

STATE OF WISCONSIN,

Plaintiff,

Case No. 04-CV-1709
Unclassified - Civil: 30703

v.

AMGEN INC., et al.,Defendants.

**ANSWER OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION
TO THE STATE OF WISCONSIN'S SECOND AMENDED COMPLAINT**

Defendant Novartis Pharmaceuticals Corporation ("NPC"), for its Answer to the State of Wisconsin's ("State of Wisconsin" or "Plaintiff") Second Amended Complaint ("Complaint") in the captioned action, by its undersigned counsel, alleges upon knowledge as to itself, and upon information and belief as to all other matters, as follows:

NATURE OF THE ACTION.¹

1. Denies each and every allegation set forth in numbered paragraph 1 of the Complaint as to NPC, except states that the State of Wisconsin purports to bring this action, but denies that there is any basis on which to permit it to do so, and states that NPC is a manufacturer of branded prescription drugs, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. To the extent numbered paragraph 1 states conclusions of law, no response is required.

¹ For ease of reference, NPC has included in this Answer the headings used in the Complaint, but does not thereby admit any inference that could be drawn from those headings.

I. PARTIES AND JURISDICTION.

2. Denies each and every allegation set forth in numbered paragraph 2 of the Complaint as to NPC, except states that the State of Wisconsin purports to bring this action in its sovereign capacity, but denies that there is any basis on which to permit it to do so, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein. To the extent numbered paragraph 2 states conclusions of law, no response is required.

3. Denies each and every allegation set forth in numbered paragraph 3 of the Complaint as to NPC, except states that NPC is a pharmaceutical company, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

4. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 4 of the Complaint.

5. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 5 of the Complaint.

6. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 6 of the Complaint.

7. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 7 of the Complaint.

8. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 8 of the Complaint.

9. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 9 of the Complaint.

10. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 10 of the Complaint.

11. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 11 of the Complaint.

12. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 12 of the Complaint.

13. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 13 of the Complaint.

14. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 14 of the Complaint.

15. Admits that Plaintiff purports to refer to NPC and Sandoz Inc. as the “Novartis Group,” but denies that such a group exists, states that (i) NPC is engaged in the business of manufacturing and selling branded pharmaceuticals, (ii) NPC’s principal place of business is located at One Health Plaza, East Hanover, New Jersey 07936, (iii) Sandoz Inc. is engaged in the business of manufacturing and selling generic pharmaceuticals, (iv) Sandoz Inc.’s principal place of business is located in Princeton, New Jersey, and (v) Sandoz Inc. is a wholly owned, but independently operated, subsidiary of NPC, and denies that (i) NPC is a New Jersey Corporation, and (ii) Sandoz Inc. is a Delaware corporation.

16. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 16 of the Complaint.

17. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 17 of the Complaint.

18. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 18 of the Complaint.

19. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 19 of the Complaint.

20. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 20 of the Complaint.

21. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 21 of the Complaint.

22. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 22 of the Complaint.

23. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 23 of the Complaint.

24. Numbered paragraph 24 of the Complaint states conclusions of law to which no response is required.

25. Numbered paragraph 25 of the Complaint states conclusions of law to which no response is required.

II. FACTUAL BACKGROUND

A. The Market For Prescription Drugs.

26. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 26 of the Complaint, except admits that (i) there is a separate NDC number for each dosage and package size of each drug manufactured by NPC, (ii) NPC sells drugs to wholesalers and warehousing retailers (retail chains of ten or more stores that have warehouses performing wholesale-type functions for those stores that do not purchase NPC product through wholesalers) who may then sell the drugs to “providers,” such as physicians,

hospitals, and retail pharmacies, and (iii) where a patient has private or public health insurance, private insurance companies, self-insured entities, or government entities pay for a portion of certain prescription drugs prescribed to the patient.

27. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 27 of the Complaint.

28. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 28 of the Complaint, except (i) admits that prescription drugs are only dispensed on a physician's or other qualified medical professional's order, and that pharmacists do not prescribe drugs, (ii) states that hospitals and long term care pharmacies may have formularies, and (iii) states that NPC does not market or sell generic drugs, and that none of the drugs attributed to NPC in Exhibits D and E of the Complaint is a generic drug.

29. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 29 of the Complaint, but states that the prescription drug market differs from other markets.

