

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

NOVO NORDISK INC. and)	
NOVO NORDISK A/S,)	
)	
<i>Plaintiffs/Counterclaim Defendants</i>)	
)	
v.)	
)	Case No. 23-22112 (ES)(JSA)
DR. REDDY’S LABORATORIES, LTD. and)	
DR. REDDY’S LABORATORIES, INC.,)	
)	
<i>Defendants/Counterclaim Plaintiffs</i>)	
)	
)	

DRL’S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories Inc. (collectively, “DRL”), through their undersigned counsel, hereby answer and assert the following defenses and counterclaims to the Complaint brought by Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Novo”).

ANSWER TO THE COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in Novo’s Complaint. DRL denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation admitted below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or specifications that arguably follow from the admitted facts. DRL denies that Novo is entitled to the relief requested or any other relief.

With respect to the allegations made in the Complaint, DRL states as follows:

NATURE OF THE ACTION

1. DRL admits that the Complaint purports to bring an action for infringement arising under the patent laws of the United States, Title 35, United States Code. DRL admits that DRL submitted Abbreviated New Drug Application (“ANDA”) No. 214411 (“DRL’s ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to market a generic version of VICTOZA® prior to the expiration of United States Patent Nos. 8,114,833 (“833 patent”) and 9,265,893 (“893 patent”) (collectively, the “patents-in-suit”). Except as expressly admitted, DRL denies any remaining allegations of paragraph 1.

THE PARTIES

2. DRL lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 2, and therefore denies them.

3. DRL lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 3, and therefore denies them.

4. Dr. Reddy’s Laboratories, Inc. (“DRL Inc.”) admits that it is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. DRL Inc. admits that its business includes selling generic pharmaceutical products in the State of New Jersey and throughout the United States. DRL otherwise denies the remaining allegations of paragraph 4.

5. Dr. Reddy’s Laboratories, Ltd. (“DRL Ltd.”) admits that it is a corporation organized and existing under the laws of India having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India. DRL Ltd. admits that its business includes making and selling generic pharmaceutical products. DRL otherwise denies the remaining allegations of paragraph 5.

6. DRL admits that DRL Ltd. is the ultimate parent company of DRL Inc., and that DRL Inc. is a wholly owned subsidiary of DRL Ltd., directly or indirectly through Dr. Reddy's Laboratories SA.

7. DRL admits that DRL Inc. acted as DRL Ltd.'s agent in submitting DRL's ANDA. Except as expressly admitted, DRL denies the remaining allegations of paragraph 7.

8. DRL admits that DRL Inc. acted as DRL Ltd.'s agent in submitting DRL's ANDA. DRL admits that DRL's ANDA seeks FDA approval to market a generic version of VICTOZA®, Liraglutide Injection, 18 mg/3 mL (6 mg/mL), in the United States, including in New Jersey. Except as expressly admitted, DRL denies the remaining allegations of paragraph 8.

JURISDICTION AND VENUE

9. DRL admits that the Complaint purports to bring an action for infringement arising under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271 specifically, but denies that Novo is entitled to any such relief. DRL otherwise denies any remaining allegations in paragraph 9.

10. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest subject matter jurisdiction under 28 U.S.C. §§ 1331 or 1338(a) for the purposes of this action only. DRL otherwise denies the remaining allegations of paragraph 10.

11. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest venue for purposes of this action only and expressly reserves the right to contest venue in any other case as to any party. DRL otherwise denies the remaining allegations of paragraph 11.

12. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL Inc. does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest

personal jurisdiction in any other case as to any party. DRL otherwise denies the remaining allegations of paragraph 12.

13. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL Ltd. does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. DRL otherwise denies the remaining allegations of paragraph 13.

14. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL admits that it has previously litigated patent infringement disputes in this Judicial District, and DRL does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. DRL otherwise denies the remaining allegations of paragraph 14.

15. DRL admits that DRL's ANDA seeks FDA approval to market a generic version of VICTOZA®, Liraglutide Injection, 18 mg/3 mL (6 mg/mL), in the United States. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, DRL does not contest the Court's exercise of personal jurisdiction over it for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party. DRL otherwise denies the remaining allegations of paragraph 15.

