” (Ex. 1057).² Mot. 2–3; Ex. 2049.

¹ The Greb Declaration is currently not of record.

² Service of supplemental evidence is permitted under 37 C.F.R. § 42.64(b)(2), which provides as follows: “The party relying on evidence to which an objection is timely served may respond to the objection by serving supplemental evidence within ten business days of service of the objection.”

Patent Owner contends that Replacement Exhibit 1010 “is not the same document as Ex. 1010 and bears dates after the relevant time period.”³ Mot. 3. Petitioner, however, contends that the Replacement Exhibit 1010 “shows the same substance of originally submitted Exhibit 1010 (authenticated by Mr. Mihail) as retrieved from the public website ClinicalTrials.gov on February 26, 2019.” Opp. 2.

B. Analysis

In its Motion, Patent Owner requests additional discovery in the form of cross-examination of Mr. Mihail and Ms. Greb. *See* Mot. 3–4.

With respect to the cross-examination of Mr. Mihail, Patent Owner contends that Mr. Mihail’s testimony is “[t]he only support for [Ex. 1010’s] alleged authenticity and public accessibility.” *Id.* at 2. Patent Owner further contends that “there is already evidence that the Mihail Declaration’s accuracy is more than merely suspect,” namely that the URL, provided by Mr. Mihail as the source of Ex. 1010, results in an error message. *Id.* at 4; Ex. 2050. Pursuant to our rules, a party wishing to challenge the admissibility of evidence, such as Ex. 1010 here, must object timely to the evidence at the point it is offered and then preserve the objection by filing a motion to exclude the evidence. 37 C.F.R. § 42.64(a), (b)(1), and (c). Here,

³ Patent Owner does not provide an explanation of any identified differences between Ex. 1010 and Replacement Exhibit 1010 or how any such differences would impact the merits of Petitioner’s patentability challenges that rely on Ex. 1010. Petitioner, however, suggests that one such difference may be “allegedly inconsistent dates in the ClinicalTrials.gov exhibits (Sept. 14, 2005 for Exhibit 1010, and an estimate of Sept. 15, 2005 for Exhibit 1057).” Opp. 3.

Patent Owner has done so, and is already in possession of supplemental evidence that Petitioner has served to address Patent Owner's objections—that is, the Greb Declaration and Replacement Exhibit 1010. That information was served to Patent Owner as supplemental evidence under 37 C.F.R. § 42.64(b)(2), which is the proper procedure for responding to admissibility objections.

We note, however, that Rule 42.64(b)(1) provides for objection to evidence, not for objection to supplemental evidence. If Patent Owner, now in possession of supplemental evidence, is still of the opinion that the originally objected to evidence is inadmissible (i.e., Ex. 1010), Patent Owner may file a motion to exclude the evidence. 37 C.F.R. § 42.64(c); *see* Paper 13, 8 (setting forth the DUE DATE 4 for filing a motion to exclude). Petitioner may file the previously served supplemental evidence with any opposition to the motion to exclude, and Patent Owner may respond to the supplemental evidence in its reply to the opposition. Patent Owner also may address the sufficiency of and the proper weight the Board should give to Mr. Mihail's testimony and Ex. 1010, in its Patent Owner Response. We are not persuaded that Patent Owner has shown that the cross-examination of Mr. Mihail, whose testimony was not prepared for this proceeding, is in the interests of justice based on the facts and circumstances present here.

Turning to the cross-examination of Ms. Greb, our Rule 42.51 provides that routine discovery includes, “[e]xcept as the Board may otherwise order: . . . (ii) Cross examination of affidavit testimony prepared for the proceeding is authorized within such time period as the Board may set.” 37 C.F.R. § 42.51(b)(1). As noted by Patent Owner, the declaration from Ms. Greb, purportedly relating to the authenticity of Replacement

Exhibit 1010, was prepared for this proceeding. Mot. 3. Accordingly, if that declaration is filed with an opposition to a motion to exclude, it will be subject to routine discovery. In its Motion, Patent Owner requests cross-examination of Ms. Greb prior to the filing of the Greb Declaration. We recognize Petitioner's concern that the possibility that the Greb Declaration may never be of record makes "taking the deposition now [] an inappropriate use of time and resources." Opp. 7. We determine, however, that this concern is outweighed by the timing considerations implicated by waiting to see if the Greb Declaration is filed in response to any motion to exclude filed by Patent Owner. *See* Mot. 7.

We, thus, authorize cross-examination of Ms. Greb at this time, limited to the factual issue of "how publicly available information from [the ClinicalTrials.gov website] . . . was collected" (Opp. 1).⁴ The parties are instructed to confer to determine a date for and an appropriate length of time for Ms. Greb's deposition. Alternatively, Petitioner may withdraw the Greb Declaration as supplemental evidence, and provide assurance that it will not rely on that declaration in this proceeding. In addition, in the event Patent Owner elects to depose Ms. Greb, the transcript of that deposition is not to be made of record in this proceeding unless and until Petitioner files the Greb Declaration as an exhibit to its opposition to Patent Owner's motion to exclude.

⁴ Petitioner requests that if the deposition of Ms. Greb is granted "it should be limited to the ClinicalTrials.gov portion of the declaration." Opp. 4 n.1. Because the Greb Declaration is not of record, the panel has not reviewed the contents thereof. We recognize, however, that Ms. Greb is counsel for Petitioner in this proceeding, and caution Patent Owner's counsel to limit its questions to the factual issue at hand.

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