IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. 20-747 (CFC)
SANDOZ INC.,	)	
Defendant.	)	

SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendant Sandoz Inc. ("Sandoz"), by and through the undersigned attorneys, answers the Complaint of Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively "Plaintiffs"), as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Sandoz seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Victoza® prior to the expiration of United States Patent Nos. 6,268,343 (the "'343 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent"), 8,579,869 (the "'869 patent"), 8,846,618 (the "'618 patent"), and 9,265,893 (the "'893 patent"), which cover inter alia, Victoza® and/or its use.

ANSWER: Sandoz admits that Plaintiffs purport to bring this action for infringement of United States Patent Nos. 6,268,343 (the "'343 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent"), 8,579,869 (the "'869 patent"), 8,846,618 (the "'618 patent"), and 9,265,893 (the "'893 patent") under the patent laws of the United States, Title 35 of the United States Code. Sandoz denies all remaining allegations of Paragraph 1.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") 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.

ANSWER: Upon information and belief, Sandoz admits that Novo Nordisk Inc. purports to be a Delaware corporation with a principal place of business in Plainsboro, New Jersey. Sandoz is without sufficient information to admit or deny the remaining allegations of Paragraph 2 and therefore denies the same.

3. Plaintiff Novo Nordisk A/S ("NNAS") 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. NNI is an indirect, wholly-owned subsidiary of NNAS.

ANSWER: Upon information and belief, Sandoz admits that Novo Nordisk A/S purports to be an entity organized and existing under the laws of the Kingdom of Denmark with a principal place of business in Bagsværd, Denmark, and that Novo Nordisk Inc. purports to be an indirect, wholly-owned subsidiary of Novo Nordisk A/S. Sandoz is without sufficient information to admit or deny the remaining allegations of Paragraph 3 and therefore denies the same.

4. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 100 College Road West, Princeton, NJ 08540. On information and belief, Sandoz Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

ANSWER: Admitted that Sandoz Inc. has its principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz further admits that it sells generic drug products in the United States. Sandoz denies any and all remaining allegations of Paragraph 4.

THE PATENTS-IN-SUIT

5. On July 31, 2001, the United States Patent and Trademark Office issued the '343 patent, entitled "Derivatives of GLP-1 Analogs," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '343 patent.

ANSWER: Sandoz admits that the '343 patent is titled "Derivatives of GLP-1 Analogs." Sandoz further admits that what purports to be a copy of the '343 patent is attached to the Complaint as Exhibit A. Sandoz denies the remaining allegations of Paragraph 5.

6. On July 27, 2010, the United States Patent and Trademark Office issued the '994 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '994 patent.

ANSWER: Sandoz admits that the '994 patent is titled "Needle Mounting System and a Method for Mounting a Needle Assembly." Sandoz further admits that what purports to be a copy of the '994 patent is attached to the Complaint as Exhibit B. Sandoz denies the remaining allegations of Paragraph 6.

7. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '833 patent.

ANSWER: Sandoz admits that the '883 patent is titled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices." Sandoz further admits that what purports to be a copy of the '883 patent is attached to the Complaint as Exhibit C. Sandoz denies the remaining allegations of Paragraph 7.

8. On November 12, 2013, the United States Patent and Trademark Office issued the '869 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '869 patent.

ANSWER: Sandoz admits that the '869 patent is titled "Needle Mounting System and a Method for Mounting a Needle Assembly." Sandoz further admits that what purports to be a copy of the '869 patent is attached to the Complaint as Exhibit D. Sandoz denies the remaining allegations of Paragraph 8.

9. On September 30, 2014, the United States Patent and Trademark Office issued the '618 patent, entitled "Stable Formulation of Modified GLP-1," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '618 patent.

ANSWER: Sandoz admits that the '618 patent is titled "Stable Formulation of Modified GLP-1." Sandoz further admits that what purports to be a copy of the '618 patent is attached to the Complaint as Exhibit E. Sandoz denies the remaining allegations of Paragraph 9.

10. On February 23, 2016, the United States Patent and Trademark Office issued the '893 patent, entitled "Injection Button," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '893 patent.

ANSWER: Sandoz admits that the '893 patent is titled "Injection Button." Sandoz further admits that what purports to be a copy of the '893 patent is attached to the Complaint as Exhibit F. Sandoz denies the remaining allegations of Paragraph 10.

