IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ONYX THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
INNOPHARMA INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Onyx Therapeutics, Inc. ("Plaintiff" or "Onyx") brings this action for patent infringement against InnoPharma Inc. ("Defendant" or "InnoPharma").

THE PARTIES

1. Plaintiff Onyx is a corporation organized under the laws of the State of Delaware, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Onyx is a wholly owned subsidiary of Onyx Pharmaceuticals, Inc. Onyx Pharmaceuticals, Inc. is a wholly owned subsidiary of Amgen Inc.

2. On information and belief, Defendant InnoPharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Knightsbridge Road, Piscataway, NJ 08854.

3. On information and belief, InnoPharma has made or has caused to be made the proposed generic carfilzomib 60 mg lyophilized powder for reconstitution and for intravenous administration (the "Proposed ANDA Product") that is the subject of ANDA No. 209447 and, through the filing of that ANDA with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), seeks

regulatory approval to market and sell the Proposed ANDA Product throughout the United States, including within this District.

NATURE OF THE ACTION

4. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of InnoPharma's ANDA No. 209447, filed with the FDA seeking approval to engage in the commercial manufacture, use and sale of the Proposed ANDA Product prior to the expiration of U.S. Patent Nos. 7,232,818; 7,491,704; 8,129,346; 8,207,125; 8,207,126; and 8,207,127 ("the Patents-in-Suit"), which are owned by Onyx.

5. The Proposed ANDA Product is a generic version of Onyx's KYPROLIS® (carfilzomib) for injection.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 35 U.S.C. § 1 et seq.

7. This Court has personal jurisdiction over InnoPharma because, on information and belief, InnoPharma is a company existing under the laws of Delaware. On information and belief, InnoPharma directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

8. This Court also has jurisdiction over InnoPharma because, inter alia, this action arises from actions of InnoPharma directed toward Delaware, and because InnoPharma has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, InnoPharma regularly and

continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, InnoPharma derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

9. This Court also has jurisdiction over InnoPharma because InnoPharma has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware by having been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g.*, *Shire Orphan Therapies LLC et al. v. InnoPharma Inc.*, Civil Action No. 16-0456 (D. Del.); *Spectrum Pharms., Inc. et al. v. InnoPharma Inc.*, Civil Action No. 12-0260 (D. Del.).

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

THE PATENTS-IN-SUIT

11. United States Patent No. 7,232,818 (the "'818 Patent"), entitled "Compounds For Enzyme Inhibition," was duly and legally issued on June 19, 2007 and will expire on April 14, 2025. Onyx is the owner of the '818 Patent. A copy of the '818 Patent is attached as Exhibit A.

12. United States Patent No. 7,491,704 (the "'704 Patent"), entitled "Compounds For Enzyme Inhibition," was duly and legally issued on February 17, 2009 and will expire on April 14, 2025. Onyx is the owner of the '704 Patent. A copy of the '704 Patent is attached as Exhibit B.

13. United States Patent No. 8,129,346 (the "'346 Patent"), entitled "Compounds For Enzyme Inhibition," was duly and legally issued on March 6, 2012 and will expire on April 14, 2025. Onyx is the owner of the '346 Patent. A copy of the '346 Patent is attached as Exhibit C.

14. United States Patent No. 8,207,125 (the "'125 Patent"), entitled "Compounds For Enzyme Inhibition," was duly and legally issued on June 26, 2012 and will expire on April 14, 2025. Onyx is the owner of the '125 Patent. A copy of the '125 Patent is attached as Exhibit D.

15. United States Patent No. 8,207,126 (the "'126 Patent"), entitled "Compounds For Enzyme Inhibition," was duly and legally issued on June 26, 2012 and will expire on April 14, 2025. Onyx is the owner of the '126 Patent. A copy of the '126 Patent is attached as Exhibit E.

16. United States Patent No. 8,207,127 (the "'127 Patent"), entitled "Compounds For Enzyme Inhibition," was duly and legally issued on June 26, 2012 and will expire on April 14, 2025. Onyx is the owner of the '127 Patent. A copy of the '127 Patent is attached as Exhibit F.

