UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

AMERICAN SALES COMPANY, INC., on behalf of itself and all others similarly situated, Plaintiff, - against - NOVO NORDISK A/S and NOVO NORDISK, INC., Defendants.	Case No. **CLASS ACTION** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff American Sales Company, Inc. ("Plaintiff"), individually and on behalf of all others similarly situated, for its complaint against defendants Novo Nordisk A/S and Novo Nordisk, Inc. (collectively "Novo Nordisk" or "Defendants"), upon knowledge as to itself and its own acts, and upon information and belief as to all other matters, alleges as follows:

NATURE OF THE ACTION

1. Plaintiff brings this action on behalf of itself and a class of direct purchasers of Prandin. Prandin is the brand name for the prescription drug repaglinide, which is used to treat Type 2 (non-insulin dependent) diabetes, either alone or in combination with other anti-diabetes medicines, as part of a diet and exercise program. Prandin is part of a class of diabetes drugs called meglitinides. These medications help the pancreas make more insulin, which helps to lower blood sugar. It is designed to lower blood sugar levels following a meal. Prandin sales in the United States approximate $150 million per year.

2. On December 22, 1997, Novo Nordisk Inc. received approval from the U.S. Food and Drug Administration ("FDA") to sell 0.5 mg, 1 mg, and 2 mg Prandin tablets (NDA No.

020741). FDA has approved three uses of repaglinide to treat non-insulin dependent diabetes mellitus: (1) repaglinide by itself, known as monotherapy; (2) repaglinide in combination with thiazolidinediones (TZDs); and (3) repaglinide in combination with metformin.

3. In the FDA publication *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), Novo Nordisk listed U.S. Pat. No. RE37,035 ("the compound patent"), which covered the repaglinide compound and expired on March 14, 2009. Novo Nordisk also listed U.S. Pat. No. 6,677,358 ("the '358 patent"), entitled "NIDDM REGIMEN", which issued on January 13, 2004 and expires June 12, 2018. "NIDDM" is an abbreviation for non-insulin dependent diabetes mellitus. The '358 patent claims, among other things, the method for treating NIDDM by administering repaglinide in combination with metformin (claim 4). The '358 patent relates to the repaglinide-metformin combination only and does not relate to the other two approved uses of Prandin, *i.e.*, monotherapy and in combination with TZDs.

4. Caraco Pharmaceutical Laboratories, Inc. ("Caraco"), a generic drug manufacturer, seeks to market a less expensive, generic version of Prandin. On February 9, 2005, Caraco filed and Abbreviated New Drug Application ("ANDA") for approval to market 0.5 mg, 1 mg, and 2 mg repaglinide tablets in the United States. Caraco's ANDA did not challenge the compound patent, but included a certification that the '358 patent was either invalid or not infringed and provided notice of this certification to Novo Nordisk. Caraco proposed labeling for its generic product that included an instruction to consumers about the combination of repaglinide with metformin, as on the Prandin label.

5. In June 2005, Novo Nordisk sued to block Caraco's generic drug by asserting infringement of the '358 patent. *Novo Nordisk A/S et al. v. Caraco Pharmaceutical Laboratories, Inc.*, No. 2:05-cv-40188 (E.D. Mich.). The patent infringement action remains pending. In defense, Caraco alleges that the '358 patent is unenforceable due to Novo Nordisk's inequitable conduct and patent misuse.

6. In April 2008, Caraco amended its ANDA to include a "split certification," by which it maintained its certification challenging the non-method claims of the '358 patent (claims 1-3 and 5), but included a "section viii statement" specifying that it did not seek approval for the method of use (claim 4). On December 4, 2008, FDA ruled that Caraco's section viii statement properly "carved out" the '358 patent's method of use claim and FDA was poised to approve Caraco's ANDA following the expiration of the compound patent in March 2009.

7. Shortly before the compound patent expired, however, Novo Nordisk changed the "use code" for the '358 patent reference in the Orange Book by filing an objectively baseless use code narrative that expanded the claim under the '358 patent beyond the repaglinide-metformin combination and effectively claimed that the patent covers all combinations therapy with repaglinide. This sham tactic prevented FDA from accepting Caraco's previously approved section viii statement (which it deemed moot) and prevented FDA from approving Caraco's ANDA.

8. On September 25, 2009, the United States District Court for the Eastern District of Michigan entered an injunction requiring Novo Nordisk to change the use code back to its original form — *i.e*, that the '358 patent's method claim only covers use of repaglinide in

combination with metformin to lower blood glucose. *See Novo Nordisk A/S v. Caraco Pharmaceuticals Laboratories, Ltd.*, 656 F. Supp.2d 729 (E.D. Mich. 2009). However, the United States Court of Appeals for the Federal Circuit initially stayed and then vacated the injunction on the ground that the relevant provision of the Hatch-Waxman Act (21 U.S.C. § 355(j)(5)(C)(ii)(I)) authorized a counterclaim to correct or delete an erroneous patent number or expiration date, but not to change a use code narrative. *Novo Nordisk A/S v. Caraco Pharmaceuticals Laboratories, Ltd.*, No. 2010-1001, __ F.3d __, 2010 1462300, at *7 (Fed. Cir. April 14, 2010) ("[T]he terms of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative."). As a result, Novo Nordisk has continued to maintain an objectively baseless use code narrative that prevents FDA from approving Caraco's section viii statement or ANDA.

