IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
FRESENIUS KABI USA, LLC,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck") for its Complaint against Defendant Fresenius Kabi USA, LLC ("Fresenius") hereby alleges as follows:

THE PARTIES

1. Merck is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Upon information and belief, Fresenius is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. Upon information and belief, Fresenius expanded its presence in the United States in 2008 with the acquisition of APP Pharmaceuticals, LLC, which was merged with Fresenius. Upon information and belief, APP Pharmaceuticals, LLC, *inter alia*, developed, manufactured, and/or marketed injectable pharmaceutical products with a primary focus on the oncology, anti-infective, anesthetic/analgesic and critical care markets. Upon information and belief, APP Pharmaceuticals, LLC maintained a corporate agent at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

4. Upon information and belief, APP Pharmaceuticals, LLC was organized under the laws of the State of Delaware. Upon information and belief, on August 1, 2012, APP Pharmaceuticals, LLC changed its name to Fresenius Kabi USA, LLC.

5. Upon information and belief, Fresenius, *inter alia*, markets a portfolio of "pharmaceuticals and medical devices used to care for critically and chronically ill patients inside and outside the hospital," including "intravenous specialty and generic medicines," "infusion therapies," and "clinical nutrition." *Acetylcysteine Solution, USP 20% in 4 mL vials Now Available*, FRESENIUS KABI, http://www.fresenius-kabi.us/news-and-media/news-releases/196-acetylcysteine-solution-usp-20-in-4-ml-vials-now-available.html (last visited July 9, 2014).

6. Upon information and belief, Fresenius expanded its presence in the United States in 2012 with the acquisition of Fenwal Inc. Upon information and belief, Fenwal Inc. has an active business entity status registered with the New Jersey Secretary of State. Upon information and belief, Fenwal Inc. maintains a corporate agent for service of process at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

7. Upon information and belief, Fresenius expanded its presence in the United States in 2012 with the acquisition of Fenwal Inc. Upon information and belief, Fenwal Inc. was organized under the laws of the State of Delaware.

8. Upon information and belief, Fresenius engages, *inter alia*, in the development, manufacture, sale, distribution, and/or importation of generic pharmaceutical versions of branded products throughout the United States, including in the District of New Jersey and in this Judicial District.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

11. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

13. This Court has personal jurisdiction over Fresenius by virtue of the fact that, *inter alia*, Fresenius has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Merck in this Judicial District. Fresenius states that it intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic fosaprepitant dimeglumine, wherein the "dosage strength is EQ 150 mg acid/vial of fosaprepitant dimeglumine for injection, sterile lyophilized," prior to the expiration of United States Patent No. 5,691,336 ("the '336 patent") in this Judicial District.

14. This Court also has personal jurisdiction over Fresenius by virtue of the fact that, upon information and belief, *inter alia*, it: (1) is a corporation organized and existing under the laws of the State of Delaware, which is within this judicial district; (2) has affiliations with this Judicial District that are pervasive, continuous, and systematic, including the direct marketing, distribution, and/or sale of generic pharmaceutical drugs within this Judicial District and to residents of this Judicial District; and (3) has previously submitted to the jurisdiction of

this Court and has availed itself of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction, including in the matter of *Celgene Corp. v. Fresenius Kabi USA, LLC*, C.A. No. 14-571-RGA, D.I. 9, at 2, 8-14 (D. Del. May 9, 2014).

CLAIM FOR RELIEF

15. Merck is the holder of New Drug Application ("NDA") No. 22-023, by which the United States Food and Drug Administration ("FDA") granted approval for single dose vials containing sterile lyophilized powder of fosaprepitant dimeglumine for intravenous use after reconstitution and dilution, in 115 mg and 150 mg dosage strengths.

16. The Fosaprepitant dimeglumine product described in Merck's NDA is indicated, *inter alia*, for use in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin, and to prevent nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy. Merck markets the single dose vials in the United States under the tradename "EMEND® (fosaprepitant dimeglumine) for Injection" ("EMEND® IV").

17. The FDA granted fosaprepitant dimeglumine New Chemical Entity status pursuant to 21 C.F.R. § 314.108.

18. EMEND® IV is the only FDA-approved drug that is a prodrug of an NK-1 receptor antagonist compound.

19. EMEND® IV is the only drug approved by the FDA for intravenous administration for the prevention of emesis by NK-1 receptor antagonism.

20. Plasma concentrations of fosaprepitant are below the limits of quantification (10 ng/mL) within 30 minutes of the completion of infusion in accordance with the EMEND® IV product label.