FACTUAL BACKGROUND

KYPROLIS® (CARFILZOMIB) FOR INJECTION

17. On July 20, 2012, the FDA granted accelerated approval to Onyx to market KYPROLIS® (carfilzomib) for injection to treat relapsed or refractory multiple myeloma, a type of cancer, and more specifically a type of hematopoietic cancer. Per the FDA, the accelerated approval program is designed to provide patients with earlier access to promising new drugs. Previously, in January 2011, the FDA had granted KYPROLIS® (carfilzomib) for injection "Fast Track" designation, which is a unique FDA process designed to facilitate the development and expedite the review of drugs based on the FDA's determination that it has the potential to treat serious conditions and fill an unmet medical need.

18. As described in the FDA approved label for KYPROLIS® (carfilzomib) for injection, several clinical studies have established the drug's effectiveness for treating relapsed or refractory multiple myeloma. One such clinical study is the pivotal Phase 3 head-to-head ENDEAVOR study comparing KYPROLIS® (carfilzomib) for injection plus dexamethasone to

VELCADE® (bortezomib) plus dexamethasone, which is a current standard of care in relapsed multiple myeloma. The data showed that patients treated with KYPROLIS® (carfilzomib) for injection plus dexamethasone achieved progression-free survival of 18.7 months compared to 9.4 months in those receiving VELCADE® (bortezomib) plus dexamethasone. Put differently, the ENDEAVOR study demonstrates that patients treated with KYPROLIS® (carfilzomib) for injection lived almost twice as long without disease worsening as those treated with VELCADE® (bortezomib).

19. KYPROLIS® (carfilzomib) for injection is approved by the FDA in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy; and as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

20. KYPROLIS® (carfilzomib) for injection is FDA approved for intravenous use. It is FDA approved as a lyophilized powder in a single-dose 30 mg or 60 mg vial. Each 30 mg vial contains 30 mg of carfilzomib, 1500 mg sulfobutylether beta-cyclodextrin, and 28.9 mg anhydrous citric acid and sodium hydroxide for pH adjustment (target pH 3.5). Each 60 mg vial contains 60 mg of carfilzomib, 3000 mg sulfobutylether beta-cyclodextrin, 57.7 mg citric acid, and sodium hydroxide for pH adjustment (target pH 3.5). The FDA approved label for KYPROLIS® (carfilzomib) for injection, provides detailed instructions for reconstituting the lyophilized KYPROLIS® (carfilzomib) powder before injection, including reconstituting each vial by slowly injecting Sterile Water for Injection, USP through the stopper and directing the solution into the inside wall of the vial, then gently swirling and/or inverting the vial slowly for about one minute, or until complete dissolution.

21. Carfilzomib, the active ingredient in KYPROLIS® (carfilzomib) for injection, is a proteasome inhibitor. The proteasome is the cell's "garbage disposal"; it breaks down unneeded or damaged proteins for reuse in the cell. Carfilzomib, a tetrapeptide epoxyketone, inhibits proteasome function by irreversibly binding to the N-terminal threonine-containing active sites of the 20S proteasome, the proteolytic core particle within the 26S proteasome. This causes the accumulation of protein in multiple myeloma cells, which triggers the body's mechanisms to kill the multiple myeloma cell through a process called apoptosis. According to the FDA approved label for KYPROLIS® (carfilzomib) for injection, carfilzomib has antiproliferative and proapoptotic activities *in vitro* in solid and hematologic tumor cells. In animals, carfilzomib inhibits proteasome activity in blood and tissue and delays tumor growth in models of multiple myeloma, hematologic, and solid tumors.

22. Onyx is the holder of approved New Drug Application ("NDA") No. 20-2714 for KYPROLIS® (carfilzomib) for injection. Onyx is the authorized agent for matters related to NDA No. 20-2714 in the United States.

23. KYPROLIS® (carfilzomib) for injection, its active pharmaceutical ingredient carfilzomib, its method of manufacture, and use are covered by one or more claims of the Patents-in-Suit, and the Patents-in-Suit have been listed for NDA No. 20-2714 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

24. Pursuant to NDA No. 20-2714, Onyx markets and distributes KYPROLIS® (carfilzomib) for injection in the United States.