9. As alleged herein, Novo Nordisk has maintained an unlawful monopoly in the market for repaglinide by blocking generic versions of Prandin from the market with sham Orange Book filings and sham litigation. Were it not for Novo Nordisk's unlawful conduct, Novo Nordisk's generic competitors (including but not limited to Caraco and Mylan Pharmaceuticals, Inc.) would have obtained FDA approval to market competing generic drugs beginning on March 15, 2009, thereby causing prices of repaglinide to decline significantly.

10. Defendants' continuing anticompetitive acts have allowed them to charge supracompetitive prices for Prandin, thereby causing Plaintiff and all purchasers of Prandin to pay overcharges on their purchases made directly from Defendants.

JURISDICTION AND VENUE

11. Plaintiff brings this action alleging violation of § 2 of the Sherman Act, 15 U.S.C. § 2, pursuant to Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, as a result of exclusionary, monopolistic and unlawful restraints on trade that have harmed and continue to harm Plaintiff and the Class. The jurisdiction of this Court is based upon 28 U.S.C. §§1331 and 1337(a).

12. Venue is proper within this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), because Defendants are found or transact business within this District and because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. Jurisdiction over both Defendants comports with the United States Constitution and 15 U.S.C. §§ 15, 22 and 26.

THE PARTIES

The Plaintiff

13. Plaintiff American Sales Company, Inc. is a Delaware corporation with its principal place of business in Lancaster, Erie County, New York. Plaintiff purchases health products, including prescription drugs, for retail stores owned and operated by affiliated companies. During the relevant period, Plaintiff purchased Prandin from Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler which during the relevant period purchased Prandin directly from Defendants. Cardinal was injured as a result of defendants' misconduct. Cardinal resold Prandin to Plaintiff and has assigned its claims arising out of those purchases to Plaintiff. ASC brings this action on its own behalf as the assignee of Cardinal.

The Defendants

14. Defendant Novo Nordisk A/S is a Danish corporation having a place of business at Novo Alle, DK-2880 Bagsvaerd, Denmark. Novo Nordisk has become one of the world's largest sellers of prescription drugs for diabetes. Novo Nordisk has production facilities in six countries, with affiliates or offices in 80 countries. Novo Nordisk employs approximately 26,000 people globally and markets its products in 179 countries, including the United States. Novo Nordisk A/S is the owner by assignment of United States Patent No. 6,677,358 ("the '358 patent").

15. Defendant Novo Nordisk, Inc. is a Delaware corporation having a principal place of business 100 College Road West, Princeton, New Jersey. Pursuant to NDA No. 020741, Novo Nordisk Inc. received approval from FDA to sell 0.5 mg, 1 mg, and 2 mg Prandin tablets in the United States.

INTERSTATE COMMERCE

16. During all or part of the Class Period, Defendants manufactured and sold substantial amounts of Prandin in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

17. At all material times, Prandin manufactured and sold by Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

18. During all or part of the Class Period, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of

Prandin.

19. In furtherance of its efforts willfully to obtain and/or maintain monopoly power over Prandin and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

20. Defendants' efforts to willfully maintain monopoly power over Prandin and its generic equivalents, as alleged herein, have substantially affected interstate and foreign commerce.

CLASS ALLEGATIONS

21. Plaintiff brings this class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, sub-sections 23(a) and 23(b)(2) and/or (b)(3), on behalf of a class (the "Class") defined as follows:

> All persons and entities in the United States who purchased Prandin directly from Defendants from March 15, 2009 to the present. Excluded from the Class are Defendants and their parents, employees, subsidiaries, and affiliates.

22. The Class is so numerous that joinder of all members is impracticable. Plaintiff believes that the Class numbers one hundred or more.

23. There are questions of law or fact common to the Class, including:

a. whether Novo Nordisk willfully maintained monopoly power over repaglinide and its actual or potential generic equivalents;

b. whether Novo Nordisk filed an objectively baseless method of use code with FDA for the purpose of preventing or delaying competition;

c. whether the '358 patent was obtained through fraud and/or inequitable conduct;

d. whether Novo Nordisk's lawsuits asserting infringement of the '358 patent

are baseless;

e. whether Novo Nordisk filed such lawsuits for the purpose of preventing or delaying competition; and

f. whether, and to what extent, Novo Nordisk's conduct caused direct purchasers of Prandin to be overcharged and therefore injured.

24. These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

25. Plaintiff's claims are typical of the claims of the Class because all Class members suffered antitrust injury in the same way as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

26. Plaintiff will fairly and adequately represent and protect the interests of the Class. Plaintiff has retained counsel experienced in class action and pharmaceutical antitrust litigation, and Plaintiff has no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

27. A class action is superior to any other available methods for the fair and efficient adjudication of this controversy. Plaintiff knows of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

28. In addition, Defendants have acted and refused to act, as alleged herein, on grounds generally applicable to the Class.

BACKGROUND

FEDERAL REGULATION OF PRESCRIPTION DRUGS

A. Brand Name Drugs vs. Generic Drugs

29. The brand name prescription drugs industry is one of the most profitable industries in the United States. Over $300 billion was spent on prescription drugs in the United States in 2009, with $226 billion spent on brand name drugs. The cost of prescription drugs has been rising at a rate of 14% to 18% per year. From 2004 to 2007, brand name drug prices increased by an average of 21%, while generic drug prices decreased by an average of 12.8% during the same period.

30. Securing the availability of generic drugs is one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which must be approved by FDA, by law have the same active chemical composition and provide the same therapeutic effects as the brand name drugs to which they correspond.

31. FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand name drugs. To be deemed a therapeutic equivalent, and receive an "AB" rating from FDA, the generic drug must contain the same active ingredient(s), dosage form, route of administration, and strength. According to FDA, a bioequivalent drug rated "AB" may be substituted for the reference pioneer or branded drug.

32. Once the safety and effectiveness of a new prescription drug is approved by FDA, the drug may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed

pharmacist. The pharmacist, in turn, must fill the prescription with the drug brand specified by the physician, unless an AB-rated generic version of that pioneer drug approved by FDA is available.

33. If a generic version of a brand name drug exists and the physician has not specifically indicated to the pharmacist to dispense the branded drug then: (i) in many states, the pharmacist by law must substitute the generic drug; (ii) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug, and (iii) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the option of purchasing the branded drug or the AB-rated generic drug at a lower price.

34. Once a physician writes a prescription for a brand name drug, such as Prandin, that prescription defines and limits the market to the drug name or its AB-rated generic equivalents. Only drugs that are AB-rated by FDA may be substituted by a pharmacist for a physician's prescription for the brand name drug.

35. Generic drugs are priced substantially below the brand name drugs to which they are bioequivalent. A recent study by the Generic Pharmaceutical Association based on an independent analysis of data from IMS showed that the use of generic drugs has saved consumers, patients, and healthcare providers $734 billion from 1998 through 2008, with approximately $121 billion in savings in 2008 alone.

36. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand name drug during periods of generic marketing exclusivity. As additional manufacturers

bring generic versions of the drug to market, the price continues to drop.

37. A brand name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, as much as 90% in just the first year of generic sales.

B. Federal Scheme for Approval of Pioneer Drugs

38. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (The "FFDCA") regulates the manufacture and distribution of drugs and medical devices in the United States. Under the FFDCA, approval by FDA (the governmental body charged with the regulation of the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 335(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with FDA under § 335(b) of the FFDCA, demonstrating that the drug is safe and effective for its intended use.

39. New drugs that are approved for sale in the United States by FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patent, plus any extension of exclusivity granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

40. Pursuant to 21 U.S.C. § 335(b), the pioneer drug manufacturer must list in its NDA those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could

reasonably be asserted against an unlicensed manufacturer or seller of the drug. If a particular patent does not meet this test with respect to the NDA, the patent cannot properly be listed with FDA. Once the NDA is approved by FDA, any such patents are listed in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book."

41. Federal regulations impose strict limitations on the types of the patents that an NDA holder can submit to FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

42. Despite FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, in order to force generic manufacturers to file what, as described below, is commonly known as a "Paragraph IV Certification."

43. FDA does not police the listing of patents. FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book. FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . . .").

44. FDA's role in the patent listing process is purely ministerial, and it relies entirely

on the NDA holder to list its patent accurately. For that reason, courts have held that the patent listing process is not "government petitioning," and Defendants are specifically not entitled to rely upon any defense of immunity pursuant to the *Noerr-Pennington* doctrine.

C. Approval of Generic Drugs

45. Congress enacted the Hatch-Waxman Act in 1984. The Hatch-Waxman Act was principally designed to streamline the process by which generic drugs are brought to market. The Hatch-Waxman Act simplified the regulatory hurdles faced by prospective generic drug manufacturers by eliminating the need for such manufacturers to file lengthy and costly NDAs. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with FDA by the manufacturer of the equivalent brand name drug.

46. Under the Hatch-Waxman Act, a generic drug manufacturer's ANDA must contain a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) addressing the patents, if any, listed in the Orange Book as applying to the brand name or pioneer drug. Four types of certifications are available:

I. The brand name manufacturer has not filed patent information with FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent or patents listed in the Orange Book will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III

Certification"); or

IV. The patent or patents listed in the Orange Book are invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii).

47. If a generic manufacturer files a Paragraph IV Certification, seeking to market the generic drug before patent expiration and asserting that any listed patent is invalid or will not be infringed, the brand name manufacturer has the opportunity to delay the generic manufacturer's receipt of final FDA approval, and, thus, its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue, and this certification may constitute a "technical act of infringement" under the Hatch-Waxman Act.

48. The filing of a Paragraph IV Certification thus creates jurisdiction in the federal courts to entertain a patent infringement action, and the NDA holder has 45 days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. §271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, FDA's approval of the ANDA is automatically stayed for up to 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

49. Because of this 30-month stay of ANDA approval, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action's underlying merit, gives the brand name company the equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without requiring the brand company to establish likelihood of success on the merits, irreparable harm, that the balance of

hardships tips in its favor, or that the public good is served by the blocking of entry.

50. As a practical matter, the brand name company obtains an injunction simply by filing a complaint, even a complaint with little or no merit, as it automatically protects its monopoly for up to two-and-a-half years while the infringement action winds its way through the court system. Moreover, the brand name company has an incentive to stall the progress of the litigation. There are no disgorgement provisions for profits earned during the 30-month period of exclusivity if a court eventually determines that the suit was without merit.

51. An improper Orange Book listing also has additional anticompetitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). Absent an improper Orange Book listing, no Paragraph IV Certification would be required and, thus, no generic company would receive any 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously, resulting in prices even lower than one would find during the 180-day exclusivity period when only one generic manufacturer is permitted to market its product.

52. Defendants were at all times fully familiar with the ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

D. "Section viii statements" that "carve out" methods of use.

53. FDA regulations require NDA holders like Novo Nordisk 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 Orange Book, one purpose of which is to provide notice to ANDA applicants of those patents an NDA holder represents cover the listed product.

54. The FTC 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, Dkt. No. 02N-0417 (Dec. 23, 2002).

55. 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). "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).

