UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC, ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMA GLOBAL FZE,

Petitioners,

v.

NOVARTIS AG,

Patent Owner.

Case IPR2017-00854[1]

U.S. Patent No. 9,187,405

PATENT OWNER NOVARTIS'S REPLY IN SUPPORT OF ITS SUPPLEMENTAL MOTION TO EXCLUDE

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[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

Petitioners begin their defense of admissibility of Exhibits 1065-1069 with a straw man, knocking down an authenticity argument under Fed. R. Evid. 901 that Novartis never made. (Paper 101 at 1–2.) As for the untimeliness of these Exhibits, that is an objection under the Board's rules, which some Board panels have permitted in a motion to exclude. *See, e.g.*, *Toshiba Corp. v. Optical Devices, LLC*, IPR2014-01447, Paper 34 at 44–47 (Mar. 9, 2016) (excluding evidence improperly first submitted in reply as untimely).

In the remainder of their opposition, Petitioners do not dispute the reasons these exhibits lack relevance and would be prejudicial under Fed. R. Evid. 401-403. Two of the exhibits post-date the '405 Patent (Exhibits 1068 and 1069), and none has anything to do with neurological disease, multiple sclerosis, or fingolimod drug dosing regimens. (Mot. at 1–2.) Without expert evidence linking these documents to the facts that matter in this case, the Exhibits are plainly irrelevant and prejudicial and should be excluded. The meaning of terms in the proposed amended claims must be evaluated from the perspective of a person of ordinary skill, as must the meaning of supposedly invalidating prior art. *Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1362 (Fed. Cir. 2016) ("Claim construction requires a determination as to how a person of ordinary skill in the art would understand a claim term 'in the context of the entire patent, including the specification.'") (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313

(Fed.Cir.2005) (en banc)); Pre-AIA 35 U.S.C. § 103(a) (inquiry whether the claimed "subject matter as a whole would have been obvious at the time the invention was made *to a person having ordinary skill in the art to which said subject matter pertains*.") (emphasis added); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1376-78 (Fed. Cir. 2012) (vacating summary judgment of obviousness in part because district court considered prior art from perspective other than that of a POSA). Petitioners could have supplied an expert declaration with their sur-reply to provide that meaning if they had chosen to do so. They did not, rendering these documents unusable here.

Unable to contest these facts, Petitioners seize the opportunity to make a brand new merits argument, contending that the '405 Patent specification lacks written description support for the proposed amended claims' use of the term "dosing regimen." The Board should disregard this new argument in a motion to exclude. In any event, it is plainly wrong.

The '405 Patent repeatedly uses the word "dose" and uses the word "regimen" too when describing the methods of administering fingolimod. (Ex. 1001 at 10:63, 11:25, 11:37, 12:30.) The '405 patent describes multiple embodiments of dosing regimens. (*Id.* at 9:48-51, 11:3-19.) Both experts have also testified that a person of ordinary skill in the art at the time reading the patent specification would have understood that the inventors had possession of the claimed invention. (Ex. 2022 ¶¶

182–89; Ex. 2024 ¶¶ 171–76.) Written description is found in the specification. Nothing more is needed for written description support. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) ("[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys *to those skilled in the art* that the inventor had possession of the claimed subject matter as of the filing date.) (emphasis added).

Terms must be given the broadest reasonable interpretation to a person of ordinary skill in the art in the context of the patent. Here, that hypothetical "person" has been defined by the Board, the parties have not disputed that definition, and Novartis has offered testimony from experts about how such persons would read the specification. (Paper 11 at 9.) Yet Petitioners offered no testimony from a person of skill about Exhibits 1065-69; they offered only attorney argument. (Mot. at 1.) The Board should disregard this improper attempt at further merits briefing, and exclude the Exhibits 1065-1069 under Fed. R. Evid. 401-403.

Respectfully submitted,

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