

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN INSTITUTIONAL LLC,  
Petitioner,

v.

NOVO NORDISK A/S,  
Patent Owner.

---

Case IPR2020-00324  
Patent 8,114,833

---

**DECLARATION OF DAVID NOLAN**

IPR2020-00324

Patent 8,114,833 B2

I, David Nolan, hereby declare as follows:

1. I submit this Declaration in support of the Patent Owner Response of Novo Nordisk A/S (“Novo Nordisk”) in IPR2020-00324 of U.S. Patent No. 8,114,833 (the “833 patent”).

2. I have personal knowledge of all information set forth in this declaration unless I specifically note otherwise.

3. I am a full-time employee of Novo Nordisk, and I am not being separately compensated for my work preparing this declaration.

4. I received a Master of Science in engineering from the Technical University of Denmark in 2006. While a student at the Technical University of Denmark, I joined Novo Nordisk in 2003 as a Student Assistant in the Pharmaceuticals, Biopharm Department.

5. I have been employed by Novo Nordisk since 2003. I worked as a Student Assistant until 2006, when I became a Chemist in the Biopharm DP Support Department. Over the years I held a variety of positions within Novo Nordisk, until in 2013, I became a Department Manager in the Analytical Department. Then, in 2018, I assumed my present role of Director, Injectable Formulation Development. As Director, Injectable Formulation Development at Novo Nordisk, I am responsible for development of formulations for new injectable drug products.

6. Based on my 17 years of experience working at Novo Nordisk, I have personal knowledge about how Novo Nordisk keeps business records including reports and raw data, as well as the practices and protocols for ensuring the accurate reporting of such data. As part of my responsibilities as a Student Assistant, I reviewed data referenced in reports for accuracy. Pursuant to Novo Nordisk's ordinary practice at the time, the scientist who drafted the report would provide me with archive boxes that contained printouts of the raw data from the experiments referenced in the report. I would then check whether the data referred to in the report matched the printouts of raw data from the archive boxes.

7. One of the scientists with whom I worked while I was a Student Assistant was Dr. Tina Pedersen. Dr. Pedersen drafted the report entitled "NN2211: Physical and Chemical Stability of 5 mg/ml NNC 90-1170, pH 7.85, in Presence of Different Isotonic Agents," dated April 22, 2003, which was given an internal report No. 03433088 ("April 22, 2003 Report"). (Ex2068.) Reports such as the April 22, 2003 Report were generated at Novo Nordisk as part of our normal business practice.

8. Dr. Pedersen asked me to conduct the data review for the April 22, 2003 Report. I reviewed the underlying data in the April 22, 2003 Report for accuracy by comparing the data in the report against the printouts of raw data provided to me in the archive boxes. On April 23, 2003, I signed page 2 of the April 22, 2003 Report to indicate that I had checked the data reported in the report for accuracy, in

IPR2020-00324

Patent 8,114,833 B2

accordance with the standard procedure of our formulation group at Novo Nordisk.

(Ex2068 at 2.)

9. I confirm that the business record cited in my declaration (Ex2068) is a true and accurate copy of the original record created and maintained by Novo Nordisk in the manner described above in the ordinary course of business.

IPR2020-00324  
Patent 8,114,833 B2

**ACKNOWLEDGEMENT**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. The statements in this declaration were made with the knowledge that willful false statements and the like are made punishable by fine or imprisonment under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the results of these proceedings.

  
\_\_\_\_\_  
David Nolan

17 - SEP - 2020  
Date