BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re Ozempic® (Semaglutide) Patent Litigation	)	MDL No. _____

PLAINTIFFS' MOTION FOR TRANSFER OF ACTION TO THE DISTRICT OF DELAWARE PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

NOW COMES Novo Nordisk Inc. and Novo Nordisk A/S (collectively "Novo Nordisk"), Plaintiffs in:

a) *Novo Nordisk Inc. and Novo Nordisk A/S v. Rio Biopharmaceuticals, Inc. and EMS S/A*, 1:22-cv-00294-CFC (D. Del.);

b) *Novo Nordisk Inc. and Novo Nordisk A/S v. Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc.*, 1:22-cv-00296-CFC (D. Del.);

c) *Novo Nordisk Inc. and Novo Nordisk A/S v. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd.*, 1:22-cv-00297-CFC (D. Del.);

d) *Novo Nordisk Inc. and Novo Nordisk A/S v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, 1:22-cv-00298-CFC (D. Del.);

e) *Novo Nordisk Inc. and Novo Nordisk A/S v. Alvogen, Inc.*, 1:22-cv-00299-CFC (D. Del.);[1] and

f) *Novo Nordisk Inc. and Novo Nordisk A/S v. Mylan Pharmaceuticals Inc.*, 1:22-cv-00023-JPB (N.D. W. Va.).

Novo Nordisk, by and through its undersigned counsel, respectfully moves the Judicial Panel on Multidistrict Litigation to enter an order pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, to transfer

[1] Novo Nordisk filed, but subsequently voluntarily dismissed without prejudice, an additional action in the District of Delaware. *See Novo Nordisk Inc. and Novo Nordisk A/S v. Aurobindo Pharma USA, Inc. et al.*, 1:22-cv-00295-CFC, ECF No. 7 (D. Del. Mar. 28, 2022) (voluntarily dismissing the action under Rule 41(a)(1)(A)(i)).

Novo Nordisk Inc. and Novo Nordisk A/S v. Mylan Pharmaceuticals Inc., 1:22-cv-00023-JPB, which is pending before Judge John Preston Bailey in the United States District Court for the Northern District of West Virginia, to Chief Judge Colm Connolly in the United States District Court for the District of Delaware, for coordinated and consolidated pretrial proceedings with five related actions already pending in that District.

Transfer for pretrial consolidation and coordination is proper and necessary for the following reasons, as set forth more fully in the accompanying memorandum:

1. This motion seeks transfer of one action and consolidation of that action with five other actions for patent infringement brought under the patent laws of the United States, Title 35, United States Code, by Novo Nordisk against the following entities: Rio Biopharmaceuticals Inc. and EMS S/A (collectively, "Rio"); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"); Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (collectively, "Zydus"); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's"); Alvogen, Inc. ("Alvogen"); and Mylan Pharmaceuticals Inc. ("Mylan"). Rio, Sun, Zydus, Dr. Reddy's, Alvogen, and Mylan are collectively referred to herein as "Defendants."

2. All six actions arise under the Hatch-Waxman Act. Specifically, the actions arise from Defendants' submissions of Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Ozempic® (semaglutide) prior to expiration of patents listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Novo Nordisk's Ozempic® drug product.

3. Novo Nordisk filed the above-listed actions against Rio, Sun, Zydus, Dr. Reddy's, and Alvogen in the District of Delaware on March 4, 2022 (collectively, the

"Delaware Actions"). Dr. Reddy's filed its Answer, Defenses, and Counterclaims on May 3, 2022. *Novo Nordisk Inc. et al. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Case No. 22-cv-298-CFC, ECF No. 10 (D. Del. May 3, 2022). All remaining Defendants in the Delaware Actions are due to respond to Novo Nordisk's complaints by May 9, 2022. Novo Nordisk expects that the Delaware Actions will be consolidated for all purposes, including discovery, claim construction proceedings, and trial.

4. Because Mylan refused to consent to venue in Delaware, Novo Nordisk filed the sixth action, against Mylan, in the Northern District of West Virginia, where Mylan is located and incorporated, on March 18, 2022 (the "West Virginia Action"). The West Virginia Action is pending before Judge John Preston Bailey in the Northern District of West Virginia. Mylan filed its Answer, Separate Defenses, and Counterclaims in the West Virginia Action on April 8, 2022. Mylan did not contest personal jurisdiction or venue in the West Virginia Action. *Novo Nordisk Inc. et al. v. Mylan Pharmaceuticals Inc.*, Case No. 22-cv-00023-JPB, ECF No. 19, ¶¶ 5-8 (N.D. W. Va. Apr. 8, 2022).