56. 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." *See* 21 U.S.C. § 355(j)(2)(A)(viii). As 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" (emphasis added).

57. Indeed, when submitting a use code description to 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." *Id*. at 36681 (emphasis added).

58. This listing must be "*accurate and detailed*" [*id*.]; 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).

59. Form FDA 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.

60. By placing these strict requirements on the NDA-holder, Section 314.53 and Form FDA 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 in a section viii statement. 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 patented method of use. *See* 68 Fed. Reg. at 36681 ("In determining whether an ANDA applicant can 'carve out' the method of use, rather than certify to the listed patent, *we will rely on the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book*.") (emphasis added).

NOVO NORDISK'S ANTICOMPETITIVE CONDUCT

A. Novo Nordisk's Scheme to Block Generic Approval By Filing a Sham "Use Code" in the FDA Orange Book

1. FDA Approved Three Uses of Repaglinide to Treat Non-insulin Dependent Diabetes Mellitus

61. On December 22, 1997, Novo Nordisk, Inc. received FDA approval to sell 0.5 mg, 1 mg, and 2 mg Prandin tablets (NDA No. 020741). FDA has approved three uses of repaglinide to treat non-insulin dependent diabetes mellitus: (1) repaglinide by itself, known as monotherapy; (2) repaglinide in combination with thiazolidinediones (TZDs); and (3) repaglinide in combination with metformin.

62. Novo Nordisk listed at least three patents in the Orange Book in reference to Prandin: (1) U.S. Pat. No. RE37,035 ("the compound patent"), which covered the repaglinide compound and expired on March 14, 2009; (2) U.S. Patent No. 5,312,924, which covered the use of repaglinide in monotherapy to treat diabetes and expired in September 2006; and (3) U.S. Patent No. 6,677,358 ("the '358 patent"), entitled "NIDDM REGIMEN", which was issued on January 13, 2004 and expires June 12, 2018. "NIDDM" is an abbreviation for non-insulin dependent diabetes mellitus. The '358 patent claims a pharmaceutical composition which includes repaglinide, metformin, and a carrier (claim 1) in the form of a tablet (claim 2) or capsule (claim 3); the method for treating NIDDM by administering a patient in need of treatment, repaglinide in combination with metformin (claim 4); and a kit which includes repaglinide and metformin (claim 5). The '358 patent relates to the repaglinide-metformin combination *only* and does not relate to the other approved uses of Prandin. On June 23, 2008,

FDA approved Novo Nordisk Inc.'s application to market a drug that includes a combination of repaglinide and metformin, which Novo Nordisk markets under the brand name PrandiMet®

2. Caraco's ANDA

63. On February 9, 2005, Caraco filed ANDA No. 77-571 for approval to market 0.5 mg, 1 mg, and 2 mg repaglinide tablets in the United States. Under FDA regulations, the language of Caraco's proposed label had to match the Prandin label, including reference to all FDA-approved uses of repaglinide. *See* 21 U.S.C. § 355(j)(2)(A)(v). Caraco's ANDA included a Paragraph III certification with respect to the compound patent (*i.e.*, Caraco will not seek to market its product until expiration of the patent) and a Paragraph IV certification with respect to all five claims of the '358 patent. Caraco was the first generic manufacturer to file a Paragraph IV ANDA challenging the '358 patent, making it eligible for a 180-day marketing exclusivity period.

64. On April 26, 2005, Caraco sent a notice of its Paragraph IV certification to Novo Nordisk A/S and Novo Nordisk, Inc., pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

65. On June 9, 2005, within 45 days of the notice described above, Novo Nordisk filed a complaint against Caraco in the United States District Court for the Eastern District of Michigan, alleging that a generic label referencing the approved repaglinide-metformin use would actively induce infringement of the '358 patent. *Novo Nordisk A/S et al. v. Caraco Pharmaceutical Laboratories, Inc.*, No. 2:05-cv-40188 (E.D. Mich.). On September 14, 2005, Novo Nordisk filed an amended complaint adding Caraco's parent company (Sun Pharmaceutical Industries, Ltd.) as a defendant.

66. In August 2007, FDA granted tentative approval to Caraco's ANDA, which signifies FDA approval that Caraco was capable of manufacturing a bioequivalent version of Prandin, but that intellectual property rights precluded final marketing approval.

3. Prandin Label Revised in 2007

67. In November 2007, as part of an ongoing reevaluation of the labeling of all oral antidiabetic drugs, FDA required Novo Nordisk to replace all separate indications with the following sentence: "Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus."

4. Caraco's Amended ANDA and section viii statement

68. In 2008, at the suggestion of FDA, Caraco amended its ANDA to include a "split certification," by which Caraco maintained its Paragraph IV certification for the non-method claims of the '358 patent (claims 1-3, 5), but submitted a section viii statement for method claim 4. Caraco's proposed label omitted all references to the patented metformin-repaglinide combination, such that its generic repaglinide products would be labeled and marketed only for non-infringing, FDA-approved uses.

69. On June 9, 2008, Novo Nordisk challenged Caraco's proposed carve-out label in a citizen petition filed with FDA (FDA- 2008-P-0343-0001). On December 4, 2008, FDA rejected Novo Nordisk's citizen petition and held that Caraco's section viii statement was proper in light of Novo Nordisk's use code description at the time — *i.e.*, "U-546: use of repaglinide in combination with metformin to lower blood glucose." This code made it clear that the '358 patent does not claim the other two approved repaglinide uses that would remain in Caraco's

generic label. FDA also rejected an alternative argument by Novo Nordisk that omitting the patented combination therapy from Caraco's generic label would compromise the safety and efficacy of the drug.