VICTOZA®

11. NNI holds approved New Drug Application No. 022341 (the "Victoza® NDA") for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Victoza®.

ANSWER: Sandoz is without sufficient information to admit or deny the allegations of Paragraph 11 and therefore denies the same.

12. The claims of the patents-in-suit cover, inter alia, Victoza® and/or its use.

ANSWER: Paragraph 12 contains legal allegations and conclusions to which no answer is required. To the extent any answer is necessary, Sandoz denies the allegations of Paragraph 12.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '994, '833, '869, '618, and '893 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Victoza®.

ANSWER: Sandoz does not contest that the electronic version of the United States Food and Drug Administration's ("FDA") publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book"), identifies the '343, '994, '833, '869, '618, and '893 patents with respect to Victoza®. The remaining allegations in

Paragraph 13 contain legal conclusions to which no answer is required. To the extent any answer is necessary, Sandoz denies the remaining allegations of Paragraph 13.

SANDOZ'S ANDA

14. On information and belief, Sandoz submitted ANDA No. 212972 ("Sandoz's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Sandoz's Product").

ANSWER: Admitted that Sandoz filed ANDA No. 212972 seeking FDA approval to market a liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Sandoz's Product"). Sandoz objects to and therefore denies the remaining allegations of Paragraph 14 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

15. On information and belief, Sandoz's ANDA refers to and relies upon the Victoza® NDA and contains data that, according to Sandoz, demonstrate the bioequivalence of Sandoz's Product and Victoza®.

ANSWER: Admitted that Sandoz's ANDA contains data that supports the bioequivalence of the Sandoz Product. The remaining allegations in Paragraph 15 contain legal conclusions to which no answer is required. To the extent any answer is necessary, Sandoz denies the remaining allegations of Paragraph 15.

16. By letter to NNI and NNAS, dated April 20, 2020 and sent via FedEx Priority Overnight Service (the "Notice Letter"), Sandoz stated that Sandoz's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '994, '833, '869, '618, and '893 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Product (the "Paragraph IV Certifications"). Sandoz attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certifications. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

ANSWER: Admitted that Sandoz sent Plaintiffs a letter, dated April 20, 2020, via FedEx Priority Overnight Service stating that the '343, '994, '833, '869, '618, and '893 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Sandoz's ANDA. Further admitted that Sandoz provided factual

and legal bases for its statements regarding invalidity, unenforceability, and non-infringement. Sandoz objects to and therefore denies the remaining allegations of Paragraph 16 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz does not contest that subject matter jurisdiction is proper for any properly listed patents asserted under 35 U.S.C. § 271(e)(2)(A). Sandoz denies any and all remaining allegations of Paragraph 17.

18. This Court has personal jurisdiction over Sandoz by virtue of, inter alia, it having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court; having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, *Merck Sharp & Dohme Corp. v. Sandoz Inc.,* No. 19-312 (D. Del.); *Otsuka Pharm. Co., Ltd. v. Sandoz Inc.*, No. 19-2080 (D. Del.)); and having engaged in systematic and continuous contacts with the State of Delaware.

ANSWER: Paragraph 18 contains legal and factual conclusions to which no answer is required. Sandoz further answers that Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action only for any claims properly before this Court. Otherwise denied.

19. On information and belief, Sandoz intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product, directly or indirectly, throughout the United States and in this District. Sandoz's filing of Sandoz's ANDA confirms this intention and subjects Sandoz to the specific personal jurisdiction of this Court. *See Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*, 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

ANSWER: Paragraph 19 contains legal and factual conclusions to which no answer is required. Sandoz further answers that Sandoz does not contest specific personal jurisdiction in

this judicial district solely for the limited purposes of this action only for any claims properly before this Court. Otherwise denied.

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 20 contains legal conclusions to which no response is required. To the extent an answer is required, denied. Sandoz further answers that Sandoz does not contest venue in this judicial district solely for the limited purposes of this action only for any claims properly before this Court.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,268,343

21. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-20 of this Complaint.

ANSWER: Sandoz incorporates by reference its answers to the allegations in Paragraphs 1-21 as if fully set forth herein.

