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

NOVO NORDISK INC. and NOVO NORDISK A/S,	
Plaintiffs,	
v.	
	C.A. No. 23-cv-13
VIATRIS INC. and MYLAN PHARMACEUTICALS INC.,	
Defendants.	

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 April 3, 2023 (Dkt. No. 27) as amended by the Order Extending Deadlines dated May 18, 2023 (Dkt. No. 32), Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk" or "Plaintiffs") and Defendants Viatris Inc. ("Viatris") and Mylan Pharmaceuticals Inc. ("MPI") (collectively, "Defendants") submit this Joint Report of Initial Planning Meeting.[1] The parties represent as follows:

[1] Plaintiffs' Position: Due to the overlap between this case and the Wegovy® Delaware Action as well as the various Ozempic® matters in Delaware (*see* Section 2.c below), and in order to conserve both judicial and party resources and to avoid multiple trials on the same patents, the parties are discussing a stipulation relating to streamlining litigation and ultimately having a single trial of the patents-in-suit to be tried in the District of Delaware instead of this District. As Plaintiffs have made clear to Defendants, Plaintiffs will dismiss this action after there is finalized agreement. Plaintiffs expect the parties are close and will reach resolution shortly, after which Plaintiffs expect to dismiss this action.

Defendants' Position: Defendants have answered the complaint filed by Plaintiffs in the Delaware Wegovy Action asserting the identical patents against identical products. Plaintiffs have requested that the litigation proceed in Delaware, and Defendants have repeatedly represented to Plaintiffs

1. Initial Planning Meeting

The parties' counsel met and conferred by telephone on June 12, 2023. 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 Jenny C. Wu of Groombridge, Wu, Baughman & Stone LLP, representing Novo Nordisk; and

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

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

a. Initial Disclosures

The parties served their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) on June 5, 2023.

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. Defendant Mylan Pharmaceuticals Inc. ("MPI") filed Abbreviated New Drug Application No. 217705 ("MPI's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market semaglutide injection, 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, 1 mg/0.5 mL, 1.7 mg/0.75 mL and 2.4 mg/0.75 mL, which is a generic version of Plaintiffs' Wegovy® drug product ("MPI's Product"), prior to the expiration of United States Patent Nos. 8,129,343 (the "'343 patent"), 8,536,122 (the "'122 patent"), 9,764,003 (the "'003

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that Defendants will proceed in Delaware. To that end, Defendants appeared before the Delaware court at a scheduling conference on June 6, 2023. A scheduling order issued on June 21, 2023, ordering the parties to trial in Delaware in December 2024. *Novo Nordisk Inc. and Novo Nordisk A/S v. Viatris Inc. and Mylan Pharmaceuticals Inc.*, 1:23-cv-00101-CFC (D. Del.), ECF. No. 27. Because Defendants are proceeding in Delaware, this duplicative case should be dismissed. Yet, despite Defendants' repeated requests, Plaintiffs have refused to dismiss this action for reasons unknown to Defendants, and Plaintiffs' insistence on maintaining this action is unnecessarily wasting the Court's and parties' resources.

patent"), 10,888,605 (the "'605 patent"), and 11,318,191 (the "'191 patent") (collectively, the "patents-in-suit").

Discovery is needed on at least the following matters:

i. Defendants' infringement or non-infringement of the patents-in-suit; and

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

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

All the patents-in-suit are currently the subject of ongoing litigation between Plaintiffs and Defendants in the District of Delaware with respect to MPI's ANDA and MPI's Product (the "Wegovy® Delaware Action").[2] Plaintiffs filed the Wegovy® Delaware Action on January 27, 2023, and Defendants answered and counterclaimed on March 31, 2023. The court in the Wegovy® Delaware Action entered a full schedule on June 21, 2023. *Novo Nordisk Inc. and Novo Nordisk A/S v. Viatris Inc. and Mylan Pharmaceuticals Inc.*, 1:23-cv-00101-CFC (D. Del.), ECF. No. 27.