70. The FDA ruling meant that Caraco's repaglinide product would not be marketed for a use that infringes the '358 patent, which paved the way for: (1) mooting the patent infringement litigation; and (2) final marketing approval of Caraco's ANDA following the expiration of the compound patent on March 14, 2009.

5. Novo Nordisk Filed a Sham "Use Code" with FDA on the Brink of Generic Approval

71. On May 6, 2009, shortly before the expiration of the repaglinide compound patent, Novo Nordisk amended its use code narrative for Prandin in the Orange Book to read: "U-968: A method for improving glycemic control in adults with Type 2 diabetes mellitus." Novo Nordisk represented to FDA that the amendment was intended "to correspond with the change in labeling required by FDA in November 28, 2007." While FDA did require a general change in oral diabetes drug labeling in November 2007 that required a corresponding change in the Prandin label, there is absolutely nothing in the statute or regulations that required Novo Nordisk to change the use code narrative to track this change. FDA did not direct or request that Novo Nordisk make any change.

72. Novo Nordisk changed the use code narrative as part of an improper effort to frustrate Caraco's ability to obtain final FDA approval of its ANDA. Contrary to the representation that Novo Nordisk made to FDA under penalty of perjury, Novo Nordisk's new use code (U-968) did not specifically or accurately describe the patented method of use found in

claim 4 of the ’358 patent — in fact, it did not describe that patented method at all. Instead, it vaguely suggested that the ’358 patent is much broader in scope than it actually is, covering other approved but unpatented methods of use, including monotherapy and combination therapy with thiazolidinediones (TZDs).

73. Novo Nordisk could not assert such a position in good faith and its use code change was a sham submitted for listing in the Orange Book for the sole purpose of preventing FDA from approving Caraco’s ANDA. 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. An approved label may cover both patented and unpatented uses. Nothing in the FDA regulations or FDA Form 3542 suggest that the patentee may derive Orange Book use code information from the portion of the label referring to unpatented uses. On the contrary, the applicable regulations and FDA Form 3542 are clear that the patentee is required to utilize those portions of the label that refer to the patented use. *See* 21 C.F.R. § 314.53(c)(2)(ii)(P)(2) (requiring NDA holder to identify “the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted”).

74. Other than this instance, Novo Nordisk has always maintained that claim 4 of the ’358 patent covers only the metformin-repaglinide combination— the only plausible reading of that claim. Indeed, Novo Nordisk continues to use its original ‘358 patent use code description (U-546) for its repaglinide-metformin combination tablet PrandiMet, which does not face an imminent threat of generic competition. Novo Nordisk’s complaint for patent infringement

against Caraco 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)." [Caraco Am. Compl. ¶ 10]. Novo Nordisk took the same position in other litigation involving the `358 patent. *See, e.g.*, Complaint ¶ 10, *Novo Nordisk et al. v. Mylan Pharmaceuticals Inc.*, U.S. District Court for the District of New Jersey Case No. 3-09-cv-02445. Novo Nordisk represented to 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 Nordisk Citizen Petition, FDA- 2008-P-0343-0001, at 3 n.4 (Jun. 9, 2008).

75. For these reasons, Novo Nordisk's conduct in changing the use code narrative in the Orange Book was a sham. Indeed, Novo Nordisk's general counsel acknowledged that the amended code description was intended to circumvent FDA's December 2008 ruling and cause FDA "to prevent generic applicants [like Caraco] from withholding critical information about the predominant approved use of repaglinide from consumers and health care practitioners."

76. As a result of this sham tactic, FDA will no longer permit Caraco to file a section viii statement carving out the patented repaglinide-metformin combination therapy as a predicate for securing approval of Caraco's ANDA to market its generic repaglinide for non-infringing uses. Novo Nordisk asserted that FDA should reject Caraco's section viii statement as to claim 4 of the '358 patent based on the new use code description. Novo Nordisk 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, Novo Nordisk claimed in effect that its monopoly on repaglinide (which expired with the compound patent on March 14, 2009) should

extend until the expiration date of the compound patent.

77. Novo Nordisk's filing of the sham use code has had the intended effect of delaying market entry of generic repaglinide. Novo Nordisk was aware that FDA could not construe the '358 patent and that it would not grant final approval to Caraco's ANDA with such a use code in place. On June 16, 2009, FDA denied Novo Nordisk's petition for reconsideration as moot because of the new use code, stating:

> FDA's role in listing patents in ministerial. FDA lists the patents submitted by the sponsor and publishes in the Orange Book the use codes that the sponsor provides. Sponsors must verify under penalty of perjury that the patent declaration represents "an accurate and complete submission of patent information" and attest that they are familiar with the requirements of 21 CFR 314.53 and that their submission complies with that of regulation (21 CFR 314.53(c)(2)(i)(Q)). FDA relies on the sponsors to craft an accurate and complete description of the relevant patent claims (to form the basis of the use code) and to identify the approved labeling that corresponds to those claims. Because FDA lacks expertise in assessing patents, the Agency determines which labeling corresponds to a submitted patent (and thus which labeling may be available to carve out) by relying on the use code submitted by the sponsor. Because the use code for the '358 patent has changed since our issuance of Citizen Petition Response and because our analysis and conclusions regarding labeling carveouts in that Citizen Petition Response were based on the previous use code, the factual predicate on which our previous response was based no longer applies.

(Footnote omitted.)