22. Sandoz has infringed the '343 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '343 patent.

ANSWER: Denied. Sandoz further objects to the allegations in Paragraph 22 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

23. Claims 1-3 and 14 of the '343 patent encompass liraglutide; claims 28, 29, 31, 32 and 33 of the '343 patent encompass pharmaceutical compositions comprising liraglutide; and claim 39 of the '343 patent encompasses a method of treating diabetes comprising administering to a patient a therapeutically effective amount of liraglutide. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '343 patent would infringe at least claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the '343 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Sandoz further objects to the allegations in Paragraph 23 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

24. Upon information and belief, Sandoz's sale or offer for sale of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, or commercial marketing of Sandoz's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Sandoz's Product in the United States, thus inducing infringement of claim 39 of the '343 patent.

ANSWER: Denied. Sandoz further objects to the allegations in Paragraph 24 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

25. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '343 patent.

ANSWER: Denied.

26. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

27. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,762,994

28. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-27 of this Complaint.

ANSWER: Sandoz incorporates by reference its answers to the allegations in Paragraphs 1-27 as if fully set forth herein.

29. Sandoz has infringed the '994 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '994 patent.

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. § 271(e)(2)(A). Sandoz further objects to the allegations in Paragraph 29 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

30. Claims 1-8 of the '994 patent encompass a mounting system for mounting two different needle arrangements. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '994 patent would infringe claims 1-8 of the '994 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Sandoz further objects to the allegations in Paragraph 30 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

31. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '994 patent.

ANSWER: Denied.

32. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

33. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

34. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-33 of this Complaint.

ANSWER: Sandoz incorporates by reference its answers to the allegations in Paragraphs 1-33 as if fully set forth herein.

35. Sandoz has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '833 patent.

ANSWER: Denied. Sandoz further objects to the allegations in Paragraph 35 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

36. Claims 1-15 of the '833 patent are directed to GLP-1 formulations. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing clogging by replacing the isotonicity agent in a formulation with propylene glycol.

Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Sandoz further objects to the allegations in Paragraph 36 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

37. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '833 patent.

ANSWER: Denied.

38. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

39. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,579,869

40. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-39 of this Complaint.

ANSWER: Sandoz incorporates by reference its answers to the allegations in Paragraphs 1-39 as if fully set forth herein.

41. Sandoz has infringed the '869 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '869 patent.

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. § 271(e)(2)(A). Sandoz further objects to the allegations in Paragraph 41 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

42. Claims 1-6 of the '869 patent are directed to a needle mount. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or

importation of Sandoz's Product into the United States, during the term of the '869 patent would infringe claims 1-6 of the '869 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Sandoz further objects to the allegations in Paragraph 42 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

43. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '869 patent.

ANSWER: Denied.

44. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

45. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,846,618

46. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-45 of this Complaint.

ANSWER: Sandoz incorporates by reference its answers to the allegations in Paragraphs 1-45 as if fully set forth herein.

47. Sandoz has infringed the '618 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '618 patent.

ANSWER: Denied. Sandoz further objects to the allegations in Paragraph 47 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

48. Claims 1-3 and 5-14 of the '618 patent are directed to pharmaceutical formulations comprising liraglutide wherein the pharmaceutical formulation has a pH from 7.5 to 9.4. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States,

or importation of Sandoz's Product into the United States, during the term of the '618 patent would infringe claims 1-3 and 5-14 of the '618 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Sandoz further objects to the allegations in Paragraph 48 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

49. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '618 patent.

ANSWER: Denied.

50. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

51. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

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

52. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-51 of this Complaint.

ANSWER: Sandoz incorporates by reference its answers to the allegations in Paragraphs 1-51 as if fully set forth herein.

53. Sandoz has infringed the '893 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '893 patent.

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. § 271(e)(2)(A). Sandoz further objects to the allegations in Paragraph 53 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

54. Claims 1-6 of the '893 patent are directed to a push button connection for an injection device. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's

Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '893 patent would infringe claims 1-6 of the '893 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied. Plaintiffs have no legal basis to allege infringement under 35 U.S.C. §§ 271(a), (b), and/or (c). Sandoz further objects to the allegations in Paragraph 54 because they are not a short and plain statement and because they contain mixed allegations of law and fact.

55. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '893 patent.

ANSWER: Denied.

56. Novo Nordisk has no adequate remedy at law.

ANSWER: Denied.

57. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

A response is not required to Plaintiffs' prayer for relief. To the extent any answer is necessary, Sandoz denies that Plaintiffs are entitled to any of the relief requested in Plaintiffs' Prayer For Relief, or any relief whatsoever. Sandoz has not infringed, directly or indirectly, any valid and enforceable claim of any of the '343, '994, '833, '869, '618 patent, and/or '893 patents, and Plaintiffs are not entitled to any remedy or recovery. Plaintiffs' prayer should therefore be denied in its entirety with prejudice. Further responding to Plaintiffs' Complaint, Sandoz alleges as follows:

AFFIRMATIVE DEFENSES

Sandoz asserts the following affirmative defenses and reserves the right to amend its Answer and conform its pleadings to the evidence as additional information becomes available.

First Affirmative Defense
(Non-Infringement)

The manufacture, use, sale, offer for sale, or importation into the United States of the drug product described in ANDA No. 212972 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '343, '994, '833, '869, '618, and '893 patents directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

Second Affirmative Defense
(Invalidity)

The claims of the '343, '994, '833, '869, '618, and '893 patents are invalid for failure to comply with the requirements of at least 35 U.S.C. §§ 101, 102, 103, and/or 112, for obviousness-type double patenting, and/or for any other judicially created and/or non-statutory bases for invalidity or unenforceability.

Third Affirmative Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim against Sandoz upon which relief can be granted.

Fourth Affirmative Defense
(Lack of Subject Matter Jurisdiction)

The Court does not have subject matter jurisdiction for an action brought pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

Fifth Affirmative Defense
(Prosecution History Estoppel)

Plaintiffs' claims of patent infringement under the doctrine of equivalents, if any, are barred in whole or in part by the doctrine of prosecution history estoppel and/or prosecution disclaimer.

Sixth Affirmative Defense
(Ensnarement)

Plaintiffs' claims of patent infringement under the doctrine of equivalents, if any, are barred

under the doctrine of ensnarement.

Seventh Affirmative Defense
(Safe Harbor Provision of 35 U.S.C. § 271(e)(1))

The activities Sandoz performed in relation to Sandoz's ANDA Product have been solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

Eighth Affirmative Defense
(No Injunctive Relief)

Plaintiffs may not seek injunctive relief against Sandoz because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

Ninth Affirmative Defense
(No Exceptional Case)

Plaintiffs cannot prove that this is an exceptional case justifying an award of attorney fees against Sandoz pursuant to 35 U.S.C. § 285.

RESERVATION OF ALL AFFIRMATIVE DEFENSES

Sandoz reserves the right to offer any other and additional defense that is now or may become available or appear during, or as a result of, discovery proceedings in this action.

WHEREFORE, Sandoz requests that the Complaint be dismissed with prejudice and that Sandoz be awarded the costs of this action, their attorneys' fees, and all other relief that this Court deems just and proper.

SANDOZ'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Sandoz Inc., by way of its attorneys, hereby pleads the following Counterclaims against Counterclaim-Defendants Novo Nordisk A/S and Novo Nordisk Inc.

THE PARTIES

1. Sandoz, Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 100 College Road West, Princeton, New Jersey 08540.

2. On information and belief, Counterclaim-Defendant Novo Nordisk Inc. avers it 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.

3. On information and belief, Counterclaim-Defendant Novo Nordisk A/S avers it 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.

4. Upon information and belief, Counterclaim-Defendant Novo Nordisk Inc. avers it is an indirect, wholly-owned subsidiary of Novo Nordisk A/S.

JURISDICTION AND VENUE

5. These counterclaims seek declaratory relief arising under the patent laws of the United States, Title 35, United States Code.

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 21 U.S.C. § 355(j)(5)(C)(ii)(I).

7. The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and 21 U.S.C. § 355(j)(5)(C)(ii)(I).

8. The Court has personal jurisdiction over Novo Nordisk A/S because, *inter alia*, Novo Nordisk Inc. subjected itself to the jurisdiction of this Court by filing this action.