21. EMEND® IV has a 24-month shelf life.

22. Merck owns the ’336 patent, which was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on November 25, 1997 and is titled “Morpholine compounds are prodrugs useful as tachykinin receptor antagonists.” A copy of the ’336 patent is attached as Exhibit A.

23. The ’336 patent was granted on U.S. Application Serial No. 08/525,870, filed September 8, 1995.

24. The specification of U.S. Application Serial No. 08/525,870, filed September 8, 1995, includes a statement on page 1, within the section entitled CROSS REFERENCE TO RELATED APPLICATIONS, that this application is a “continuation-in-part of PCT Application No. US 95/02551, filed February 28, 1995.”

25. The ’336 patent refers on its cover page under “Related U.S. Application Data” to PCT/US95/02551, filed February 28, 1995.

26. Claim 14 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

27. Claim 15 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

28. Claim 16 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

29. Claim 17 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

30. Claim 18 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

31. Claim 19 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

32. Claim 23 of the ’336 patent is entitled to the benefit of the February 28, 1995 filing date of Application PCT/US95/02551 under 35 U.S.C. § 120.

33. Prior to February 1995, companies other than Merck had performed research relating to non-peptide NK-1 receptor antagonists.

34. Prior to February 1995, at least one company other than Merck had performed research to discover novel non-peptide compounds that were NK-1 receptor antagonists.

35. Prior to 1995, at least Glaxo Group Ltd. and Pfizer Inc. had reported research relating to NK-1 receptor antagonist compounds.

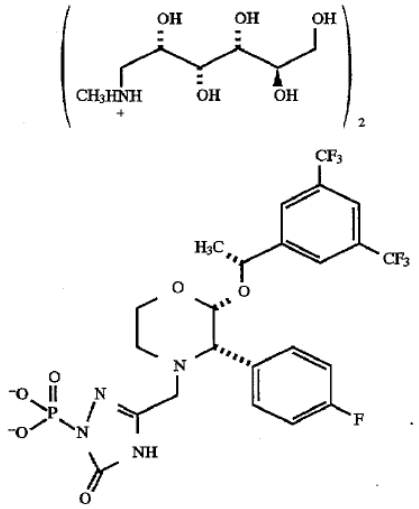
36. Upon information and belief, Fresenius submitted to the FDA Abbreviated New Drug Application No. 206197 (“ANDA”) seeking approval to manufacture, use, and sell generic fosaprepitant dimeglumine, wherein the “dosage strength is EQ 150 mg acid/vial of fosaprepitant dimeglumine for injection, sterile lyophilized,” (“the Fresenius ANDA product”) prior to the expiration of the ’336 patent.

37. Fosaprepitant is a compound having the chemical name: 2-(R)-(1-(R)-(3,5-bis(trifluouromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(1-phosphoryl-5-oxo-4H-1,2,4-triazolo)methylmorpholine.

38. Fosaprepitant dimeglumine is the bis(N-methyl-D-glucamine) salt of fosaprepitant.

39. Fosaprepitant dimeglumine has the chemical name: 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(1-phosphoryl-5-oxo-4H-1,2,4-triazolo)methylmorpholine, bis(N-methyl-D-glucamine).

40. Fosaprepitant dimeglumine is represented by the following chemical structure:



41. Upon information and belief, the Fresenius ANDA product contains fosaprepitant dimeglumine.

42. Upon information and belief, Fresenius has never performed research to discover a novel NK-1 receptor antagonist compound.

43. Upon information and belief, Fresenius has never filed a new drug application with the FDA seeking approval to market an NK-1 receptor antagonist compound.

44. Upon information and belief, Fresenius does not own any United States patents claiming a novel NK-1 receptor antagonist compound useful in the prevention of emesis.

45. Upon information and belief, the only NK-1 receptor antagonist compound that Fresenius seeks to market in the United States is a generic version of a compound sold by Merck.

46. Upon information and belief, Fresenius's ANDA contains a certification with respect to the '336 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Upon information and belief, Fresenius has not submitted to the FDA an Abbreviated New Drug Application with respect to a 115 mg dosage strength fosaprepitant dimeglumine product.

47. Fresenius sent a letter dated May 29, 2014 ("Fresenius Notice Letter") to Merck, which was delivered thereafter, in which Fresenius represented that it had filed an ANDA for the Fresenius ANDA product containing a certification with respect to the '336 patent, and that it sought approval of its ANDA prior to the expiration of the '336 patent.

48. This action was commenced within 45 days of the date of the Fresenius Notice Letter.

49. Upon information and belief, Fresenius was aware prior to May 29, 2014 of the lawsuit *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, Civil Action No. 12-cv-3289 (PGS)(LHG), pending in the District of New Jersey.