DEFENDANT'S ANDA

25. On July 7, 2017, Onyx received a letter, dated July 6, 2017, from InnoPharma notifying Onyx that InnoPharma seeks through ANDA No. 209447 approval to engage in the

commercial manufacture, use, sale, and offer for sale of the Proposed ANDA Product prior to the expiration of U.S. Patent Nos. 7,232,818, 7,491,704, 8,129,346, 8,207,125, 8,207,126, and 8,207,127. Included within ANDA No. 209447 is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that U.S. Patent Nos. 7,232,818, 7,491,704, 8,129,346, 8,207,125, 8,207,126, and 8,207,127 are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed ANDA Product.

26. Onyx commenced this action within 45 days of receipt of the Notice Letter.

27. Defendant was aware of the Patents-in-Suit when ANDA No. 209447 was filed with a Paragraph IV Certification.

28. On information and belief, carfilzomib is the active ingredient in the Proposed ANDA Product and is a proteasome inhibitor approved by the FDA in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy; and as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(5).

29. On information and belief, ANDA No. 209447 refers to and relies upon the NDA for KYPROLIS® (carfilzomib) for injection and contains data that, according to Defendant, demonstrate the bioequivalence of the Proposed ANDA Product and KYPROLIS® (carfilzomib) for injection. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

30. On information and belief, the Proposed ANDA Product will have instructions for use that substantially copy the instructions accompanying KYPROLIS® (carfilzomib) for injection, including instructions for administering the Proposed ANDA Product by intravenous

injection to treat multiple myeloma in humans, as well as instructions for reconstituting the Proposed ANDA Product before injection by slowly injecting Sterile Water for Injection, USP into each vial through the stopper and directing the solution into the inside wall of the vial, then gently swirling and/or inverting the vial slowly for about one minute, or until complete dissolution. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4) and (8). The instructions accompanying the Proposed ANDA Product will induce healthcare providers to use the Proposed ANDA Product in a manner set forth in those instructions.

31. On information and belief, InnoPharma intends to have healthcare providers use its Proposed ANDA Product, if approved, as set forth in its Proposed ANDA Product label. On information and belief, InnoPharma's Proposed ANDA Product label instructs healthcare providers to administer its Proposed ANDA Product by intravenous injection to treat multiple myeloma in humans after reconstituting the Proposed ANDA Product by slowly injecting Sterile Water for Injection, USP into each vial through the stopper and directing the solution into the inside wall of the vial, then gently swirling and/or inverting the vial slowly for about one minute, or until complete dissolution. Thus, InnoPharma knowingly intends to encourage healthcare providers to administer its ANDA Product by intravenous injection to treat multiple myeloma in humans in a manner that infringes one or more of the Patents-in-Suit.

32. On information and belief, the active ingredient in the Proposed ANDA Product—carfilzomib—will irreversibly bind to the N-terminal threonine-containing active sites of the 20S proteasome and inhibit proteasome activity in blood and tissue and delay tumor growth when administered by healthcare providers as directed by InnoPharma's Proposed ANDA Product label. Thus, InnoPharma knows and intends for the carfilzomib in its ANDA Product to irreversibly bind to the N-terminal threonine-containing active sites of the 20S

proteasome and inhibit proteasome activity in blood and tissue and delay tumor growth in humans in a manner that infringes one or more of the Patents-in-Suit.

33. On information and belief, the Proposed ANDA Product will have no substantial non-infringing use.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,232,818

34. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 34 of this Complaint.

35. On information and belief, the Proposed ANDA Product is covered by at least Claims 1-4, 23-25, 38, and 49-50 of the '818 Patent, because it contains carfilzomib as its active ingredient.

36. Defendant's submission of ANDA No. 209447 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '818 Patent constitutes infringement of the '818 Patent under 35 U.S.C. § 271(e)(2).

37. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 209447 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

38. On information and belief, Defendant knows that the Proposed ANDA Product, when commercially manufactured, offered for sale, sold, and/or imported, and when used will directly infringe at least Claims 1-4, 23-25, 38, and 49-50 of the '818 Patent under 35 U.S.C. § 271(a).

39. Upon FDA approval of ANDA No. 209447, Defendant will infringe at least Claims 1-4, 23-25, 38, and 49-50 of the '818 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

40. On information and belief, Defendant had knowledge of the '818 Patent when Defendant submitted ANDA No. 209447 to the FDA and Defendant knows or should know that it will induce or contribute to another's direct infringement of at least Claims 1-4, 23-25, 38, and 49-50 of the '818 Patent.

41. Absent from the Notice Letter are any allegations that Claims 1-4, 23-25, or 49-50 of the '818 Patent are not infringed by the Proposed ANDA Product.

42. Defendant has knowledge of the '818 Patent and is knowingly and intentionally infringing the '818 Patent.

43. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

44. On information and belief, Defendant lacked a good faith basis for alleging non-infringement and invalidity of the '818 Patent when Defendant filed its Paragraph IV Certification. Accordingly, this case is exceptional under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,491,704

45. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 44 of this Complaint.

46. On information and belief, the use of the Proposed ANDA Product is covered by at least Claims 1-3, 22-24, 37, and 48 of the '704 Patent, because the Proposed ANDA Product

contains carfilzomib as its active ingredient and Defendant's Proposed Product label will have instructions for administering the Proposed ANDA Product to treat cancer, specifically multiple myeloma. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4) and (8).

47. Defendant's submission of ANDA No. 209447 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '704 Patent constitutes infringement of the '704 Patent under 35 U.S.C. § 271(e)(2).

48. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 209447 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

49. On information and belief, Defendant knows that the Proposed ANDA Product, when commercially manufactured, offered for sale, sold, and/or imported, and when used as directed in its proposed product labelling, will be used in a manner that would directly infringe at least Claims 1-3, 22-24, 37, and 48 of the '704 Patent under 35 U.S.C. § 271(a).

50. Upon FDA approval of ANDA No. 209447, Defendant will infringe at least Claims 1-3, 22-24, 37, and 48 of the '704 Patent by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

51. On information and belief, Defendant had knowledge of the '704 Patent when Defendant submitted ANDA No. 209447 to the FDA and Defendant knows or should know that it will induce and contribute to another's direct infringement of at least Claims 1-3, 22-24, 37, and 48 of the '704 Patent.

52. Absent from the Notice Letter are any allegations that Claims 1-3, 22-24, 37, or 48 of the '704 Patent are not infringed by the Proposed ANDA Product.

53. Defendant has knowledge of the '704 Patent and is knowingly and intentionally infringing the '704 Patent.

54. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

55. On information and belief, Defendant lacked a good faith basis for alleging non-infringement and invalidity of the '704 Patent when Defendant filed its Paragraph IV Certification. Accordingly, this case is exceptional under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 8,129,346

56. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 55 of this Complaint.

57. On information and belief, the use of the Proposed ANDA Product is covered by at least Claims 1-3, 22-24, 37, 48-49, and 52-60 of the '346 Patent, because the Proposed ANDA Product contains carfilzomib as its active ingredient and Defendant's Proposed Product label will have instructions for administering the Proposed ANDA Product to inhibit an N-terminal nucleophile hydrolase. Specifically, as described in the FDA approved label for KYPROLIS® (carfilzomib) for injection that will be substantially copied by Defendant's Proposed Product Label, when administered according to the instructions, carfilzomib will irreversibly bind to the N-terminal threonine-containing active sites of the 20S proteasome and inhibit proteasome activity in blood and tissue and delay tumor growth. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4) and (8).

58. Defendant's submission of ANDA No. 209447 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '346 Patent constitutes infringement of the '346 Patent under 35 U.S.C. § 271(e)(2).

59. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 209447 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

60. On information and belief, Defendant knows that the Proposed ANDA Product, when commercially manufactured, offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least Claims 1-3, 22-24, 37, 48-49, and 52-60 of the '346 Patent under 35 U.S.C. § 271(a).

