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

| IN RE: OZEMPIC (SEMAGLUTIDE)<br>PATENT LITIGATION | )<br>MDL NO. 22-MD-3038 (CFC)<br>ANDA CASE<br>)         |
|---|---|
| NOVO NORDISK INC. and<br>NOVO NORDISK A/S,        | )   |
| Plaintiffs,                                       | )   |
| v.<br>RIO BIOPHARMACEUTICALS INC.,<br>et al.,     | )<br>C.A. No. 22-294 (CFC)<br>CONSOLIDATED<br>ANDA CASE |
| Defendants.                                       | )   |
| NOVO NORDISK INC. and<br>NOVO NORDISK A/S,        | )   |
| Plaintiffs,                                       | )   |
| V.  | )<br>C.A. No. 22-1040 (CFC)<br>ANDA CASE                |
| MYLAN PHARMACEUTICALS INC.                        | )   |
| Defendant.  | )   |

# **AMENDED JOINT CLAIM CONSTRUCTION CHART**

Pursuant to Section 21 of the Scheduling Order governing this Action (*see* D.I. 22; *see also* D.I. 53 in C.A. No. 22-1040-CFC, adopting the Scheduling Order entered in C.A. No. 22-294-CFC as D.I. 22), the parties respectfully submit the attached Amended Joint Claim Construction Chart, addressing the claim

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|  | component<br>having a thread<br>or spline for<br>engaging the<br>limiter, and that<br>during dose<br>setting transfers<br>rotational torque<br>from one<br>component to<br>another |  |
|--|--|--|
|  | component."  |  |

| CLAIM TERMS AT ISSUE IN THE '462 PATENT |   |          |  |   |   |  |
|---|---|----------|--|---|---|--|
| Term<br>No.                             | Term or Phrase for<br>Construction            | Claim(s) | Novo Nordisk's<br>Proposed<br>Construction   | Novo Nordisk's<br>Intrinsic Evidence<br>Citations   | Defendants'<br>Proposed<br>Construction   | Defendants'<br>Intrinsic<br>Evidence<br>Citations  |
| 14                                      | "A method for<br>treating type 2<br>diabetes" | 1        | The phrase is an<br>express<br>limitation of<br>claims 1-10, and<br>it carries its plain<br>and ordinary<br>meaning.<br>Original<br>Proposal: "a | <ul> <li>'462 Patent</li> <li>Specification: <ul> <li>Abstract</li> <li>Figs. 1-3</li> <li>Col.1, 11.17-18</li> <li>Col.1, 11.31-36</li> <li>Col.1, 11.45-50</li> <li>Col.1, 11.56-62</li> <li>Col.2, 11.6-33</li> <li>Col.2, 1.51 -</li> </ul> </li> </ul> | The preambles<br>are non-limiting.<br>To the extent the<br>term is a<br>limitation, the<br>term means<br>administering<br>semaglutide to<br>alleviate the | '462 patent at<br>1:31-2:2;<br>5:16-31<br>1:29-32; 1:45-<br>49; 1:56-60;<br>2:51-55; 2:63-<br>66; 3:3-18;<br>4:7-16; 4:25-<br>34; 5:16-17; |

