UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

SANDOZ INC., Plaintiff, v. NOVO NORDISK INC. and NOVO NORDISK A/S, Defendants.	Civil Action No. 11-cv-13594

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff, Sandoz Inc. ("Sandoz"), for its Complaint against Defendants Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. Sandoz brings – and is entitled by statute to maintain – this action for declaratory judgment of patent non-infringement, invalidity, and unenforceability under, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA")

seeking approval to market a generic version of Defendants' brand-name drug Prandin®, known generically as repaglinide.

3. Defendants purport to own U.S. Patent No. 6,677,358 ("the '358 patent"). A true and accurate copy of the '358 patent is attached hereto as **Exhibit A**.

4. On January 19, 2011, the District Court for the Eastern District of Michigan held that claim 4 of the '358 patent is invalid as obvious under 35 U.S.C. § 103 and that the '358 patent is unenforceable due to Novo's inequitable conduct before the Patent Office. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, No. 05-40188, 2011 WL 163996, *29, 37 (E.D. Mich. Jan. 19, 2011).

5. Upon submission by Defendants, the '358 patent was listed in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." As a consequence of such listing, Defendants maintain, and have affirmatively represented to the world, that the '358 patent claims the approved drug, Prandin®, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Sandoz, attempting to market a generic repaglinide product before patent expiration.

6. Sandoz seeks to market a non-infringing repaglinide product before the expiration of the '358 patent. Sandoz's ANDA product will not infringe any valid claim of the '358 patent. Thus, as required by statute, Sandoz has certified to FDA that the '358 patent is invalid or will not be infringed by Sandoz's ANDA product, and notified Defendants of the legal and factual bases for that certification on or about January 25, 2007.

7. Sandoz's submission of a so-called "paragraph IV" certification to the '358 patent constitutes an artificial act of patent infringement putting Sandoz at considerable risk

of being sued by Defendants both before and after market entry. Indeed, this regulatory submission created the necessary case or controversy and subject matter jurisdiction for Defendants to sue Sandoz for patent infringement. It likewise created the necessary case or controversy for Sandoz to file and maintain an action for declaratory judgment of patent invalidity and non-infringement regarding the '358 patent.

8. By listing the '358 patent in the Orange Book and not suing Sandoz on that patent, Defendants have created patent and legal uncertainty that impairs Sandoz's right to market a non-infringing generic product without the risk of infringement damages.

9. This patent and legal uncertainty and impairment of Sandoz's rights are, alone or in combination, sufficiently concrete and cognizable injuries-in-fact that are fairly traceable to the Defendants and that can be redressed only by a declaratory judgment from this Court.

10. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Sandoz and Defendants regarding infringement and invalidity of the '358 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

11. Sandoz is entitled to a judicial declaration that the '358 patent is invalid, unenforceable and/or the manufacture, sale, offer for sale, use, or importation of Sandoz's proposed generic repaglinide product does not and will not infringe the '358 patent. Absent the exercise of jurisdiction by this Court and such declaratory relief, Sandoz faces both patent uncertainty and indefinite delay in approval of its generic repaglinide tablets.

THE PARTIES

12. Plaintiff Sandoz Inc. is a corporation organized and existing under the laws of Colorado having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

13. On information and belief, Defendant Novo Nordisk Inc. is a Delaware corporation, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

14. On information and belief, Defendant Novo Nordisk A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Alle, 2880 Bagsvaerd, Denmark.

15. On information and belief, Defendants, through their various agents, affiliates, representatives, subsidiaries and/or alter egos, develop, manufacture, and sell pharmaceutical products throughout the world, including in the United States and in this District.

16. On information and belief, Defendants maintain such a continuous and systematic contact with the State of Michigan and this District by conducting substantial, regular and systematic business therein through the marketing and sales of their pharmaceutical products, including Prandin®, to allow this Court to reasonably exercise personal jurisdiction over Defendants.

17. On information and belief, Defendants purposefully avail themselves of the privilege of doing business in the State of Michigan and in this District.

18. On information and belief, Defendants also allegedly own United States patents that purport to cover pharmaceutical products sold in the United States and in this District, and from which Defendants derive substantial revenue. On information and belief,

Defendants facilitate the sale of its pharmaceutical products in the United States and in this District through various agents, affiliates, representatives, subsidiaries and/or alter egos.

19. On information and belief, Defendants' prescription medicines – including Prandin® – are regularly prescribed by physicians and dispensed by pharmacists in the United States and in this District.

JURISDICTION AND VENUE

20. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

21. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq*.; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the infringement of the '358 patent; and under the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

22. There exists a substantial and continuing actual, justiciable case or controversy between Sandoz and Defendants regarding invalidity, unenforceability and non-infringement of the '358 patent. (see paragraphs 112-130, below).

23. This Court can and should declare the rights and legal relations of the parties regarding invalidity, unenforceability and non-infringement of the '358 patent pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

24. Sandoz has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Sandoz's claims pursuant to 35 U.S.C. § 271(e)(5).

25. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants conduct substantial business in, and have regular and systematic contact with, this District. On information and belief, Defendants, *inter alia*:

a) market, promote and sell in this District, on a continuous and systematic basis, their pharmaceutical products, including purported commercial embodiments of the '358 patent, through various agents, affiliates, representatives, subsidiaries and/or alter egos;

b) derive substantial revenues, on a continuous and systematic basis, from their pharmaceutical products, including purported commercial embodiments of the '358 patent that are marketed, promoted and sold in the United States and within this District;

c) promote physicians in the State of Michigan to prescribe their medicines, including purported commercial embodiments of the '358 patent, through its agents, affiliates, representatives, subsidiaries and/or alter egos;

d) have created various agents, affiliates, representatives, subsidiaries and/or alter egos in the United States and in this District that serve no other business purpose or goal except to act solely for, in concert with and/or at the direction of Defendants;

e) through their various agents, affiliates, representatives, subsidiaries and/or alter egos, have previously submitted to and/or benefited from the jurisdiction of this District;

f) have availed themselves of the rights and privileges of this forum by suing other ANDA applicants in this District relating to the '358 patent purportedly covering the drug Prandin®, including in *Novo Nordisk, Inc. et al. v. Caraco Pharmaceutical Laboratories, Ltd. et al.*, Case No. 05-cv-40188; and

g) have otherwise purposefully availed themselves of the privileges of conducting activities within this District.

