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 No.: 2014-00549

U.S. Patent No. 6,316,023

DECLARATION OF AGIS KYDONIEUS, PH.D.

Mylan Ex. 1010
Mylan v. Novartis

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

I. QUALIFICATIONS

1. I am currently the President of Samos Pharmaceuticals LLC, a company through which I am providing consulting services to pharmaceutical companies in the field of drug delivery. Samos also develops innovative drug delivery technologies for its own use. Currently I am also cofounder and Chief Scientific Officer of InteguRx Therapeutics LLC a company developing transdermal products in the women's health area. I am also cofounder and President of KAT Transdermals LLC a company developing transdermal products in the CNS area. Additionally I am Senior Scientific Advisor to Agile Therapeutics Inc, a company developing contraceptive transdermal products.

2. I received my B.S.Ch.E. in 1959, and my Ph.D. (chemical engineering) in 1964, both from the University of Florida in Gainsville. The last 35 years of my career have focused on the development of transdermal drug delivery systems. Prior to assuming my current positions, I served as Vice President of Convatec, previously a subsidiary of Bristol Myers Squibb. Convatec developed a variety of topically applied products, including transdermal drug delivery systems and in association with BMS. I also served as President of Hercon Laboratories, a company focused on transdermal drug delivery systems. I am also a founding member of the Controlled Release Society, a scientific body dedicated to drug

delivery science and technology.

3. Over the course of my career, I have been awarded 23 US issued patents for inventions concerning the topical and transdermal delivery of drugs and edited ten books pertaining to the delivery of bioactive materials, four of which pertain to topical and transdermal delivery. I have authored over 100 book chapters, scientific publications, abstracts and presentations regarding delivery of bioactive agents including transdermal drug delivery.

4. A copy of my curriculum vitae, which sets forth my education and experience in further detail, is attached at Exhibit 1023.

5. I have been engaged as an expert on behalf of Petitioner, Noven Pharmaceuticals, Inc. I am being compensated at my customary rates of $300.00-400.00 per hour (depending on the total hours worked per month). My compensation increases to $500.00 per hour for time spent attending depositions, trials, or other legal proceedings. My compensation is not related in any way to the outcome of this proceeding. In the previous four years, I have not testified as an expert in any case, whether at trial or deposition.

II. INFORMATION CONSIDERED

6. In forming the opinions set forth herein, I have relied on my own experiences and knowledge. I have also considered the documents discussed herein, which include the following:

- U.S. Patent No. 6,316,023 ("the '023 patent") (Ex. 1001)
- U.S. Patent 4,948,807 ("Rosin") (Ex. 1008)
- Neuropharmacology (1991) 30: 1059-1064 ("Elmalem") (Ex. 1009)
- European Patent Application No. 0155,229 ("Kissel")(Ex. 1007)
- UK Patent No. 2,203,040 ("Enz") (Ex. 1002)
- PCT Publication WO 95/24172 ("Ebert") (Ex. 1006)
- a certified translation of Japanese Published Application No. JP 59-184121 ("Sasaki") (Ex. 1005)
- The Handbook of Pharmaceutical Excipients (2nd Ed. 1994, Wade, A. and Weller, P.J., Eds.) ("Handbook") (Ex. 1003)
- Declaration of Christian Schoneich, Ph.D. (Ex. 1011)
- ICH Topic Q 1 A, Stability Testing Guidelines: Stability Testing of New Drug Substances and Products (CPMP/ICH/380/95) (Ex. 1014)
- "New acetylcholinesterase inhibitor shows promise in largest Alzheimer's trial to date," Formulary, Vol. 32, Dec. 1997 ("Formulary Article") (Ex. 1013)
- "Safety/Tolerability Trial of SDZ ENA 713 in Patients with Probable Alzheimer's Disease," John J. Sramek et al., Life

Sciences, Vol. 58, No. 15, pp. 1201-1207 (1996) ("Sramek") (Ex. 1012)

III. SUMMARY OF OPINIONS AND EXPECTED TESTIMONY

7. I have reviewed the documents referenced above, in view of my own knowledge and experience concerning the development of pharmaceuticals, including transdermal drug delivery systems. It is my opinion that at the time of the alleged invention, a person of ordinary skill in the art would have been aware of the compound rivastigmine (also known as ENA 713), and that it was being developed as a treatment for Alzheimer's disease. It is my opinion that at the time of the alleged invention, a person of ordinary skill in the art working to develop a pharmaceutical composition comprising rivastigmine, including a transdermal rivastigmine delivery system, would have been motivated to combine rivastigmine with an antioxidant. It is my opinion that the person of ordinary skill in the art would have reasonably expected that an antioxidant would reduce or prevent the oxidative decomposition of rivastigmine in the transdermal device.

IV. LEGAL STANDARDS

8. I have been instructed by counsel for Noven, and understand, that a patent is not written for the general public, but instead is directed to a "person of ordinary skill" in the field of the patent. I have been informed by counsel for Noven that factors such as the education level of those working in the field, the sophistication

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