The '343 and '122 patents (collectively, the "Compound Patents") are both the subject of this litigation and a separate litigation between Plaintiffs and MPI with respect to Plaintiffs' Ozempic® drug product (the "MPI Ozempic® Action"). The MPI Ozempic® Action was originally filed in this District and has been transferred to the District of Delaware as part of a Multidistrict Litigation (the "Ozempic® MDL") captioned *In re: Ozempic (Semaglutide) Patent Litigation*, MDL No. 22-md-3038 (CFC) (D. Del.).[3] Plaintiffs filed the MPI Ozempic® Action on March 18, 2022, and MPI answered and counterclaimed on April 8, 2022.

[2] The case is captioned *Novo Nordisk Inc. and Novo Nordisk A/S v. Viatris Inc. and Mylan Pharmaceuticals Inc.*, 1:23-cv-00101-CFC (D. Del.).

[3] The case as filed in this District is captioned *Novo Nordisk Inc. and Novo Nordisk A/S v. Mylan Pharmaceuticals Inc.*, 1:22-cv-00023-JPB (N.D.W. Va.), and upon transfer to the District of Delaware was renumbered as 1:22-cv-01040-CFC (D. Del.).

The Compound Patents are also the subject of five separate litigations between Plaintiffs and five other ANDA filers in the District of Delaware with respect to Plaintiffs' Ozempic® drug product (collectively, "Ozempic® Delaware Actions"),[4] which have been consolidated with the transferred MPI Ozempic® Action as part of the Ozempic® MDL. 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.

d. Proposed Case Schedules

While Defendants are proceeding in Delaware, and Defendants' position is that there should be no need for Plaintiffs to maintain this action, should the case proceed in this District, the parties propose the following schedules for discovery, pretrial disclosures, and trial.

Event	Novo Nordisk's Proposed Deadline	Defendants' Proposed Deadline
Rule 26(a)(1) Initial Disclosures	June 5, 2023	
MPI's production of MPI's ANDA[5]	March 1, 2023	
Motion for Joint Protective Order	21 days after entry of a full Scheduling Order	
Defendants' disclosure of noninfringement contention, invalidity contentions, and preliminary disclosure of asserted prior art and accompanying production (*see section 2(h) infra*)	June 22, 2023	

[4] 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.).

[5] MPI produced MPI's ANDA to Plaintiffs in the context of the Wegovy® Delaware Action. Pending entry of a protective order or other agreement between the Parties, any discovery materials produced in this case, including MPI's ANDA, will be produced on an Outside Counsel's Eyes Only basis.

Event	Novo Nordisk's Proposed Deadline	Defendants' Proposed Deadline
Plaintiffs' disclosure of infringement contentions, responses to invalidity contentions, and accompanying production (*see section 2(h) infra*)	August 4, 2023	
Substantial completion of document production	November 10, 2023	
Last day to move to join parties or amend the pleadings	November 17, 2023	
Close of fact discovery	March 1, 2024	
Final deadline to supplement infringement and invalidity contentions	March 8, 2024	
Claim Construction		
Parties exchange proposed terms for claim construction	July 11, 2023	
Parties exchange preliminary proposed constructions for disputed terms and identify intrinsic evidence support	July 21, 2023	
Parties file a joint claim construction statement	July 31, 2023	
Plaintiffs' Opening Markman Brief	August 24, 2023	
Defendants' Response Markman Brief	September 21, 2023	
Plaintiffs' Reply Markman Brief	October 12, 2023	
Defendants' Surreply Markman Brief	November 2, 2023	
Markman Hearing	TBD at the Court's convenience	
Expert Discovery		
Opening expert reports on issues for which the party bears the burden of proof	April 19, 2024	
Responsive/rebuttal expert reports	May 31, 2024	
Reply expert reports	June 21, 2024	
Close of expert discovery	August 9, 2024	
Dispositive Motions		
Dispositive Motions under Fed. R. Civ. P. 56	Novo Nordisk proposes that dispositive motions under Rule 56 are unnecessary in this bench trial and the parties should seek leave of the Court before filing	No later than August 30, 2024
Responses to Dispositive Motions		3 weeks after the filing of any dispositive motion

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