

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUPERNUS PHARMACEUTICALS,
INC.,

C.A. No. 3-22-CV-04705 (GC)(LHG)

Plaintiffs,

v.

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

Defendants.

**DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S
ANSWER TO COMPLAINT**

Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively, "DRL" or "Defendants") answer Plaintiff Supernus Pharmaceuticals, Inc.'s ("Supernus" or "Plaintiff's") Complaint as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and 10,314,790 ("the '790 patent") attached hereto as Exhibits A–J (collectively, "the patents-in-suit").

ANSWER:

DRL admits the Complaint alleges this is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent Nos. 8,298,576 ("the '576 patent"), 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), 8,992,989 ("the '989 patent"), 9,549,940 ("the '940 patent"), 9,555,004 ("the '004 patent"), 9,622,983 ("the '983 patent"), and

10,314,790 ("the '790 patent") (collectively, "the patents-in-suit") and that the Complaint alleges that the patents-in-suit are attached thereto as Exhibits A-J thereto. DRL denies the remaining allegations in paragraph 1 of the Complaint.

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER:

DRL lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and, on that basis, denies them.

3. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, India.

ANSWER:

DRL admits DRL Ltd. is a company organized and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500034, India. DRL denies the remaining allegations of paragraph 3 of the Complaint.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 107 College Road East, Princeton, NJ 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary, directly or indirectly, of Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Inc. acts at the direction of, under the control of, and for the direct benefit of Dr. Reddy's Laboratories, Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

ANSWER:

DRL admits DRL Inc. is a corporation organized under the laws of the State of New Jersey, with a principal place of business at 107 College Road East, Princeton, New Jersey 08540. DRL

admits that DRL Inc. is a subsidiary of DRL Ltd. DRL denies the remaining allegations of paragraph 4 of the Complaint.

5. Upon information and belief, DRL filed Abbreviated New Drug Application No. 217231 (“the DRL ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of generic topiramate extended-release capsules, containing 25 mg, 50 mg, 100 mg, and 200 mg of topiramate (“DRL ANDA Products”).

ANSWER:

DRL admits that DRL filed Abbreviated New Drug Application No. 217231 (the DRL ANDA” or “DRL’s ANDA”) seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 5 of the Complaint.

6. Upon information and belief, Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. are acting cooperatively with respect to the DRL ANDA.

ANSWER:

DRL admits that DRL filed DRL’s ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 6 of the Complaint.

7. Upon information and belief, Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products (e.g., ciprofloxacin dexamethasone otic suspension, diclofenac sodium topical gel, sapropterin dihydrochloride tablets, and colchicine tablets)¹ that will be manufactured and sold, pursuant to an ANDA, throughout the United States, including throughout the State of New Jersey.

ANSWER:

¹ See Dr. Reddy’s Laboratories, Ltd.’s Annual Report 2020-21 at 45,
<https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf> (last visited July 22, 2022).

DRL admits DRL develops, manufactures, imports, markets, distributes, and/or sells pharmaceutical products, including generic drug products. DRL admits that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 7 of the Complaint.

8. Upon information and belief, Defendants and/or their affiliates manufacture and/or direct the manufacture of generic pharmaceutical products for which DRL is the named ANDA applicant. Upon information and belief, Defendants each, directly or indirectly, derive substantial revenue from the sales of such generic pharmaceutical products.

ANSWER:

DRL admits DRL develops, manufactures, imports, markets, distributes, and/or sells pharmaceutical products, including generic drug products. DRL admits that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 8 of the Complaint.

9. Upon information and belief, DRL will market the DRL ANDA Products throughout the United States, including in New Jersey, upon approval of the DRL ANDA.

ANSWER:

DRL admits that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 9 of the Complaint.

10. On or about June 9, 2022, DRL sent a letter purportedly pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 regarding the DRL ANDA Products and the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents (the "June 9 Notice Letter") to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850.

