

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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.

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Case IPR2017-00854<sup>1</sup>

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

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**FIFTH DECLARATION OF WILLIAM J. JUSKO, PH.D.**

Mail Stop Patent Board  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
ALEXANDRIA, VA 22313-1450

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<sup>1</sup> Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

**Apotex v. Novartis**

I, William J. Jusko, Ph.D., declare as follows:

1. I am the same William J. Jusko who submitted four prior declarations in this matter, Exhibit 2005 (“First Declaration”), Exhibit 2024 (“Second Declaration”), Exhibit 2076 (“Third Declaration”), and Exhibit 2095 (“Fourth Declaration”). My Third Declaration was served on December 5, 2017 as supplemental evidence.

2. In paragraph 31 of my Fourth Declaration, I stated the following: “Dr. Benet’s human weight range artificially skews the dose lower; women are the predominant victims of MS, and the average female weight in the U.S. in 2006 was about 75 kg according to the U.S. Centers for Disease Control (Ex. 2104 at 7, Table 3), yielding a dose of 0.6 mg using Dr. Benet’s methodology.”

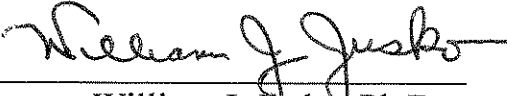
3. Exhibit 2104 was published in 2008 and reports that the average female weight in the U.S. in 2006 was about 75 kg according to the U.S. Centers for Disease Control. (Ex. 2104 at 7, Table 3.) Exhibit 2109 was published in 2005 and confirms that a person of skill in 2006 would have understood that the average female weight in the U.S. for women aged 20 to 69 was about 75.02 kg. (Ex. 2109 at 18, Table 16.) 75.02 kg is the weighted average of the mean weights for the age groups covering women ages 20 to 69 in Table 16 of Exhibit 2109. The age groups of women aged 70-79 and over 80 were not included because I understand from counsel that Dr. Steinman’s view is that it would be exceptionally rare for a woman older

than 70 years of age to be diagnosed with multiple sclerosis.

4. In signing this Declaration, I understand that it will be served as supplemental evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross-examination will take place in the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted.

DATED: April 3, 2018

By:

  
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William J. Jusko, Ph.D.