61. Upon FDA approval of ANDA No. 209447, Defendant will infringe at least Claims 1-3, 22-24, 37, 48-49, and 52-60 of the '346 Patent by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

62. On information and belief, Defendant had knowledge of the '346 Patent when Defendant submitted ANDA No. 209447 to the FDA and Defendant knows or should know that it will induce or contribute to another's direct infringement of at least Claims 1-3, 22-24, 37, 48-49, and 52-60 of the '346 Patent.

63. Absent from the Notice Letter are any allegations that the Claims 1-3, 22-24, 37, 48-49, or 52-60 of the '346 Patent are not infringed by the Proposed ANDA Product.

64. Defendant has knowledge of the '346 Patent and is knowingly and intentionally infringing the '346 Patent.

65. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

66. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '346 Patent when Defendant filed its Paragraph IV Certification. Accordingly, this case is exceptional under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 8,207,125

67. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 66 of this Complaint.

68. On information and belief, the Proposed ANDA Product is covered by at least Claims 1, 4, 5, 7-10, 12, 13, 16, 18-25, and 27-30 of the '125 Patent, because it is a composition comprising carfilzomib.

69. Defendant's submission of ANDA No. 209447 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '125 Patent constitutes infringement of the '125 Patent under 35 U.S.C. § 271(e)(2).

70. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 209447 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

71. On information and belief, Defendant knows that the Proposed ANDA Product, when commercially manufactured, offered for sale, sold, and/or imported, and when used as

directed, will directly infringe at least Claims 1, 4, 5, 7-10, 12, 13, 16, 18-25, and 27-30 of the '125 Patent under 35 U.S.C. § 271(a).

72. Upon FDA approval of ANDA No. 209447, Defendant will infringe at least Claims 1, 4, 5, 7-10, 12, 13, 16, 18-25, and 27-30 of the '125 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

73. On information and belief, Defendant had knowledge of the '125 Patent when Defendant submitted ANDA No. 209447 to the FDA and Defendant knows or should know that it will induce or contribute to another's direct infringement of at least Claims 1, 4, 5, 7-10, 12, 13, 16, 18-25, and 27-30 of the '125 Patent.

74. Absent from the Notice Letter are any allegations that Claims 1, 4, 5, 7-10, 12, 13, 16, 18-25, or 27-30 of the '125 Patent are not infringed by the Proposed ANDA Product.

75. Defendant has knowledge of the '125 Patent and is knowingly and intentionally infringing the '125 Patent.

76. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

77. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '125 Patent when Defendant filed its Paragraph IV Certification. Accordingly, this case is exceptional under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,207,126

78. Plaintiff hereby realleges and incorporates by reference the allegations of paragraphs 1 – 77 of this Complaint.

79. On information and belief, the Proposed ANDA Product and its method of manufacture is covered by at least Claims 1-5, 7-14, and 16-21 of the '126 Patent, because it is a composition comprising carfilzomib prepared by the claimed method. Specifically, on information and belief, the Defendant's Proposed Product label will instruct healthcare providers to reconstitute the Proposed ANDA Product by slowly injecting Sterile Water for Injection, USP into each vial through the stopper and directing the solution into the inside wall of the vial, then gently swirling and/or inverting the vial slowly for about one minute, or until complete dissolution.

80. Defendant's submission of ANDA No. 209447 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '126 Patent constitutes infringement of the '126 Patent under 35 U.S.C. § 271(e)(2).

81. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 209447 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

82. On information and belief, Defendant knows that the Proposed ANDA Product, when commercially manufactured, offered for sale, sold, and/or imported, and when used as directed, will directly infringe at least Claims 1-5, 7-14, and 16-21 of the '126 Patent under 35 U.S.C. § 271(a) and/or § 271(g).

83. Upon FDA approval of ANDA No. 209447, Defendant will infringe at least Claims 1-5, 7-14, and 16-21 of the '126 Patent by making, using, offering to sell, selling, and/or importing the Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

84. On information and belief, Defendant had knowledge of the '126 Patent when Defendant submitted ANDA No. 209447 to the FDA and Defendant knows or should know that it will induce or contribute to another's direct infringement of at least Claims 1-5, 7-14, and 16-21 of the '126 Patent.

