IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE OZEMPIC (SEMAGLUTIDE) PATENT LITIGATION	MDL No. 22-md-3038-CFC-EGT **ANDA CASE**
NOVO NORDISK INC. AND NOVO NORDISK A/S, Plaintiffs/Counterclaim Defendants, v. RIO BIOPHARMACEUTICALS INC., et al., Defendants/Counterclaim Plaintiffs.	C.A. No. 22-294-CFC-EGT **CONSOLIDATED ANDA CASE**
NOVO NORDISK INC. AND NOVO NORDISK A/S, Plaintiffs/Counterclaim Defendants, v. MYLAN PHARMACEUTICALS INC., Defendant/Counterclaim Plaintiff.	C.A. No. 22-1040-CFC-EGT **ANDA CASE**

DEFENDANTS' STIPULATION REGARDING INVALIDITY GROUNDS FOR U.S. PATENT NO. 10,335,462

Defendants Mylan Pharmaceuticals Inc. ("Mylan"), Rio Biopharmaceuticals Inc. and EMS S/A (collectively "Rio"), and Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, (collectively "Zydus") (collectively, "Defendants") submit the following stipulation to remove certain invalidity grounds related to U.S. Patent Number 10,335,462 ("the '462 patent") from this action.

WHEREAS, in 2022, Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Plaintiffs") asserted the '462 patent against each Defendant in this case, including Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") and Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"), in connection with their respective Abbreviated New Drug Applications for semaglutide injection products. *See* C.A. No. 22-294, D.I. 1; C.A. No. 22-296, D.I. 1; C.A. No. 22-297, D.I. 1; C.A. No. 22-298, D.I. 1; C.A. No. 22-1040, D.I. 1.

WHEREAS, on March 16, 2023, Mylan filed petition number IPR2023-00724 ("Mylan's petition") with the Patent Trial and Appeal Board ("PTAB"), requesting *inter partes* review ("IPR") of the '462 patent. Mylan's petition included the following grounds ("the IPR Grounds"):

Claim(s) Challenged	Statutory Basis[1]	Reference(s)/Combinations
1-3	Anticipation under § 102(a), (e)	WO421[2]
1-3	Anticipation under § 102(b)	Lovshin[3]
1-10	Obviousness under § 103(a)	WO537[4], Lovshin
1-10	Obviousness under § 103(a)	W0421 considering the '424 publication[5]
1-10	Obviousness under § 103(a)	NCT657[6] and NCT773[7] considering the '424 publication

On October 4, 2023, the PTAB instituted Mylan's petition on the IPR Grounds. The PTAB scheduled oral argument for Mylan's petition to be held on August 27, 2024.

WHEREAS, on October 20, 2023, DRL filed petition number IPR2024-00009 ("DRL's petition") with the PTAB, requesting *inter partes* review of the '462 patent. DRL's petition relied on the same grounds as those in Mylan's petition. On April 25, 2024, the PTAB instituted DRL's petition and joined DRL as a party to Mylan's petition.

[1] The pre-Leahy-Smith America Invents Act ("pre-AIA") provisions apply to the '462 patent.

[2] International patent application publication number WO 2011/138421.

[3] Lovshin, *Incretin-Based Therapies for Type 2 Diabetes Mellitus*, 5 NATURE REV. ENDOCRINOLOGY 262 (2009).

[4] International patent application publication number WO 2006/097537.

[5] U.S. Patent Application Publication No. 2007/0010424.

[6] Clinical Trial No. NCT00696657.

[7] Clinical Trial No. NCT00851773.

WHEREAS, on November 2, 2023, Sun filed petition number IPR2024-00107 ("Sun's petition") with the PTAB, requesting *inter partes* review of the '462 patent. Sun's petition relied on the same grounds as those in Mylan's petition. On May 28, 2024, the PTAB instituted Sun's petition and joined Sun as a party to Mylan's petition.

WHEREAS, DRL and Sun previously stipulated to be bound by the estoppel provisions in 35 U.S.C. § 315(e)(2). C.A. No. 22-md-3038, D.I. Nos. 333, 334.

WHEREAS, Rio and Zydus did not file IPR petitions related to the '462 patent.

WHEREAS, a ten day trial is scheduled to begin in this action on December 9, 2024, which is likely after the PTAB will issue its decision regarding the unpatentability of the '462 patent.

NOW THEREFORE, Defendants[8] hereby stipulate and agree as follows:[9]

1. Because the PTAB will determine whether the '462 patent is unpatentable as anticipated or obvious with respect to the IPR Grounds, Defendants will not raise those same invalidity grounds at trial in this action;[10]

2. To the extent any of Defendants' experts in this action have opined that the '462 patent is invalid as anticipated or obvious on the basis of the IPR Grounds, Defendants agree those experts will not testify on those invalidity grounds at trial in this action;

3. Nothing in this stipulation affects Defendants' right to appeal an adverse decision from the PTAB with respect to the '462 patent to the United States Court of Appeals for the Federal Circuit;

[8] As noted above, this stipulation has been filed on behalf of Mylan, Rio, and Zydus. Defendants DRL and Sun previously stipulated to be bound by the estoppel provisions in 35 U.S.C. § 315(e)(2). C.A. No. 22-md-3038, D.I. Nos. 333, 334.

[9] Defendants Rio and Zydus make this stipulation without prejudice to their right to pursue all available defenses in this action, including the IPR Grounds, should the PTAB terminate or otherwise conclude the pending IPRs without reaching a final written decision on the merits of the patentability of the challenged claims.

[10] Defendants reserve the right to introduce for consideration at trial or prior to any final disposition of the Court any Final Written Decision issued by the PTAB or any final decision issued by the United States Court of Appeals for the Federal Circuit relating to the IPR petitions.

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