26. Venue is proper in this District under 28 U.S.C. § 1400(b). Venue is also proper in this District under 28 U.S.C. §§ 1391 because, *inter alia*, Defendants are subject to personal jurisdiction in this District.

BACKGROUND

I. Statutory Scheme For Approval Of New And Generic Drugs

27. The approval of new and generic drugs is governed by the applicable provisions of the FFDCA, 21 U.S.C. §§ 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by the MMA (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271).

II. New/Previously-Unapproved Drugs And Patent Listing Requirements

28. Before marketing a previously-unapproved drug (*i.e.*, not a generic drug) in the United States, the FFDCA, as amended by Hatch-Waxman and the MMA, requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C. § 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

29. An NDA applicant is required, within its NDA, to submit information (*e.g.*, the patent number and purported expiration date) regarding each patent that claims the "drug" or a "method of using [the] drug" that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the

patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(l); *see also id*. § 355(c)(2).

30. Upon approval of the NDA, FDA publishes patent information submitted by an NDA-holder in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

31. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent version of the NDA drug before patent expiration.

32. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

33. Such conduct by the NDA-holder/patent owner gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit, or the threat of one, if it attempts to seek approval for or to market a generic version of the NDA drug before patent expiration.

III. Generic Drugs And Patent Certification Requirements

34. The FFDCA, as amended by Hatch-Waxman and the MMA, provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain

regulatory approval of lower-priced generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

35. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to FDA under 21 U.S.C. § 355(j).

36. Instead of repeating the clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already-approved NDA drug (*i.e.*., has no significant difference in rate and extent of absorption) and that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

37. An ANDA applicant also is required to address each patent properly listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each properly listed patent: (I) that the NDA-holder/patent owner has not submitted any patent information to FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or

sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent. Such a paragraph IV certification constitutes an artificial act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

38. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder/patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal bases for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(iv).

39. The submission of a paragraph IV certification has two important consequences.

40. First, an applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic market exclusivity during which time no other ANDA for that drug product will be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

41. Second, the submission of a paragraph IV certification for a listed patent constitutes an act of patent infringement that creates the necessary case or controversy and

subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement-before the generic drug is actually made, used, or sold-to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

42. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued within the applicable 45-day period, as set forth below.

43. Upon receiving notice of a paragraph IV certification for a listed patent submitted by an ANDA applicant, the NDA-holder/patent owner may file suit for alleged infringement of the listed patent under 35 U.S.C. § 27l(e)(2)(A) within 45 days of receiving such notification. Such a suit automatically delays FDA from issuing final approval of the ANDA for up to thirty (30) months. 21 U.S.C. § 355(j)(5)(B)(iii). An ANDA applicant is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder/patent owner may bring suit after receiving notification of the ANDA and paragraph IV certification. *Id*.

44. If the NDA-holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, as explained below, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

45. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of lower-priced generic drug products. Congress intended that the

generic manufacturing and marketing of a drug should be allowed as soon as it is determined that the particular generic drug does not violate patent rights. Congress also determined that full generic competition would not be delayed indefinitely by the 180-day exclusivity period.

IV. Congress Explicitly Mandated That An ANDA-Filer May Bring And Maintain A Declaratory Judgment Action When The Brand Company Does Not Bring An Infringement Action

46. On December 8, 2003, the MMA was signed into law. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, Hatch-Waxman.

47. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/ patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

48. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

49. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

50. The new declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes these proceedings.

51. Congress' intent in amending 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) was to extend to ANDA applicants, like Sandoz here, the right to file and maintain a declaratory judgment action for patent non-infringement and/or invalidity against an NDA-holder/patent owner, and grant the court subject matter jurisdiction in such an action.

52. The purpose of this provision was two-fold. The first purpose was to allow generic applicants to obtain patent certainty before marketing their generic products.

53. The second purpose was to allow generic applicants to obtain court decisions that would expedite the introduction of generic drugs by triggering any 180-day exclusivity that would block or delay the timely approval of a subsequent applicant's ANDA.

V. The '358 Patent

54. The Patent Office issued the '358 patent on January 13, 2004. It is entitled "NIDDM Regimen." The '358 patent lists Peter Giørtz Müller as the purported named inventor.

55. According to the electronic records of the FDA, the '358 patent is purportedly scheduled to expire on or about June 12, 2018.

56. Upon information and belief, Novo Nordisk A/S is the purported owner of the '358 patent.

57. Upon information and belief, Defendants purport and claim to own and have the right to enforce the '358 patent.

A. Prosecution Of The '358 Patent

58. The '358 patent issued from U.S. Patent Application No. 09/459,526 ("the '526 application). On or about December 13, 1999, applicants Dr. Peter Müller and Dr. Lisbeth Hemingsen filed the '526 application with the United States Patent and Trademark Office ("USPTO") which claimed, *inter alia*, a method of treating patients with non-insulin dependent diabetes mellitus ("NIDDM") by administering a combination of repaglinide with another drug that was used to treat NIDDM, metformin. Dr. Müller subsequently became the only listed inventor and applicant because of amendments to the claimed subject matter during the prosecution of the '526 application. The '526 application was assigned to Plaintiff Novo A/S and was prosecuted by attorneys at Novo Nordisk Inc.

