IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

IN RE: OZEMPIC (SEMAGLUTIDE)
PATENT LITIGATION

No. 22-md-3038-CFC

NOVO NORDISK INC. and NOVO NORDISK A/S,

No. 22-cv-294-CFC CONSOLIDATED **ANDA CASE**

Plaintiffs/Counterclaim Defendants,

CONFIDENTIAL

v.

RIO BIOPHARMACEUTICALS INC. et al.,

Defendants/Counterclaim Plaintiffs.

NOVO NORDISK INC. and NOVO NORDISK A/S,

Plaintiffs/Counterclaim Defendants,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant/Counterclaim Plaintiff.

No. 22-cv-1040-CFC **ANDA CASE**

CONFIDENTIAL

REPLY EXPERT REPORT OF DR. JOHN BANTLE REGARDING INVALIDITY OF U.S. PATENT NO. 10,335,462



I am the same Dr. John Bantle who submitted an opening report 1. dated March 19, 2024, in this litigation. See generally OPENING EXPERT REPORT OF DR. JOHN BANTLE REGARDING INVALIDITY OF U.S. PATENT NO. 10,335,462 ("Opening Report" or "Op. Rpt."), dated March 19, 2024. I submit this reply report on behalf of defendants Mylan Pharmaceuticals Inc., Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., Rio Biopharmaceuticals and EMS S/A; Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc.; and Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited to respond to certain opinions expressed by Dr. Michael Trautmann on behalf of Novo Nordisk Inc. and Novo Nordisk A/S ("Novo"), related to invalidity of the claims of U.S. Patent No. 10,335,462 ("'462 patent"). Specifically, in this report I respond to Dr. Trautmann's opinions in the REBUTTAL EXPERT REPORT OF MICHAEL E. TRAUTMANN, M.D. REGARDING VALIDITY OF U.S. PATENT NO. 10,335,462 ("Trautmann Report" or "Trautmann Rpt."), served June 3, 2024.

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¹ I understand that Dr. Reddy's and Sun do not adopt my opinions as they relate to anticipation or obviousness of the '462 patent, *see also* Op. Rpt. §§ IX.A and IX.B, because they stipulated in related proceedings not to pursue such arguments in this case. I also understand that Mylan Pharmaceuticals Inc. will not pursue by motion or at trial in this litigation anticipation of the claims of the '462 patent by WO '421 or Lovshin or obviousness of the claims of the '462 patent by WO '537 in view of Lovshin, *see also* Op. Rpt. §§ IX.A.1, IX.A.3, and IX.B.3, unless a change in law otherwise permits.

- 2. My education and experience are described in my Opening Report, and my *curriculum vitae* submitted with my opening report is current. *See* Op. Rpt. at 1 and Ex. A.
- 3. As noted in my Opening Report, I was retained as a technical expert to provide opinions related to the '462 patent. I receive \$400 per hour plus expenses for consulting and expert report work. My compensation is in no way tied to the outcome of this case or to the content of this report.
- 4. In the previous four years, I provided testimony in the proceedings listed in my Opening Report.

I. BASIS OF OPINIONS AND MATERIALS CONSIDERED

5. To reach the conclusions and opinions described in my report, I considered certain materials recited in the Trautmann Report, the materials recited in Exhibit B to my Opening Report, any materials cited in my Opening Report and not otherwise identified in Exhibit B to that report, the materials recited in Exhibit A to this report, any materials cited in this report and not otherwise identified in Exhibit A to this report (such as materials already cited by Dr. Trautmann), and my education, training, experience.

II. SUMMARY OF OPINIONS

6. As noted in my Opening Report, my opinions are limited to the treatment of diabetes with semaglutide, as claimed in the '462 patent. I present



I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code. Dated: July 16, 2024

By: Dr. John Bantle