ANSWER:

DRL admits that by letter dated June 9, 2022 (the “June 9 Notice Letter” or “DRL’s Notice Letter”), and sent to Supernus at 9715 Key West Avenue, Rockville, Maryland 20850, DRL notified Plaintiffs of its ANDA certification that the claims of the ’576, ’580, ’683, ’248, ’191, ’989, ’940, ’004, ’983, and ’790 patents are invalid, unenforceable, and or/will not be infringed by DRL’s proposed ANDA product. DRL admits DRL’s Notice Letter is a document that speaks for itself. DRL admits it filed DRL’s ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 10 of the Complaint.

11. The June 9 Notice Letter was signed by Anjum Swaroop, the Vice President, Intellectual Property at Dr. Reddy’s Laboratories, Inc. and the authorized representative for DRL.

ANSWER:

The June 9 Notice Letter was signed by Anjum Swaroop, Ph.D., Esq. Vice President, Intellectual Property, Dr. Reddy’s Laboratories, Inc. as an agent in the United States authorized to accept service of process for DRL with respect to the June 9 Notice Letter. DRL denies the remaining allegations of paragraph 11 of the Complaint.

JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER:

Paragraph 12 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction in this Court. DRL denies the remaining allegations of paragraph 12 of the Complaint.

13. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

ANSWER:

Paragraph 13 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest personal jurisdiction in this Court. DRL denies the remaining allegations of paragraph 13 of the Complaint.

14. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, DRL states that the United States is one of DRL's "principal markets."² Regarding its U.S. business, DRL's Annual Report 2020-2021 states that the company "filed 20 new Abbreviated New Drug Applications (ANDAs) and one New Drug Application (NDA) under the section 505(b)(2) with the US Food and Drug Administration (USFDA)."³ DRL's Annual Report 2020-2021 also states that "[a]s on [sic] March 31, 2021, [DRL] had 95 generic filings pending approval from the USFDA" and "[t]hese comprise 92 ANDAs and three New Drug Applications (NDAs) filed under the Section 505(b)(2) route of the US Federal Food, Drug and Cosmetics Act."⁴

ANSWER:

Paragraph 14 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 14 of the Complaint.

² Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 109,
<https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf> (last visited July 22, 2022).

³ Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 42,
<https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf> (last visited July 22, 2022).

⁴ Dr. Reddy's Laboratories, Ltd.'s Annual Report 2020-21 at 42,
<https://www.drreddys.com/media/1003010/drl-annual-report-fy2021.pdf> (last visited July 22, 2022).

15. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its various subsidiaries, including Defendant Dr. Reddy's Laboratories, Inc., the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) in concert with and/or through its various subsidiaries, including Defendant Dr. Reddy's Laboratories, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER:

Paragraph 15 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 15 of the Complaint.

16. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, *inter alia*: (i) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (ii) in concert with and/or through its parent, including Defendant Dr. Reddy's Laboratories, Ltd. and various subsidiaries, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (iii) alone or in concert with and/or through its parent, including Defendant Dr. Reddy's Laboratories, Ltd. and various subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER:

Paragraph 16 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 16 of the Complaint.

17. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. at least because, upon information and belief: (i) Dr. Reddy's Laboratories, Inc. maintains a principal place of business in New Jersey located at 107 College Road East, Princeton, NJ 08540; (ii) Dr. Reddy's Laboratories, Inc. is doing business in New Jersey and maintains continuous and systematic contacts with this Judicial District; (iii) Dr. Reddy's Laboratories, Inc., together with its parent Dr. Reddy's Laboratories, Ltd., is in the business of developing and manufacturing generic pharmaceutical products for importation, sale, and/or distribution in the State of New Jersey; (iv) Dr. Reddy's Laboratories, Inc., together with its parent Dr. Reddy's Laboratories, Ltd., has committed, induced, and/or contributed to acts of patent infringement in New Jersey; and (v) Dr. Reddy's Laboratories, Inc. has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.⁵

ANSWER:

Paragraph 17 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 17 of the Complaint.