59. Upon examination of the '526 application, the PTO Examiner rejected the claims because the prior art showed that it would have been obvious to combine repaglinide and metformin to treat patients with NIDDM. For example, on or about October 19, 2000, the Examiner stated that the prior art "teaches combination therapy as a rational approach to the treatment of NIDDM comprising administering agents that have different mechanisms of action and different side-effect profiles."

60. Despite Defendants' arguments in response to the rejection, the Examiner maintained the rejection of the claims in three more Office Actions. For example, in the April 16, 2002 Office Action, the Examiner did not find Defendants' arguments persuasive

because "the prior ar[t] is replete with examples of combination therapy wherein side-effects are minimized, dosages are reduced and a more clinically beneficial outcome is observed as compared with monotherapy."

61. In response to these rejections, Defendants argued that the combination of repaglinide and metformin had synergistic effects that a skilled artisan would not have predicted. In support of their contention, Defendants relied on results from a clinical trial labeled as Example 3 in the application ("Example 3"). Defendants also referred to the statement in the '526 application that "[s]urprisingly, it has been found that when repaglinide is administered together with metformin to NIDDM patients whose glycaemic control is poor on metformin alone a significant improvement in the glycaemic control is observed. More particularly, it has been found that there is a synergism between repaglinide and metformin."

62. On or about April 16, 2002, the USPTO issued a final office action rejecting all of the pending claims of the '526 application as obvious and/or anticipated.

63. On or about October 16, 2002, the applicant submitted an "Amendment and Response" to the April 16, 2002 office action along with a declaration from Dr. Jeppe Sturis, a principal scientist for Novo Nordisk A/S. Dr. Sturis described the result of a study in which he examined the effects of treating obese Zucker rats with a combination of repaglinide and metformin, the results of which he concluded, when considered in combination with Example 3 in the patent specification, "strongly suggest[ed] that the combination of repaglinide and metformin has synergistic properties in type 2 diabetic patients." The applicant argued in the "Amendment and Response" that "data presented in the Declaration of Dr. Sturis, provides clear evidence of synergy for the use of the claimed combination of repaglinide and metformin in the treatment of Type II diabetes."

64. Dr. Sturis did not attach the actual study report to his declaration. That report makes it clear that the study did not support a finding that the rat study had any clinical relevance to the effect of the repaglinide-metformin combination in humans. In his report, which is an internal Novo Nordisk document not disclosed to the USPTO, Dr. Sturis stated that "[i]n conclusion, we have demonstrated synergistic effects of repaglinide and metformin on glucose tolerance in the male Zucker rat. We speculate that the presence of greater than additive effects may be clinically relevant." *See* NOVO-0028139-41 at NOVO-0028140.

65. After Defendants ' submission of Dr. Sturis's declaration, on or about December 30, 2002, the examiner allowed the claims directed to the combination of repaglinide and metformin "[b]ased solely on the Declaration submitted by Dr. Sturis and reconsideration of the synergistic effects demonstrated in Example 3[.]"

66. Novo Nordisk has conceded in *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, No. 2:05-cv-40188 (E.D. Mich.) ("*Caraco*"), that Example 3 and Dr. Sturis's declaration are the only scientific data submitted during the prosecution of the '526 application to support the contention that the combination of repaglinide and metformin has synergistic effects.

67. As discussed in more depth in the following paragraphs, Novo Nordisk misled the examiner by not disclosing material information during the prosecution of the '358 patent.

68. Novo Nordisk never disclosed to the USPTO three clinical studies conducted by Novo Nordisk A/S that directly conflicted with applicant's representation to the Examiner that "it has been found" that the combination of repaglinide and metformin had a synergistic effect:

a) On January 16, 2001, Novo Nordisk A/S initiated a clinical study with a trial ID of AGEE-3010. *See* NOVO-2536342-412. Upon information and belief, the study assessed the effect on glycaemic control before and after treatment with repaglinide or repaglinide and metformin combination therapy in patients with type 2 diabetes. *See* NOVO-2536344. On or about December 2, 2002, Novo Nordisk A/S issued a final report for AGEE-3010. The final report states "[w]hen analysed by repaglinide monotherapy and repaglinide and metformin combination therapy, the synergistic effect of combination therapy observed by Moses *et al* was not consistently seen in this trial." *See* NOVO-2536403 (footnote omitted). Upon information and belief, the Moses et al. publication referenced in this final report contained the same data and results as described in Example 3.

b) On or about July 25, 2002, Novo Nordisk A/S initiated a clinical study with a trial ID of AGEE-3018. *See* NOVO-6854351-416. The study was conducted to compare the efficacy profile of repaglinide in combination with metformin as compared to metformin or repaglinide given as monotherapy for the treatment of type 2 diabetes. *See* NOVO-6854353. On or about September 29, 2003, Novo Nordisk A/S issued a final report for AGEE-3018. The final report states "[t]he results observed in this study were contrary to the study by Moses *et al* which showed that HbA_{1c} and FPG were significantly improved in the combination therapy of repaglinide/metformin compared to treatment with either drug as monotherapy in obese type 2 diabetic subjects. The synergistic effect of combination therapy observed by Moses *et al* was not consistently seen in this trial (only between combination and repaglinide for HbA_{1c})." *See* NOVO-6854407 (footnotes omitted).

c) On or about March 6, 2002, Novo Nordisk A/S initiated a clinical study with a trial ID of AGEE-1411. *See* NOVO-1321712-70. The study was conducted to compare the efficacy of metformin and repaglinide used in monotherapy with the combination therapy of metformin and repaglinide. *See* NOVO-1321713. On or about February 20, 2006, Novo Nordisk A/S issued a final report for AGEE-1411. The final report states that "[t]here was not a statistically significant difference among treatments for the change of HbA1c (%) in blood from baseline, neither for the intent to treat population, nor for per protocol population; that is, the three treatments [repaglinide monotherapy, metformin monotherapy, and the combination therapy of metformin and repaglinide] have the same effect over the patients, as the HbA1c was reduced in all treatments from visit 1 to visit 6." *See* NOVO-1321761.