50. Upon information and belief, Fresenius was aware prior to May 29, 2014 of Exhibit A, D.I. 131-1, filed by Sandoz Inc. on October 17, 2013 in *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, Civil Action No. 12-cv-3289 (PGS)(LHG) (D.N.J.) ("D.I. 131-1").

51. Upon information and belief, Fresenius reviewed D.I. 131-1 prior to May 29, 2014.

52. Upon information and belief, Fresenius relied upon information disclosed in D.I. 131-1 when drafting the Fresenius Notice Letter.

53. Upon information and belief, Fresenius created the allegations of obviousness under 35 U.S.C. § 103 disclosed in the Fresenius Notice Letter based on D.I. 131-1.

54. Upon information and belief, Fresenius substantially copied sections of D.I. 131-1 in drafting the Fresenius Notice Letter.

55. Upon information and belief, Fresenius copied statements from sections II(C)(5)-II(C)(16) of D.I. 131-1 into the Fresenius Notice Letter.

56. Upon information and belief, sections III(B)(1)(h)-III(B)(1)(s) of Fresenius's Notice Letter contain a discussion of alleged prior art presented in the same order as sections II(C)(5)-II(C)(16) of D.I. 131-1.

57. The only invalidity defense with respect to Claims 1-22 and 24-25 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

58. The only invalidity defense with respect to Claim 14 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

59. The only invalidity defense with respect to Claim 15 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

60. The only invalidity defense with respect to Claim 16 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

61. The only invalidity defense with respect to Claim 17 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

62. The only invalidity defense with respect to Claim 18 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

63. The only invalidity defense with respect to Claim 19 of the '336 patent in the Fresenius Notice Letter is a defense of obviousness under 35 U.S.C. § 103.

64. The only invalidity defenses with respect to Claim 23 of the ’336 patent in the Fresenius Notice Letter are a defense of obviousness under 35 U.S.C. § 103 and lack of enablement, lack of written description, and indefiniteness under 35 U.S.C. § 112.

65. 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine has a solubility in water of 3-7 µg/mL.

66. 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine has a solubility in water of less than 8 µg/mL.

67. The Fresenius Notice Letter does not identify the solubility in water of 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

68. The Fresenius Notice Letter does not identify the solubility in water of fosaprepitant dimeglumine.

69. The Fresenius Notice Letter does not cite any prior art reference that identifies the solubility of 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

70. International Patent Application Publication No. WO 94/00440 (“WO ’440”) is discussed on pages 22-23 of the Fresenius Notice Letter.

71. WO ’440 was of record during the prosecution of the ’336 patent.

72. WO ’440 does not provide any biological data regarding activity that distinguishes any of the compounds identified by name from the others.

73. WO ’440 does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

74. Murdock, et al., *N-Phosphoryl Derivatives of Bisantrene. Antitumor Prodrugs with Enhanced Solubility and Reduced Potential for Toxicity*, J. MED. CHEM. 36: 1098-2101 (July 1993) (“Murdock 1993”) is discussed on pages 23-24 of the Fresenius Notice Letter.

75. Murdock 1993 discloses that bisantrene, administered as a soluble dihydrochloride salt, has a solubility in water of at least 40 mg/mL.

76. The solubility of bisantrene in water is more than 5,000 times greater than the solubility of 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine in water.

77. Murdock 1993 discloses that the prodrug salt of bisantrene decomposes within six months.

78. The compound that Murdock 1993 states “could be attractive as a second generation prodrug successor to bisantrene” is the “[b]is(phosphonoguanidinic acid) 6” compound identified in Murdock 1993.

79. At page 2099, Murdock 1993 reports that hydrolysis to bisantrene requires several hours.

80. Murdock 1993 does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

81. U.S. Patent No. 4,748,174 (the “’174 patent”) is discussed on page 24 of the Fresenius Notice Letter.

82. The ’174 patent does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

83. European Patent Office Publication No. 0,338,372 (“EP ’372”) is discussed on pages 24-25 of the Fresenius Notice Letter.

84. EP ’372 does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

85. Anderson, et al., “Strategies in the Design of Solution-Stable, Water Soluble Prodrugs II: Properties of Micellar Prodrugs of Methyl-Prednisolone,” 74(4) J. Pharm. Sci. 375-381 (1985) (“Anderson”) is discussed on page 25 of the Fresenius Notice Letter.

86. The discussion of Anderson on page 25 of the Fresenius Notice Letter is substantively identical to that on page 15 of D.I. 131-1.