18. Upon information and belief, Dr. Reddy's Laboratories, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0100518911.⁶ Upon information and belief, Dr. Reddy's Laboratories, Inc. is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesale[r]" with Registration Number

⁵ This Court also has personal jurisdiction over Defendants because Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by initiating lawsuits and asserting counterclaims in other civil actions initiated in this jurisdiction. See, e.g., *Dr. Reddy's Labs. Inc. v. Amarin Pharma, Inc.*, No. 21-10309 (D.N.J. Apr. 27, 2021), ECF No. 1 (showing that DRL filed an action under the Sherman Act in New Jersey); *Celgene Corp. v. Dr. Reddy's Labs., Ltd.*, No. 21-2111 (D.N.J. Apr. 23, 2021), ECF No. 10 (showing that DRL filed a counterclaim and did not contest personal jurisdiction); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-3324 (D.N.J. Feb. 19, 2016), ECF No. 28 (showing that DRL admitted to personal jurisdiction).

⁶ New Jersey's Division of Revenue and Enterprise Services Website, <https://www.njportal.com/DOR/BusinessNameSearch/Search/BusinessName> (search business name field for "Dr. Reddy's Laboratories") (last visited July 22, 2022).

5002312.⁷ Dr. Reddy's Laboratories, Inc. has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

ANSWER:

To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. DRL admits Dr. Reddy's Laboratories, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey with Business Identification Number 0100518911 and that Dr. Reddy's Laboratories, Inc. is registered with the State of New Jersey's Department of Health as a drug and medical device "manufacturer and wholesale[r]" with Registration Number 5002312. To the extent further response is required, DRL denies the remaining allegations of paragraph 18 of the Complaint.

19. Upon information and belief, DRL derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

ANSWER:

For the purpose of this action only, DRL admits DRL sells generic pharmaceutical products in the United States. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 19 of the Complaint.

⁷ New Jersey Department of Health Website, <https://healthapps.state.nj.us/fooddrug/fdList.aspx> (search company name field for "Dr. Reddy's Laboratories, Inc.") (last visited July 22, 2022).

20. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. at least because, upon information and belief: (i) Dr. Reddy's Laboratories, Ltd. has purposefully directed its activities and the activities of Dr. Reddy's Laboratories, Inc. at residents and corporate entities within the State of New Jersey; (ii) the claims set forth herein against Dr. Reddy's Laboratories, Ltd. arise out of or relate to those activities; (iii) Dr. Reddy's Laboratories, Ltd.'s contacts with the State of New Jersey (direct and indirect) are continuous and systematic; (iv) it is reasonable and fair for this Court to exercise personal jurisdiction over Dr. Reddy's Laboratories, Ltd.; and (v) Dr. Reddy's Laboratories, Ltd. has previously submitted to the jurisdiction of this Court, has availed itself of New Jersey's legal protections in prior litigations, and previously consented to personal jurisdiction and venue in this Judicial District.⁸

ANSWER:

Paragraph 20 contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 20 of the Complaint.

21. Upon information and belief, the tortious acts of DRL of (i) preparing and filing the DRL ANDA with a paragraph IV certification to the patents-in-suit for the purpose of obtaining approval to engage in the commercial manufacture, use, offer to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products before the expiration of the patents-in-suit, and (ii) directing notice of its ANDA submission to Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, offer to sell, and/or sale of the DRL ANDA Products by Defendants before the expiration of the patents-in-suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, DRL should reasonably anticipate being sued in New Jersey.

ANSWER:

⁸ This Court also has personal jurisdiction over Defendants because Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. See, e.g., *Celgene Corp. v. Dr. Reddy's Labs., Ltd.*, No. 21-2111 (D.N.J. Apr. 23, 2021), ECF No. 10 (showing that DRL filed a counterclaim and did not contest personal jurisdiction); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-3324 (D.N.J. Feb. 19, 2016), ECF No. 28 (showing that DRL admitted to personal jurisdiction).

Paragraph 21 contains legal conclusions to which no response is required. DRL admits that DRL submitted DRL's ANDA to the U.S. Food and Drug Administration ("FDA") seeking approval for the matters described in DRL's ANDA. To the extent further response is required, for purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 21 of the Complaint.