5. Novo Nordisk filed the above-listed actions in response to separate notice letters received from each Defendant notifying Novo Nordisk that the Defendant had submitted an ANDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of a generic version of Ozempic® prior to the expiration of certain patents identified in the Defendant's notice letter. The six ANDAs giving rise to the actions are referred to collectively as "Defendants' ANDAs."

6. Each Defendant informed Novo Nordisk in its notice letter that the Defendant's ANDA included a certification pursuant to 21 U.S.C. § 355(i)(2)(A)(vii)(IV) (a "Paragraph IV certification"), asserting that certain Orange Book-listed patents for Ozempic® are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or

importation of the product that is the subject of the Defendant's ANDA (collectively, "Defendants' ANDA Products").

7. In each action, Novo Nordisk alleges, among other things, patent infringement under 35 U.S.C. § 271(e)(2)(A), which makes submission of the Defendant's ANDA with a Paragraph IV certification against an Orange Book-listed patent an act of infringement.

8. All six actions involve the same core issue: whether Defendants' ANDA Products infringe Novo Nordisk's patents listed in the Orange Book for Ozempic®. While the patents asserted in each action vary to some extent, depending on which patents each Defendant challenged in its notice letter, there is considerable overlap, which will lead to a high level of commonality of claims, defenses, and other issues. U.S. Patent Nos. 9,132,239 and 10,335,462 are common to all six actions, and the Delaware Actions against Dr. Reddy's and Alvogen share ten patents in common with the West Virginia Action against Mylan. Additionally, there is almost complete overlap in "patent families" between the Delaware Actions and the West Virginia Action, as discussed in more detail in the accompanying memorandum.

9. The actions present numerous common issues of fact and law, including without limitation the research and development underlying the claimed inventions; the prosecution history of the asserted patents; the construction of claim terms; the level of ordinary skill in the art; the scope and content of the prior art; the differences between the claimed inventions and the prior art; Orange Book listability of certain asserted patents; and secondary indicia of non-obviousness, such as the unexpected properties of the claimed inventions, the long felt need for the claimed inventions, and the commercial success of the claimed inventions, among others.

10. All six actions are in their early stages. As of the date of filing of this motion, neither Court has held a conference, neither Court has issued a substantive order, and the parties have not served any discovery requests.

11. Because the six actions assert infringement based on the submission of ANDAs referencing the same drug product, the effect of inconsistent rulings on claim construction, patent validity, and/or infringement would be significant, harmful, and unnecessarily strain court resources. Transfer of the West Virginia Action and consolidation with the Delaware Actions is therefore necessary to: (a) eliminate the potential for inconsistent rulings on pretrial motions, including but not limited to claim construction rulings; (b) eliminate the burden of duplicative discovery on common issues; (c) avoid the unnecessary use of judicial resources; and (d) reduce the overall costs and burdens on all parties.

12. Chief Judge Connolly has experience presiding over complex patent litigation cases and has substantial experience with cases involving patent infringement claims against multiple defendants arising under the Hatch-Waxman Act. *See, e.g., Genzyme Corp. et al. v. Apotex Corp. et al.*, Case No. 18-cv-1795-CFC, ECF No. 18 (D. Del. Feb. 4, 2019) (consolidating Hatch-Waxman litigations against five ANDA-filers concerning the drug Cerdelga®); *Boehringer Ingelheim Pharm. Inc. et al. v. Mankind Pharma Ltd. et al.*, Case No. 18-cv-1689-CFC, ECF No. 20 (D. Del. Mar. 5, 2019) (consolidating Hatch-Waxman litigations against 16 ANDA-filers concerning the drug Jardiance®); *UCB, Inc. et al. v. Annora Pharma Private Ltd. et al.*, Case No. 20-cv-00987-CFC, ECF No. 99 (D. Del. July 7, 2021) (consolidating Hatch-Waxman litigations against eight ANDA-filers concerning the drug Briviact®). Notably, Chief Judge Connolly has previously presided over Hatch-Waxman litigations involving Novo Nordisk's drug product Victoza®, which, like Ozempic®, is an injectable GLP-1 product indicated for the treatment of type 2 diabetes, giving Judge Connolly valuable background on the relevant technology. *See Novo Nordisk Inc. et al. v. Sandoz Inc.*, 20-cv-00747 (D. Del.) and *Novo Nordisk Inc. et al. v. Mylan Institutional LLC*, 19-cv-1551 (D. Del.). Chief Judge Connolly is additionally currently presiding over a case involving Victoza®, which is still in early stages and also involves the '833 patent, which is asserted against Mylan

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