30. Denies each and every allegation set forth in numbered paragraph 30 of the Complaint as to NPC, except denies knowledge or information sufficient to form a belief as to the truth of the allegation that "spreads" for particular drugs influence providers' choice of drugs, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

B. The Purpose of the Medicaid Program and How it Responds to the Complexity of the Drug Markets.

31. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 31 of the Complaint.

32. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 32 of the Complaint, except states that (i) NPC has chosen to participate in the Wisconsin Medicaid program, (ii) the Wisconsin Medicaid program reimburses pharmacists for certain NPC drugs administered to Medicaid recipients, and (iii) NPC sells drugs to wholesalers, distributors, and warehousing retailers (retail chains of ten or more stores that have warehouses performing wholesale-type functions for those stores that do not purchase NPC product through wholesalers) who may then sell the drugs to providers, such as physicians, hospitals, and retail pharmacies, who may then provide certain NPC drugs to Wisconsin Medicaid recipients.

33. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 33 of the Complaint, except states that some state Medicaid programs use reimbursement formulas for certain drugs, and respectfully refers the Court to 42 C.F.R. § 447.301 and 42 C.F.R. § 447.331 for a full and complete reading of their provisions. To the extent numbered paragraph 33 states a conclusion of law and purports to recite laws and regulations, no response is required.

34. Denies each and every allegation set forth in numbered paragraph 34 of the Complaint as to NPC, except states that (i) First DataBank and the Redbook are compendiums that publish price information on NPC's drugs, (ii) from time to time during the relevant period, NPC provided price lists to third party publishers, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

35. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 35 of the Complaint, but denies that First DataBank has always purported to supply the states with AWP information that it received from the drug

manufacturers during the entire relevant period, states that NPC does not have control over the information that First DataBank, an independent third party, publishes, and respectfully refers the Court to Exhibit A to the Complaint for a full and complete reading of its contents.

36. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 36 of the Complaint, except states that (i) from time to time during the relevant period, NPC provided price lists to third party publishers, including First DataBank, which contained, *inter alia*, “AWPs” and “WACs” for certain of its drugs, (ii) AWP is commonly understood to be a benchmark used throughout the industry and not an average price charged by wholesalers, (iii) NPC’s WAC or “ex-factory” price is the price NPC charges wholesalers and certain commercial direct purchasers for its product, (iv) from at least mid-1997 to present, NPC’s published price lists containing AWP have stated that AWP is a mathematical construct and is not intended to be a price charged by NPC for any product to any customer, (v) NPC does not have control over the information that First DataBank, an independent third party, publishes, and (vi) 42 U.S.C.A. § 1396a(a)(30)(A) provides that Wisconsin Medicaid must “provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments . . . are sufficient to enlist enough providers so that care and services available under the plan at least to the extent that such care and services are available to the general population in the geographic area.”

37. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 37 of the Complaint, and states that NPC does not have control over the information that First DataBank, an independent third party, publishes.

38. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 38 of the Complaint.

39. Denies each and every allegation set forth in numbered paragraph 39 of the Complaint as to NPC, except states that (i) from time to time during the relevant period, NPC provided price lists to third party publishers, including First DataBank, which contained, *inter alia*, “AWPs” and “WACs” for certain of its drugs, (ii) AWP is commonly understood to be a benchmark used throughout the industry and not an average price charged by wholesalers, (iii) NPC’s WAC or “ex-factory” price is the price NPC charges wholesalers and certain commercial direct purchasers for NPC products, (iv) from at least mid-1997 to present, NPC’s published price lists containing AWP have stated that AWP is a mathematical construct and is not intended to be a price charged by NPC for any product to any customer, and (v) NPC does not have control over the information that First DataBank, an independent third party, publishes, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

C. Defendant’s Corruption of the Government Medicaid Assistance Programs.

40. Denies each and every allegation set forth in numbered paragraph 40 of the Complaint as to NPC, states that 42 U.S.C.A. § 1396a(a)(30)(A) provides that Wisconsin Medicaid must “provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments . . . are sufficient to enlist enough providers so that care and services available under the plan at least to the extent that such care and services are available to the general population in the geographic area,” and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

41. Denies each and every allegation set forth in numbered paragraph 41 of the Complaint as to NPC, except denies knowledge or information sufficient to form a belief as to the truth of the allegation that the higher the spread between AWP and the wholesale price providers pay, the more profit providers can make, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

42. Denies each and every allegation set forth in numbered paragraph 42 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

43. Denies each and every allegation set forth in numbered paragraph 43 of the Complaint as to NPC, states that from at least mid-1997 to present, NPC's published price lists containing AWP have stated that AWP is a mathematical construct and is not intended to be a price charged by NPC for any product to any customer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

44. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 44 of the Complaint, and to the extent this paragraph purports to recite testimony, no response is required.

45. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 45 of the Complaint, and to the extent that such a lawsuit exists, respectfully refers the Court to the pleadings in that lawsuit for a full and complete reading of their contents.

46. Denies each and every allegation set forth in numbered paragraph 46 of the Complaint as to NPC, states that none of the drugs listed in Exhibit C is an NPC branded product, respectfully refers the Court to Exhibit C to the Complaint and to Payment Reform for

Part B Drugs, 68 Fed. Reg. 50, 430 (August 20, 2003) for a full and complete reading of their contents, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

47. Denies each and every allegation set forth in numbered paragraph 47 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

48. Denies each and every allegation set forth in numbered paragraph 48 of the Complaint as to NPC, except admits that Cardinal and AmerisourceBergen are national drug wholesalers, denies knowledge or information sufficient to form a belief as to the truth of the allegations regarding (i) Plaintiff's efforts to secure data from First DataBank, Cardinal, and AmerisourceBergen, (ii) summaries Plaintiff has generated relating to other NDC codes, and (iii) whether First DataBank is the business that supplies Plaintiff with pricing information for use in its Medicaid program, respectfully refers the Court to Exhibits D and E for a full and complete reading of their contents, states that NPC has produced pricing data for certain drugs, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

49. Denies each and every allegation set forth in numbered paragraph 49 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein and states that (i) NPC's WAC price is the price at which it sells its products directly to wholesalers and warehousing retailers (retail chains of ten or more stores that have warehouses performing wholesale-type functions for those stores that do not purchase NPC product through wholesalers) and (ii) the "charge back system" referred to in numbered paragraph 49 is used to reimburse wholesalers for sales made by them on NPC's

behalf to end-user customers such as state owned hospitals and health care facilities, private hospitals, nursing homes, and staff-model health maintenance organizations (HMOs that own pharmacies to dispense drugs to their beneficiaries) pursuant to discount contracts between NPC and such end-user customers. NPC further states that the “charge back” is and has been broadly known throughout the industry, and to Plaintiff, for many years; Plaintiff benefits from the system whenever one of its facilities uses it to obtain lower net prices for NPC products while being able to purchase through a wholesaler; and the lawfulness of the system was challenged by pharmacists who do not benefit from it in *In re Brand Name Prescription Drug Antitrust Litigation* and was determined in that case to be entirely lawful. 1999 WL 301653, at *4 (N.D. Ill. Apr. 30, 1999).

III. DEFENDANTS’ EXACERBATION OF THE COMPLEXITIES OF THE MARKET AND AFFIRMATIVE CONCEALMENT OF THEIR WRONGDOING.

50. Denies each and every allegation set forth in numbered paragraph 50 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

51. Denies each and every allegation set forth in numbered paragraph 51 of the Complaint as to NPC, except states that the published prices of NPC products change from time to time, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

52. Denies each and every allegation set forth in numbered paragraph 52 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

53. Denies each and every allegation set forth in numbered paragraph 53 of the Complaint as to NPC, otherwise denies knowledge or information sufficient to form a belief as to

the truth of the allegations set forth therein, and states (i) that NPC's WAC price is the price at which it sells its products directly to wholesalers and warehousing retailers (retail chains of ten or more stores that have warehouses performing wholesale-type functions for those stores that do not purchase NPC product through wholesalers) and (ii) that the "charge back system" referred to in numbered paragraph 53 is used to reimburse wholesalers for sales made by them on NPC's behalf to end-user customers such as state owned hospitals and health care facilities, private hospitals, nursing homes, and staff-model health maintenance organizations (HMOs that own pharmacies to dispense drugs to their beneficiaries) pursuant to discount contracts between NPC and such end-user customers. NPC further states that the "charge back" is and has been broadly known throughout the industry, and to Plaintiff, for many years; Plaintiff benefits from the system whenever one of its facilities uses it to obtain lower net prices for NPC products while being able to purchase through a wholesaler; and the lawfulness of the system was challenged by pharmacists who do not benefit from it in *In re Brand Name Prescription Drug Antitrust Litigation* and was determined in that case to be entirely lawful. 1999 WL 301653, at *4 (N.D. Ill. Apr. 30, 1999).

