Filed: April 13, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and
AMNEAL PHARMACEUTICALS LLC

Petitioners,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.

Patent Owner.

Case No. IPR2015-00643 (8,232,250 B2)
Case No. IPR2015-00644 (8,399,413 B2)
Case No. IPR2015-00830 (8,969,302 B2)[1,2]

PETITIONERS' MOTION TO EXCLUDE

[1] Case Nos. IPR2015-01976, IPR2015-01980 and IPR2015-01981 have been joined with these proceedings.

[2] A word-for-word identical Motion is being filed in each proceeding.

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RULES AND REGULATIONS

Pursuant to 37 C.F.R. §§ 42.61(a), 42.62 and 42.64(c), Petitioners move to exclude the following:

(1) Paragraphs 13-23, 26-32, 37-45 and 50-56 of the Grabowski Declaration (Ex. 2133); and

(2) Exhibits 2108-2122.

I. FACTUAL BACKGROUND

The patents at issue claim a glatiramer acetate ("GA") dosing regimen in which three 40 mg subcutaneous injection are administered each week. Petitioners have conclusively shown that the claimed dosing regimen is obvious over prior art disclosing, *inter alia*, the safety of 20 mg and 40 mg GA subcutaneous dosing regimens administered every-other-day. In response, the Patent Owner argues that its alleged invention is a commercial success, relying on the declaration of Dr. Henry Grabowski (Ex. 2133[3]) ("the Grabowski Declaration"), which relies on Exhibits 2108-2122. The Grabowski Declaration and the evidence identified in alleged support thereof suffer from a major unalterable defect: most of the evidence is not of record. While the Grabowski Declaration identified over fifty references, only a few of those references are of record in this proceeding.

[3] The Grabowski Declaration is filed with the same exhibit number in IPR2015-00643, IPR-2015-00644, and IPR2015-00830. The Grabowski Declaration filed in each proceeding is substantively identical.

Because Patent Owner failed to file with the Board most of the evidence it relies on in the Grabowski Declaration, most of the Declaration is entirely unsupported, rendering it unreliable and inadmissible under Fed. R. Evid. 702 and 703.

Accordingly, and for the reasons explained more fully below, Petitioners move to exclude Exhibits 2108-2122 and paragraphs 13-23, 26-32, 37-45 and 50-56 of the Grabowski Declaration (Exhibit 2133).

II. ALL EXHIBITS AND TESTIMONY REFERRING TO IMS DATA SHOULD BE EXCLUDED.

Exhibits 2108-2114 and 2120-2122 are summary demonstrative exhibits prepared specifically for the Grabowski Declaration. These exhibits summarize data compiled from a third party vendor, IMS, into tables and graphs to illustrate purported sales and prescription trends for Copaxone and a subset of other MS treatments. The underlying IMS data, however, was not produced to Petitioners and is not of record in this case. Indeed, Patent Owner moved to supplement the record (IPR2015-00643, Paper 42), but that motion was denied as to the IMS data (IPR2015-00643, Paper 48).

A. EXHIBITS 2108-2114 AND 2120-2122 SHOULD BE EXCLUDED

Federal Rule of Evidence 1006 requires that the underlying evidence used to create a summary exhibit must be made available and produced to the other party. Fed. R. Evid. 1006; *see* 37 C.F.R. 42.62(a) ("[T]he Federal Rules of Evidence shall apply to a proceeding."); 37 C.F.R. § 42.6(c) ("Each exhibit must be filed with the

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