

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS, INC.,
Petitioner

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Inter Partes Review IPR2014-00550

U.S. Patent No. 6,335,031

REPLY DECLARATION OF AGIS KYDONIEUS, PH.D.

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APPENDICIES

APPENDIX A: Sasaki (Exhibit 1005) Working Examples Calculation

APPENDIX B: Calculation of Antioxidant Weight Percentage for Elmalem (Exhibit 1009)

I, Agis Kydonieus, Ph.D., declare and state as follows:

I. QUALIFICATIONS

1. I previously submitted a Declarations in IPR2014-00550 (Exhibit 1010) setting forth my background and credentials. My curriculum vitae (Exhibit 1022) sets forth my education and experience in further detail, and I further explained my background during my January 13, 2015 deposition (Exhibit 1029 at 107:2-109:13).

II. INFORMATION CONSIDERED

2. In forming the opinions set forth herein, I have considered the documents and exhibits referenced by Patent Owners and those referenced by Dr. Klibanov in his declaration (Exhibit 2012). I have also relied on my own experiences and knowledge, and have also considered the documents referenced in my initial declaration (Exhibit 1010) and those I mentioned during my deposition (Exhibit 1029).

3. I have also considered the documents discussed herein, which include the following:

- The Board's institution Decision for IPR2014-00550 (Paper 10).
- The transcript for the *Novartis v Noven* trial that was held December 1-3, 2014. (Exhibits 1025-1027.)

- Internal Novartis memorandum written by Dr. Tiemessen, N0272228-29. (Exhibit 1033.)
- Internal Novartis e-mail communication from Dr. Tiemessen to O. Garinot, N0272563. (Exhibit 1034.)
- [REDACTED] Meeting minutes of the LTS-Sandoz (Novartis) working group, N0317247-64. (Exhibit 1035.)
- Excerpts of the confidential transcript of the October 17-18, 2012 deposition of Dr. Henricus L.G.M. Tiemessen. (Exhibit 1036.)
- Morrison and Boyd 2nd Ed. 1992. (Exhibit 1038.)
- PDR Medical Dictionary, 1st Ed. 1995. (Exhibit 1039.)
- CRC Handbook of Chemistry and Physics. (Exhibit 1040.)
- U.S. Patent 7,683,205. (Exhibit 1041.)
- U.S. Patent 8,324,429. (Exhibit 1042.)
- Toronto Research Chemicals Inc. web page. (Exhibit 1044.)
- David Shamah, *Alzheimer Drug Pioneer to Get Israel Prize, Professor Weinstock-Rosin, who developed Exelon, will be recognized for her work on Israel Independence Day*, TIMES OF ISRAEL, Mar. 4, 2014. (Exhibit 1045.)
- Textbook of Polymer Science, Chapter 9 (Billmeyer, 2d ed. 1971). (Exhibit 1046.)

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