54. Denies each and every allegation set forth in numbered paragraph 54 of the Complaint as to NPC, except states that NPC may keep certain competitively sensitive pricing information confidential, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

55. Denies each and every allegation set forth in numbered paragraph 55 of the Complaint as to NPC, except states that (i) NPC offers discounts and rebates from its WAC price for certain customers on certain products, and has contractual arrangements with certain customers regarding the prices of certain products, (ii) NPC sells its products directly to

wholesalers, distributors, and warehousing retailers (retail chains of ten or more stores that have warehouses performing wholesale-type functions for those stores that do not purchase NPC product through wholesalers), and (iii) generally, NPC does not know the price at which wholesalers resell its products, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

56. Denies each and every allegation set forth in numbered paragraph 56 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

57. Denies each and every allegation set forth in numbered paragraph 57 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

58. Denies each and every allegation set forth in numbered paragraph 58 of the Complaint as to NPC, except denies knowledge and information sufficient to form a belief as to the truth of the allegations that (i) the greater the difference between the actual price and the reported AWP, the more money the providers make and (ii) that all providers are reimbursed in some manner on the basis of AWP for at least some of the drugs they sell or administer, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

59. Denies each and every allegation set forth in numbered paragraph 59 of the Complaint as to NPC, respectfully refers the Court to the 2000 Edition of Novartis Pharmacy Benefit Report: Facts and Figures for a full and complete reading of its contents, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

60. Denies each and every allegation set forth in numbered paragraph 60 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

IV. THE INJURY TO GOVERNMENTAL HEALTH PLANS CAUSED BY DEFENDANTS' FALSE WHOLESALE PRICES.

A. The Wisconsin Medicaid Program.

61. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 61 of the Complaint, except admits that Medicaid is a joint federal and state health care entitlement program authorized by federal law, with mandatory and optional provisions for eligibility and benefits covered, including prescription drugs.

62. Denies knowledge or information sufficient to form a belief as to the truth of the specific allegations set forth in numbered paragraph 62 of the Complaint, except (i) admits that the State of Wisconsin utilizes formulas to calculate drug reimbursement to medical providers who dispense certain drugs to Medicaid recipients, and (ii) states that the reimbursement formulas used by the State of Wisconsin are not always clear.

63. Denies knowledge or information sufficient to form a belief as to the truth of the specific allegations set forth in numbered paragraph 63 of the Complaint, except states that CMS generally establishes FUL for certain drugs, and respectfully refers the Court to 42 C.F.R. § 447.332 for a full and complete reading of its provisions. To the extent that numbered paragraph 63 states conclusions of law, no response is required.

64. Denies each and every allegation set forth in numbered paragraph 64 of the Complaint as to NPC, except states that (i) at all relevant times, NPC was generally aware that the State of Wisconsin utilizes formulas to calculate drug reimbursement to medical providers

who dispense certain drugs to Medicaid recipients, and (ii) the reimbursement formulas used by the State of Wisconsin are not always clear, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

65. Denies each and every allegation set forth in numbered paragraph 65 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

66. Denies each and every allegation set forth in numbered paragraph 66 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

B. Medicare.

67. Admits the allegations set forth in numbered paragraph 67 of the Complaint, and respectfully refers the Court to 42 U.S.C. 1395, *et. seq.* for a full and complete reading of their provisions. To the extent numbered paragraph 67 states conclusions of law, no response is required.

68. Denies knowledge or information sufficient to form a belief as to the truth of the specific allegations set forth in numbered paragraph 68 of the Complaint, except admits that Medicare Part B is an optional program that provides coverage of some healthcare services for certain Wisconsin citizens, and respectfully refers the Court to 42 U.S.C. 1395j through 1395w-4 for a full and complete reading of their provisions. To the extent numbered paragraph 68 states conclusions of law no response is required.

69. Denies knowledge or information sufficient to form a belief as to the truth of the allegation that Medicare Part B's limited benefit for drugs is "at issue here," and otherwise admits the allegations set forth in numbered paragraph 69 of the Complaint, except to the extent numbered paragraph 69 states conclusions of law, as to which no response is required.

