

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 TINA BJELDSKOV PEDERSEN, PH.D.

IPR2020-00324

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I, Tina Bjeldskov Pedersen, hereby declare as follows:

1. I am an inventor named in U.S. Patent No. 8,114,833 (the “’833 patent”) owned by Novo Nordisk A/S (“Novo Nordisk”).
2. I have personal knowledge of the 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 my Ph.D. from the University of Copenhagen in 2002. I began working at Novo Nordisk in 2001 as a Research Scientist within the formulation development of injectables. In 2006, I advanced to Team Leader within the formulation development of injectables. In 2011, I transitioned to Team Leader within oral formulation development. In 2015, I became the Head/Director for Oral Formulation Research, which is the position I hold today.
5. As Director for Oral Formulation Research at Novo Nordisk, I am responsible for a department that provides and progresses state-of-the-art oral formulation technology platforms for our oral project pipeline.
6. I have about 19 years of experience formulating drug products, including more than 19 years of experience working with peptides and proteins for clinical use.

7. I was a member of the Novo Nordisk formulation team tasked with developing an injectable liraglutide formulation (the “liraglutide project”). The documents cited in this declaration were generated in the normal course of business at Novo Nordisk in connection with our work on the liraglutide project.

8. In the ordinary course of business, and in connection with our work on the liraglutide project, we regularly corresponded by e-mail. I confirm that Ex2051 is an e-mail chain with an earliest email dated December 19, 2001. I confirm that I received all e-mails in the chain dated January 23, 2002 and earlier due to the fact that I was copied into the e-mail chain on January 2, 2002. Ex2051 is a true and accurate copy of an original record that was prepared and kept in the course of regularly conducted business activity of Novo Nordisk, as well as a certified English translation thereof. The e-mail messages in the chain that I received (dated from December 19, 2001 to January 23, 2002) contained in Ex2051 were created at or near the time of the activities described therein.

9. In the ordinary course of business, and in connection with our work on the liraglutide project, I made a presentation at the April 4, 2002 NN2211 Formulation and Production Group Meeting, which both Dr. Engelund and I attended. Details of the meeting were memorialized in meeting minutes (“04-04-02 Meeting Minutes”). (Ex2055.) The 04-04-02 Meeting Minutes were generated in accordance with Novo Nordisk’s usual practice. My attendance at the meeting is

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indicated by my initials on the 04-04-02 Meeting Minutes. (See Ex2055 at 2, 12.)¹

At Novo Nordisk, employees are identified by initials. “Kot” refers to Dr. Engelund and “TinP” refers to me. The 04-04-02 Meeting Minutes were created at or near the time of the activities set forth therein. I confirm that Ex2055 is a true and accurate copy of the 04-04-02 Meeting Minutes, which is an original record that was kept in the course of regularly conducted business activity of Novo Nordisk, as well as a certified English translation thereof.

10. In connection with our work on the liraglutide project, I authored and signed a protocol entitled: “Investigation of Several Alternative Isotonic Agents for the NN2211 Drug Product (Continuation of Protocol No. 02433030),” which is dated June 3, 2002 (“June 3, 2002 Drop Test Protocol”). (Ex2057.) The June 3, 2002 Drop Test Protocol was given internal report number “02433195.” The June 3, 2002 Drop Test Protocol was created at or near the time of the work set forth therein and summarized the drop test as well as the related results. Protocols such as the June 3, 2002 Drop Test Protocol, and the protocols identified below in paragraphs 11 and 13, are generated at Novo Nordisk as part of our normal business practice. I confirm that Ex2057 is a true and accurate copy of the June 3, 2002 Drop

¹ In citing to a Danish language Exhibit, I have provided the page number of the original Danish language document and the certified English translation thereof.

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Test Protocol, which is an original record that was prepared and kept in the course of regularly conducted business activity of Novo Nordisk, as well as a certified English translation thereof.

11. In connection with our work on the liraglutide project, I authored and signed a protocol entitled: “Protocol: Study of Potential Clogging of Needles Placed on NovoPen® with Various Isotonicity Agents (Supersedes Protocol No. 02433148 and 02433162),” which is dated June 5, 2002 (“June 5, 2002 Clogging Test Protocol”). (Ex2058.) The June 5, 2002 Clogging Test Protocol was given an internal report number of “02433229.” The June 5, 2002 Clogging Test Protocol was created at or near the time of the work set forth therein and summarized the clogging test as well as the related results. I confirm that Ex2058 is a true and accurate copy of the June 5, 2002 Clogging Test Protocol, which is an original record that was prepared and kept in the course of regularly conducted business activity of Novo Nordisk, as well as a certified English translation thereof.

12. In connection with our work on the liraglutide project, I received a memo from Peter Buus entitled “Testing of Isotonic Agents for NN2211,” and dated June 27, 2002 (“June 27, 2002 Simulated Filling Test Memo”). (Ex2059.) The June 27, 2002 Simulated Filling Test Memo was created at or near the time of the work set forth therein. Memoranda like the June 27, 2002 Simulated Filling Test Memo are generated at Novo Nordisk as part of our normal business practice. The

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