IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: OZEMPIC (SEMAGLUTIDE) PATENT LITIGATION	MDL NO. 22-MD-3038 (CFC) **ANDA CASE**
NOVO NORDISK INC. and NOVO NORDISK A/S, Plaintiffs, v. RIO BIOPHARMACEUTICALS INC., et al., Defendants.	C.A. No. 22-294 (CFC) CONSOLIDATED **ANDA CASE**

DR. REDDY'S LABORATORIES, LTD.'S AND DR. REDDY'S LABORATORIES, INC.'S STIPULATION CONCERNING INVALIDITY GROUNDS

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") submit this stipulation concerning its invalidity grounds.

On October 20, 2023, DRL filed petition number IPR2024-00009 with the Patent Trial and Appeal Board ("PTAB") requesting *inter partes* review of U.S. Patent No. 10,335,462 ("the '462 patent") (the "Petition") and joinder to IPR2023-00724 ("the Mylan IPR"). The Petition asserted the same grounds of invalidity as the Mylan IPR:

Ground	Claims	Basis for Unpatentability
1	1-3	Anticipated by WO421
2	1-3	Anticipated by Lovshin
3	1-10	Obvious over WO421 considering the ’424 publication
4	1-10	Obvious over WO537 considering Lovshin
5	1-10	Obvious over NCT657 and NT773 considering the ’424 publication

On _____, 2024, the PTAB instituted IPR2024-00009 and joined DRL as a party (“Institution Decision”) to the Mylan IPR. Accordingly, DRL stipulates[1] that it is bound by the estoppel provisions set forth in 35 U.S.C. § 315(e)(2) in this civil action as of the date of the Institution Decision. For the avoidance of doubt, DRL also stipulates that it is bound by the estoppel provisions set forth in 35 U.S.C. § 315(e)(2) in this civil action as of the date of the Institution Decision as such provisions would apply to Petitioner Mylan Pharmaceutical, Inc. in the Mylan IPR. This stipulation is not intended, and should not be construed, to limit DRL’s ability to assert invalidity of the ’462 patent in this civil action on any other ground beyond the scope of the estoppel provisions set forth in 35 U.S.C. § 315(e)(2).

[1] Pursuant to Director Vidal’s *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, Petitioner DRL offered a stipulation before the PTAB consistent with the stipulation set forth in *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to§ II.A).

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Dated: March __, 2024