UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.

*Petitioner*

v.

BIOGEN MA INC.

*Patent Owner*

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Case No. IPR2018-01403
U.S. Patent No. 8,399,514

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**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION FOR ADDITIONAL DISCOVERY**

Biogen MA Inc. ("Patent Owner") failed to carry its burden of proving that its request for additional discovery is "in the interests of justice." 37 C.F.R. § 42.51(b)(2)(i). Patent Owner seeks unnecessary depositions of two attorneys, one of which is not within Mylan Pharmaceuticals Inc.'s ("Petitioner") control, who merely described how publicly available information from ClinicalTrials.gov, a website equally available to Patent Owner, was collected. Patent Owner failed to satisfy the *Garmin* factors in its motion. Patent Owner's request for additional discovery should be denied.

## I. BACKGROUND

Patent Owner's motion relates to a single prior art reference. This publicly available reference from ClinicalTrials.gov (Ex. 1010) is not before the Board for the first time. In IPR2015-01993, the Mihail Declaration (Ex. 1054) described the process in which the content of the ClinicalTrials.gov exhibit was accessed. In that earlier IPR, Patent Owner did not object to the Mihail Declaration, did not depose Mr. Mihail, and did not move to exclude ClinicalTrials.gov. Biogen's Objections to Petitioner's Exhibits, *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01993, Paper 25 (PTAB Apr. 5, 2016).

Now, in this IPR, Petitioner submitted the same Mihail Declaration describing how the same ClinicalTrials.gov information, Exhibit 1010, was collected. Ex. 1054. Patent Owner now objects to Exhibit 1010 as, among other things, not

properly authenticated. Paper 14 at 1. In response, Petitioner served as supplemental evidence in accordance with 37 C.F.R. § 42.64(b)(2) a replacement Exhibit 1010 authenticated by the Greb Declaration. *See* Ex. 2049. The replacement Exhibit 1010 (filed with this motion as Exhibit 1057) 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.

Patent Owner now seeks depositions of Mr. Mihail (who is not under Petitioner's control) and Ms. Greb, counsel for Petitioner.

## II. ARGUMENT

Patent Owner's motion fails to meet the standard for additional discovery. Instead it appears an attempt to circumvent the rules for excluding evidence. Its three-listed justifications for seeking the depositions is to attack Exhibit 1010's (1) prior art status, (2) reliability and credibility, and (3) weight of such evidence. Paper 24 at 1. But, "[a]s explained by the Board, parties may raise issues related to admissibility of evidence (e.g., authenticity or hearsay) *in a motion to exclude*" and "issues related to credibility and the weight of the evidence should be raised *in responses and replies*." *Bloomberg Inc. v. Markets-Alert Pty Ltd.*, CBM2013-00005, Paper 56 at 5 (PTAB Nov. 15, 2013) (emphasis added) (citing 37 C.F.R. §§ 42.64, 42.62). Moreover, each of the five *Garmin* factors, which frame the analysis for determining whether additional discovery is in the interests of justice,

fails to support the requested depositions. *See Garmin Int'l Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, 2013 WL 11311697, at *3 (PTAB Mar. 5, 2013).

### A. *Garmin* Factor #1: Patent Owner failed to show that there is more than a possibility or mere allegation that something useful will be uncovered by deposing Mr. Mihail and Ms. Greb.

Patent Owner failed to identify anything it may discover besides a *verbatim* recitation of what is already in the two declarations—the steps Mr. Mihail and Ms. Greb took to access the publicly available ClinicalTrials.gov website. Patent Owner asserts that it "has . . . evidence" that the two declarations are purportedly "inconsistent." Paper 24 at 4. To satisfy this *Garmin* test, Patent Owner needs to show that there is more than a possibility and *mere allegation that something useful will be uncovered*. *Garmin*, 2013 WL 11311697, at *3. "Useful" in this context "does not mean merely 'relevant.'" *Id.*

Patent Owner fails to even make a "mere allegation" as to what could be uncovered in the requested depositions, useful or not. *Id.* at *4 ("Yet, conspicuously absent from Cuozzo's motion is a threshold amount of evidence or reasoning tending to show beyond speculation that the information to be discovered will be 'useful' to Cuozzo."). Assuming Patent Owner will attempt to uncover facts relating to the allegedly inconsistent dates in the ClinicalTrials.gov exhibits (Sept. 14, 2005 for Exhibit 1010, and an estimate of Sept. 15, 2005 for Exhibit 1057), both dates irrefutably establish the exhibits as prior art. All Patent Owner can obtain from the

depositions is the fact that the Sept. 14, 2005 version is no longer available in the ClinicalTrials.gov archive (*see* Ex. 2050). But the version containing the same relevant information is still available, thus there is nothing to be gained from the requested depositions. And, importantly, Biogen's admission that it already has the evidence of an alleged inconsistency alone demonstrates why its motion fails. *See Shelton v. Am. Motors Corp*., 805 F.2d 1323, 1327 (8th Cir. 1986) (depositions of counsel are limited "to where the party seeking to take the deposition has shown that (1) no other means exist to obtain the information than to depose opposing counsel; (2) the information sought is relevant and nonprivileged; and (3) the information is crucial to the preparation of the case" (citation omitted)). There is no further need for additional discovery when Patent Owner admits it already has the evidence it needs.

### B. *Garmin* Factor #2: Patent Owner is seeking Petitioner's litigation positions and the underlying basis for those positions.

Patent Owner argues that Petitioner "cannot use the status of Mr. Mihail and Ms. Greb as counsel to shield cross-examination." Paper 24 at 5. Anything beyond the express statements in the declarations is likely privileged.[1] *See Garmin*, 2013

[1] If the Board grants the deposition of Ms. Greb, it should be limited to the ClinicalTrials.gov portion of the declaration.

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