70. Denies knowledge or information sufficient to form a belief as to the truth of the specific allegations set forth in numbered paragraph 70 of the Complaint, except (i) denies that NPC “falsely reported” AWP, (ii) admits that Medicare utilizes formulas to determine how much providers are to be reimbursed for the administration of certain drugs to Medicare Part B beneficiaries, and respectfully refers the Court to 42 C.F.R. § 405.517 for a full and complete reading of its provisions. To the extent numbered paragraph 70 states conclusions of law, no response is required.

71. Denies each and every allegation set forth in numbered paragraph 71 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

V. DEFENDANTS’ CONDUCT WAS INTENTIONALLY IN DISREGARD OF ESTABLISHED LAW.

72. Admits the allegations set forth in numbered paragraph 72 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth herein.

73. Denies each and every allegation set forth in numbered paragraph 73 of the Complaint as to NPC, respectfully refers the Court to *FTC v. Colgate-Palmolive Co.*, 380 U.S. 372 (1965) and *FTC v. The Crescent Publishing Group, Inc.*, 129 F. Supp.2d 311 (S.D.N.Y. 2001) for a full and complete reading of their contents, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 73 states conclusions of law, no response is required.

74. Denies the applicability of Wis. Stat. § 100.18(10)(b) to NPC, respectfully refers the Court to Wis. Stat. § 100.18(10)(b) for a full and complete reading of its provisions, and states that numbered paragraph 74 states conclusions of law to which no response is required.

75. Denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in numbered paragraph 75 of the Complaint.

76. Denies each and every allegation set forth in numbered paragraph 76 of the Complaint as to NPC, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 76 states conclusions of law, no response is required.

77. Denies each and every allegation set forth in numbered paragraph 77 of the Complaint as to NPC, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent the numbered paragraph 77 states conclusions of law, no response is required.

VI. HARM TO WISCONSIN AND ITS CITIZENS.

78. Denies each and every allegation set forth in numbered paragraph 78 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

COUNT I — Violation of Wis. Stat. § 100.18(1)

79. NPC repeats and incorporates by reference its responses to numbered paragraphs 1 through 78 above.

80. Denies each and every allegation set forth in numbered paragraph 80 of the Complaint as to NPC, respectfully refers the Court to Wis. Stat. § 100.18(1) for a full and complete reading of its provisions, otherwise denies knowledge or information sufficient to form

a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 80 states conclusions of law, no response is required.

81. Denies each and every allegation set forth in numbered paragraph 81 of the Complaint as to NPC, respectfully refers the Court to Wis. Stat. § 100.18(1) and Wis. Stat. § 100.264(2) for full and complete readings of their provisions, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 81 states conclusions of law, no response is required.

82. Denies each and every allegation set forth in numbered paragraph 82 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

NPC further denies that Plaintiff is entitled to a judgment or any other relief requested in the unnumbered “WHEREFORE” paragraph immediately following numbered paragraph 82 of the Complaint.

COUNT II — Violation of Wis. Stat. § 100.18(10)(b)

83. NPC repeats and incorporates by reference its responses to numbered paragraphs 1 through 82 above.

84. Denies each and every allegation set forth in numbered paragraph 84 of the Complaint as to NPC, respectfully refers the Court to Wis. Stat. § 100.18(10) for a full and complete reading of its provisions, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 84 states conclusions of law and/or purports to recite laws or regulations, no response is required.

85. Denies each and every allegation set forth in numbered paragraph 85 of the Complaint as to NPC, respectfully refers the Court to Wis. Stat. §§ 100.18(10)(b) and 100.264(2) for a full and complete reading of their provisions, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 85 states conclusions of law, no response is required.

86. Denies each and every allegation set forth in numbered paragraph 86 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

NPC further denies that Plaintiff is entitled to a judgment or any other relief requested in the unnumbered “WHEREFORE” paragraph immediately following numbered paragraph 86 of the Complaint.

COUNT III — Violation Of the Wisconsin Trust And Monopolies Act

87. NPC repeats and incorporates by reference its responses to numbered paragraphs 1 through 86 above.

88. Denies each and every allegation set forth in numbered paragraph 88 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

89. Denies each and every allegation set forth in numbered paragraph 89 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

90. Denies each and every allegation set forth in numbered paragraph 90 of the Complaint as to NPC, respectfully refers the Court to Wis. Stat. § 133.05 for a full and complete reading of its provisions, otherwise denies knowledge or information sufficient to form a belief

as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 90 states conclusions of law, no response is required.