78. Novo Nordisk has been engaged in patent infringement litigation with Caraco since June 9, 2005 and, had it filed its use code change promptly after the 2007 labeling change, the issue could have been addressed in a timely manner well before the expiration of the repaglinide compound patent. Instead, Novo Nordisk manipulated the process by waiting until May 6, 2009 — eight (8) days before the compound patent expired — to change the use code narrative for the sole purpose of unlawfully obstructing FDA final approval of Caraco's ANDA.

6. The Injunction Requiring Novo Nordisk to Revert to its Original Use Code has been Vacated.

79. On September 25, 2009, the district court presiding over the patent infringement litigation entered an injunction requiring Novo Nordisk "to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended Form FDA 3542 that reinstates its form U-546 listing for Prandin and describes claim 4 of the '358 patent in section 4.2b as covering the 'use of repaglinide in combination with metformin to lower blood glucose.'" *See Novo Nordisk A/S v. Caraco Pharmaceuticals Laboratories, Ltd.*, 656 F. Supp.2d 729 (E.D. Mich. 2009). On April 14, 2010, however, a split decision by the United States Court of Appeals for the Federal Circuit vacated the injunction on the ground that the provision of the Hatch-Waxman Act at issue relative to Caraco's counterclaim (*i.e.*, 21 U.S.C. § 355(j)(5)(C)(ii)(I)) could not be applied to use code narratives and could only be used to correct or delete an erroneous patent number or expiration date. *Novo Nordisk A/S v. Caraco Pharmaceuticals Laboratories, Ltd.*, No. 2010-1001, __ F.3d __, 2010 1462300, at *7 (Fed. Cir. April 14, 2010) ("[T]he terms of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative."). As a result, Novo Nordisk has continued to maintain an objectively baseless use code narrative that prevents FDA from approving Caraco's section viii statement or ANDA. Novo Nordisk's use of the sham used code for Prandin may also prevent Caraco from disproving infringement in the patent infringement litigation because it is compelled to include information regarding the patented combination therapy in its label.

B. Novo Nordisk's Scheme to Wrongfully Suppress Generic Competition with a Fraudulently Obtained Patent and/or Sham Litigation.

1. Fraud on the PTO to Obtain the '358 Patent

80. 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 Muller and Dr. Lisbeth Hemingsen filed the '526 application with the United States Patent and Trademark Office ("PTO") which claimed, *inter alia*, a method of treating patients with NIDDM by administering a combination of repaglinide with another drug that was used to treat NIDDM, metformin. Dr. Muller 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 Novo Nordisk A/S and was prosecuted by attorneys at Novo Nordisk Inc.

81. 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 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."

82. Despite Novo Nordisk's 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 Novo Nordisk's 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."

83. In response to these rejections, Novo Nordisk argued that the combination of repaglinide and metformin had synergistic effects that a skilled artisan would not have predicted. In support of their contention, Novo Nordisk relied on results from a clinical trial labeled as Example 3 in the application ("Example 3"). Novo Nordisk 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."

84. Because the Examiner maintained her rejection of the claims notwithstanding Example 3, Novo Nordisk submitted a declaration from Dr. Jeppe Sturis, a Principal Scientist for Novo Nordisk A/S. In his declaration, Dr. Sturis described the results of a study in which he examined the effect of the combination of repaglinide and metformin on Zucker obese rats. Dr. Sturis concluded that his rat study, along with Example 3, "strongly suggest[ed] that the combination of repaglinide and metformin has synergistic properties in type 2 diabetic patients."

85. 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 PTO, 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." (Emphasis added.)

86. Moreover, Dr. Sturis did not say in his declaration that the repaglinide-metformin combination resulted in synergistic properties that were surprising or otherwise unexpected. Rather, the only "evidence" to support unexpected results from the combination submitted to the PTO is an attorney argument that accompanied the declaration. Specifically, Novo Nordisk's attorney contended that the Examiner's rejection was rebutted by "the evidence of synergistic and surprising results" shown in Example 3 and Dr. Sturis' study.

87. After Novo Nordisk's submission of Dr. Sturis' 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." (Emphasis added.) In fact, Novo Nordisk conceded in the *Caraco* litigation that Example 3 and Dr. Sturis's declaration are the only scientific data submitted during the prosecution of the '526 application to support Novo Nordisk's contention that the combination of repaglinide and metformin has synergistic effects.

2. Novo Nordisk's Inequitable Conduct Before The PTO

88. Novo Nordisk misled the Examiner by not disclosing material information to during the prosecution of the '358 patent.

89. *First*, Novo Nordisk never disclosed to the PTO three clinical studies conducted by Novo Nordisk A/S that directly conflicted with Novo Nordisk'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 A/S initiated a clinical study with a trial ID of AGEE-3010. 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. On or about December 2, 2002, Novo Nordik A/S issued a final report for AGEE-3010. The final report states "[w]hen analyzed 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*." (Emphasis added.) 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. 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. 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 HbA1c 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 HbA1c)." (Emphasis added.)

c. On or about March 6, 2002, Novo Nordisk A/S initiated a clinical study with a trial ID of AGEE-1411. The study was conducted to compare the efficacy of metformin and repaglinide used in monotherapy with the combination therapy of metformin and

repaglinide. 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."

90. 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 PTO during the prosecution of that patent.

91. Novo Nordisk's failure to disclose these three clinical studies to the Examiner constitutes a material omission. Again, the results of these clinical trials conflict with the representations made by Novo Nordisk A/S, Dr. Muller, 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 Examiners' repeated rejections of the application underlying the '358 patent.

