IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	
MYLAN PHARMACEUTICALS INC.,	)	C.A. No. 22-cv-23-JPB
Defendant.	)	

JOINT REPORT OF INITIAL PLANNING MEETING

Pursuant to the Federal Rules of Civil Procedure 16 and 26(f), Local Rules of Civil Procedure 16.01(b) and (c), and the Court's First Order and Notice Regarding Discovery and Scheduling dated March 28, 2022 (Dkt. No. 8), Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk" or "Plaintiffs") and Defendant Mylan Pharmaceuticals Inc. ("MPI" or "Defendant") submit this Joint Report of Initial Planning Meeting. The parties represent as follows:

1. Initial Planning Meeting

The parties' counsel met and conferred by telephone on April 25, 2022. The parties discussed matters required by Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 16.01(b). The participants were:

i. James Companion of Schrader Companion Duff & Law, PLLC, and Jeffrey J. Oelke and Laura T. Moran of Fenwick & West LLP, representing Novo Nordisk; and

ii. Brandon White of Perkins Coie LLP, representing MPI.

2. Fed. R. Civ. P. 26(f) Discovery Plan

a. Initial Disclosures

The parties will complete initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) by May 23, 2022.

b. Subjects on Which Discovery May Be Needed

This is an action for patent infringement brought under the patent laws of the United States and the Hatch-Waxman Act. MPI filed Abbreviated New Drug Application No. 216991 ("MPI's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market semaglutide injection (2 mg/1.5 ml (1.34 mg/ml) and 4 mg/3 ml (1.34 mg/ml)), which is a generic version of Plaintiffs' Ozempic® drug product ("MPI's Product"), prior to the expiration of United States Patent Nos. 8,114,833 (the "'833 patent"), 8,129,343 (the "'343 patent"), 8,536,122 (the "'122 patent"), 8,684,969 (the "'969 patent"), 8,920,383 (the "'383 patent"), 9,108,002 (the "'002 patent"), 9,132,239 (the "'239 patent"), 9,457,154 (the "'154 patent"), 9,616,180 (the "'180 patent"), 9,687,611 (the "'611 patent"), 9,775,953 (the "'953 patent"), 9,861,757 (the "'757 patent"), 10,220,155 (the "'155 patent"), 10,335,462 (the "'462 patent"), 10,357,616 (the "'616 patent"), 10,376,652 (the "'652 patent"), 11,097,063 (the "'063 patent"), and RE46,363 (the "'363 patent") (collectively, the "patents-in-suit").

Discovery is needed on at least the following matters:

i. MPI's infringement or non-infringement of the patents-in-suit;

ii. Validity or invalidity of the patents-in-suit; and

iii. The listing of certain patents-in-suit in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book").

c. Co-pending Litigations Involving Certain Patents-in-Suit

MPI is one of six ANDA-filers currently challenging at least some of the patents that are listed in the Orange Book with respect to Plaintiffs' Ozempic® drug product. The other five ANDA-filers are defendants in cases pending in the District of Delaware (collectively, the "Ozempic® Delaware Actions"), each of which involves some of the patents that are asserted against MPI in this case[1]. Plaintiffs filed the Ozempic® Delaware Actions on March 4, 2022, and all defendants in those actions responded to the complaints on or before May 9, 2022.

Additionally, fifteen of the patents-in-suit are the subject of a lawsuit in the District of Delaware involving Plaintiffs' Saxenda® drug product, which contains a different active ingredient (liraglutide) than Ozempic®, but uses the same device as Ozempic® (FlexTouch®) for the branded product. *See Novo Nordisk Inc. et al. v. Teva Pharmaceuticals, Inc. et al.*, 21-cv-01782-CFC (D. Del.) (the "Saxenda® Action"). A scheduling conference is scheduled in the Saxenda® Action on May 12, 2022.

Finally, one of the patents-in-suit, the '833 patent, is the subject of a lawsuit in the District of Delaware involving Plaintiffs' Victoza® drug product, which also contains the active ingredient liraglutide. *See Novo Nordisk Inc. et al. v. Hikma Pharmaceuticals USA Inc.,* 21-cv-01783-CFC

[1] The cases pending in the District of Delaware include: *Novo Nordisk Inc. and Novo Nordisk A/S v. Rio Biopharmaceuticals, Inc. and EMS S/A*, 1:22-cv-00294-CFC (D. Del.); *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.); *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.); *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.); and *Novo Nordisk Inc. and Novo Nordisk A/S v. Alvogen, Inc.,* 1:22-cv-00299-CFC (D. Del.). Judge Connolly has requested Novo Nordisk's position on whether consolidation, at least for discovery and *Markman* proceedings, is needed. *See, e.g.,* C.A. No. 1:22-cv-00294, Dkt. No. 15 (D. Del. May 11, 2022). Novo Nordisk will submit that consolidation is needed. None of the Delaware generic defendants have indicated to the contrary, and Novo Nordisk anticipates that the Ozempic® Delaware Actions will be consolidated. Details of the patents asserted in each case are provided in tables below.

