

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.: IPR2014-00549

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

DECLARATION OF CHRISTIAN SCHÖNEICH, PH.D.

Mylan Ex. 1011
Mylan v. Novartis

I, Christian Schöneich, Ph.D., declare and state as follows:

I. QUALIFICATIONS

1. I am currently the Chair of the Department of Pharmaceutical Chemistry at the University of Kansas. I have been Chair of that department since 2005. I have been a professor in that department since 2003.

2. In addition, I currently hold the position of Takeru Higuchi Distinguished Professor for Bioanalytical Chemistry. I also have an appointment as Courtesy Professor in the Department of Chemistry at the University of Kansas.

3. From 1998 to 2003, I was an associate professor and from 1992 to 1998, I was an assistant professor in the Department of Pharmaceutical Chemistry at the University of Kansas.

4. Prior to those appointments, I was a Postdoctoral Fellow in the same department from 1991 to 1992. I earned my Ph.D. in chemistry with honors from the Technical University Berlin in 1990.

5. I have been fortunate to receive a number of distinctions for my research on free radical and oxidation chemistry including: “Young Investigator Award” of the Society For Free Radical Research (SFRR) in 1990 and 1994; the Pfizer Research Scholar Award in 2001, 2002, 2003, and 2004; and Dolph Simons Award in Biomedical Sciences. For a full list of my awards and honors, please see my *curriculum vitae*, which is included as Exhibit 1024.

6. I serve on the Editorial Board of the journals *Experimental Gerontology* and *Free Radical Biology and Medicine*, and on the Editorial Advisory Board for the *Journal of Pharmaceutical Sciences* and *Chemical Research in Toxicology*. I am also a review editor for the journal *Free Radical Research*. As an editor, I routinely review scientific manuscripts concerning free radical reactions, oxidation reactions, and the degradation of small and large molecule pharmaceuticals.

7. My research interests include mechanisms of free radical reactions. This includes, for example, the oxidative post-translational modifications of proteins, which are generally carried out by reactive oxygen species and/or reactive nitrogen species. Such oxidative modifications accompany physiological disorders associated with biological aging or disease. My research spans the behavior of proteins in solutions and the solid state, including stability of proteins in pharmaceutical formulations, mechanisms for protein instability in these formulations, and methods to stabilize proteins in these formulations.

8. I am being compensated for my time in this proceeding at a rate of \$550 per hour. My compensation is not dependent upon the conclusions I reach or the outcome of this proceeding. In the last four years I testified in *Graceway Pharmaceuticals, LLC et al. v. Perrigo Company* (C.A. No. 10-937-WJM-MF (D.N.J.)).

II. INFORMATION CONSIDERED

9. In forming the opinions I have also considered the documents discussed herein, which include the following:

- U.S. Patent No. 6,316,023 (“the ’023 patent,” Ex. 1001).
- UK Patent Application GB 2,203,040 (Ex. 1002).
- Connors, Amidon, & Stella, Oxidation and Photolysis in Chemical Stability of Pharmaceuticals – A Handbook for Pharmacists (2nd Edition), John Wiley & Sons, NY (1986), pp. 82-114 (Ex. 1015).
- Howard C. Ansel, Introduction to Pharmaceutical Dosage Forms, 4th Edition, Lea & Febiger, Philadelphia (1985), pp. 83-116 (Ex. 1016).
- Ho-Leung Fung, Chapter 7 – Chemical Kinetics and Drug Stability in MODERN PHARMACEUTICS (G.S. Banker and C.T. Rhodes, eds.), Marcel Dekker, NY (1978), pp. 227-62 (Ex. 1017).
- Carey & Sundberg, ADVANCED ORGANIC CHEMISTRY, 2nd ed. Part A: Structure and Mechanism, Plenum Press, New York, 1984, pp. 652 (Ex. 1018).
- Boccardi G. et al. Photochemical Iron(III)-Mediated Autoxidation of Dextromethorphan. Chemical & Pharmaceutical Bulletin. Vol. 37, 308–310 (1989) (“Boccardi,” Ex. 1020).
- Linnell, R.H., The Oxidation of Nicotine. I. Kinetics of the Liquid Phase

Reaction Near Room Temperature. Tobacco Science, Vol. 4, pp. 89–90 (1960) (“Linnell,” Ex. 1022).

- Bateman, L., Olefin Oxidation, Quarterly Review (1954) Vol. 8, pp. 147–167 (Ex. 1021).

III. SUMMARY OF OPINIONS

10. I understand that Noven Pharmaceuticals, Inc. (“Noven”) is submitting a petition to the United States Patent and Trademark Office’s Patent Trial and Appeal Board requesting *Inter Partes* Review (“IPR”) of claims 1, 2, 4, 5, 7, and 8 of the ’023 patent (Ex. 1001).

11. I have been asked to provide my analysis and expert opinions on what a person of ordinary skill in the art¹, in 1998, would have expected about the

¹ I have been advised that a person of ordinary skill in the art would have been a collaborative team of individuals in which each person would have been able to draw upon the experiences and knowledge of the others. In particular, the person of ordinary skill in the art at the time of the alleged invention would have been a chemist, chemical engineer, polymer chemist or pharmaceutical chemist working to develop pharmaceutical formulations, including transdermal drug delivery systems. The person of ordinary skill would have been familiar with testing that accompanies the development of any pharmaceutical formulation, including testing

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