22. This Court has personal jurisdiction over DRL at least because, upon information and belief, if the DRL ANDA is approved, the DRL ANDA Products will be marketed and distributed by Dr. Reddy's Laboratories, Inc., purportedly at the direction and control of Dr. Reddy's Laboratories, Ltd., in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, upon information and belief, if DRL succeeds in obtaining FDA approval, DRL will sell the DRL ANDA Products in the State of New Jersey.

ANSWER:

Paragraph 22 contains legal conclusions to which no response is required. DRL admits that DRL submitted DRL's ANDA to the U.S. Food and Drug Administration ("FDA") seeking approval for the matters described in DRL's ANDA. For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 22 of the Complaint.

23. Upon information and belief, Dr. Reddy's Laboratories, Ltd. intends to benefit directly if the DRL ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the DRL ANDA.

ANSWER:

DRL admits that DRL submitted DRL's ANDA to the U.S. Food and Drug Administration ("FDA") seeking approval for the matters described in DRL's ANDA. For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 23 of the Complaint.

24. Upon information and belief, Dr. Reddy's Laboratories, Inc. intends to benefit directly if the DRL ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of the generic drug products that are the subject of the DRL ANDA.

ANSWER:

DRL admits that DRL submitted DRL's ANDA to the U.S. Food and Drug Administration ("FDA") seeking approval for the matters described in DRL's ANDA. For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 24 of the Complaint.

25. Upon information and belief, Dr. Reddy's Laboratories, Inc. acts at the direction, and for the benefit, of Dr. Reddy's Laboratories, Ltd. and is controlled and/or dominated by Dr. Reddy's Laboratories, Ltd.

ANSWER:

For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 25 of the Complaint.

26. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. act, operate, and/or hold themselves out to the public as a single integrated business.

ANSWER:

For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 26 of the Complaint.

27. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Dr. Reddy's Laboratories, Inc. has a principal place of business in New Jersey and has and will continue to engage in infringing activities in New Jersey.

ANSWER:

Paragraph 27 contains legal conclusions to which no response is required. For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 27 of the Complaint.

28. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b) because, upon information and belief, Dr. Reddy's Laboratories, Ltd. is incorporated in India and may be sued in any judicial district in which the Defendant is subject to the court's personal jurisdiction.

ANSWER:

Paragraph 28 contains legal conclusions to which no response is required. For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 28 of the Complaint.

29. Venue is proper under 28 U.S.C. §§ 1391(b) and (c) and/or § 1400(b). DRL has previously consented to venue in this Judicial District.⁹

ANSWER:

Paragraph 29 contains legal conclusions to which no response is required. For purposes of this action only, DRL does not contest subject matter jurisdiction, personal jurisdiction or venue in this Court. To the extent further response is required, DRL denies the remaining allegations of paragraph 29 of the Complaint.

ALLEGED FACTS AS TO ALL COUNTS

30. Supernus's Trokendi XR® is sold and marketed under New Drug Application ("NDA") No. 201635, which was approved by the FDA for the manufacture and sale of topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

ANSWER:

DRL admits FDA's publication, titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists Supernus as the "Applicant Holder" and "Trokendi XR" as the proprietary name with respect to NDA 201635. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 30 of the Complaint and, on that basis, denies them.

31. Trokendi XR® is an antiepileptic drug indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

⁹ See, e.g., *Celgene Corp. v. Dr. Reddy's Labs., Ltd.*, No. 21-2111 (D.N.J. Apr. 23, 2021), ECF No. 10 (showing that DRL filed a counterclaim and did not contest personal jurisdiction); *Horizon Pharma, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 15-3324 (D.N.J. Feb. 19, 2016), ECF No. 28 (showing that DRL admitted to personal jurisdiction).

ANSWER:

DRL admits the Trokendi XR® Prescribing Information is a document that speaks for itself. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 31 of the Complaint and, on that basis, denies them.

32. Trokendi XR®'s recommended dosage: (i) for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and in patients 6 to 9 years of age is based on weight; (ii) for adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and for adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

ANSWER:

DRL admits the Trokendi XR® Prescribing Information is a document that speaks for itself. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 32 of the Complaint and, on that basis, denies them.