THE PATENTS-IN-SUIT

16. DRL admits that the '833 patent is titled, on its face, "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices," and bears an issuance date of February 14, 2012. DRL admits that a purported copy of the '833 patent is attached to the Complaint as Exhibit A. DRL denies that the '833 patent was duly and legally

issued. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 16, and therefore denies the same.

17. DRL admits that the '893 patent is titled, on its face, "Injection Button," and bears an issuance date of February 23, 2016. DRL admits that a purported copy of the '893 patent is attached to the Complaint as Exhibit B. DRL denies that the '893 patent was duly and legally issued. DRL is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 17, and therefore denies the same.

VICTOZA®

18. DRL admits that the FDA's publication, entitled Approved Drug Products With Therapeutic Equivalence Evaluations ("Orange Book"), indicates that Novo Nordisk Inc. is the holder of NDA No. 022341 for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml) (VICTOZA®). Except as expressly admitted, DRL denies the remaining allegations of paragraph 18.

19. Denied.

20. DRL admits that Novo Nordisk Inc. has listed the '833 and '893 patents in the Orange Book in connection with NDA No. 022341. DRL denies that the listing of the '893 patent is "[p]ursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations." DRL asserts that the '893 patent is improperly listed in the Orange Book, as alleged in DRL's counterclaims. DRL otherwise denies the allegations of paragraph 20.

DRL'S ANDA

21. DRL admits that DRL Inc. submitted DRL's ANDA to the FDA seeking approval to market a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("DRL's ANDA Product"). DRL otherwise denies the remaining allegations of paragraph 21.

22. DRL admits that it represented to the FDA that DRL's ANDA Product is a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) and refers to VICTOZA® as the reference listed drug. DRL otherwise denies the remaining allegations of paragraph 22.

23. DRL admits that it sent Novo a letter dated September 25, 2023 (the "Notice Letter") notifying Novo that DRL's ANDA includes a Paragraph IV Certification with respect to the '833 and '893 patents because said patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of DRL's ANDA Product, and setting forth the factual and legal bases for its Paragraph IV Certification. DRL admits that Novo filed this suit on November 8, 2023, within 45 days of receipt of the Notice Letter. DRL denies the remaining allegations of paragraph 23.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,114,833

24. DRL repeats and incorporates by reference each of its answers to paragraphs 1 through 23 as if fully set forth herein.

25. Denied.

26. Denied.

27. Denied.

28. Denied.

29. DRL admits that it had knowledge of the '833 patent through the listing of the '833 patent in the Orange Book at the time DRL submitted its ANDA. DRL otherwise denies the allegations of paragraph 29.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 9,265,893

30. DRL repeats and incorporates by reference each of its answers to paragraphs 1 through 29 as if fully set forth herein.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. DRL admits that it had knowledge of the '893 patent through the listing of the '893 patent in the Orange Book at the time DRL submitted its ANDA. DRL otherwise denies the allegations of paragraph 35.

RESPONSE TO PRAYER FOR RELIEF

DRL denies all allegations not specifically admitted herein, and further denies that Novo is entitled to the judgment and relief requested in Paragraphs A-H of the Complaint or to any other relief. DRL respectfully requests that the Court: (a) dismiss the Complaint with prejudice; (b) enter judgment in favor of DRL; (c) award DRL the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award DRL such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in DRL's responses to Paragraphs 1 through 35 of the Complaint and DRL's Response to Prayer for Relief, and without undertaking any of the burdens imposed by law on Novo, DRL avers and asserts the following separate defenses to the Complaint. DRL expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE **(Failure to State a Claim)**

Novo has failed to state a claim for which relief can be granted because, *inter alia*, DRL has not committed an act of infringement as prescribed in 35 U.S.C. § 271(e)(2).

SECOND AFFIRMATIVE DEFENSE
(Non-infringement)

The manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of DRL's ANDA Product that is the subject of DRL's ANDA has not and will not infringe directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner any valid and enforceable claim of the Patents-in-Suit.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the Patents-in-Suit are invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability of patents and/or the defenses recognized in 35 U.S.C. § 282.

FOURTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Novo may not seek injunctive relief under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 against DRL because Novo's alleged damages are not irreparable and Novo has an adequate remedy at law.

FIFTH AFFIRMATIVE DEFENSE
(No Costs)

Novo is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

DRL's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE
(Improper Orange Book Listing)

Pursuant to 21 U.S.C. §§ 355(b) and (c) and 21 C.F.R. §§ 314.53(b) and (c), one or more of the Patents-in-Suit does not claim the drug substance, drug product, or methods of using the drug substance or drug product, that are the subject of NDA No. 022341, and is therefore improperly listed in the Orange Book for VICTOZA®.

EIGHTH AFFIRMATIVE DEFENSE
(Additional Defenses)

DRL reserves the right to add or amend this list of Affirmative Defenses with additional defenses that discovery may yield, including unenforceability.

COUNTERCLAIMS

In further response to the Complaint, Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), without admitting any of the allegations of Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo") other than those expressly admitted herein, and without prejudice of the rights of DRL to plead additional Counterclaims as the facts of the matter warrant, allege as follows:

THE PARTIES

1. Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having a principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

2. Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

3. On information and belief, Novo Nordisk Inc. is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey 08536.

4. On information and belief, Novo Nordisk A/S is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. Novo Nordisk Inc. is an indirect, wholly-owned subsidiary of Novo Nordisk A/S.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C)(ii)(I).

6. This Court has personal jurisdiction over Novo because, among other reasons, Novo subjected itself to the jurisdiction of this Court by filing its Complaint here.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b), and by Novo's choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and validity of U.S. Patent Nos. 8,114,833 ("833 patent") and 9,265,893 ("893 patent") (collectively, the "Patents-in-Suit") arising under the United States patent laws, 35 U.S.C. § 100 *et. seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

FACTUAL BACKGROUND

The Hatch-Waxman Amendments and Listing Patents in the Orange Book

9. This case involves the unlawful exploitation of provisions in the Federal Food Drug and Cosmetic Act ("FD&C Act") by Novo to slow competition of generic versions of liraglutide injection prefilled pens for the treatment of type 2 diabetes.

10. On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the "Hatch-Waxman Amendments." The Hatch-Waxman Amendments amended the FD&C Act by creating, among other things, an abbreviated approval pathway for generic pharmaceutical products. A central component of the Hatch-Waxman Amendments was creating a mechanism to allow brand pharmaceutical companies to assert claims of patent infringement against would-be generic competitors *before* the generic competitors launched their product into the market. To address this concern, the Hatch-Waxman Amendments required FDA to make publicly available a list of approved drug products and any patents that cover those approved drug products. *See* 21 U.S.C. § 355(j)(7)(A)(iii). FDA complies with this statutory mandate through the publication of a catalogue entitled, "*Approved Drug*

Products with Therapeutics Equivalence Evaluation,” which is commonly known as the “Orange Book.”

11. FDA obtains this so-called “patent information” from the brand drug companies that have received approval to market brand drugs pursuant to a “New Drug Application” or NDA. Specifically, the FD&C Act requires brand drug companies to provide to FDA “the patent number and expiration of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug” as part of NDA or within 30 days of the NDA approval. *See id.* § 355(b)(1)(A)(viii).

12. There are two important limitations imposed on brand drug companies for identifying patents to be listed in the Orange Book. The patent must be one that either “(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application.” *Id.*

13. The FD&C Act also makes clear that “[p]atent information that is not the type of patent information required by subsection (b)(1)(a)(viii) shall not be submitted” to FDA. *Id.* § 355(c)(2).

14. The FDA serves a purely “ministerial” role with regard to the listing of patent information. *See, e.g.,* Applications for FDA Approval to Market a New Drug, 68 Fed. Reg. 36676 (June 18, 2003). That is, FDA does not scrutinize the patent information submitted by an NDA holder to determine if the submitted patent actually claims a “drug substance (active ingredient),” a “drug product (formulation or composition),” or a “method of using” the drug that is the subject of the NDA.