69. These three clinical studies are all dated *before* the '358 patent issued on January 13, 2004, yet neither the existence nor the outcome of studies AGEE-3010, AGEE-3018, or AGEE-1411 were disclosed to the USPTO during the prosecution of that patent.

70. Novo Nordisk's failure to disclose these three clinical studies to the Examiner constitutes a material omission. The results of these clinical trials conflict with the representations made by Novo A/S, Dr. Müller, and Dr. Sturis during the prosecution of the '358 patent that the combination of repaglinide and metformin had synergistic effect when used to treat patients with NIDDM. These were the very representations that provided the *sole* basis for overcoming the Examiner's repeated rejections of the application underlying the '358 patent.

71. One of Novo Nordisk's own documents confirms that these studies were material to the prosecution of the '358 patent. In an email dated January 9, 2007, Novo Nordisk employees highlighted the importance of one of the studies, AGEE-3018, to the subject of a combination of repaglinide and metformin to treat patients with type 2 diabetes. The email concerned the potential disclosure of AGEE-3018 to the FDA as part of the NN4440 project. Upon information and belief, project "NN4440" concerns or concerned the development of a fixed combination product of repaglinide and metformin. In this email, Defendants' employee Cliff Hall stated, "this trial appears relevant, and I don't see how we can avoid including it" in a production to FDA. *See* NOVO-1651059-61 at NOVO-1651060. There is no basis to believe that the study would be relevant to FDA's consideration of the NN4440 project, but not relevant to the prosecution of the '358 patent, which concerns the identical subject matter.

72. Upon information and belief, the existence and/or outcome of studies AGEE-3010, AGEE-3018, and AGEE-1411 were known to Defendants' attorneys who prosecuted the '358 patent, Dr. Müller and/or Dr. Sturis. In the alternative, these individuals were deliberately ignorant of those studies. There is no credible explanation for the nondisclosure

of these studies to Defendants' attorneys who prosecuted the '358 patent, Dr. Müller and/or Dr. Sturis.

73. Defendants never disclosed to the USPTO that one skilled in the art could not determine if a synergistic effect existed from the results of Example 3. Upon information and belief, one of the principal investigators of the study described in Example 3, Dr. Robert Moses, testified under oath that this study was unable to determine if the combination of repaglinide and metformin had synergistic effects. Upon information and belief, Defendants and Dr. Sturis knew this to be the case because Dr. Richard Carr, a scientist at Novo Nordisk Inc., notified Dr. Sturis, among others, in a August 24, 2000 email that there was no "mathematical proof that synergy really exists" and that such data would be useful for patenting. *See* NOVO-6460530. Nevertheless, Defendants affirmatively represented to the Examiner that "it has been found that there is a synergism between repaglinide and metformin" based on the results from Example 3. Upon information and belief, Novo Nordisk had no basis for such a representation and they knew it to be untrue.

74. Novo Nordisk never disclosed to the USPTO that Dr. Sturis himself did *not* believe that his rat study had any clinical relevance to the effect of the repaglinide-metformin combination in humans, let alone showed synergism between repaglinide and metformin. The report underlying that study – a report never disclosed to the USPTO – merely said: "In conclusion, we have demonstrated synergistic effects of repaglinide and metformin on glucose tolerance in the male Zucker rat. We speculate that the presence of greater than additive effects *may* be clinically relevant." *See* NOVO-0028140 (emphasis added).

75. This is not the first instance in which Novo Nordisk has committed inequitable conduct. On a previous occasion, Novo Nordisk similarly misrepresented study results

disclosed in a pharmaceutical patent application. In the August 3, 2004 decision entitled *Bio-Technology General Corp. v. Novo Nordisk A/S and Novo Nordisk Pharmaceuticals, Inc.*, No. Civ. 02-235-SLR, 2004 WL 1739722 (D. Del. Aug. 3, 2004), the United States District Court for the District of Delaware held that Novo Nordisk committed inequitable conduct by failing to inform the patent examiner that the procedure described in their patent application was, in fact, never performed, and the procedure actually failed despite repeated attempts to perform it. This finding of inequitable conduct was affirmed by the Federal Circuit on October 5, 2005 in *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005).

B. Listing Of The '358 Patent In The Orange Book

76. Defendants continue to engage in inequitable and unlawful conduct with regard to the '358 patent in an effort to continue its monopoly on the now-expired repaglinide composition patent, U.S. Patent No. RE 37,035 (the "RE '035 patent"). In particular, Defendants have illegally submitted materially misleading and incomplete information to the FDA in a deliberate effort to delay or prevent approval of any ANDA that seeks approval to market repaglinide solely for non-infringing uses.

77. FDA regulations require NDA holders like Defendants to submit "patent information" to FDA "for each patent that claims the drug or a method of using the drug that is the subject of the new drug application . . . and with respect to 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 product." 21 C.F.R. § 314.53(b); *see also* 21 U.S.C. § 355(c)(2). This patent information is listed in the so-called "Orange Book,"

one purpose of which is to provide notice to ANDA applicants of those patents an NDA holder represents cover the listed product.

