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 SUPPLEMENTAL MOTION TO EXCLUDE

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

The parties agreed that Novartis could object to and serve a supplemental motion to exclude on evidence submitted with Petitioners sur-reply on Novartis's motion to amend. (Paper 74.) Novartis filed objections on April 23, 2018 (Paper 87), and hereby moves to exclude the **Exhibits 1065-1069** cited in the sur-reply as untimely under the Board's rules, and for lack of any relevance foundation under Fed. R. Evid. 401-403.

First, Petitioners submitted these five Exhibits for the first time with their sur-reply, without any expert testimony or other evidence to lay any foundation whatsoever. Petitioners' offer only new attorney argument about the purported content of these documents in their sur-reply, which is improper and too late. The Exhibits should be excluded on this basis alone. 37 C.F.R. 42.23(b).

Second, these Exhibits are five patents or patent applications, two of which are not even prior art to the '405 Patent. (Exhibits 1069 and 1068.) Exhibit 1069 was published on September 8, 2017, and Exhibit 1068 was published on December 24, 2008, both years after the priority date of the '405 patent. These two Exhibits should be excluded as irrelevant for this reason alone.

All of the Exhibits are also outside the field of multiple sclerosis and thus irrelevant. Exhibit 1065 is a U.S. Patent directed to "methods and products for stimulating hematopoiesis." (Ex. 1065, Abstract.) Exhibit 1066 is a publication of a U.S. patent application directed to methods for treating individuals having a

hepatitis C virus infection. (Ex. 1066, Abstract.) Exhibit 1067 is a PCT publication directed to methods of reducing liver fibrosis, and methods of increasing liver function and methods of reducing the incidence of complications associated with HCV and cirrhosis of the liver. (Ex. 1067, Abstract.) Exhibit 1068 is a PCT publication directed to methods and drug products for treating inflammatory joint disease. (Ex. 1068, Abstract.) And, Exhibit 1069 is a PCT publication directed to a method combining a checkpoint inhibitor and a glucocorticoid receptor modulator to treat cancer. (Ex. 1069, Abstract.) None of the documents even mention fingolimod, and no expert or other evidence purports to link these documents to the therapeutic field at issue here, *i.e.*, treatments for multiple sclerosis using fingolimod. These documents are therefore irrelevant.

Third, Petitioners argue that these patent documents show that "[m]ethods of treatment routinely employ more than one dosing regimen for a given active at different times." (Paper 85 at 10.) From this, Petitioners say that the close-ended dosing regimen described in the proposed amended claims as "consisting of" daily 0.5 fingolimod doses allegedly still leaves open the possibility of other dosing regimens for the drug.

The point Petitioners say these documents make is irrelevant—if anything, the documents prove Novartis's point. In these documents, each separate dosing regimen is discussed as a separate thing, typically separated by time. Each dosing

regimen is modified with an adjective such as "first" or "second" or "induction" or "maintenance." (Paper 85 at 10.) No such language appears in the '405 Patent specification or the proposed amended claims. Rather, the Patent and the proposed amended claims speak of only one dosing regimen for fingolimod, and the claim amendments make clear that any such regimen would be limited solely to 0.5 mg daily. That would exclude a loading dose or any other dosing scheme. Thus, the Exhibits proffered by Petitioners are prejudicial in that they distract from the appropriate time period and from the relevant factual language used in the specification at issue in this case.

These new documents accordingly are irrelevant, prejudicial, without foundation, and should be excluded under Fed. R. Evid. 401–403.

Respectfully submitted,

Dated: April 30, 2018

/Jane M. Love, Ph.D./

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6, I hereby certify that on April 17, 2018, true and accurate copies of the foregoing MOTION TO EXCLUDE for IPR2017-00854 were served via electronic mail, on the following counsel of record for Petitioners:

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