15. The listing of a patent in the Orange Book provides brand drug companies a significant competitive advantage over would-be generic drug competitors. Any application for a generic drug submitted to FDA—referred to as an “Abbreviated New Drug Application” or “ANDA”—must make one of four certifications with respect to any Orange Book-listed patent for the brand counterpart drug: “(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii). If a generic manufacturer application certifies that an Orange Book-listed patent is invalid or will not be infringed by the generic drug, the generic manufacturer must provide notice of that certification to the brand drug company that holds the NDA and the owner of the affected patent. *Id.* § 355(j)(2)(B). That notification to the brand drug company and patent owner is referred to as a “Paragraph IV Notice.”

16. Under 21 U.S.C. § 355(j)(5)(B)(iii), if an NDA holder brings a suit for infringement of an Orange Book-listed patent within 45 days of receiving an ANDA applicant’s Paragraph IV Notice, FDA approval of the ANDA may not be made effective until expiration of the thirty-month period beginning the day notice was received, subject to certain statutory exceptions. The purpose of this automatic 30-month stay of FDA approval of the generic drug is to give the brand drug company the opportunity to litigate its claims of patent infringement—and perhaps obtain an injunction—*before* the generic drug launches into the market. By listing patents in the Orange Book, brand drug companies may obtain an automatic 30-month extension of their monopoly without regard to whether a court ultimately finds the patent at issue valid or infringed by the competing product.

17. This automatic 30-month stay, however, creates an incentive for brand companies to improperly submit patents to FDA for listing in the Orange Book.

The Improper Listing of Patents in the Orange Book

18. On September 14, 2023, the Federal Trade Commission (“FTC”) issued a policy statement, supported by FDA, warning brand pharmaceutical companies that they could face legal action if they improperly list patents in FDA’s Orange Book. *See* FTC, Federal Trade Commission Statement Concerning Brand Drug Manufacturers’ Improper Listing of Patents in the Orange Book (Sept. 14, 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf. FTC’s policy statement is attached as Exhibit 1. According to the policy statement, “[t]he goal of this policy statement is to put market participants on notice that the FTC intends to scrutinize improper Orange Book listings to determine whether these constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act.” Ex. 1, at 1. The FTC’s policy statement recognizes that improper listing of patents in the Orange Book is not a new problem:

Improper Orange Book listings may have played a role in distorting pharmaceutical markets for decades. The Supreme Court has observed that since the late 1990s there has been evidence that some brand drug companies were exploiting the Orange Book listing process “to prevent or delay the marketing of generic drugs.” The FTC examined the potential anticompetitive effect of improper Orange Book listings as part of a 2002 study, in which it identified numerous instances in which the 30-month stay was used to block competition. The same year, the FTC charged Biovail Corporation for, among other things, wrongfully listing a patent in the Orange Book to block generic competition in violation of the FTC Act. Over the years, the FTC has filed amicus briefs in private litigations relating to the anticompetitive effects of improper Orange Book patent listings, including most recently in *Jazz Pharms., Inc. v. Avadel CNS Pharms.*

Id. at 3–4.

19. The FTC recognized that “[i]mproper Orange Book patent listings may disincentivize investments in developing a competing product and increase risk of delayed generic and follow-on product entry, reducing patient access to more affordable prescription drugs and increasing the costs to the healthcare system.” *Id.* at 4. Importantly, “a generic company with a competing product facing an infringement suit based on a patent that was improperly listed in the Orange Book cannot launch its product because the automatic stay would prevent the FDA from granting approval to market the product.” *Id.* “Patients suffer because they are deprived of the ability to choose between competing products and may be forced to pay inflated prices.” *Id.*

20. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 641 F. Supp. 3d 85 (D. Del. 2022) is one example of a case in which the NDA holder was found to have improperly listed a patent in the Orange Book and was ordered to request deletion of that patent from the Orange Book for the drug at issue. In *Jazz*, the patent that was held to have been improperly listed was directed to using a computer-implemented system to address certain safety conditions required by FDA for using the NDA drug. The court held that the patent “does not belong in the Orange Book” because it “does not claim a drug” for which the NDA was approved and “does not claim ‘an approved method of using the drug’” because the claims were directed “to systems, not methods.” *Id.* at 90. The court therefore granted judgment on the pleadings that the patent was improperly listed in the Orange Book.