78. The U.S. Federal Trade Commission was involved in the discussions leading to the current iteration of section 314.53, provided a detailed study of generic drug entry prior to patent expiration, and previously asked FDA to clarify its patent listing rules via Citizen Petition. *See, e.g.*, Citizen Petition, O1P-0248 (May 16, 2001). As FTC explained: "The FDA has proposed to clear away unnecessary roadblocks to the approval of generic drug products. The FDA's important action addressing the competitive problems existing in the approval process for generic drugs, if promulgated and upheld, will [be] an effective way to bring the economic benefits of generic drugs to consumers more quickly. The Commission urges FDA, however, to make the proposed reforms even more effective by tightening its patent listing requirements." FTC Comments, No. 02N-0417 (Dec. 23, 2002).

79. The NDA holder's obligation to submit patent information for method claims includes "use codes" and specific descriptions of the protected methods of use. 21 C.F.R. § 314.53(b)(1).

80. "Use codes" are listed in the Orange Book and are intended to alert ANDA applicants to the existence of a patent that claims an approved use. Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of [ANDAs] Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, Final Rule, 68 Fed. Reg. 36676, 36683 (June 18, 2003).

81. The FDA expects a high degree of specificity in these use codes so that ANDA applicants may, if they so elect, carve out the protected use from its label and seek approval

solely for non-protected uses by submitting what is called a "section viii statement." As the FDA put it: "To effectively implement the certification and section viii statement provisions set out in the statute, we must have adequate information concerning method-of-use patents." 68 Fed. Reg. at 36683. Thus, under section 314.53(b)(1), "[t]he applicant shall separately identify each pending or approved method of use and related patent claim" and "identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent submitted".

82. When submitting a use code description to the FDA, the NDA holder "must describe each individual method of use for which a patent is submitted for listing, and identify the corresponding language found in the labeling of the approved NDA that corresponds to that method of use." 68 Fed. Reg. at 36681.

83. This listing must be "accurate and detailed" (68 Fed. Reg. at 36681); the applicant must provide "a description of each approved method of use or indication and related patent claim of the patent being submitted," along with "the specific section of the approved labeling of the drug product that corresponds to the method of use claimed by the patent" and a "description of the patented method of use as required for publication." 21 C.F.R. § 314.53(c)(2)(ii)(P).

84. Form 3542, the form NDA holders must complete in connection with the use code requirements, also mandates that the NDA holder attest to the accuracy of a use code under penalty of perjury and specifically cautions that willfully and knowingly false statements are a criminal offense under 18 U.S.C. § 1001. *See* 68 Fed. Reg. at 36686. The instructions to Form 3542 make clear that generic companies must be able to rely on specific use codes to determine whether a section viii statement is appropriate: "The use code

designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified in this section and contain adequate information to assist . . . ANDA applicants in determining whether a listed method of use patent claims a use for which the . . . ANDA applicant is not seeking approval." This instruction prevents the NDA holder from asserting a broad use code that would unnecessarily prevent ANDA applicants from seeking approval for non-protected uses.

85. By placing these strict requirements on the NDA-holder, section 314.53 and Form 3542 implement a critical component of the Hatch-Waxman statutory scheme because they allow ANDA applicants to know precisely what methods they can carve out under section viii. The FDA does not construe patents, so it relies heavily on the good-faith compliance of the NDA holder to provide an accurate and detailed description of the scope of the patented method of use. 68 Fed. Reg. at 36682. The FDA allows the NDA applicant or holder to draft the exact use code description because it believes that this system is "more efficient and accurate" than having the FDA create the use code descriptions. *Id.*

86. Defendants listed the '358 patent in the Orange Book in reference to their repaglinide drug branded as Prandin® and in reference to their metformin-repaglinide combination tablet branded as PrandiMet®. Claim 4 of the '358 patent claims a single method: "A method for treating non-insulin dependent diabetes mellitus (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin."

87. Defendants identified this method to FDA through its submission of a use code for the '358 patent specifically identifying this method. This was listed in the Orange Book

entry for Prandin® from 2004 to 2009 as: "U-546: use of repaglinide in combination with metformin to lower blood glucose."

88. On or about May 6, 2009, Defendants changed the use code for the '358 patent in reference to Prandin® to read: "U-968: a method for improving glycemic control in adults with Type 2 diabetes mellitus." This new use code does not describe the patented method of use. Nevertheless, upon information and belief, an in-house Novo Nordisk attorney declared under penalty of perjury that this vague use code description is "an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct."

89. Defendants changed this use code for the '358 patent in reference to Prandin® as part of an improper effort to frustrate competitors' ability to obtain final FDA approval of any ANDA for a repaglinide drug product. Contrary to the representation that Defendants made to FDA under penalty of perjury, Novo Nordisk's new use code (U-968) does not specifically or accurately describe the patented method of use found in claim 4 of the '358 patent—in fact, it does not describe that patented method at all. Instead, it vaguely suggests that the '358 patent is much broader in scope than it actually is.

90. Defendants asserted that FDA should reject a section viii statement as to claim 4 of the '358 patent, which was submitted by another generic competitor, Caraco Pharmaceutical Laboratories, Ltd., based on the new use code description. Defendants therefore asserted that this patent claim covers all methods of using repaglinide to treat type-

2 diabetes, not just metformin-repaglinide combination therapy. In so doing, Defendants claimed in effect that their monopoly on repaglinide (which expired with the RE '035 patent on March 14, 2009) should extend until the expiration date of the '358 patent.

91. Defendants could not and cannot assert such a position in good faith. The language of claim 4 of the '358 patent is expressly limited to the use of "repaglinide in combination with metformin" and cannot possibly be construed to cover repaglinide monotherapy or combination therapy with TZDs.