87. Upon information and belief, Fresenius relied upon the discussion of Anderson disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

88. Upon information and belief, Fresenius did not conduct an independent investigation of Anderson for the Fresenius Notice Letter.

89. Anderson reports research work on carboxylic acid ester prodrugs of a corticosteroid.

90. Anderson does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

91. International Patent Application Publication No. WO 95/16679 ("WO '679") is discussed on pages 25-29 of the Fresenius Notice Letter.

92. The discussion of WO '679 on pages 25-29 of the Fresenius Notice Letter is substantively identical to that on pages 16-19 of D.I. 131-1.

93. Upon information and belief, Fresenius relied upon the discussion of WO '679 disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

94. Upon information and belief, Fresenius did not conduct an independent investigation of WO '679 for the Fresenius Notice Letter.

95. WO '679 was of record during the prosecution of the '336 patent.

96. The Fresenius Notice Letter asserts that WO '679 is prior art pursuant to the provisions of 35 U.S.C. § 103 based on a statement referring to WO '679 appearing in the specification of the '336 patent.

97. WO '679 identifies its International Publication Date as June 22, 1995.

98. The Fresenius Notice Letter at page 26 identifies the date on which WO '679 was published as June 22, 1995.

99. The publication date of WO '679 is after the February 28, 1995 filing date of Application PCT/US95/02551.

100. The Fresenius Notice Letter does not assert that WO '679 is prior art to the '336 patent pursuant to the provisions of 35 U.S.C. § 102.

101. WO '679 is not prior art to the '336 patent pursuant to the provisions of 35 U.S.C. § 102.

102. The only statement in the '336 patent specification referring to WO '679 is the following sentence: "PCT Publication No. WO 94/00440, EPO Publication No. 0,577,394

and PCT Publication No. WO 95/16679 disclose certain morpholine and thiomorpholine substance P antagonists, some of which are the parent compounds to the instant prodrugs."

103. The specification of Application PCT/US95/02551 does not refer to WO '679.

104. The prosecution history of U.S. Application Serial No. 08/525,870 contains an information disclosure statement ("IDS"), dated April 23, 1996, and bearing a stamp "96 May-6 PM 1:40 Group: 120."

105. WO '679 was listed on Form PTO-1449 included with the IDS dated April 23, 1996 in the prosecution of U.S. Application Serial No. 08/525,870.

106. The IDS dated April 23, 1996 in the prosecution of U.S. Application Serial No. 08/525,870 includes the following statement: "This Information Disclosure Statement is not an admission that any patent, publication, or other information referred to herein is 'prior art' for this invention."

107. WO '679 includes the statement that peptide-like antagonists are "too labile from a metabolic point of view to serve as practical therapeutic agents in the treatment of disease."

108. WO '679 includes the statement that non-peptidic NK-1 receptor antagonists "are expected to be more stable from a metabolic point of view than" agents discussed in pages 1-5 of WO '679.

109. WO '679 does not provide any biological data regarding activity that distinguishes any of the compounds identified by name from the others.

110. WO '679 states that non-peptidic NK-1 receptor antagonists may be incorporated for administration orally or by injection.

111. WO ’679 does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

112. U.S. Patent No. 5,070,082 (“the ’082 patent”) is discussed on page 29-32 of the Fresenius Notice Letter.

113. The discussion of the ’082 patent on pages 29-32 of the Fresenius Notice Letter is substantively identical to that on pages 19-22 of D.I. 131-1.

114. Upon information and belief, Fresenius relied upon the discussion of the ’082 patent disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

115. Upon information and belief, Fresenius did not conduct an independent investigation of the ’082 patent for the Fresenius Notice Letter.

116. The ’082 patent lists sodium, potassium, and ammonium as examples of the cations used for making salts of the ’082 patent prodrugs.

117. The Fresenius Notice Letter at page 30 cites the portion of the ’082 patent that discloses sodium, potassium, and ammonium as pharmaceutically acceptable cations of the drugs disclosed in the ’082 patent.

118. The ’082 patent does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

119. U.S. Patent No. 4,885,380 (“the ’380 patent”) is discussed on pages 32-33 of the Fresenius Notice Letter.

120. The discussion of the ’380 patent on pages 32-33 of the Fresenius Notice Letter is substantively identical to that on pages 23-24 of D.I. 131-1.

121. Upon information and belief, Fresenius relied upon the discussion of the ’380 patent disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

122. Upon information and belief, Fresenius did not conduct an independent investigation of the ’380 patent for the Fresenius Notice Letter.