9. The Court has personal jurisdiction over Novo Nordisk Inc. because, *inter alia*, Novo Nordisk A/S subjected itself to the jurisdiction of this Court by filing this action, and because, on information and belief, Novo Nordisk A/S manufactures and markets branded drug

products, and continuously and systematically conducts business throughout the United States, including in Delaware and because, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

10. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400 and by virtue of the Counterclaim Defendants' filing of this action in this Court.

FACTUAL BACKGROUND

11. According to the United States Food & Drug Administration ("FDA") publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations (the "Orange Book"), Novo Nordisk Inc. is the holder of New Drug Application ("NDA") No. 022341 for Victoza®, Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), approved on January 25, 2010.

12. Upon information and belief, Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in patients ten years and older with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

13. A company seeking FDA approval to market a drug subject to an NDA may submit to the FDA for listing in the Orange Book the "patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug." 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists these patents in the Orange Book.

14. The Orange Book for Victoza® lists in relevant part U.S. Patent Nos. 6,268,343 (the "'343 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent"), 8,579,869 (the "'869 patent"), 8,846,618 (the "'618 patent"), and 9,265,893 (the "'893 patent") (collectively, "the Asserted Patents") .

15. The '343 patent is entitled "Derivatives of GLP-1 Analogs" with an issue date of July 31, 2001.

16. The '994 patent is entitled "Needle Mounting System and a Method for Mounting a Needle Assembly" with an issue date of July 27, 2010.

17. The '833 patent is entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and for Use in Injection Devices" with an issue date of February 14, 2012.

18. The '869 patent is entitled "Needle Mounting System and a Method for Mounting a Needle Assembly" with an issue date of November 12, 2013.

19. The '618 patent is entitled "Stable Formulation of Modified GLP-1" with an issue date of September 30, 2014.

20. The '893 patent is entitled "Injection Button" with an issue date of February 23, 2016.

21. Upon information and belief, Novo Nordisk A/S owns the Asserted Patents.

22. Sandoz filed its Abbreviated New Drug Application ("Sandoz ANDA") No. 212972 under 21 U.S.C. § 355(j) seeking FDA approval for the commercial manufacture, use, or sale in the United States of Liraglutide Injection 18 mg/3 ml (6 mg/ml) prefilled pens ("the Sandoz Product"). The Sandoz ANDA contained certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal, Food, Drug and Cosmetic Act ("FDCA") that the Asserted Patents are unenforceable, invalid, and/or will not be infringed by the Sandoz ANDA or the marketing, use or sale of the Sandoz Product.

23. Sandoz sent notice of these certifications to Counterclaim-Defendants on or about April 20, 2020. On information and belief, and as Counterclaim-Defendants allege in their

Complaint, Counterclaim-Defendants received this letter.

24. On June 3, 2020, Counterclaim-Defendants filed suit in this Judicial District against Sandoz in connection with Sandoz's efforts to gain approval from the FDA to market the Sandoz Product. D.I. 1.

25. An actual and justiciable controversy exists as to infringement of the Asserted Patents and the validity of the Asserted Patents because Counterclaim-Defendants brought an action alleging that the importation, manufacture, use, offer for sale, or sale of the products that are the subject of the Sandoz ANDA would infringe those patents, and Sandoz has denied the alleged infringement and further alleges that the claims of the Asserted Patents are invalid. These controversies are of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

COUNT I

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,268,343

26. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-25 above as if fully set forth herein.

27. Counterclaim-Defendants claim to be the owner of all rights, title, and interest in the '343 patent.

28. Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the '343 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the '343 patent.

29. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any valid claim of the '343 patent at least for the representative and nonlimiting reasons set forth in the letter, dated

April 20, 2020, sent by Counterclaim-Plaintiff to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the '343 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Sandoz's ANDA and/or as apparent from Sandoz's ANDA.

30. Counterclaim-Plaintiff 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, any claim of the '343 patent.

COUNT II

Declaratory Judgment of Invalidity of United States Patent No. 6,268,343

31. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-30 above as if fully set forth herein.

32. The claims of the '343 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.

33. By way of non-limiting example, claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the '343 patent, which Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes, are invalid pursuant to 35 U.S.C. § 103 as obvious in view of prior art disclosing the limitations of one or more claims of the '343 patent. Non-limiting examples of such art include U.S. Patent No. 5,118,666, U.S. Patent No. 5,512,549, and International Patent Application Publication No. WO 96/29342, in addition to the knowledge of a person of ordinary skill in the art ("POSA") and the state of the art.

34. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiff and Counterclaim-Defendants concerning whether the claims of the '343 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or

equitable doctrines.

35. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

36. Counterclaim-Plaintiff is entitled to a judicial declaration that claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the ’343 patent are invalid.

COUNT III

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,762,994

37. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-36 above as if fully set forth herein.

38. Counterclaim-Defendants claim to be the owner of all rights, title, and interest in the ’994 patent.

39. Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes claims 1–8 of the ’994 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the ’994 patent.

40. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any claim of the ’994 patent, at least for the representative and nonlimiting reasons set forth in the letter, dated April 20, 2020, sent by Counterclaim-Plaintiff to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the ’994 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Sandoz’s ANDA and/or as apparent from Sandoz’s ANDA.

41. Counterclaim-Plaintiff 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,

any claim of the '994 patent.

COUNT IV

Declaratory Judgment of Invalidity of United States Patent No. 7,762,994

42. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-41 above, as if fully set forth herein.

43. The claims of the '994 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.

44. By way of non-limiting example, claims 1–8 of the '994 patent, which Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes, are invalid pursuant to 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious in view of prior art disclosing the limitations of claims 1–8 of the '994 patent. Non-limiting examples of such art include U.S. Patent No. 5,129,888, in addition to the knowledge of a POSA and the state of the art.

45. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiff and Counterclaim-Defendants concerning whether the claims of the '994 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

46. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

47. Counterclaim-Plaintiff is entitled to a judicial declaration that claims 1–8 of the '994 patent are invalid.

COUNT V

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,114,833

48. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-47 above as if fully set forth herein.

49. Counterclaim-Defendants claim to be the owner of all rights, title, and interest in the '833 patent.

50. Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes claims 1-31 of the '833 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the '833 patent.

51. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any valid claim of the '833 patent at least for the representative and nonlimiting reasons set forth in the letter, dated April 20, 2020, sent by Counterclaim-Plaintiff to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the '833 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Sandoz's ANDA and/or as apparent from Sandoz's ANDA.

52. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '833 patent.

53. Counterclaim-Plaintiff 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, any claim of the '833 patent.

COUNT VI

Declaratory Judgment of Invalidity of United States Patent No. 8,114,833

54. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-53 above as if fully set forth herein.

55. 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.

56. By way of non-limiting example, claims 1-31 of the '833 patent, which Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes, are invalid pursuant to 35 U.S.C. § 103, as obvious in view of prior art disclosing the limitations of one or more claims of the '618 patent. Non-limiting examples of such art include International Patent Application Publication No. WO 2003/002136 A2, in addition to the knowledge of a POSA and the state of the art.

57. In addition, the claims of the '833 patent are invalid for obviousness-type double patenting in view of at least the '618 patent.

58. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiff and Counterclaim-Defendants concerning whether claims of the '833 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

59. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

60. Counterclaim-Plaintiff is entitled to a judicial declaration that claims 1-31 of the '833 patent are invalid.

COUNT VII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,579,869

61. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-60 above as if fully set forth herein.

62. Counterclaim-Defendants claim to be the owner of all rights, title, and interest in the ’869 patent.

63. Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes claims 1–6 of the ’869 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the ’869 patent.

64. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any claim of the ’869 patent, at least for the representative and nonlimiting reasons set forth in the letter, dated April 20, 2020, sent by Counterclaim-Plaintiff to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the ’869 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Sandoz’s ANDA and/or as apparent from Sandoz’s ANDA.

65. Counterclaim-Plaintiff 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, any claim of the ’869 patent.

COUNT VIII

Declaratory Judgment of Invalidity of United States Patent No. 8,579,869

66. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-65 above as if fully set forth herein.

67. The claims of the '869 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.

68. By way of non-limiting example, claims 1–6 of the '869 patent, which Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes, are invalid pursuant to 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious in view of prior art disclosing the limitations of claims 1–6 of the '869 patent. Non-limiting examples of such art include U.S. Patent No. 5,129,888, in addition to the knowledge of a POSA and the state of the art.

69. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiff and Counterclaim-Defendants concerning whether one or more claims of the '869 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

70. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

71. Counterclaim-Plaintiff is entitled to a judicial declaration that claims 1-6 of the '869 patent are invalid.

COUNT IX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,846,618

72. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-71 above as if fully set forth herein.

73. Counterclaim-Defendants claim to be the owner of all rights, title, and interest in the '618 patent.

74. Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes claims

1-3 and 5-14 of the '618 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the '618 patent.

75. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any valid claim of the '618 patent at least for the representative and nonlimiting reasons set forth in the letter, dated April 20, 2020, sent by Counterclaim-Plaintiff to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the '618 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug products described in Sandoz's ANDA and/or as apparent from Sandoz's ANDA.

76. Counterclaim-Plaintiff 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, any claim of the '618 patent.

COUNT X

Declaratory Judgment of Invalidity of United States Patent No. 8,846,618

77. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-76 above, as if fully set forth herein.

78. The claims of the '618 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.

79. By way of non-limiting example, claims 1-3 and 5-14 of the '618 patent, which Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes, are invalid pursuant to 35 U.S.C. § 103 as obvious in view of prior art disclosing the limitations of one or more claims of the '618 patent. Non-limiting examples of such art include International Patent Application Publication No. WO 99/43341, in addition to the knowledge of a POSA and the state of the art.

80. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiff and Counterclaim-Defendants concerning whether claims of the ’618 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

81. The controversy between the parties is amenable to specific relief through a decree of conclusive character.

82. Counterclaim-Plaintiff is entitled to a judicial declaration that claims 1-3 and 5-14 of the ’618 patent are invalid.

COUNT XI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,265,893

83. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-82 above, as if fully set forth herein.

84. Counterclaim-Defendants claim to be the owner of all rights, title, and interest in the ’893 patent.

85. Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes claims 1–6 of the ’893 patent, and has created a real, substantial, and justiciable controversy between the parties as to the infringement of the ’893 patent.

86. Counterclaim-Plaintiff has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more of any claim of the ’893 patent, at least for the representative and nonlimiting reasons set forth in the letter, dated April 20, 2020, sent by Counterclaim-Plaintiff to Counterclaim-Defendants via FedEx Priority Overnight Service stating that the ’893 patent is invalid, unenforceable, and/or will not be infringed

by the commercial manufacture, use, or sale of the drug products described in Sandoz's ANDA and/or as apparent from Sandoz's ANDA.

87. Counterclaim-Plaintiff 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, any claim of the '893 patent.

COUNT XII

Declaratory Judgment of Invalidity of United States Patent No. 9,265,893

88. Counterclaim-Plaintiff restates and incorporates by reference the allegations in Paragraphs 1-87 above as if fully set forth herein.

89. 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.

90. By way of non-limiting example, claims 1–6 of the '893 patent, which Counterclaim-Defendants have alleged that Counterclaim-Plaintiff infringes, are invalid pursuant to 35 U.S.C. §§ 102 and 103 as anticipated and/or obvious in view of prior art disclosing the limitations of claims 1–6 of the '893 patent. Non-limiting examples of such art include International Patent Application Publication No. WO 2006/076921 and U.S. Patent No. 3,318,289, in addition to the knowledge of a POSA and the state of the art.

91. There is a real, substantial, and justiciable controversy between Counterclaim-Plaintiff and Counterclaim-Defendants concerning whether the claims of the '893 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

92. The controversy between the parties is amenable to specific relief through a decree

of conclusive character.

93. Counterclaim-Plaintiff is entitled to a judicial declaration that claims 1–6 of the '893 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully prays for judgment in its favor and against Plaintiff:

(a) Declaring that the filing of Sandoz's ANDA did not infringe one or more valid and enforceable claims of the '343, '994, '833, '869, '618, and '893 patents;

(b) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Product described in Sandoz's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of the '343, '994, '833, '869, '618, and '893 patents, either literally or under the doctrine of equivalents;

(c) Declaring that the claims of the '343, '994, '833, '869, '618, and '893 patents are invalid;

(d) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Sandoz;

(e) Denying Plaintiffs any of the relief requested in the Complaint;

(f) Declaring this case exceptional and awarding Sandoz its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(g) Awarding Sandoz such other and further relief as the Court may deem just and proper.

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