92. Indeed, up until the use code change made on or about May 6, 2009, Defendants consistently maintained that claim 4 of the '358 patent covered only the metformin-repaglinide combination.

a) Until the use code change made on or about May 6, 2009, Defendants expressly asserted in the Orange Book in reference to Prandin® that the '358 patent's method claim only covered the "use of repaglinide in combination with metformin to lower blood glucose."

b) Defendants' complaint for patent infringement in *Novo Nordisk A/S et al. v. Caraco Pharmaceutical Laboratories, Ltd.*, No. 2:05-cv-40188 (E.D. Mich.) alleged that "[t]he '358 patent claims . . . a method for treating NIDDM by administering to a patient in need of treatment, repaglinide in combination with metformin (claim 4)." *Novo Nordisk A/S. et al. v. Caraco Pharm. Labs., Ltd.*, No. 2:05-cv-40188 (E.D. Mich.), Am. Compl. ¶ 10 (Dkt. 23). Defendants have taken the same position in other litigation involving the '358 patent. *See, e.g.*, *Novo Nordisk et al. v. Mylan Pharmaceuticals Inc.*, No. 3-09-cv-02445 (D.N.J.), Complaint ¶ 10 (Dkt. 1).

c) Defendants represented to the FDA that "the '358 patent contains 5 claims, one of which (claim 4) is directed to a method of treatment of NIDDM with a combination of repaglinide and metformin." Novo Citizen Petition, FDA 2008-P-0343-0001, at 3 n.4 (Jun. 9, 2008).

d) Defendants also continue to use the original Prandin® use code (U-546) for the '358 patent in reference to PrandiMet®, Defendants ' metformin-repaglinide combination tablet. This demonstrates that Defendants continue to believe, and represent to FDA, that the '358 patent covers only the "use of repaglinide in combination with metformin to lower blood glucose." Defendants have

made no effort to explain how their method claim can be construed one way for PrandiMet® and a different way for Prandin®.

VI. Prandin® (Repaglinide)

93. Novo Nordisk Inc. is the purported holder of approved NDA No. 20741 for repaglinide tablets, which are sold under the brand-name Prandin®.

94. Prandin® (repaglinide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

95. FDA approved Prandin® in 2002. Today, Prandin® remains the only repaglinide tablet product on the market.

96. On information and belief, Defendants submitted information on the '358 patent to FDA for listing in the Orange Book. By virtue of that submission, FDA listed the '358 patent in the Orange Book in connection with Novo Nordisk Inc.'s approved NDA for Prandin® (repaglinide) tablets. The '358 patent remains listed in the Orange Book today.

97. The listing of the '358 patent in the Orange Book creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer to file and maintain a declaratory judgment action if it is not sued by Defendants within the requisite 45-day period.

VII. Sandoz's ANDA For Repaglinide Tablets

98. Sandoz has submitted an ANDA (No. 78-555) to FDA seeking approval to market a generic version of Prandin® (repaglinide) tablets in 0.5 mg, 1 mg, and 2 mg dosages ("Sandoz's ANDA Product").

99. Sandoz devoted considerable resources researching, developing and testing its generic repaglinide product, all toward compiling the information necessary to submit its ANDA No. 78-555 for generic repaglinide tablets.

100. Sandoz's ANDA included a paragraph IV certification to the '358 patent, stating that the '358 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of Sandoz's generic repaglinide tablets. This certification signifies that Sandoz intends to market and commercialize its generic repaglinide product prior to expiration of the '358 patent.

101. Sandoz's ANDA No. 78-555 is substantially complete and was accepted for filing by FDA.

102. Sandoz intends, and is prepared, to market its generic repaglinide product before expiration of the '358 patent.

103. In accordance with 21 U.S.C. §§ 355(j)(2)(B), Sandoz provided Defendants with the requisite notice that it submitted ANDA No. 78-555 and a paragraph IV certification to the '358 patent.

104. Upon receipt of Sandoz's notice of paragraph IV certification to the '358 patent, Defendants did not sue Sandoz within the 45-day period for instituting an infringement suit under 21 U.S.C. § 271(e).

VIII. Sandoz's Offer Of Confidential Access To Application

105. Sandoz – by letter and as required under 21 U.S.C. § 355(j)(5)(C) – extended to Defendants an Offer of Confidential Access to Application to access certain information in

Sandoz's ANDA for repaglinide tablets in its notice of paragraph IV certification to the '358 patent dated January 25, 2007.

106. By providing an Offer of Confidential Access to Application, and because Defendants did not sue Sandoz within 45 days of receipt of Sandoz's notices of paragraph IV certification, Sandoz is statutorily entitled to file and maintain a declaratory judgment action against Defendants under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

IX. Defendants' Litigious Conduct And Vigorous Enforcement Of Its Intellectual Property Rights Regarding Prandin®

107. Defendants have a long history and orchestrated program of vigorously enforcing their intellectual property for Prandin® against generic ANDA applicants.

108. For example, Defendants have sued multiple ANDA-filers for alleged infringement of the '358 patent purportedly covering its drug Prandin®, including in the Eastern District of Michigan. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.,* No. 2:05-cv-40188 (E.D. Mich.); *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 3:09-cv-02445 (D.N.J.); *Novo Nordisk Inc. v. Paddock Labs., Inc.,* No. 0:10-cv-02199 (D. Minn.).

X. There Is A Substantial And Continuing Justiciable Controversy Between Sandoz And Defendants Regarding Invalidity, Unenforceability, And Non-infringement Of The '358 Patent

109. By listing the '358 patent in the Orange Book, Defendants maintain, and have affirmatively represented to the world, that the '358 patent claims Prandin® (repaglinide) tablets, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Sandoz, that attempts to seek approval for, and market, a generic version of Prandin® before patent expiration. The

Orange Book listing of the ’358 patent creates an independent barrier to Sandoz’s entrance into the marketplace for generic repaglinide that cannot be overcome without a judgment that the ’358 patent is invalid, unenforceable and/or will not be infringed by Sandoz’s generic repaglinide product.

110. Defendants have not consented to a judgment of invalidity, unenforceability or non-infringement on the ’358 patent, nor have they covenanted or otherwise promised not to sue or otherwise hold Sandoz liable for infringement of such patents.

