

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioners,

v.

BIOGEN MA INC.,

Patent Owner.

Case IPR2018-01403

Patent 8,399,514

Motion for Additional Discovery

Ground 4 in Mylan’s Petition is based on Exhibit 1010 (“Clinical Trials”), the alleged public availability and authenticity of which rest solely on a declaration from Robert Mihail, Esq. (Exhibit 1054) originally filed in a prior IPR. In response to evidentiary objections to Exhibit 1010, Mylan served alternative “Replacement Exhibit 1010,” supported solely by the declaration of Mylan’s counsel Emily Greb, Esq, which was served but not filed. Mylan refused to provide either witness for deposition. It is not clear that Mylan even attempted to secure Mr. Mihail. Ms. Greb is, of course, under Mylan’s control and could readily be produced. Ex. 2041 at 17:15-17. Depositions of these witnesses would serve the interests of justice because: (1) the declarations provide the only support for Mylan’s assertion that Clinical Trials and its “Replacement” are prior art; (2) inconsistencies between the declarations and the evidence call into question their reliability and credibility; and (3) the declarations should be entitled to no weight without depositions such that Ground 4 would necessarily fail. *Mexichem Amanco Holdings S.A. de C.V. v. Honeywell Int’l, Inc.*, IPR2013-00576, Paper 29 at 3 (PTAB Aug. 15, 2014); *Borror v. Herz*, 666 F.2d 569, 573 (C.C.P.A. 1981) (in the interference context); *see also IBG LLC v Trading Techs.*, CBM2015-00179, Paper 39 at 3 (PTAB Apr. 15, 2016) (burden is on proponent of testimony to secure witnesses’ availability). Biogen is entitled to cross-examine the witnesses presented against it.

I. Statement of Facts

Mylan's Ground 4 rests on "Clinical Trials" (Ex. 1010). Pet. 5, 23. The only support for its alleged authenticity and public accessibility at the relevant time is the declaration of Robert Mihail (Ex. 1054). Pet. 23 ("It is a document publicly available from ClinicalTrials.gov as of September 14, 2005."). Rather than having personal knowledge of ClinicalTrials.gov from 2005, Mr. Mihail was counsel advocating for a different petitioner in an earlier IPR. IPR2015-01993, Paper 29. Mr. Mihail does not state that he accessed the document at the relevant time, instead describing a process he allegedly followed to obtain Ex. 1010 in 2015. Ex. 1054, ¶ 8. However, the Mihail process for obtaining Ex. 1010 leads to an error message:

ClinicalTrials.gov archive

A service of the U.S. National Institutes of Health

Developed by the National Library of Medicine

The document you requested was not found.

Study archives

View the history for NCT id:

Ex. 2050 (clinicaltrials.gov/archive/NCT00168701/2005_09_14).

In response to Biogen's objections to Exs. 1010 and 1054 (Paper 14, 1, 11), Mylan served as supplemental evidence the "Declaration of Emily J. Greb" ("Greb Declaration") addressing both prior exhibits as well as a "Replacement Exhibit

1010.” Ex. 2049. While the Greb Declaration was specifically prepared for this IPR, it lacks the required attestation to be a proper declaration. *See* 37 C.F.R. §§ 1.68, 42.2; *see also* 28 U.S.C. § 1746; Ex. 2049. Mylan’s assertion of the public availability of Ex. 1010 at the relevant time period is based solely on the Mihail declaration. Pet. 23 (citing Ex. 1054). Although plainly inconsistent with Mylan’s public availability assertion, the Greb Declaration fails to disclose that Ex. 1010 is *not* available as described in the Mihail declaration (Ex. 1054). Instead, the Greb Declaration refers to an allegedly “substantially identical” Replacement Exhibit 1010, which is not the same document as Ex. 1010 and bears dates after the relevant time period.

Biogen requested dates for the cross-examination of both Mr. Mihail and Ms. Greb. Nearly three weeks after repeated follow-up correspondence that went unanswered regarding these witnesses, Mylan refused to make them available. Biogen requested a call with the Board the next day. The call transcript was filed as Ex. 2041, and the Board issued an order (Paper 22) authorizing this motion.

II. If the Declarations Are to be Given Any Weight, Cross-Examination Is in the Interest of Justice

Discovery in IPRs is governed by 35 U.S.C. § 316(a)(5), which provides for the “deposition of witnesses submitting affidavits or declarations” and discovery “otherwise necessary in the interest of justice.” *Id.* Cross-examination of Mr.

Mihail and Ms. Greb should be authorized because Mylan's Ground 4 necessarily rests on their credibility and veracity, making their declarations and depositions significant issues in this IPR. Each of the five factors in *Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC* confirm that this discovery is "necessary in the interest of justice." IPR2012-00001, Paper 26 at 6-7 (PTAB Mar. 5, 2013) (precedential).

Factor 1 - "More Than A Possibility And Mere Allegation": The first factor focuses on whether a "party requesting discovery ... already [is] in possession of evidence tending to show beyond speculation that in fact something useful will be uncovered." *Garmin*, IPR2012-00001, Paper 26 at 6. Here, Biogen has precisely such evidence for both declarants.

First, there is already evidence that the Mihail Declaration's accuracy is more than merely suspect. As explained above, entering the URL provided by Mr. Mihail as the source of Ex. 1010 results in an error message. *Supra* at I. Second, both the lack of the required 37 CFR § 1.68 attestation and objective evidence—the omission of inconsistent facts regarding the availability of Ex. 1010—call into question the reliability of the Greb Declaration, which, in turn, undermines the Mihail Declaration and the Petition. *Supra* at I.

Factor 2 - "Litigation Positions And Underlying Basis": This factor focuses on whether the discovery is seeking "the other party's litigation positions and the underlying basis for those positions." *Garmin*, IPR2012-00001, Paper 26 at 6, 13.

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