33. FDA's publication, titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), lists ten (10) patents, specifically the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents, as covering Supernus's Trokendi XR®. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), these ten (10) patents were submitted to the FDA with or after the approval of NDA No. 201635. These ten (10) patents are listed in the Orange Book as covering Trokendi XR®.

ANSWER:

DRL admits FDA's publication, titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), is a document that speaks for itself. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 33 of the Complaint and, on that basis, denies them.

34. The '576 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '576 patent.

ANSWER:

DRL admits the '576 patent is a document that speaks for itself. DRL denies the '576 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 34 of the Complaint and, on that basis, denies them.

35. The '580 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on October 30, 2012, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '580 patent.

ANSWER:

DRL admits the '580 patent is a document that speaks for itself. DRL denies the '580 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 35 of the Complaint and, on that basis, denies them.

36. The '683 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '683 patent.

ANSWER:

DRL admits the '683 patent is a document that speaks for itself. DRL denies the '683 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks

knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 36 of the Complaint and, on that basis, denies them.

37. The '248 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '248 patent.

ANSWER:

DRL admits the '248 patent is a document that speaks for itself. DRL denies the '248 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 37 of the Complaint and, on that basis, denies them.

38. The '191 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on November 18, 2014, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '191 patent.

ANSWER:

DRL admits the '191 patent is a document that speaks for itself. DRL denies the '191 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 38 of the Complaint and, on that basis, denies them.

39. The '989 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on March 31, 2015, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '989 patent.

ANSWER:

DRL admits the '989 patent is a document that speaks for itself. DRL denies the '989 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 39 of the Complaint and, on that basis, denies them.

40. The '940 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 24, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '940 patent.

ANSWER:

DRL admits the '940 patent is a document that speaks for itself. DRL denies the '940 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 40 of the Complaint and, on that basis, denies them.

41. The '004 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on January 31, 2017, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '004 patent.

ANSWER:

DRL admits the '004 patent is a document that speaks for itself. DRL denies the '004 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 41 of the Complaint and, on that basis, denies them.

42. The '983 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on April 18, 2017, to Supernus

upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '983 patent.

ANSWER:

DRL admits the '983 patent is a document that speaks for itself. DRL denies the '983 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 42 of the Complaint and, on that basis, denies them.

43. The '790 patent, titled, "Sustained-Release Formulations of Topiramate," was duly and legally issued by the United States Patent and Trademark Office on June 11, 2019, to Supernus upon assignment from inventors Likan Liang, Hua Wang, Padmanabh P. Bhatt, and Michael L. Vieira. Supernus owns all rights, title, and interest in the '790 patent.

ANSWER:

DRL admits the '790 patent is a document that speaks for itself. DRL denies the '790 patent was duly and legally issued by the United States Patent and Trademark Office. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 43 of the Complaint and, on that basis, denies them.

44. Upon information and belief, the DRL ANDA is based upon Trokendi XR® (topiramate extended-release capsules), 25 mg, 50 mg, 100 mg, and 200 mg, as its reference listed drug.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 44 of the Complaint.

45. Upon information and belief, the DRL ANDA Products are topiramate extended-release capsules, 25 mg, 50 mg, 100 mg, and 200 mg.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 45 of the Complaint.

46. Upon information and belief, the proposed prescribing information for the DRL ANDA Products includes a header titled "Indications and Usage" and states that the DRL ANDA Products are indicated: (i) as an initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; (ii) as an adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 6 years of age and older; and (iii) for the preventive treatment of migraine in patients 12 years of age and older.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 46 of the Complaint.