111. The ’358 patent is the only patent listed in the Orange Book for Prandin. Sandoz has not stipulated to the validity, infringement or enforceability of any other patent that is listed in the Orange Book for Prandin.

112. Sandoz is not subject to any final judgment regarding an Orange Book patent for Prandin that would prevent Sandoz from selling products covered by the Sandoz ANDA.

113. Sandoz has challenged every listed patent, i.e. the ’358 patent, on the basis of invalidity, unenforceability, and non-infringement.

114. By preparing and filing Sandoz’s ANDA No. 78-555, Sandoz has substantially prepared to make, use, import, offer to sell, and sell generic repaglinide tablets in the United States.

115. By submitting its ANDA No. 78-555 to engage in the commercial manufacture, use, offer for sale, sale, or importation of generic repaglinide tablets before the expiration of the ’358 patent, with a paragraph IV certification to the ’358 patent, Sandoz has committed an artificial act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2) and Article III of the Constitution.

116. Defendants' listing of the '358 patent and Sandoz's paragraph IV certification to the '358 patent satisfy Article III of the Constitution by creating the necessary case or controversy between Defendants and Sandoz regarding invalidity, unenforceability, and infringement of the '358 patent.

117. By listing the '358 patent in the Orange Book and not suing Sandoz on those patents, Defendants have created patent and legal uncertainty that impairs Sandoz's right to market a non-infringing generic product without the risk of catastrophic infringement damages. This patent and legal uncertainty and impairment of Sandoz's rights is a sufficiently concrete and cognizable injury-in-fact that is fairly traceable to the Defendants and that can be redressed only by a declaratory judgment from this Court. Sandoz has a legally cognizable interest in obtaining patent certainty via a declaratory judgment action. These facts alone give rise to a substantial and continuing case or controversy under Article III of the Constitution over which this Court has subject matter jurisdiction.

118. By virtue of Defendants' actions, Sandoz is suffering the harm of being unable to launch generic products covered by the Sandoz ANDA because of another applicant's 180-day marketing exclusivity.

119. Upon information and belief, Sandoz is not the first ANDA-filer to submit a paragraph IV certification to the '358 patent. Upon information and belief, another ANDA-filer (Caraco Pharmaceutical Labs.) submitted the first paragraph IV certification to the '358 patent and secured a period of 180-day exclusivity that will delay the approval of Sandoz's ANDA products absent a declaratory judgment from this Court. This FDA-approval-blocking-injury – or the harm of being unable to launch generic products covered by the Sandoz ANDA because of another applicant's 180-day exclusivity – is a sufficiently concrete

and cognizable injury-in-fact, that is fairly traceable to Defendants' actions, and that can be redressed by a declaratory judgment of non-infringement, invalidity or unenforceability that would trigger the first-filer's exclusivity period, which currently blocks FDA approval of the Sandoz ANDA. Sandoz has a legally cognizable interest in beginning or triggering the first-filer's exclusivity period via a declaratory judgment action. These facts also give rise to a substantial and continuing case or controversy under Article III of the Constitution over which this Court has subject matter jurisdiction.

120. The FDA has not yet granted tentative approval of Sandoz's ANDA No. 78-555. The lack of tentative approval is directly caused by Defendants' conduct in connection with the listing of the '358 patent. Sandoz would have tentative approval but for Novo's actions.

121. Sandoz's injury (i.e., exclusion from the market) is fairly traceable to the Defendants' actions because but-for the Defendants' decision to list the '358 patent in the Orange Book, FDA approval of Sandoz's ANDA would not have been independently delayed by the '358 patent.

122. Sandoz has been deprived of an economic opportunity to compete because the listing of the '358 patent in the Orange Book creates an independent barrier to entering the marketplace that cannot be overcome without a court judgment that the listed patent is invalid or not infringed. A declaratory judgment redresses this injury because it eliminates the potential for the '358 patent to exclude the Sandoz ANDA product from the market.

123. Novo is appealing the January 19, 2011 invalidity and unenforceability decision of the District Court for the Eastern District of Michigan. *See Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, Appeal No. 2011-1223 (Fed. Cir).

124. In a separate, earlier decision, the District Court for the Eastern District of Michigan ruled that Novo must change the use-code that Novo listed in the Orange Book for the '358 patent because Novo's use-code is not an accurate description of the method claimed in the '358 patent. The Federal Circuit reversed the district court. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010). The Supreme Court granted Caraco's petition for certiorari to review the Federal Circuit's use-code decision on June 27, 2011.

125. The Federal Circuit stayed the appeal of the invalidity and unenforceability ruling pending the Supreme Court's decision in the use-code appeal. This stay will delay a final decision by the Federal Circuit that the '358 patent is invalid and unenforceable and, thus, delay the commencement of Caraco's marketing exclusivity. This delay, in turn, would delay Sandoz's ability to launch a generic repaglinide product.

126. Defendants did not sue Sandoz for infringement of the '358 patent within 45 days of receipt of Sandoz's notice of paragraph IV certification. In compliance with 21 U.S.C. § 355(j)(5)(C), Sandoz granted Defendants an Offer of Confidential Access to Sandoz's ANDA for generic repaglinide tablets. As such, Sandoz is statutorily entitled to institute—and this Court has constitutional authority to adjudicate—a declaratory judgment action against Defendants. 35 U.S.C. § 271(e)(5).

127. To avoid legal uncertainty, to protect its substantial investment, to protect its anticipated future investments in its manufacturing process for Sandoz's generic repaglinide tablets, and to obtain earlier approval of its generic repaglinide products, Sandoz has instituted this action and is entitled to a declaration of the rights of the parties with respect to the '358 patent.