91. Denies each and every allegation set forth in numbered paragraph 91 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

NPC further denies that Plaintiff is entitled to a judgment or any other relief requested in the unnumbered “WHEREFORE” paragraph immediately following numbered paragraph 91 of the Complaint.

**COUNT IV — VIOLATION OF WIS. STAT. § 49.49(4m)(a)(2)
MEDICAL ASSISTANCE FRAUD**

92. NPC repeats and incorporates by reference its responses to numbered paragraphs 1 through 91 above.

93. Admits the allegations set forth in numbered paragraph 93 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

94. Denies each and every allegation set forth in numbered paragraph 94 of the Complaint as to NPC, respectfully refers the Court to Wis. Stat. § 49.49(4m)(a)(2) for a full and complete reading of its provisions, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 94 states conclusions of law, no response is required.

95. Denies each and every allegation set forth in numbered paragraph 95 of the Complaint as to NPC, respectfully refers the Court to Wis. Stats. § 893.87 for a full and complete reading of its provisions, otherwise denies knowledge or information sufficient to form a belief

as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 95 states conclusions of law, no response is required.

COUNT V — Unjust Enrichment

96. NPC repeats and incorporates by reference its responses to numbered paragraphs 1 through 95 above.

97. Denies each and every allegation set forth in numbered paragraph 97 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

98. Denies each and every allegation set forth in numbered paragraph 98 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

99. Denies each and every allegation set forth in numbered paragraph 99 of the Complaint as to NPC, otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein, and states that to the extent numbered paragraph 99 states conclusions of law, no response is required.

100. Denies each and every allegation set forth in numbered paragraph 100 of the Complaint as to NPC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth therein.

NPC further denies that Plaintiff is entitled to a judgment or any other relief requested in the unnumbered “WHEREFORE” paragraph immediately following numbered paragraph 100 of the Complaint.

PLAINTIFF DEMANDS TRIAL BY JURY OF 12.

NPC further denies that Plaintiff has asserted any viable claims that would necessitate a trial by jury.

**NOVARTIS PHARMACEUTICALS
CORPORATION'S AFFIRMATIVE DEFENSES**

By alleging the matters set forth below, NPC does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters or that Plaintiff is relieved of its burdens to prove each and every element of its claims and the damages, if any, to which it is entitled. As and for its affirmative defenses, NPC alleges as follows:

FIRST AFFIRMATIVE DEFENSE

Plaintiff and/or its agents knew and were aware that AWP was not an average wholesale price or the actual acquisition cost of drugs. Legal and equitable principles preclude this action for damages and injunctive relief, and the Due Process Clause of the U.S. Constitution, prohibiting the absolute and arbitrary abuse of power, preclude Plaintiff from bringing claims and seeking damages as alleged in the Complaint.

SECOND AFFIRMATIVE DEFENSE

Some or all of Plaintiff's claims against NPC arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligations to properly establish appropriate reimbursement rates. To the extent that Plaintiff established Medicaid reimbursement rates by reference to AWP, it violated federal law in failing to establish Medicaid reimbursement rates as prescribed by federal law. Plaintiff is precluded by federal law from seeking damages, especially by reference to a different, lower AWP as alleged.

THIRD AFFIRMATIVE DEFENSE

Plaintiff was required by federal law to conduct surveys and have statistics and data justifying, and to represent and warrant to the federal government, that its Medicaid reimbursement rates for single source drugs were necessary and appropriate, as a condition to obtaining federal funds. This action, with respect to single source drugs, is inconsistent with and precluded by Plaintiff's actions, representations, and promises, and assumes that, with respect to single source drugs, Plaintiff made false claims to the federal government to obtain federal funds.

FOURTH AFFIRMATIVE DEFENSE

The claims alleged herein, based on the facts alleged, are barred by Plaintiff's own negligence or gross negligence. Among other things, the claims disregard Plaintiff's obligation under federal law, and they ignore Plaintiff's affirmative misstatements and declarations that were intended to cover up and hide from the view of the federal regulatory authority, and the Plaintiff's citizens and taxpayers, Plaintiff's failings referred to herein, as well as other inappropriate conduct by Plaintiff.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's reimbursement for drugs for Medicaid recipients were filed with, reviewed, and approved by a federal regulatory agency with authority to do so under the Medicaid Act. Actions in a state court seeking relief, including alleged damages, contending that the rates approved by a federal regulatory agency do not apply or are not binding are, as the United States Supreme Court directed, precluded by the Supremacy Clause. This action is barred by the Supremacy Clause of the Constitution.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted by the Commerce Clause and/or the dormant Commerce Clause of the United States Constitution.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated there under.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC are barred, in whole or in part, because it has suffered no damages as a result of the matters alleged in the Complaint.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on any alleged statements or conduct by NPC in judicial, legislative, or administrative proceedings of any kind or at any level of federal government.