47. Upon information and belief, the proposed prescribing information for the DRL ANDA Products includes a header titled "Dosage and Administration" and states that: (i) the recommended dose for monotherapy in adults and in pediatric patients 10 years of age and older is 400 mg orally once daily, and dosing in patients 6 to 9 years of age is based on weight; (ii) the recommended total daily dose as adjunctive therapy in adults with partial-onset seizures or Lennox-Gastaut syndrome is 200 mg to 400 mg orally once daily and with primary generalized tonic-clonic seizures is 400 mg orally once daily, and the recommended total daily dose as adjunctive therapy for patients 6 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 mg/kg to 9 mg/kg orally once daily; and (iii) the recommended total daily dose as treatment for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 47 of the Complaint.

48. Upon information and belief, the proposed prescribing information for the DRL ANDA Products also states under the header "Dosage and Administration" that the DRL ANDA Products can be taken without regard to meals, to swallow capsule whole and intact, and do not sprinkle on food, chew, or crush.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 48 of the Complaint.

49. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted in concert to develop the DRL ANDA Products and/or seek approval from the FDA to sell the DRL ANDA Products throughout the United States, including within this Judicial District.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 49 of the Complaint.

50. Upon information and belief, both Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. participated in the preparation and/or filing of the DRL ANDA.

ANSWER:

DRL admits DRL's ANDA is a document that speaks for itself and that DRL filed DRL's ANDA seeking approval for the matters described therein. DRL denies the remaining allegations of paragraph 50 of the Complaint.

51. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

ANSWER:

Paragraph 51 contains legal conclusions to which no response is required. To the extent an answer is required DRL denies the remaining allegations of paragraph 51 of the Complaint.

52. Upon information and belief, as of the date of the June 9 Notice Letter, DRL was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

DRL admits DRL's Notice Letter is a document that speaks for itself. DRL denies the remaining allegations of paragraph 52 of the Complaint.

53. The June 9 Notice Letter does not include any noninfringement contentions for the '576 patent, the '580 patent, the '683 patent, the '191 patent, the '004 patent, and the '790 patent. The June 9 Notice Letter does not include any noninfringement contentions unique to claims 2-6, 8-20 of the '248 patent, claims 2-6 and 8-20 of the '989 patent, claims 2-6 and 8-20 of the '940 patent, and claims 2-5, 7-12, 14-23, and 25-30 of the '983 patent.

ANSWER:

DRL admits DRL's Notice Letter is a document that speaks for itself. DRL denies the remaining allegations of paragraph 53 of the Complaint.

54. Supernus and DRL did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, DRL has not produced the DRL ANDA to Supernus.

ANSWER:

DRL admits Supernus did not accept the Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8) included in DRL's Notice Letter and that DRL did not produce the DRL ANDA to Supernus before the Complaint was filed. DRL denies the remaining allegations of paragraph 54 of the Complaint.

FIRST COUNT
(Defendants' Alleged Infringement of the '576 Patent)

55. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

56. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '576 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '576 patent is an act of infringement of the '576 patent by DRL of one or more claims of the '576 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 56 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 56 of the Complaint.

57. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 57 of the Complaint.

58. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '576 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

59. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '576 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

60. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '576 patent do not comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

61. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '576 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

62. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

SECOND COUNT
(Defendants' Alleged Infringement of the '580 Patent)

63. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

64. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '580 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '580 patent is an act of infringement of the '580 patent by DRL of one or more claims of the '580 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 64 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 64 of the Complaint.

65. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 65 of the Complaint.

66. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '580 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

67. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '580 patent under 35 U.S.C. § 271.

ANSWER:

Denied

68. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '580 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied

69. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '580 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied

70. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied

THIRD COUNT
(Defendants' Alleged Infringement of the '683 Patent)

71. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

72. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '683 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '683 patent is an act of infringement of the '683 patent by DRL of one or more claims of the '683 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 72 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 72 of the Complaint.

73. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 73 of the Complaint.

74. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '683 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

75. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '683 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

76. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '683 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

77. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '683 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

78. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

FOURTH COUNT
(Defendants' Alleged Infringement of the '248 Patent)

79. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

80. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '248 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '248 patent is an act of infringement of the '248 patent by DRL of one or more claims of the '248 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 80 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 80 of the Complaint.

81. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 81 of the Complaint.

82. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '248 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

83. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '248 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

84. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '248 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

85. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '248 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

86. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

FIFTH COUNT
(Defendants' Alleged Infringement of the '191 Patent)

87. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

88. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '191 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '191 patent is an act of infringement of the '191 patent by DRL of one or more claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 88 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 88 of the Complaint.

89. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 89 of the Complaint.

90. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '191 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

91. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '191 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

92. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '191 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

93. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '191 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

94. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

SIXTH COUNT
(Defendants' Alleged Infringement of the '989 Patent)

95. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

96. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '989 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '989 patent is an act of infringement of the '989 patent by DRL of one or more claims of the '989 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 96 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 96 of the Complaint.

97. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 97 of the Complaint.

98. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '989 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

99. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '989 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

100. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '989 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

101. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '989 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

102. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

SEVENTH COUNT
(Defendants' Alleged Infringement of the '940 Patent)

103. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

104. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '940 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '940 patent is an act of infringement of the '940 patent by DRL of one or more claims of the '940 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 104 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 104 of the Complaint.

105. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 105 of the Complaint.

106. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '940 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

107. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '940 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

108. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '940 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

109. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '940 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

110. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

EIGHTH COUNT
(Defendants' Alleged Infringement of the '004 Patent)

111. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

112. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '004 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '004 patent is an act of infringement of the '004 patent by DRL of one or more claims of the '004 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 112 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 112 of the Complaint.

113. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 113 of the Complaint.

114. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '004 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

115. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '004 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

116. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '004 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

117. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '004 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

118. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

NINTH COUNT
(Defendants' Alleged Infringement of the '983 Patent)

119. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein.

120. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '983 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the DRL ANDA Products before the expiration of the '983 patent is an act of infringement of the '983 patent by DRL of one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 120 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 120 of the Complaint.

121. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 121 of the Complaint.

122. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '983 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

123. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '983 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

124. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '983 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

125. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '983 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

126. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

TENTH COUNT
(Defendants' Alleged Infringement of the '790 Patent)

127. Supernus repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

ANSWER:

DRL repeats and re-alleges its Answers to each of the foregoing Paragraphs as if fully set forth herein

128. Upon information and belief, DRL's submission and filing of the DRL ANDA with a paragraph IV certification to the '790 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale in, and/or importation into, the United States of the

DRL ANDA Products before the expiration of the '790 patent is an act of infringement of the '790 patent by DRL of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Paragraph 128 contains legal conclusions to which no response is required. DRL admits it filed DRL's ANDA seeking approval of the matters described therein. To the extent an answer is required, for purposes of this action only, DRL does not contest subject matter jurisdiction. DRL denies the remaining allegations of paragraph 128 of the Complaint.

129. Upon information and belief, DRL will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States, the DRL ANDA Products upon, or in anticipation of, FDA approval of the DRL ANDA.

ANSWER:

DRL admits it filed DRL's ANDA seeking approval of the matters described therein. DRL denies the remaining allegations of paragraph 129 of the Complaint.

130. Upon information and belief, DRL's commercial manufacture, use, offering to sell, and/or sale within the United States, and/or importation into the United States, of the DRL ANDA Products will infringe, directly and/or indirectly, one or more claims of the '790 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

131. Upon information and belief, the commercial offering for sale and/or sale of the DRL ANDA Products by DRL will induce and/or contribute to third-party infringement of one or more claims of the '790 patent under 35 U.S.C. § 271.

ANSWER:

Denied.

132. Upon information and belief, the factual and legal bases in the June 9 Notice Letter regarding the '790 patent do not establish good-faith bases to comply with the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

ANSWER:

Denied.

133. DRL acted without a reasonable basis for believing that it would not be liable for infringement of the '790 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285 and entitling Supernus to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

134. The acts of infringement set forth above will cause Supernus irreparable harm for which there is no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

ANSWER:

Denied.

RESPONSE TO PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to any relief sought in Plaintiffs' Prayer for Relief.

DEFENDANTS' SEPARATE DEFENSES

Without prejudice to the admissions and denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, DRL asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs.