123. The compounds included in the ’380 patent are not disclosed as prodrugs.

124. The compounds included in the ’380 patent are disclosed as hypotensive agents.

125. The ’380 patent does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

126. SA Varia et al., Phenytoin prodrugs III: Water-soluble prodrugs for oral and/or parenteral use, 73(8) J. Pharm. Sci. 1068 (1984) (“Varia”) is discussed on page 33 of the Fresenius Notice Letter.

127. The discussion of Varia on page 33 of the Fresenius Notice Letter is substantively identical to that on pages 24-25 of D.I. 131-1.

128. Upon information and belief, Fresenius relied upon the discussion of Varia disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

129. Upon information and belief, Fresenius did not conduct an independent investigation of Varia for the Fresenius Notice Letter.

130. The drug fosphenytoin contains an oxymethylene linker moiety.

131. The oxymethylene linker moiety acts as a synthetic handle in the drug fosphenytoin, to which various other functional groups were added.

132. Varia does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

133. International Patent Application Publication No. WO 93/01169 ("WO '169") is discussed on pages 33-34 of the Fresenius Notice Letter.

134. The discussion of WO '169 on pages 33-34 of the Fresenius Notice Letter is substantively identical to that on pages 25-26 of D.I. 131-1.

135. Upon information and belief, Fresenius relied upon the discussion of WO '169 disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

136. Upon information and belief, Fresenius did not conduct an independent investigation of WO '169 for the Fresenius Notice Letter.

137. WO '169 does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

138. Emonds-Alt et al., "A Potent and Selective Non-Peptide Antagonist of the Neurokinin A (NK2) Receptor," 50(15) Life Sci., PL-101-PL-106 (1992) ("Emonds-Alt") is discussed on pages 34-35 of the Fresenius Notice Letter.

139. The discussion of Emonds-Alt on pages 34-35 of the Fresenius Notice Letter is substantively identical to that on pages 26-27 of D.I. 131-1.

140. Upon information and belief, Fresenius relied upon the discussion of Emonds-Alt publication disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

141. Upon information and belief, Fresenius did not conduct an independent investigation of Emonds-Alt for the Fresenius Notice Letter.

142. Emonds-Alt was of record during the prosecution of the ’336 patent.

143. Emonds-Alt does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

144. European Patent Office Publication No. 0,360,390 (“EP ’390”) is discussed on pages 35-36 of the Fresenius Notice Letter.

145. The discussion of EP ’390 on pages 35-36 of the Fresenius Notice Letter is substantively identical to that on pages 27-28 of D.I. 131-1.

146. Upon information and belief, Fresenius relied upon the discussion of EP ’390 disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

147. Upon information and belief, Fresenius did not conduct an independent investigation of EP ’390 for the Fresenius Notice Letter.

148. EP ’390 does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

149. Stephen M. Berge, et al., Review, Pharmaceutical Salts, 66(1) J. Pharm. Sci. 1 (Jan. 1977) (“Berge”) is discussed on page 37 of the Fresenius Notice Letter.

150. The discussion of Berge on page 37 of the Fresenius Notice Letter is substantively identical to that on page 29 of D.I. 131-1.

151. Upon information and belief, Fresenius relied upon the discussion of Berge disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

152. Upon information and belief, Fresenius did not conduct an independent investigation of Berge for the Fresenius Notice Letter.

153. Berge does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

154. Orrie M. Friedman & Arnold M. Seligman, Preparation of N-Phosphorylated Derivatives of Bis-β-chloroethylamine, 26 J. Am. Chem. Society 655-57, 656 (1954) ("Friedman & Seligman") is discussed on page 37 of the Fresenius Notice Letter.

155. The discussion of Friedman & Seligman on page 37 of the Fresenius Notice Letter is substantively identical to that on page 29 of D.I. 131-1.

156. Upon information and belief, Fresenius relied upon the discussion of Friedman & Seligman disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

157. Upon information and belief, Fresenius did not conduct an independent investigation of Friedman & Seligman for the Fresenius Notice Letter.

158. Friedman & Seligman does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

159. U.S. Patent No. 3,732,340 ("the '340 patent") is discussed on pages 37-38 of the Fresenius Notice Letter.

160. The discussion of the '340 patent on pages 37-38 of the Fresenius Notice Letter is substantively identical to that on page 30 of D.I. 131-1.

161. Upon information and belief, Fresenius relied upon the discussion of the '340 patent disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

162. Upon information and belief, Fresenius did not conduct an independent investigation of the ’340 patent for the Fresenius Notice Letter.