COUNT I

Declaratory Judgment Of Non-Infringement Of Any Valid Or Enforceable Claim Of The '358 Patent

128. Sandoz re-alleges and incorporates by reference paragraphs 1-127 of this Complaint.

129. The manufacture, use, sale, offer for sale, or importation of Sandoz's repaglinide tablets, which are the subject of ANDA No. 78-555, have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid and/or enforceable claim of the '358 patent.

130. Sandoz is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Sandoz's repaglinide tablets, which are the subject of ANDA No. 78-555, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '358 patent.

COUNT II

Declaratory Judgment Of Invalidity Of The '358 Patent

131. Sandoz re-alleges and incorporates by reference paragraphs 1-130 of this Complaint.

132. One or more claims of the '358 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description, indefiniteness, and incorrect inventorship in accordance with 35 U.S.C. §§ 101, 102, 103, 112, 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

133. Sandoz is entitled to a judicial declaration that one or more claims of the '358 patent are invalid.

COUNT III

Declaratory Judgment Of Unenforceability Of The '358 Patent Due To Inequitable Conduct

134. Sandoz re-alleges and incorporates by reference paragraphs 1-133 of this Complaint.

135. The claims of the '358 patent are unenforceable due to Novo Nordisk's inequitable conduct before the USPTO, as described above.

136. During the prosecution of the '358 patent, Novo Nordisk, its respective attorneys involved in the prosecution of the '358 patent, Dr. Müller, and Dr. Sturis did not disclose the results of clinical studies AGEE-3010 and AGEE-3018 and the existence of clinical study AGEE-1411 to the USPTO. The data and results from the clinical studies were material to the patentability of the '358 patent.

137. The data and results from the clinical studies were not cumulative of any information disclosed during the prosecution of the '358 patent.

138. Upon information and belief, Novo Nordisk, its respective attorneys involved in the prosecution of the '358 patent, Dr. Müller, and Dr. Sturis were aware of the materiality of the data and results from the clinical studies, or were deliberately ignorant of those studies.

139. Novo Nordisk, its respective attorneys involved in the prosecution of the '358 patent, Dr. Müller, and Dr. Sturis also did not disclose that Example 3 was insufficient to determine if the combination of repaglinide and metformin had synergistic effects. The non-

disclosure of this information was material to the patentability of the '358 patent because Example 3 provided support for the sole reason for the allowance of the '358 patent, namely the alleged synergistic effects of the combination of repaglinide and metformin to patients with NIDDM, and such information is inconsistent with Defendants', Dr. Müller's and Dr. Sturis's argument that Example 3 shows that there is a synergism between repaglinide and metformin.

140. Dr. Sturis also made materially misleading statements in his declaration concerning the applicability of the results from his rat study. Dr. Sturis did not disclose in his declaration his belief that his rat study may not be relevant to determine the effect of the combination of repaglinide and metformin in humans. This belief conflicts with Dr. Sturis's representation to the USPTO that his rat study taken with Example 3 "strongly suggest that the combination of repaglinide and metformin has synergistic properties in type 3 diabetic patients."

141. Upon information and belief, there exists a reasonable basis to infer that Defendants' attorneys, Dr. Müller, Dr. Sturis and/or others substantively involved in the preparation and/or prosecution of the application that led to the '358 patent made the aforementioned acts and omissions specified in paragraphs 58-75 and 143-149 with the intent to deceive the USPTO.

142. Sandoz is entitled to a declaration that the '358 patent is unenforceable due to inequitable conduct.

COUNT IV

Declaratory Judgment Of Unenforceability Of The '358 Patent Due To Patent Misuse

143. Sandoz re-alleges and incorporates by reference paragraphs 1-142 of this Complaint.

144. Defendants' original Prandin® use code for the '358 patent was: "U-546: use of repaglinide in combination with metformin to lower blood glucose."

145. On or about May 6, 2009, Defendants changed the use code for the '358 patent in reference to Prandin® to one with a much broader scope: "U-968: a method for improving glycemic control in adults with Type 2 diabetes mellitus." This new use code does not purport to specifically or accurately describe the patented method of use found in claim 4 of the '358 patent, as required by the FDA regulations.

146. Defendants' revised use code could be read as suggesting that the '358 patent covers all approved methods of using repaglinide (including monotherapy and combination with TZDs).

147. The only method of use covered by the '358 patent involves the use of "repaglinide in combination with metformin."

148. Through its manipulation of the use code for the '358 patent to encompass drug products and methods for using drug products not covered by the '358 patent, Defendants misused the '358 patent and have drawn anticompetitive strength from the '358 patent.

149. Defendants' anticompetitive use of the '358 patent has prevented competitors from entering the market with competing repaglinide products.

150. Sandoz is entitled to a declaration that the '358 patent is unenforceable due to patent misuse.

PRAYER FOR RELIEF

Wherefore, Sandoz prays that this Court enters judgment:

A. Declaring that the manufacture, use, sale, offer for sale, or importation of Sandoz's repaglinide tablets, which are the subject of ANDA No. 78-555, has not infringed, does not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '358 patent.

B. Declaring that the '358 patent is invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description, indefiniteness, and incorrect inventorship in accordance with 35 U.S.C. §§ 101, 102, 103, 112, 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

C. Declaring that the '358 patent is unenforceable due to inequitable conduct and/or patent misuse.

D. Adjudging and decreeing that:

(1) Judgment be awarded to Sandoz on all claims of the Complaint;

(2) Sandoz be awarded its attorney fees and costs under 35 U.S.C. § 285; and

(3) Sandoz be awarded such other relief as may be just and proper.

JURY DEMAND

Plaintiff, Sandoz Inc., hereby demands a trial by jury on all issues so triable.

***

Respectfully submitted,

DATED: August 17, 2011

By: /s/Linda D. Kennedy

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