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

DECLARATION OF PETER J. WAIBEL, ESQ. IN SUPPORT OF EVIDENCE

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

I, Peter J. Waibel declare as follows:

1. I am Head of US Patent Litigation for Novartis Pharmaceuticals Corporation ("Novartis"), the assignee of U.S. Patent No. 9,187,405 and a real party-in-interest in these proceedings. I have been employed by Novartis since 2002, as a Senior Patent Attorney until 2007, when I assumed my current role as Head of US Patent Litigation.

2. As head of US Patent Litigation, I have access to certain Novartis' business records, including Novartis' regulatory communications and filings with FDA regarding clinical trials. I have knowledge of Novartis' product development efforts, including with respect to Novartis' Gilenya product.

3. I have personal knowledge of Novartis' business practices regarding the maintenance of e-mail and internal data systems and the practices and protocols for ensuring the accuracy of the date and time stamps reflected on e-mails sent from Novartis' e-mail system.

4. In the ordinary course of business, the e-mail system used by Novartis automatically affixes a date and time stamp on each e-mail received and sent on Novartis' internal servers. It is Novartis' practice to institute security safeguards to prevent tampering with its e-mail systems.

5. I have personal knowledge of Novartis' business practices regarding the drafting and maintenance of communications with the FDA. Novartis is in the

business of selling branded pharmaceuticals. Accordingly, Novartis regulatory personnel draft communications with FDA in the ordinary course of business and as a regularly conducted business activity. Novartis continuously maintains copies of communications with the FDA and any documents included in those communications in the ordinary course of business. Novartis maintains its communications with FDA in a centralized computerized filing system, to which I can gain access as part of my job.

6. I have personal knowledge of Novartis' business practices regarding the drafting and maintenance of communications regarding clinical trials. Novartis personnel draft and maintain records of all communications with third parties regarding clinical trials in the ordinary course of business and as a regularly conducted business activity. Novartis continuously maintains copies of communications with third parties regarding clinical trials in the ordinary course of business.

7. I have reviewed the records filed as Exhibits 2037, 2040, 2057, and 2063-2066 (the "Records"), and I confirm that the Records are true and accurate copies of original records created and/or maintained by Novartis personnel in the manner described above in the ordinary course of business. I confirm that the time

stamps on the Records saved on Novartis' internal servers accurately reflect the date the Records were last modified on Novartis' internal servers.

8. The document identified as Ex. 2037 is a copy of letter sent by FDA to Novartis on September 21, 2010 approving Novartis' new drug application ("NDA") No. 022-527. This letter was received in the ordinary course of business, and filed in Novartis's electronic filing system for FDA correspondence. I confirm that Novartis made a post-marketing commitment to FDA to undertake a 0.25 mg daily dose trial of fingolimod, as is shown on page 7 of Ex. 2037. Furthermore, this approval letter is publicly available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022527Orig1s000ltr.pdf.

9. The document identified as Ex. 2040 is a copy of the Gilenya label revised in February 2016 and sent to and approved by FDA. This Gilenya label was prepared in the ordinary course of business by an employee in Novartis' regulatory department. According to Novartis' routine business practice, a copy of the approved Gilenya label as revised in February 2016 was made and filed, and I was able to access this file for inclusion in these proceedings. Furthermore, the Gilenya label is publicly available at

https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/gilenya.pdf.

10. The document identified as Ex. 2057 is a copy of an internal report prepared by the inventors of the '405 patent—Novartis scientists Christian Schnell and Peter Hiestand. This report was submitted to FDA as part of Novartis' NDA No. 022-527. According to Novartis' routine business practice, a copy of this report was made and filed, and I was able to access this file for inclusion in these proceedings.

11. The document identified as Ex. 2063 is a redacted copy of e-mail correspondence between Novartis personnel and personnel at Mount Sinai School of Medicine regarding Mount Sinai's potential participation in Gilenya clinical trials. I can confirm that Novartis personnel sent and received the correspondence represented in Ex. 2063. Sylvia Burns worked for Novartis from 2004-2010. Valentina Curovic-Perisic worked for Novartis from 2005-present. These emails came from Novartis's email system, specifically from the email box of Mr. Tom Watson, a former Novartis employee. I confirm that the data identifying the senders, recipients, date, and time of delivery reflected in Ex. 2063 matches the data collected in Novartis' internal system that is automatically affixed to these emails and saved at the time of delivery and/or receipt. I also confirm that the redacted portion of the

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