163. The ’340 patent does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

164. W.P. Jeneks, HANDBOOK OF BIOCHEMISTRY AND SELECTED DATA FOR MOLECULAR BIOLOGY, 3d ed. vol. 1, 305-317 (1976) (“Jeneks”) is discussed on page 38 of the Fresenius Notice Letter.

165. Yaw-Kuen Li & Larry D. Byers, “Inhibition of beta-glucosidase by imidazoles,” 999 BIOCHEMICA ET BIOPHYSICA ACTA 227 (1989) “Li & Byers”) is discussed on page 38 of the Fresenius Notice Letter.

166. The discussion of Jeneks and Li & Byers on page 38 of the Fresenius Notice Letter is substantively identical to that on page 30 of D.I. 131-1.

167. Upon information and belief, Fresenius relied upon the discussion of Jeneks and Li & Byers disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

168. Upon information and belief, Fresenius did not conduct an independent investigation of Jeneks and/or Li & Byers for the Fresenius Notice Letter.

169. Neither Jeneks nor Li & Byers disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

170. Kurt W. Egger & Alan T. Cocks, “Homopolar- and Heteropolar Bond Dissociation Energies and Heats of Formation of Radicals and Ions in the Gas Phase. I. Data on

Organic Molecules," 56(5) Helv. Chim. Acta 1516-36 (1973) ("Egger & Cocks") is discussed on pages 38-39 of the Fresenius Notice Letter.

171. The title of Egger & Cocks, as reflected in the Fresenius Notice Letter and in D.I. 131-1, both include the same typographical error in the phrase "Ions in the Gas***e*** Phase."

172. The discussion of Egger & Cocks on pages 38-39 of the Fresenius Notice Letter is substantively identical to that on pages 30-31 of D.I. 131-1.

173. Upon information and belief, Fresenius relied upon the discussion of Egger & Cocks disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

174. Upon information and belief, Fresenius did not conduct an independent investigation of Egger & Cocks for the Fresenius Notice Letter.

175. Egger & Cocks does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

176. Paul R. Ortiz de Montellano and Norbert O. Reich, Inhibition of Cytochrome P-456 Enzymes, CYTOCHROME P450: STRUCTURE, MECHANISM AND BIOCHEMISTRY, 273-314 (Ortiz de Montellano ed., 1986) ("Montellano & Reich"), Robert P. Hanzlik & Kah-Hiing John Ling, "Active Site Dynamics of Toluene Hydroxylation by Cytochrome P-450," 55 J. Org. Chem. 3992-97 (1990) ("Hanzlik & Ling"), and John Daly, Metabolism of Acetanilides and Anisoles with Rat Liver Microsomes, 19 Biochemical Pharmacology 2979-93 (1970) ("Daly") are cited on page 39 of the Fresenius Notice Letter.

177. The discussion of Montellano & Reich, Hanzlik & Ling, and Daly on page 39 of the Fresenius Notice Letter is substantively identical to that on pages 31 of D.I. 131-1.

178. Upon information and belief, Fresenius relied upon the discussion of Montellano & Reich, Hanzlik & Ling, and Daly disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

179. Upon information and belief, Fresenius did not conduct an independent investigation of Montellano & Reich, Hanzlik & Ling, and Daly for the Fresenius Notice Letter.

180. Montellano & Reich, Hanzlik & Ling, and Daly do not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

181. B.D. Roth et al., "Inhibitors of Cholesterol Biosynthesis. 1. trans-6-(2-Pyrrol-l-ylethyl)-4-hydroxypyran-2-ones, a Novel Series of HMG-CoA Reductase Inhibitors. 1. Effects of Structural Modifications at the 2- and 5- Positions of the Pyrrole Nucleus," 33 J. Med. Chem. 21-31 (1990) ("Roth") is discussed on page 39 of the Fresenius Notice Letter.

182. The discussion of Roth on page 39 of the Fresenius Notice Letter is substantively identical to that on page 31 of D.I. 131-1.

183. Upon information and belief, Fresenius relied upon the discussion of Roth disclosed by Sandoz in D.I. 131-1 in drafting the Fresenius Notice Letter.

184. Upon information and belief, Fresenius did not conduct an independent investigation of Roth for the Fresenius Notice Letter.