92. In fact, 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's 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 FDA as part of the NN4440 project. Project "NN4440" concerns or concerned the development of a fixed combination product of repaglinide and metformin. In this email, Cliff Hall stated (in underlined text), "this trial appears relevant, and I don't see how we can avoid including it" in a production to FDA. 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.

93. Upon information and belief, the existence and/or outcome of studies AGEE-3010, AGEE-3018, and AGEE-1411 were known to Novo Nordisk's attorneys who prosecuted the '358 patent, Dr. Muller and/or Dr. Sturis, and they intended to withhold disclosure of these studies from the PTO.

94. *Second*, Novo Nordisk never disclosed to the PTO that one skilled in the art could not determine if a synergistic effect existed from the results of Example 3. 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. Novo Nordisk 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. Despite this knowledge, Novo Nordisk 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. (Emphasis added.) Novo Nordisk had no basis for such a

representation. In fact, they knew it to be untrue.

95. *Finally*, as alleged above, Novo Nordisk never disclosed to the PTO 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 PTO – 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." (Emphasis added.)

96. 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 District Court 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).

3. Novo Nordisk's Improper Listing of the '358 patent in the Orange Book

97. As described above, Novo Nordisk obtained the '358 patent by willful fraud on the PTO.

98. As the ‘358 patent was fraudulently obtained, it is unenforceable.

99. As a wrongfully obtained and unenforceable patent, the ‘358 patent was not eligible for listing in the FDA Orange Book at the time Novo Nordisk so listed it.

100. As Novo Nordisk knowingly listed an ineligible patent in the Orange Book, Novo Nordisk has deliberately and knowingly misused the FDA’s Orange Book listing process in an effort to exclude competition for Prandin.

4. Novo Nordisk’s Filing of Sham Lawsuits

101. But for Novo Nordisk’s unlawful listing of the ‘358 patent in the Orange Book, Caraco would have filed a Paragraph III certification with its ANDA for repaglinide, alleging that the only patent listed for the product expired March 14, 2009. Under the terms of the statute, a Paragraph III certification is not an act of infringement, and Novo Nordisk would have no basis upon which to sue. Instead, Caraco had to make certifications in its ANDA relative to the to the ‘358 patent, which ultimately resulted in the patent infringement litigation against it and its parent company (Sun Pharmaceutical Industries, Ltd.).

102. In addition, Mylan Pharmaceuticals, Inc. (“Mylan”) is a manufacturer of generic pharmaceutical products with its headquarters in Morgantown, West Virginia. In 2009, Mylan filed ANDA 90-252 with FDA for approval of generic repaglinide. Mylan’s ANDA included a Paragraph IV certification that claims 1-3 and 5 of the ‘358 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan’s repaglinide. On April 7, 2009, Mylan provided notice of its Paragraph IV certification to Novo Nordisk.

103. On May 20, 2009, Novo Nordisk sued Mylan for infringement of the ‘358 patent.

Novo Nordisk Inc. et al v. Mylan Pharmaceuticals Inc., No. 3:09-cv-02445 (D.N.J.). Because Caraco was the first generic manufacturer to challenge the '358 patent, however, Mylan's ANDA may not be approved until after the expiration of Caraco's exclusivity period, if any. On March 31, 2010, the United States District Court for the District of New Jersey dismissed Novo Nordisk's infringement action against Mylan for failing to plead an act of infringement in connection with Mylan's section viii statement, which was submitted in connection with claim 4 of the '358 patent.

104. By preventing Caraco (the first ANDA filer) from obtaining final FDA approval, Novo Nordisk may have created a bottleneck by which Mylan was also excluded from the relevant market. By statute, Mylan cannot come to market until 180 days after Caraco does so. Thus, the anticompetitive scheme has effectively kept out potential generic competitors in a market in which generic entry causes immediate, rapid, and in most cases automatic, generic substitution.

105. As a result of Novo Nordisk's filing of sham litigation, Plaintiff and the Class have continued to overpay for their purchases of branded and generic forms of Prandin. But for the sham litigation, Caraco would have received final approval on March 15, 2009 (after the expiration of the compound patent). As a result, Plaintiff and the Class continue to be overcharged by paying higher prices than would have prevailed in the absence of Defendant's unlawful conduct.

106. In the alternative, but for the filing of sham litigation, the generic competitors would not have filed Paragraph IV certifications to the '358 patent, and Novo Nordisk would

have no artificial act of infringement upon which to base its otherwise baseless patent litigation to enforce the patent.

107. After filing sham litigation to enforce the '358 patent, Novo Nordisk continued to engage in inequitable and unlawful conduct with regard to the '358 patent in an effort to continue its monopoly after the expiration of the repaglinide composition patent. In particular, as alleged above, Novo Nordisk illegally submitted materially misleading and incomplete information to FDA in a deliberate effort to delay or prevent approval of Caraco's ANDA, which seeks approval to market repaglinide solely for non-infringing uses.

C. Overarching scheme to violate the Sherman Act

108. The anticompetitive conduct set forth separately above was also part of an overarching scheme by Novo Nordisk to unlawfully establish and maintain its monopoly in the market for Prandin (repaglinide) and exclude any actual or potential AB-rated generic competitors.

109. Novo Nordisk's overarching scheme consisted of the following conduct:

a. filing a baseless use code related to the '358 shortly before the expiration of the compound patent so as to prevent FDA approval of Caraco's ANDA;

b. the fraudulent procurement of the '358 patent from the PTO;

c. the improper listing of the '358 patent in the FDA's Orange Book; and

d. the filing of sham infringement litigation to enforce the fraudulently obtained '358 patent.