TENTH AFFIRMATIVE DEFENSE

Plaintiff fails to state a claim against NPC upon which relief may be granted.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff has no standing or capacity to bring some or all of the claims.

TWELFTH AFFIRMATIVE DEFENSE

To the extent Plaintiff obtains, or is barred from, recovery in any other case predicated on the same factual allegations, Plaintiff is barred from seeking recovery against NPC based on the Complaint pursuant to the doctrines of *res judicata* and collateral estoppel, and the prohibition on double recovery for the same injury.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

FOURTEENTH AFFIRMATIVE DEFENSE

Any and all actions taken by NPC with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC are barred because NPC has complied with all applicable regulations of the federal and state governments.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because they violate NPC's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution and the Wisconsin Constitution, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

EIGHTEENTH AFFIRMATIVE DEFENSE

NPC's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiff.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC for injunctive relief were mooted by the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims for injunctive relief against NPC are barred by the doctrines of *in pari delicto* and/or unclean hands.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superceding conduct of third parties.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC are barred, in whole or in part, due to its failure to join indispensable parties.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC are misjoined with Plaintiff's claims against other defendants and must be severed.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC for damages are barred, in whole or in part: (1) because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery of Plaintiff and the allocation of any fault, if any exists, attributable to NPC; (2) because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has paid for products manufactured, marketed and sold by NPC after the filing of Plaintiff's original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating of the alleged damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

NPC is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

NPC denies that it has engaged in any conduct that entitles the State to recover penalty assessments and avers that the Complaint fails to state a claim upon which penalty assessments may be awarded to Plaintiff.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

The claims contained in the Complaint, which seek the recovery of penalty assessments, under Wisconsin law, violate the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States of America on the following grounds:

- a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose penalty assessments, which are penal in nature, against a civil defendant upon the Plaintiff's satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- b) the procedures pursuant to which any penalty assessments would be awarded fail to provide a reasonable limit on the amount of the award against NPC, which violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- c) the procedures pursuant to which any penalty assessments would be awarded fail to provide specific standards for the amount of the award of penalty assessments, which violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- d) the procedures pursuant to which any penalty assessments would be awarded result in the imposition of different penalties for the same or similar acts, and thus violates the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- e) the procedures pursuant to which any penalty assessments would be awarded permit the imposition of penalty assessments in excess of the maximum criminal fine for the

same or similar conduct, which thereby infringes the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and

f) the procedures pursuant to which any penalty assessments would be awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

The recovery of penalty assessments by the State in this action would violate Article I, sections 1, 6, 7, 8 and 11 of the Wisconsin Constitution on the following grounds:

a) it is impermissible to impose penalty assessments, which are penal in nature, upon a civil defendant upon the Plaintiff satisfying a burden of proof less than the “beyond a reasonable doubt” burden of proof required in criminal cases;

b) the procedures pursuant to which any penalty assessments would be awarded fail to provide a reasonable limit on the amount of the award against NPC;

c) the procedures pursuant to which any penalty assessments would be awarded are unconstitutionally vague;

d) the procedures pursuant to which any penalty assessments would be awarded fail to provide specific standards for the amount of the award of penalty assessments;

e) the award of penalty assessments in this case would constitute a deprivation of property without due process; and

f) the procedures pursuant to which any penalty assessments would be awarded permit the imposition of an excessive fine.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff fails to state with particularity facts to support the claims of fraudulent conduct against NPC in the Complaint, in violation of Wis. Stat. § 802.03(2).

THIRTIETH AFFIRMATIVE DEFENSE

To the extent that Plaintiff attempts to seek equitable relief against NPC, it is not entitled to such relief because it has an adequate remedy at law.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's unjust enrichment claims are barred, in whole or in part, because NPC has not accepted or retained any benefits under circumstances where it would be inequitable for NPC to do so.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's unjust enrichment claims are barred, in whole or in part, because Plaintiff has no authority to bring such claims either on behalf of itself or on behalf of Medicare Part B recipients.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's unjust enrichment claims are barred, in whole or in part, by contracts to which Plaintiff and NPC are parties.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred, in whole or in part, by the filed rate doctrine.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

NPC has not knowingly made or caused to be made any false statements or representation of material fact, as required under Wis. Stat. § 49.49(4m)(a)(2).