185. Roth does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

186. The Fresenius Notice Letter does not cite any reference that is prior art to the '336 patent that discloses the chemical compound 2-(R)-(1-(R)-(3,5-

bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

187. The prior art to the ’336 patent does not disclose the chemical compound 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

188. The prior art to the ’336 patent includes disclosures of pharmacological data for NK-1 receptor antagonist compounds that were not 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

189. The Fresenius Notice Letter does not cite any reference that is prior art to the ’336 patent and reports pharmacological data for 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl) ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

190. The Fresenius Notice Letter does not cite any reference that is prior art to the ’336 patent and discloses pharmacological data specific to 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

191. The Fresenius Notice Letter does not cite any reference that is prior art to the ’336 patent and discloses pharmacokinetic data specific to 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

192. The Fresenius Notice Letter does not cite any reference that is prior art to the ’336 patent and discloses pharmacodynamic data specific to 2-(R)-(1-(R)-(3,5-

bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

193. The Fresenius Notice Letter does not identify any pharmacokinetic, pharmacodynamic, or pharmacological data specific to 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

194. The Fresenius Notice Letter does not cite any pharmacokinetic, pharmacodynamic, or pharmacological data specific to 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl) phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine that was disclosed in prior art to the ’336 patent.

195. The Fresenius Notice Letter does not cite any data for any physical property of 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine.

196. The Fresenius Notice Letter does not cite any data for any physical property of 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine disclosed in any prior art to the ’336 patent.

197. The Fresenius Notice Letter does not cite any data for any pharmacological property of 2-(R)-(1-(R)-(3,5-bis(trifluoromethyl)phenyl)ethoxy)-3-(S)-(4-fluoro)phenyl-4-(3-(5-oxo-1H,4H-1,2,4-triazolo)methylmorpholine disclosed in any prior art to the ’336 patent.

198. A party preparing a Paragraph IV Notice Letter has an affirmative duty of care to avoid making baseless certifications in its Notice Letter. 21 U.S.C.

§ 355(j)(2)(A)(viii)(IV); *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F. 3d 1339, 1347 (Fed. Cir. 2000).

199. The Fresenius Notice Letter does not allege noninfringement of claims 1-22 and 24-25 of the ’336 patent, separate and apart from its assertions that those claims are allegedly invalid.

200. The Fresenius Notice Letter does not allege that any claim limitation of Claims 1-22 and 24-25 of the ’336 patent is literally absent from the Fresenius ANDA product.

201. The Fresenius Notice Letter does not allege that any claim limitation of Claim 14 of the ’336 patent is literally absent from the Fresenius ANDA product.

202. The Fresenius Notice Letter does not allege that any claim limitation of Claim 15 of the ’336 patent is literally absent from the Fresenius ANDA product.

203. The Fresenius Notice Letter does not allege that any claim limitation of Claim 16 of the ’336 patent is literally absent from the Fresenius ANDA product.

204. The Fresenius Notice Letter does not allege that any claim limitation of Claim 17 of the’336 patent is literally absent from the Fresenius ANDA product.

205. The Fresenius Notice Letter does not allege that any claim limitation of Claim 18 of the ’336 patent is literally absent from the Fresenius ANDA product.

206. The Fresenius Notice Letter does not allege that any claim limitation of Claim 19 of the ’336 patent is literally absent from the Fresenius ANDA product.

207. The Fresenius Notice Letter does not allege that any claim limitation of Claim 23 of the ’336 patent, other than “an effective amount” of the claimed compound, is literally absent from the Fresenius ANDA product.

208. Upon information and belief, Fresenius's ANDA seeks approval for the use of fosaprepitant dimeglumine in the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high dose cisplatin.

209. Upon information and belief, Fresenius's ANDA seeks approval for a pharmaceutical composition comprising an amount of fosaprepitant dimeglumine effective for at least one pharmaceutical utility.

210. Upon information and belief, each claim limitation of Claim 14 of the '336 patent is literally present in the Fresenius ANDA product.

211. Upon information and belief, each claim limitation of Claim 15 of the '336 patent is literally present in the Fresenius ANDA product.

212. Upon information and belief, each claim limitation of Claim 16 of the '336 patent is literally present in the Fresenius ANDA product.

213. Upon information and belief, each claim limitation of Claim 17 of the '336 patent is literally present in the Fresenius ANDA product.

214. Upon information and belief, each claim limitation of Claim 18 of the '336 patent is literally present in the Fresenius ANDA product.

215. Upon information and belief, each claim limitation of Claim 19 of the '336 patent is literally present in the Fresenius ANDA product.

216. Upon information and belief, each claim limitation of Claim 23 of the '336 patent is literally present in the Fresenius ANDA product.

INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 5,691,336

217. Merck re-alleges paragraphs 1-216 as if fully set forth herein.

218. By seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '336 patent before its expiration, including its patent term extension, Fresenius has infringed the '336 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

219. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or importation of the Fresenius ANDA product, if approved by the FDA, prior to the expiration of the '336 patent, including its patent term extension, would infringe the '336 patent under 35 U.S.C. § 271.