21. On November 7, 2023, the FTC issued notice letters to ten companies notifying them that FTC “believes certain patents have been improperly or inaccurately listed in the Orange Book” with respect to the companies’ NDA products and that FTC was using FDA’s regulatory dispute process to address the improper listings. *See, e.g.*, Letter from Off. of the Dir., Bureau of Competition, FTC, to Mylan Specialty LP 1 (Nov. 7, 2023),

https://www.ftc.gov/system/files/ftc_gov/pdf/mylan-specialty-orange-book.pdf; FTC, Warning Letters by Press Release, <https://www.ftc.gov/legal-library/browse/warning-letters/81927> (last visited Feb. 2, 2024) (listing notice letters).

22. In a press release announcing the FTC's actions, the FTC noted:

When a brand pharmaceutical company lists a patent in the Orange Book, it may lead to a statutory stay that generally blocks the introduction of competing drug products for 30 months, including lower-cost generic alternatives. Listing patents in the Orange Book may negatively affect competitive conditions if listings are improper, as defined by law.

Press Release, FTC, FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), <https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book>.

23. One of the notice letters that FTC sent was to Mylan Specialty LP regarding several patents that were listed for Mylan's EPIPEN and EPIPEN JR. NDA products. Letter from Off. of the Dir. to Mylan Specialty LP, *supra* ¶ 21. On information and belief, the patents that FTC is challenging as improperly listed as to EPIPEN and EPIPEN JR. are directed to autoinjector devices and aspects thereof.

Novo's Orange Book Patent-Listings for VICTOZA®

24. Novo Nordisk Inc. is the holder of NDA No. 022341, under which the FDA granted approval for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml) ("VICTOZA®").

25. Attached as Exhibit 2 is a true and correct excerpt from the 44th Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, for 2024 (available at <https://www.fda.gov/media/71474/download?attachment>). FDA also makes information in the Orange Book available online on its website. *See* FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, <https://www.accessdata.fda.gov>

/scripts/cder/ob/index.cfm (last visited Feb. 2, 2024). As of the filing of this counterclaim, the following patent information was listed in the Orange Book for NDA No. 022341 for VICTOZA®:

Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested
7762994	05/23/2024		DP		
7762994*PED	11/23/2024				
8114833	08/13/2025	DS	DP		
8114833*PED	02/13/2026				
9265893	09/23/2032		DP		
9265893*PED	03/23/2033				
9968659	01/09/2037			U-2313	
9968659*PED	07/09/2037				

Ex. 2, at ADA 257.

26. As of the filing of this counterclaim, there were four patents listed in the Orange Book for VICTOZA®: U.S. Patent No. 7,762,994; U.S. Patent No. 8,114,833; U.S. Patent No. 9,265,893; and U.S. Patent No. 9,968,659.

DRL's ANDA Product and Novo's Infringement Allegation

27. DRL submitted Abbreviated New Drug Application (“ANDA”) No. 214411 (“DRL’s ANDA”) to the FDA seeking approval for Liraglutide Injection, 18 mg/3 mL (6 mg/mL) prefilled pens (“DRL’s ANDA Product”).

28. DRL’s ANDA includes a Paragraph IV certification under 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV certification”) that, *inter alia*, the ’833 and ’893 patents are invalid, unenforceable, or not infringed by DRL’s ANDA Product.

29. DRL sent notice of its Paragraph IV certification regarding the ’833 and ’893 patents on September 25, 2023 (“Notice Letter”), which provided a detailed statement of the factual and legal bases for its opinion that the ’833 patent and ’893 patent are invalid or not infringed, directly or indirectly either literally or under the doctrine of equivalents, by the

commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA Product. *See* Compl. ¶ 23.