110. Novo Nordisk's overarching scheme to monopolize this market has worked. Novo Nordisk remains, to this day, the only supplier of repaglinide in the United States, and

those who purchase from Novo Nordisk continue to suffer overcharges on these purchases.

111. But for Novo Nordisk's overarching scheme to monopolize the market, generic entry would have occurred on March 15, 2009.

EFFECTS ON COMPETITION

112. Novo Nordisk's scheme to delay the introduction into the U.S. marketplace of any generic version of Prandin has caused Plaintiff and the Class to pay more than they otherwise would have paid for repaglinide.

113. As noted, generic versions of a brand name drug are initially priced significantly below the brand name drug. As a result, upon generic entry, direct purchasers rapidly substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug decrease further because of competition among the generic manufacturers. This price competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand name drug at a reduced price. Consequently, brand name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial overcharges from that delay.

ANTITRUST IMPACT UPON PLAINTIFF AND MEMBERS OF THE CLASS

114. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Prandin from Defendants. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their repaglinide purchases. If generic competitors had not been unlawfully prevented from earlier

entering the market and competing with Defendants, direct purchasers, such as Plaintiff, would have paid less for repaglinide by (a) substituting purchases of less-expensive, generic repaglinide for their purchases of more-expensive branded Prandin, (b) receiving discounts and/or lowering prices on their remaining branded Prandin purchases, and (c) purchasing generic repaglinide at lower prices sooner.

115. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

MONOPOLY POWER

116. At all times referenced herein, Novo Nordisk has had monopoly power with respect to its Prandin brand. Novo Nordisk has had at all times the power to maintain the price of Prandin at supra-competitive levels profitably, without losing substantial sales.

117. Significant, non-transitory price increases by Novo Nordisk for Prandin have not caused a significant loss of sales to other products.

118. Novo Nordisk sells Prandin at prices well in excess of marginal costs and enjoys high profit margins.

119. Novo Nordisk has the power to exclude competition.

120. To the extent that defining a relevant product market is necessary in this case, the relevant product market is repaglinide in brand or generic forms.

121. The relevant geographic market is the United States.

122. During and prior to the proposed Class Period, Defendants held a 100% share in

the relevant product market in the United States.

CLAIMS FOR RELIEF

COUNT I

(FOR DAMAGES UNDER SECTION 4 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATION OF SECTION 2 OF THE SHERMAN ACT)

123. Plaintiff incorporates by reference the preceding allegations.

124. At all times relevant, Novo Nordisk possessed monopoly power in the market for repaglinide in the United States which Novo Nordisk sold as Prandin.

125. In order to prevent generic competition and unlawfully maintain its monopoly in the market for repaglinide, Novo Nordisk engaged in the anticompetitive conduct described above that included:

a. the fraudulent procurement of the '358 patent from the PTO;

b. the improper listing of the '358 patent in the FDA's Orange Book;

c. the filing of infringement litigation to enforce the fraudulently obtained '358 patent;

d. shortly before the expiration of the patent on the repaglinide compound, the filing with FDA of a baseless use code change for the '358 patent; and

e. the pursuit of an overarching anticompetitive scheme that involved the conduct set forth above that was designed to, and did, delay the introduction of generic formulations of Prandin into the market.

126. Novo Nordisk's conduct constituted unlawful acts of monopolization as set forth in *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1985) and *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*, 508 U.S. 49 (1993) and otherwise enabled it to unlawfully maintain its monopoly in violation of Section 2 of the

Sherman Act.

127. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices for their repaglinide purchases.

128. Plaintiff and members of the Class have been injured in their business or property by Novo Nordisk's antitrust violations. Their injury consists of paying higher prices for their repaglinide purchases than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent and flows from that which makes Novo Nordisk's conduct unlawful, and Plaintiff is a proper entity to bring a case concerning this conduct.

COUNT II

(INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATION OF SECTION 2 OF THE SHERMAN ACT)

129. Plaintiff repeats and realleges the preceding and subsequent paragraphs as though set forth herein.

130. As alleged above, Defendants knowingly and willfully engaged in a course of conduct designated to unlawfully maintain and prolong their monopoly position in the market for repaglinide in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

131. Plaintiff and the other members of the Class have been injured in their business or property by reason of Defendants' antitrust violation alleged in this Count. Their injury consists of being deprived of the ability to purchase less expensive, generic repaglinide, and paying higher prices for Prandin than they would have paid in the absence of the antitrust violation. The injury to Plaintiff and the Class is the type of injury antitrust laws were designed to prevent, and

the injury flows from Defendants' unlawful conduct. Plaintiff and members of the Class are threatened with further injuries as a result of Defendants' continuing scheme, as alleged herein.

132. Plaintiff and the Class seek injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, to correct for the anti-competitive market effects caused by the unlawful conduct of Defendants, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that:

A. the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiff's claim for injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages; and certify Plaintiff as representatives of the Class;

B. Defendants be enjoined from continuing the illegal activities alleged herein;

C. Judgment be entered in favor of Plaintiff and the Class and against Defendants for damages representing the overcharges paid by Plaintiff and the other members of the Class, trebled;

D. The Court award pre- and post-judgment interest;

E. The Court award costs of suit, including reasonable attorneys' fees; and

F. Plaintiff and the Class be granted such other and further as the Court deems just and necessary.

JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint that are so triable.

Respectfully submitted,

Dated: May 28, 2010

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