

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and )  
NOVO NORDISK A/S, )  
 )  
Plaintiffs, )

v. )

C.A. No. 22-294 (CFC)

RIO BIOPHARMACEUTICALS INC. )  
and EMS S/A, )  
 )  
Defendants. )

NOVO NORDISK INC. and )  
NOVO NORDISK A/S, )  
 )  
Plaintiffs, )

v. )

C.A. No. 22-296 (CFC)

SUN PHARMACEUTICAL )  
INDUSTRIES LTD. and SUN )  
PHARMACEUTICAL INDUSTRIES, )  
INC., )  
 )  
Defendants. )

NOVO NORDISK INC. and )  
NOVO NORDISK A/S, )  
 )  
Plaintiffs, )

v. )

C.A. No. 22-297 (CFC)

ZYDUS WORLDWIDE DMCC, ZYDUS )  
PHARMACEUTICALS (USA) INC. and )  
ZYDUS LIFESCIENCES LIMITED, )  
 )  
Defendants. )

NOVO NORDISK INC. and )  
NOVO NORDISK A/S, )

Plaintiffs, )

v. )

C.A. No. 22-298 (CFC)

DR. REDDY'S LABORATORIES, LTD. )  
and DR. REDDY'S LABORATORIES, )  
INC., )

Defendants. )

NOVO NORDISK INC. and )  
NOVO NORDISK A/S, )

Plaintiffs, )

v. )

C.A. No. 22-299 (CFC)

ALVOGEN, INC., )

Defendant. )

**PROPOSED SCHEDULING ORDER**

This 29<sup>th</sup> day of June, 2022, pursuant to the Court's June 6, 2022 Order directing the parties to confer about scheduling and discovery limitations, the parties have discussed pretrial management issues, have determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration, and have prepared this proposed scheduling order;

IT IS ORDERED that:

1. Case Consolidation and Caption Modification. These actions are consolidated for all purposes, and all papers shall be filed in C.A. No. 22-cv-294-CFC. The Caption shall be modified to include the words “ANDA CASE” immediately below the Civil Action Number.

2. Relevant Deadlines and Dates. All relevant deadlines and dates established by this Order are set forth in the chart attached as Exhibit A. The expiration date of any applicable 42-month period imposed pursuant to 21 U.S.C. §§ 255(j)(5)(B)(iii), 255(j)(5)(F)(ii) is set forth in the first row of the chart.

3. Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures required by Federal Rule of Civil Procedure 26(a)(1) and their initial disclosures required by Paragraph 3 of the District of Delaware Default Standard on or before **14 days after entry of the Scheduling Order.**

4. Production of the ANDAs. As required by the Standing Order Regarding Hatch-Waxman Cases in Which Infringement is Alleged, each of the five Defendant Groups listed below confirm that they produced to Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Plaintiffs”), on the date

indicated below, the entire Abbreviated New Drug Application (“ANDA”) that is the basis of the Defendant Group’s alleged infringement:

- (a) Alvogen Inc. (“Alvogen”) confirms that it produced a copy of the entire ANDA No. 215920 on May 16, 2022;
- (b) Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”) confirm that they produced a copy of the entire ANDA No. 216417 on May 4, 2022;
- (c) Rio Biopharmaceuticals Inc. and EMS S/A (collectively, “Rio”) confirm that they produced a copy of the entire ANDA No. 216305 on May 9, 2022;
- (d) Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, “Sun”) confirm that they produced a copy of the entire ANDA No. 216478 on June 7, 2022; and
- (e) Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, “Zydus”) confirm that they produced a copy of the entire ANDA No. 215704 on May 9, 2022.

**Plaintiffs’ Position:** A number of asserted patents relate to the device used to administer Ozempic<sup>®</sup>. Plaintiffs therefore requested early production of

Computer-Aided Design (CAD) files, the Design History File, and samples of the device described in each Defendant Group's ANDA to facilitate Plaintiffs' infringement assessment and selection of claims to assert. The parties were unable to reach agreement on early production of the requested materials. Production of these materials is necessary to Plaintiffs' identification of claims asserted in the Preliminary Disclosure of Asserted Claims and preparation of Infringement Contentions. Defendants' failure to timely produce these materials in response to any Requests for Production served by Plaintiffs will constitute good cause for amending Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions. The materials Plaintiffs will rely on to show infringement in this Hatch-Waxman litigation are not publicly available and are uniquely in Defendants' possession. Moreover, the materials relied on by Plaintiffs to show infringement may very well be different from the materials produced by Defendants' in support of Defendants' non-infringement positions. Accordingly, Plaintiffs' dispute any suggestion that their need for discovery of Defendants' devices would somehow be satisfied by Defendants' production obligations under Paragraph 6.

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