THIRTY-SIXTH AFFIRMATIVE DEFENSE

The State's claims are barred in whole or in part because the State did not rely on the allegedly fraudulent statements or conduct of NPC.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

NPC has made no assertion, representation or statement of fact which is "untrue," "deceptive," or "misleading," as required under Wis. Stat. §§ 100.18(1) and 100.18(10)(b).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's claims under Wis. Stat. § 100.18 are barred, in whole or in part, to the extent the claims involve the insurance business.

THIRTY-NINTH AFFIRMATIVE DEFENSE

NPC denies that Plaintiff has valid statutory claims against NPC under the state statutes alleged in Counts I, II, III and IV. However, if such claims are found to exist, NPC pleads all applicable defenses under the statutes.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC are barred, in whole or in part, because NPC did not make any false statements to Plaintiff or its agents. As to any statement asserted against NPC that

Plaintiff alleges to be false or misleading, NPC had no reasonable grounds to believe, and did not believe at the time such statement was made, that the statement was false or misleading.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff has no authority to seek restitution for third parties based on any alleged violation of Wis. Stat. § 49.49(4m)(a)(2).

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because NPC's conduct was neither "deceptive," "misleading," "unlawful," "false," nor "illegal."

FORTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because it did not consult with the Governor of the State of Wisconsin and/or the Department of Agriculture, Trade and Consumer Protection prior to bringing this suit.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims under Wis. Stat. § 49.49 are barred because NPC did not possess the requisite mental state required under the statute.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims against NPC under the Wisconsin Deceptive Trade Practices Act and the Wisconsin Secret Rebate Statute are barred in whole or in part to the extent that the Act (1)

does not allow (or did not allow at the time the conduct was alleged herein) for recovery by indirect purchasers; and (2) does not govern conduct that was primarily interstate in nature.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part with respect to any alleged overcharge or supracompetitive price because such supracompetitive price, if any, was absorbed in whole or in part by a person or entity that purchased the drugs at issue directly, and/or by an intermediate indirect purchaser, and was not passed through to Plaintiff.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiff fails to allege facts or a cause of action against NPC sufficient to support a claim for compensatory damages, attorneys' fees and/or legal fees, or any other relief.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of NPC as alleged in the Complaint.

FORTY-NINTH AFFIRMATIVE DEFENSE

Since at least 1997 NPC has affirmatively stated on its published price lists that the AWP reported on its lists was a mathematical construct and was not intended to be a price charged by NPC for any product to any customer. NPC thus disclosed in its price announcements that reported AWPs for NPC drugs did not, and were not intended to, represent the actual price paid by purchasers of such products. Accordingly, Plaintiff is estopped from claiming to have been defrauded by virtue of any action by NPC.

FIFTIETH AFFIRMATIVE DEFENSE

Any damages recovered by the Plaintiff from NPC must be limited by the applicable statutory ceilings on recoverable damages.

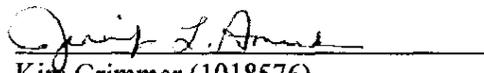
FIFTY-FIRST AFFIRMATIVE DEFENSE

NPC gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, defendant Novartis Pharmaceuticals Corporation demands that: (1) the Complaint be in all respects dismissed as to it; (2) it be awarded its costs of defending this action, including its reasonable attorneys' fees; and (3) it be awarded such other and further relief as the Court may deem just and proper.

Dated: August 11, 2006

Respectfully submitted,



Kim Grimmer (1018576)
Jennifer L. Amundsen (1037157)
SOLHEIM BILLING & GRIMMER, S.C.
One South Pinckney Street, Suite 301
P.O. Box 1644
Madison, WI 53701-1644

Jane W. Parver (admitted *pro hac vice*)
Saul P. Morgenstern (admitted *pro hac vice*)
Mark Godler (admitted *pro hac vice*)
Christine A. Neagle (admitted *pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
(212) 836-8000

*Attorneys for Defendant
Novartis Pharmaceuticals Corporation*