85. Absent from the Notice Letter are any allegations that Claims 1-5, 7-14, or 16-21 of the '126 Patent are not infringed by the Proposed ANDA Product.

86. Defendant has knowledge of the '126 Patent and is knowingly and intentionally infringing the '126 Patent.

87. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

88. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '126 Patent when Defendant filed its Paragraph IV Certification. Accordingly, this case is exceptional under 35 U.S.C. § 285.

COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 8,207,127

89. Plaintiff hereby realleges and incorporates the allegations of paragraphs 1 – 88 of this Complaint.

90. On information and belief, the use of the Proposed ANDA Product is covered by at least Claims 1, 12-17, 19, 20, and 23-27 of the '127 Patent, because the Proposed ANDA

Product contains carfilzomib as its active ingredient and Defendant's Proposed Product label will have instructions for administering the Proposed ANDA Product to treat multiple myeloma, which is a type of hematopoietic cancer. 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(4) and (8).

91. Defendant's submission of ANDA No. 209447 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product before the expiration of the '127 Patent constitutes infringement of the '127 Patent under 35 U.S.C. § 271(e)(2).

92. On information and belief, Defendant plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed ANDA Product immediately upon approval of ANDA No. 209447 and will instruct healthcare providers to use the Proposed ANDA Product in accordance with the proposed product labeling.

93. On information and belief, Defendant knows that the Proposed ANDA Product, when commercially manufactured, offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least Claims 1, 12-17, 19, 20, and 23-27 of the '127 Patent under 35 U.S.C. § 271(a).

94. Upon FDA approval of ANDA No. 209447, Defendant will infringe at least Claims 1, 12-17, 19, 20, and 23-27 of the '127 Patent by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

95. On information and belief, Defendant had knowledge of the '127 Patent when Defendant submitted ANDA No. 209447 to the FDA and Defendant knows or should know that it will induce or contribute to another's direct infringement of at least Claims 1, 12-17, 19, 20, and 23-27 of the '127 Patent.

96. Absent from the Notice Letter are any allegations that Claims 1, 12-17, 19, 20, or 23-27 of the '127 Patent are not infringed by the Proposed ANDA Product.

97. Defendant has knowledge of the '127 Patent and is knowingly and intentionally infringing the '127 Patent.

98. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiff has no adequate remedy at law.

99. On information and belief, Defendant lacked a good faith basis for alleging invalidity of the '127 Patent when Defendant filed its Paragraph IV Certification. Accordingly, this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court grant the following relief:

a) Judgment that Defendant's submission of ANDA No. 209447 to the FDA was an act of infringement of one or more Claims of the '818, '704, '346, '125, '126, and '127 Patents under 35 U.S.C. § 271(e)(2);

b) Judgment that Defendant's making, using, offering to sell, selling, or importing into the United States of the Proposed ANDA Product prior to the expiration of the '818, '704, '346, '125, '126, and '127 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of those Patents;

c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 209447 shall be a date that is not

earlier than the expiration of the '818, '704, '346, '125, '126, and '127 Patents plus any other exclusivity to which Plaintiff is or becomes entitled;

d) An Order permanently enjoining Defendant, Defendant's affiliates and subsidiaries, each of its officers, agents, servants and employees, and any person acting in concert with Defendant, from making, using, offering to sell, selling, or importing into the United States the Proposed ANDA Product until after the expiration of the '818, '704, '346, '125, '126, and '127 Patents plus any other exclusivity to which Plaintiff is or becomes entitled;

e) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

f) An award of Plaintiff's reasonable costs and expenses in this action; and

g) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Lisa B. Pensabene
Filko Prugo
Margaret O'Boyle
Carolyn Wall
Eberle Schultz
Jenny Liu
O'MELVENY & MYERS LLP
7 Times Square
New York, New York 10036
(212) 326-2000

Wendy A. Whiteford
Erica S. Olson
Brian Kao
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-1000

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