220. Upon information and belief, Fresenius was aware of the existence of the '336 patent and was aware that the filing of its ANDA and certification with respect to the '336 patent constituted an act of infringement of that patent.

221. Upon information and belief, Fresenius intends to engage in the manufacture, use, offer for sale, sale, and/or importation of its generic Fresenius ANDA product immediately and imminently upon approval of its ANDA.

222. Upon information and belief, upon FDA approval of its ANDA, Fresenius will infringe the '336 patent by making, using, offering to sell, and selling its generic Fresenius ANDA product in the United States and/or importing such a product into the United States.

223. Merck is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Fresenius's ANDA No. 206197 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '336 patent to which Merck is or becomes entitled.

224. Merck is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, or sells the Fresenius ANDA product within the United States, imports the Fresenius ANDA product into the United States, and/or induces or contributes to such conduct, Fresenius will infringe the '336 patent under 35 U.S.C. § 271(a), (b), and/or (c).

225. Merck will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Merck does not have an adequate remedy at law.

STATEMENT REGARDING PRIOR-FILED SUIT

226. Plaintiff previously filed, on June 18, 2014, an action seeking to enjoin Fresenius from infringing the '336 patent in the District of New Jersey, and that action has been assigned Civil Action No. 3:14-cv-3917 (PGS)(LHG) ("Merck-Fresenius D.N.J. Action").

227. The Merck-Fresenius D.N.J. Action involves the same patent and same Plaintiff as an action also currently pending in the District of New Jersey against Defendant Sandoz Inc., assigned Civil Action No. 3:12-cv-3289 (PGS)(LHG) ("Merck-Sandoz D.N.J. Action"). The Merck-Fresenius D.N.J. Action was designated as related to the Merck-Sandoz D.N.J. Action by the District of New Jersey and has been assigned to Judge Peter G. Sheridan, who is also presiding over the Merck-Sandoz D.N.J. Action. The only defense against patent infringement raised by Fresenius in its ANDA Notice Letter with respect to at least some claims of the '336 patent is a defense of obviousness. Fresenius created its defense of obviousness by, *inter alia*, copying assertions made by the Defendant in the Merck-Sandoz D.N.J. Action.

228. In the Merck-Fresenius D.N.J. Action, Merck alleged that the District Court for the District of New Jersey has personal jurisdiction over Fresenius with regard to Merck's claim of patent infringement.

229. Judicial economy would be promoted, and Plaintiff's choice of forum respected, if the claim related to Plaintiff's action for infringement of the '336 patent is addressed by Judge Sheridan in the District of New Jersey.

230. Fresenius had admitted to personal jurisdiction in New Jersey for the purpose of a Hatch-Waxman Act litigation in the matter of *Novartis Pharmaceuticals Corporation v. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-7914 (SDW)(MCA), D.I. 10, at 3 (D.N.J. Feb. 13, 2014).

231. Before the filing of the present action, Defendant was asked if it would agree that it would consent to personal jurisdiction in New Jersey for the purpose of the Merck-Fresenius D.N.J. Action, but Defendant declined.

232. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a patent owner has 45 days from receipt of an ANDA Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of an ANDA pending resolution of litigation regarding the submission of such ANDA. Plaintiff filed this action as a further protective measure with regard to this statutory right in light of the Defendants' refusal to agree that it will not contest personal jurisdiction in New Jersey in the Merck-Fresenius D.N.J. Action. Plaintiff expects that personal jurisdiction will be maintained in the District of New Jersey and that the action will proceed in that forum. In that circumstance, this action would be unnecessary and may be voluntarily dismissed without prejudice in favor of continued prosecution of the Merck-Fresenius D.N.J. Action, transferred to the District of New Jersey for consolidation with the Merck-Fresenius D.N.J. Action, or such other non-substantive disposition that would ensure maintenance of Merck's rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully requests the following relief:

A. A Judgment be entered that Defendant has infringed the ’336 patent by submitting the aforesaid ANDA;

B. Preliminary and permanent injunctions be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendant, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs, or from inducing and/or encouraging the use of methods, claimed in the ’336 patent;

C. An Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206197 be a date that is not earlier than the expiration of the ’336 patent, including any extensions thereof and any later expiration of exclusivity for those patents to which Merck is or becomes entitled;

D. An Order be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys’ fees pursuant to 35 U.S.C. § 285; and

E. Such other and further relief as the Court may deem just and proper.

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