

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE OZEMPIC (SEMAGLUTIDE) PATENT  
LITIGATION

C.A. No. 22-md-3038-CFC

**CONFIDENTIAL**

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NOVO NORDISK INC. AND NOVO  
NORDISK A/S,

Plaintiffs/Counterclaim Defendants,

v.

C.A. No. 22-294-CFC

RIO BIOPHARMACEUTICALS INC., et al.,

Defendants/Counterclaim Plaintiffs.

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NOVO NORDISK INC. AND NOVO  
NORDISK A/S,

Plaintiffs/Counterclaim Defendants,

v.

C.A. No. 22-cv-1040-CFC

MYLAN PHARMACEUTICALS INC.,

Defendants/Counterclaim Plaintiffs.

**REPLY EXPERT REPORT OF DR. PAUL DALBY  
REGARDING INVALIDITY OF U.S. PATENT NO. 10,335,462**

## I. Introduction

1. I am the same Paul Dalby who submitted an opening report in the above-referenced proceeding on March 19, 2024. I submit this reply expert report on behalf of Rio Biopharmaceuticals Inc. and EMS S/A (collectively “Rio”), Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, (collectively “Zydus”), and Mylan Pharmaceuticals Inc.<sup>1</sup> (“Mylan”) (collectively, “Defendants”)<sup>2</sup> to respond to certain opinions expressed in the rebuttal report of Dr. Patrick Sinko, submitted on behalf of Plaintiffs Novo Nordisk, Inc. and Novo Nordisk A/S (collectively, “Plaintiffs” or “Novo”). As I did in my opening report, I address only claims 4, 5, and 7 of the ’462 patent, which relate to my technical area of expertise.

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<sup>1</sup> I understand that Mylan has agreed not to pursue by motion or at trial in this litigation any grounds of invalidity instituted in IPR2023-00724 against the originally issued claims of the ’462 patent unless a change of law otherwise permits. Accordingly, with respect to my reports, I understand that Mylan will not pursue by motion or at trial in this litigation the prior art combination of WO ’537 in view of Lovshin.

<sup>2</sup> In my opening report, I noted that I was also retained by Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”) and Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, “Sun”). However, I was informed that DRL and Sun do not adopt my opinions, including those in my opening report, because they stipulated in related proceedings not to pursue such arguments in this case.

2. My *curriculum vitae*, submitted with my opening report, is current. *See* Dalby Op. Rep. Ex. A. A list of matters where I have provided deposition or trial testimony in the last four years was attached to my opening report as Exhibit B.

3. In addition to the materials identified in my opening report, and in addition to my education, training, and experience, I have considered the materials cited in Dr. Sinko's rebuttal report, and the materials in Exhibit C to my opening report.<sup>3</sup>

4. The scope of my work and my compensation have not changed since I submitted my opening report on March 19, 2024. Neither the amount of my compensation nor the fact that I am being compensated has altered the opinions that I have given in this report. My compensation is in no way dependent on the outcome of this proceeding.

## II. Legal Standards

5. As explained in my opening report, in preparing and forming my opinions, I have been informed of certain legal principles. Dalby Op. Rep. ¶¶ 18-24. I have applied my understanding of those principles and taken them into account when forming the opinions described in this report.

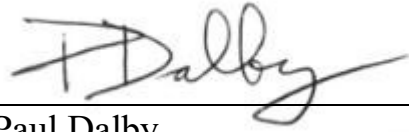
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<sup>3</sup> I have considered only the sections of Dr. Sinko's rebuttal report that respond to my opening report, along with the materials cited in those sections. This does not indicate that I agree with any opinions expressed by Dr. Sinko elsewhere in his report, or any of Novo's other expert witnesses' reports.

I declare under penalty of perjury that the factual statements contained in this report are known by me or believed by me to be correct.

Dated: July 16, 2024

By:

A handwritten signature in black ink, appearing to read "P Dalby", written over a horizontal line.

Dr. Paul Dalby