30. The Notice Letter did not contain a Paragraph IV certification regarding U.S. Patent No. 9,968,659.

31. Novo filed this lawsuit on November 8, 2023, alleging that DRL's ANDA Product will infringe the '833 patent and the '893 patent.

32. The filing of this lawsuit triggered an automatic stay of approval of DRL's ANDA Product for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

33. The 30-month stay of approval of DRL's ANDA Product expires on March 25, 2026.

34. On information and belief, the '833 patent will expire on February 13, 2026.

35. On information and belief, the '893 patent will expire on March 23, 2033.

COUNT I

Declaratory Judgment Requiring Delisting of the '893 Patent from the Orange Book

36. DRL realleges and incorporates by reference the allegations of paragraphs 1–35 as though fully set forth herein.

37. The '893 patent claims a “push button connection for an injection device.”

38. No claim of the '893 patent recites any drug substance.

39. No claim of the '893 patent recites any drug product.

40. No claim of the '893 patent recites a method of using any drug substance.

41. No claim of the '893 patent recites a method of using any drug product.

42. The '893 patent does not claim liraglutide the drug substance, the drug product for which the applicant submitted NDA No. 022341, or a method of using such drug substance or drug product.

43. The specification of the '893 patent never mentions liraglutide or VICTOZA®.

44. At the time the '893 patent issued on February 23, 2016, FDA regulations required Novo to submit Form FDA 3542, detailing specified patent information, to the FDA regarding NDA No. 022341 within 30 days of the date of issuance of the patent. 21 C.F.R. § 314.53(c)(2)(ii) (2016).

45. On information and belief, within 30 days of issuance of the '893 patent, Novo submitted Form FDA 3542 to the FDA regarding NDA No. 022341.

46. FDA regulations required Novo to submit specific information in Form FDA 3542 regarding NDA No. 022341 including whether the '893 patent “claims the drug substance that is an active ingredient in the drug product described in the approved NDA,” *id.* § 314.53(c)(2)(ii)(N)(1), whether the '893 patent “claims the approved drug product,” *id.* § 314.53(c)(2)(ii)(O)(1), and whether the '893 patent “claims one or more approved methods of using the approved drug product,” *id.* § 314.53(c)(2)(ii)(P)(1).

47. “Drug substance” is defined by FDA regulations as “an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use[d] in the synthesis of such ingredient.” *Id.* § 314.3.

48. On information and belief, Novo did not submit a request that FDA list the '893 patent in the Orange Book for VICTOZA® as a patent that “claims a drug substance that is an active ingredient in the drug product described in the approved NDA.” *Id.* § 314.53(c)(2)(ii)(N)(1).

49. “Drug product” is defined by FDA regulations as “a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.” *Id.* § 314.3.

50. On information and belief, Novo did not submit information in Form FDA 3542 regarding NDA No. 022341 detailing whether the ’893 patent “claims the approved drug product.” *Id.* § 314.53(c)(2)(ii)(O)(1).

51. On information and belief, Novo did not submit information in Form FDA 3542 regarding NDA No. 022341 detailing whether the ’893 patent “claims one or more approved methods of using the approved drug product.” *Id.* § 314.53(c)(2)(ii)(P)(1).

52. For method-of-use patents, FDA regulations require the NDA holder to submit a “description of the patented method of use as required for publication.” *Id.* § 314.53(c)(2)(ii)(P)(3).

53. On information and belief, Novo did not submit information in Form FDA 3542 regarding NDA No. 022341 with respect to the ’893 patent a “description of the patented method of use as required for publication.” *Id.* § 314.53(c)(2)(ii)(P)(3).

54. According to the Orange Book, the information provided by the NDA holder in Form FDA 3542 will be published by FDA in the Orange Book. *See* Ex. 2, at AD2.

55. Because the ’893 patent does not claim the drug substance or drug product, or methods of using the drug or drug product, that are the subject of NDA No. 022341, it is not properly listed in the Orange Book in association with that NDA. The ’893 patent should be delisted from the Orange Book as a patent that is listed for NDA No. 022341 for failure to comply with 21 U.S.C. §§ 355(b) and (c) and 21 C.F.R. §§ 314.53(b) and (c).