**FIRST SEPARATE DEFENSE
(Non-infringement of the ‘576 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘576 Patent.

**SECOND SEPARATE DEFENSE
(Invalidity of the ‘576 Patent)**

Each and every claim of the ‘576 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**THIRD SEPARATE DEFENSE
(Non-infringement of the ‘580 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘580 Patent.

**FOURTH SEPARATE DEFENSE
(Invalidity of the ‘580 Patent)**

Each and every claim of the ‘580 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**FIFTH SEPARATE DEFENSE
(Non-infringement of the ‘683 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘683 Patent.

**SIXTH SEPARATE DEFENSE
(Invalidity of the ‘683 Patent)**

Each and every claim of the ‘683 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**SEVENTH SEPARATE DEFENSE
(Non-infringement of the ‘248 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘248 Patent.

**EIGHTH SEPARATE DEFENSE
(Invalidity of the ‘248 Patent)**

Each and every claim of the ‘248 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**NINTH SEPARATE DEFENSE
(Non-infringement of the ‘191 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘191 Patent.

**TENTH SEPARATE DEFENSE
(Invalidity of the ‘191 Patent)**

Each and every claim of the ‘191 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**ELEVENTH SEPARATE DEFENSE
(Non-infringement of the ‘989 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘989 Patent.

**TWELFTH SEPARATE DEFENSE
(Invalidity of the ‘989 Patent)**

Each and every claim of the ‘989 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**THIRTEENTH SEPARATE DEFENSE
(Non-infringement of the ‘940 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘940 Patent.

**FOURTEENTH SEPARATE DEFENSE
(Invalidity of the ‘940 Patent)**

Each and every claim of the ‘940 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**FIFTEENTH SEPARATE DEFENSE
(Non-infringement of the ‘004 Patent)**

DRL has not infringed and will not infringe any valid claim of the ‘004 Patent.

SIXTEENTH SEPARATE DEFENSE
(Invalidity of the ‘004 Patent)

Each and every claim of the ‘004 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

SEVENTEENTH SEPARATE DEFENSE
(Non-infringement of the ‘983 Patent)

DRL has not infringed and will not infringe any valid claim of the ‘983 Patent.

**EIGHTEENTH SEPARATE DEFENSE
(Invalidity of the '983 Patent)**

Each and every claim of the '983 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**NINETEENTH SEPARATE DEFENSE
(Non-infringement of the '790 Patent)**

DRL has not infringed and will not infringe any valid claim of the '790 Patent.

**TWENTIETH SEPARATE DEFENSE
(Invalidity of the '790 Patent)**

Each and every claim of the '790 Patent is invalid for failure to comply with at least 35 U.S.C. §§ 102, 103 and/or 112.

**TWENTYFIRST SEPARATE DEFENSE
(Failure to State a Claim)**

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

DEFENDANTS' PRAYER FOR RELIEF

DRL respectfully requests that this Court enter judgment in its favor and against Plaintiff as follows:

- A. Dismissing the Complaint with prejudice and denying each and every Request for Relief contained therein and that Plaintiff takes nothing thereby;
- B. Finding that each and every claim of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents is invalid;
- C. Finding that each and every claim of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents is not and will not be infringed by DRL;

- D. Declaring that Plaintiffs are not entitled to any injunctive remedy for any of the '576, '580, '683, '248, '191, '989, '940, '004, '983, and '790 patents;
- E. Awarding DRL its costs and expenses in this action;
- F. Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding to DRL its reasonable attorney's fees; and
- G. Awarding to DRL such further relief this Court may deem just, proper, or equitable.

Dated: October 7, 2022

/s/Louis H. Weinstein

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Attorneys for Defendants

Dr. Reddy's Laboratories, Inc. and

Dr. Reddy's Laboratories, Ltd.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a true and accurate copy of the foregoing **DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER TO COMPLAINT** was caused to be filed with the Court's electronic filing system, and served on counsel of record for Plaintiffs via the Court's electronic filing system and electronic mail on October 7, 2022.

/s/Louis H. Weinstein

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