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|      | CLAIM TERMS AT ISSUE IN THE '462 PATENT |          |                         |                    |                        |                |
|------|---|----------|-------------------------|--------------------|------------------------|----------------|
| Term | Term or Phrase for                      | Claim(s) | Novo Nordisk's          | Novo Nordisk's     | Defendants'            | Defendants'    |
| No.  | Construction                            |          | Proposed                | Intrinsic Evidence | Proposed               | Intrinsic      |
|      |   |          | Construction            | Citations          | Construction           | Evidence       |
|      |   |          |                         |                    |                        | Citations      |
|      |   |          | method of caring        | Col.3, 1.5         | symptoms and           | 6:1-16; 6:29-  |
|      |   |          | for or managing         | - Col.3, 11.4-5    | complications,         | 36; 16:56-64;  |
|      |   |          | the care of a           | - Col.3, 11.8-18   | and/or to cure or      | 17:4-6; 20:17- |
|      |   |          | patient so as to        | - Col.3, 11. 19-28 | eliminate or           | 22; 20:31-37;  |
|      |   |          | combat type 2           | - Col.4, 11.7-14   | prevent, and/or to     | 20:55-23:26;   |
|      |   |          | diabetes"               | - Col.4, 11.25-32  | prevent the onset      | 23:26-28:36;   |
|      |   |          |                         | - Col.4, 1.62-     | of symptoms            | 35:40-36:53    |
|      |   |          | Compromise              | Col.5, 1.49        | associated with        |                |
|      |   |          | Proposal                | - Col.6, 11.2-16   | type 2 diabetes.       | See generally  |
|      |   |          | <b>Offered During</b>   | - Col.6, 11.17-19  |                        | '462 patent    |
|      |   |          | Meet and                | - Col.6, 11.24-28  | Compromise             | specification  |
|      |   |          | <b>Confer Process</b> : | - Col.6, 11.29-36  | Proposal               | -              |
|      |   |          | "A method for           | - Col.6, 11.51-60  | Offered During         | Prosecution    |
|      |   |          | treating type 2         | - Col.6, 11.65-66  | Meet and               | history of the |
|      |   |          | diabetes" is a          | - Col.7, 11.27-30  | <b>Confer Process:</b> | '462 patent at |
|      |   |          | limitation, and         | - Col.8, 11.57-59  | "A method for          | specification  |
|      |   |          | the preamble            | - Col.9, 11.40-42  | treating type 2        | and claims as  |
|      |   |          | means "the              | - Col.9, 11.52-55  | diabetes" is a         | filed, on      |
|      |   |          | claimed                 | - Col.10, 11.9-11  | limitation only as     | 7/21/2017;     |
|      |   |          | administration is       | - Col.15, 11.13-14 | to the stated          | Office action  |
|      |   |          | for the care or         | - Col.16, 11.58-64 | purpose of the         | of 7/23/2018,  |
|      |   |          | management of a         | - Col.17, 11.4-6   | claim, and             | at 3-8; Office |
|      |   |          | patient with type       | - Col.20, 11.17-22 | imparts no             | action         |
|      |   |          | patient with type       | - Col.20, 11.1/-22 | imparts no             | action         |

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|             | CLAIM TERMS AT ISSUE IN THE '462 PATENT |          |  |   |  |  |  |
|-------------|---|----------|--|---|--|--|--|
| Term<br>No. | Term or Phrase for<br>Construction      | Claim(s) | Novo Nordisk's<br>Proposed<br>Construction | Novo Nordisk's<br>Intrinsic Evidence<br>Citations   | Defendants'<br>Proposed<br>Construction  | Defendants'<br>Intrinsic<br>Evidence<br>Citations  |  |
|             |   |          | 2 diabetes" <sup>9</sup>                   | - Col.20, ll.31-37<br>- Col.20, ll.49-51<br>- Col.20, l.62 –<br>Col.21, l.5<br>- Col.21, ll.20-29<br>- Col.21, ll.31-33<br>- Col.22, ll.2-26<br>- Table 1<br>- Col.23, ll.18-26<br>- Col.25, ll.37-42 | efficacy. The<br>preamble means<br>that 'the claimed<br>administration is<br>intended as part<br>of the care or<br>management of a<br>patient with type<br>2 diabetes but<br>does not require<br>that the<br>administration be<br>efficacious in the<br>treatment of such<br>patient's type 2<br>diabetes."" <sup>10</sup> | response dated<br>1/23/2019, at<br>2-4; Notice of<br>allowance<br>dated<br>3/6/2019, at 4-<br>5. |  |

<sup>&</sup>lt;sup>9</sup> In advocating for their compromise proposal on this term, Defendants misstate Plaintiffs' position on this term. In Reply, Plaintiffs stated that "Novo Nordisk's proposed *construction* [of the preamble] does not include an efficacy *requirement* as Defendants incorrectly argue." Jt. Br. (D.I. 136) at 24-25 (emphasis added).

<sup>&</sup>lt;sup>10</sup> Defendants' proposed construction of the preamble of the '462 patent adopts Plaintiffs' position that the preamble "does not impart an efficacy requirement." Jt. Brief (D.I. 119) at 25.

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