56. DRL will be irreparably harmed if the '893 patent is not delisted from the Orange Book because the improper listing of the '893 patent and Novo's suit based on that listing currently blocks approval of DRL's ANDA Product and interferes with DRL's business.

57. A definite and concrete, real and substantial, justiciable controversy exists between DRL and Novo concerning whether the '893 patent is properly listed in the Orange Book, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

58. DRL is entitled to an order under 21 U.S.C. § 355(j)(5)(C)(ii) requiring Novo to delete the '893 patent from the Orange Book listing for NDA No. 022341 because the patent does not claim the drug for which NDA No. 022341 is approved or methods of using that drug.

COUNT II
Declaratory Judgment of Non-Infringement of the '833 Patent

59. DRL realleges and incorporates by reference the allegations of paragraphs 1–58 as though fully set forth herein.

60. A present, genuine, and justiciable controversy exists between DRL and Novo regarding, *inter alia*, whether the manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of DRL's ANDA Product would infringe any valid and enforceable claim of the '833 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

61. The manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of DRL's ANDA Product would not infringe any valid and enforceable claim of the '833 patent, either directly or indirectly.

62. DRL is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid and enforceable claims of the '833 patent.

COUNT III
Declaratory Judgment of Non-Infringement of the '893 Patent

63. DRL realleges and incorporates by reference the allegations of paragraphs 1–62 as though fully set forth herein.

64. A present, genuine, and justiciable controversy exists between DRL and Novo regarding, *inter alia*, whether the manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of DRL's ANDA Product would infringe any valid and enforceable claim of the '893 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

65. The manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of DRL's ANDA Product would not infringe any valid and enforceable claim of the '893 patent, either directly or indirectly.

66. DRL is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid and enforceable claims of the '893 patent.

COUNT IV
Declaratory Judgment of Invalidity of the '833 Patent

67. DRL realleges and incorporates by reference the allegations of paragraphs 1–66 as though fully set forth herein.

68. A present, genuine, and justiciable controversy exists between DRL and Novo regarding, *inter alia*, the invalidity of the '833 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

69. In accordance with 21 U.S.C. § 355(j)(2)(B), DRL's Notice Letter included a detailed statement of factual and legal bases for why one or more claims of the '833 patent are invalid.

70. Upon information and belief, the claims of the '833 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et. seq., including but not limited to §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

71. DRL is entitled to a judicial declaration that the claims of the '833 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

COUNT V
Declaratory Judgment of Invalidity of the '893 Patent

72. DRL realleges and incorporates by reference the allegations of paragraphs 1–71 as though fully set forth herein.

73. A present, genuine, and justiciable controversy exists between DRL and Novo regarding, *inter alia*, the invalidity of the '893 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

74. Upon information and belief, the claims of the '893 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et. seq., including but not limited to §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or judicially created doctrines of invalidity or unenforceability.

75. DRL is entitled to a judicial declaration that the claims of the '893 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for double-patenting.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully prays for judgment in its favor and against Counterclaim Defendant:

(a) Declaring that the filing of DRL's ANDA does not infringe any valid and enforceable claim of the Patents-in-Suit;

(b) Declaring that the manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of DRL's ANDA Product described in DRL's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale in the United States, or imported into the United States—infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit either literally or under the doctrine of equivalents;

(c) Declaring that the claims of the '833 patent are invalid;

(d) Declaring that the claims of the '893 patent are invalid;

(e) Ordering that Novo request FDA to delist the '893 patent from the Orange Book listings for VICTOZA®;

(f) Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of DRL;

(g) Denying Plaintiff/Counterclaim Defendant any of the relief requested in the Complaint;

(h) Declaring this case exceptional in favor of DRL pursuant to 35 U.S.C. § 285;

(i) Awarding costs and attorneys' fees to DRL; and

(j) Awarding DRL such other and further relief the Court may deem just and proper.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, DRL, by their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding.

Dated: February 5, 2024

By: /s/ Rebekah R. Conroy

OF COUNSEL:

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, DRL, by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: February 5, 2024

By: /s/ Rebekah R. Conroy

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