(D. Del.) (the "Victoza® Action"). A schedule was entered in the Victoza® Action on May 5, 2022. Several previous matters regarding the Plaintiffs' Victoza® drug product and the '833 patent have been settled.

d. Proposed Case Schedules

Novo Nordisk's Position: Novo Nordisk seeks to consolidate this case and the Ozempic® Delaware Actions for coordinated and consolidated pretrial proceedings before the United States Judicial Panel on Multidistrict Litigation ("MDL Panel") because this case shares numerous questions of fact with the Ozempic® Delaware Actions. *See* Dkt. No. 22 ("Plaintiffs' MDL Motion"). All six actions concern a common issue: whether the generic Defendants' ANDA Products infringe valid and enforceable claims of patents listed in the Orange Book for Ozempic®. In addition, claim construction of terms in the asserted patents and listability in the Orange Book of certain asserted patents will be common across actions. Accordingly, consolidation would serve the convenience of the parties and witness and promote the just and efficient conduct of the actions.

While MPI will stress that eight patents at-issue here are not presently at-issue in the Delaware Actions, this does not undermine the efficiency, consistency, and convenience benefits of transfer and consolidation.[2] Half of the patents asserted here, but not in the Ozempic® Delaware Actions, belong to patent families that are already at-issue in the Ozempic® Delaware Actions. A patent family is a group of patents that trace their lineage back to the same "priority application." Such patents concern related inventions and have very similar, if not identical, specifications and closely related claims. Accordingly, patents within the same family present highly similar litigation issues (*e.g.*, discovery, claim construction, infringement, and validity defenses).

[2] Novo Nordisk notes that it was MPI, and not Novo Nordisk, who decided which Orange Book listed patents for Ozempic® MPI would challenge, and therefore which patents would be asserted in this litigation.

Moreover, the four patents-at-issue in this case whose family members are not already at-issue in the Ozempic® Delaware Actions are already before the District of Delaware's Chief Judge Connolly in the Saxenda® Action (which involves 15 of the 18 patents-in-suit here). In other words, all of the patent families at-issue here are already before the District of Delaware, by virtue of the Ozempic® Delaware Actions and the Saxenda® Action. The below chart illustrates the overlap in patent families between this case, the Ozempic® Delaware Actions, and the Saxenda® Action. While the patents at-issue in each action are not identical, the overlap in patent families is complete, and therefore this case will present questions of fact that are common with actions pending in Delaware.

Patent Family	Mylan (W. Va.)	Alvogen (D. Del.)	Dr. Reddy's (D. Del.)	Rio (D. Del.)	Sun (D. Del.)	Zydus (D. Del.)	Saxenda® (D. Del.)
Compound Patent Family ('343 and '122 patents)	✓	✓	✓	✓			
Method Patent Family ('462 patent)	✓	✓	✓	✓	✓	✓	
Device Patent Family 1 ('239 patent)	✓	✓	✓	✓	✓	✓	✓
Device Patent Family 2 ('611 and '969 patents)	✓	✓	✓	✓			✓
Device Patent Family 3 ('154, '757, and '616 patents)	✓	✓	✓	✓			✓
Device Patent Family 4 ('063 and '155 patents)	✓	✓	✓				✓
Device Patent Family 5 (RE'363 patent)	✓	✓	✓				✓
Device Patent Family 6 ('383 and '953 patents)	✓	✓	✓				✓
Device Patent Family 7 ('002, '180, and '652 patents)	✓						✓
Formulation Patent Family ('833 patent)	✓						✓

Mylan incorrectly argues that "Plaintiffs have made this case primarily about injection devices." To the contrary, this case is very much about semaglutide, which is the novel chemical compound that is the active ingredient in Ozempic®. Semaglutide is protected by the '343 patent, which does not expire until 2031. The '343 patent will therefore be a critical part of all cases in which the generic defendant seeks to enter the market with its product prior to 2031 by challenging

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