UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner

v.
NOVO NORDISK A/S,
Patent Owner

Case IPR2023-00724
Patent 10,335,462

DECLARATION OF CHRISTINE B. JENSEN, M.D., PH.D.

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I, Dr. Christine B. Jensen, hereby declare under penalty of perjury:

1. I am the Christine B. Jensen identified as the sole inventor on U.S. Patent No. 10,335,462 (the "'462 Patent"), entitled "Use of Long-Acting GLP-1 Peptides." EX1001 ('462 Patent), 1.[1]

2. I am a citizen of Denmark, and I reside in Copenhagen, Denmark.

3. I understand that the subject matter at issue in the '462 Patent encompasses, in part, the following three claims:

> 1. A method for treating type 2 diabetes, comprising administering semaglutide once weekly in an amount of 1.0 mg to a subject in need thereof.
>
> 2. The method according to claim 1, wherein the semaglutide is administered by parenteral administration.
>
> 3. The method according to claim 2, wherein the solution is administered by subcutaneous injection.

[1] All subsequent exhibits cited herein have a single sheet appended before the start of the cited documents, which I understand identifies the underlying metadata of each cited document. My statements that I recognize the documents as true and correct copies, or that the documents were made and kept in the ordinary course of business, apply to the documents themselves, not the appended metadata readout.

4. I assigned my interest in the '462 Patent to Novo Nordisk A/S, which issued on September 19, 2017.

5. In this declaration, I provide my recollection of certain events and activities relating to the development of the subject matter of the '462 Patent and the invention in the claims. Many of these events and activities took place over a decade ago, some as many as 15 years ago. As described below, some of my recollections regarding the relevant individuals, documents, and events are specific, and some are more general. Except as otherwise indicated, I have personal knowledge of the facts set forth in this Declaration. All statements herein made of my own knowledge are true and all statements made on information and belief are believed to be true. If called upon to do so, I would testify competently thereto.

6. As detailed further below in Section II, while I was working at Novo Nordisk, based in Denmark, I came to the firm view that once-weekly dosage of 1.0 mg semaglutide administered subcutaneously would be an appropriate treatment (or maintenance) dose for patients with type-2 diabetes by March 17, 2010, and in any event no later than May 28, 2010, when that treatment dose was the subject of a final recommendation for use in Phase 3 trials. I reached the firm view that such a treatment dose would provide the right balance of efficacy and tolerability in lowering HbA_{1c} levels for patients with type-2 diabetes and, among other things, I

[redacted]

I. Background

9. I am a medical doctor who in the period between September 1, 2007 and January 30, 2016 served in a drug development role at Novo Nordisk. I earned my M.D. in 1996 and Ph.D. in 2002, both from the University of Copenhagen in Denmark. After that, I was a Postdoctoral Research Fellow at in the Joslin Diabetes

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