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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, vs. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **PLAINTIFFS' ANSWER TO DEFENDANT SANDOZ INC.'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES** **JURY TRIAL DEMANDED**

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Plaintiffs"), by and through their undersigned attorneys, answer the counterclaims of Defendant Sandoz Inc. ("Sandoz") as follows:

THE PARTIES

1. Upon information and belief, Plaintiffs admit the allegations of Paragraph 1.

2. Plaintiffs admit the allegations of Paragraph 2.

3. Plaintiffs admit the allegations of Paragraph 3.

JURISDICTION AND VENUE

4. Plaintiffs admit that Sandoz's counterclaims purport to be for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 and that an actual controversy exists as to Sandoz's obligations under 42 U.S.C. § 262(l)(2) and (l)(8). Plaintiffs deny any remaining allegations of Paragraph 4.

5. Plaintiffs deny the allegations of Paragraph 5.

6. For the purpose of this action, Plaintiffs admit the allegations of Paragraph 6.

7. For the purpose of this action, Plaintiffs admit the allegations of Paragraph 7.

THE CONTROVERSY RELATING TO BPCIA SUBSECTION (l)(9)(C)[1]

8. Plaintiffs admit filgrastim is a biological product and that one use of filgrastim is the treatment of side effects of certain forms of cancer therapy. Plaintiffs admit that the biological product license for NEUPOGEN® (filgrastim) is owned by Amgen and is exclusively licensed to AML.

9. Upon information and belief, Plaintiffs admit that Defendant submitted a Biologics License Application ("BLA") for filgrastim to the FDA. Plaintiffs deny any implication that Defendant submitted a BLA independently of other named Defendants in the

[1] Headings in Plaintiffs' Answer to Defendant's Counterclaims and Affirmative Defenses are used solely to mirror the headings in Defendant's pleading and should not be construed as an admission or denial by Plaintiffs on any issue.

suit. Plaintiffs admit that Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010) states that "[i]t is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established." Plaintiffs deny any remaining allegations of Paragraph 9.

10. Plaintiffs deny the allegations of Paragraph 10. The BPCIA creates an abbreviated approval pathway for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). By following the provisions of the BPCIA, biosimilar applicants may make use of the FDA's prior determinations as to the safety, purity, and potency of the reference product that was already approved by the FDA. Under the BPCIA, the FDA reviews the biosimilar application to determine if the information submitted is sufficient to show that the biological product is "biosimilar" to the reference product—i.e. (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(k)(3)(A), (i)(2).

11. Plaintiffs admit that, following enactment of the BPCIA, the FDA was authorized to approve a biosimilar application based on the applicant's designation of a given reference product, which approval would be effective no earlier than 12 years after the date on which that reference product was first licensed by FDA. Plaintiffs admit that NEUPOGEN® (filgrastim) was first approved by the FDA in 1991. On information and belief, Plaintiffs admit that in 2008, the European Medicines Agency ("EMA") approved products that the EMA determined, under its regulatory scheme, to be biosimilars of filgrastim. Plaintiffs deny any remaining allegations of Paragraph 11.

12. Plaintiffs deny the allegations of Paragraph 12.

13. Plaintiffs deny the allegations of Paragraph 13 to the extent they imply that the exchange of information under § 262(l) is optional, as suggested by Defendant's use of the words

"may exchange." The exchange is mandatory. Section 262(l) states that the subsection (k) applicant "shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A) (emphasis added); see also § 262(l)(1)(B). Plaintiffs admit that the exchanges under 42 U.S.C. § 262(l) occur under the confidentiality provisions of § 262(l) before any court-enforced confidentiality protections have been put into place. Plaintiffs deny any remaining allegations of Paragraph 13.

14. Plaintiffs admit the exchange procedures under the BPCIA are triggered by the FDA's acceptance of the biosimilar application for review and that, "not later than 20 days after" the application is accepted, the (k) applicant "shall provide to the reference sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A). Plaintiffs deny any remaining allegations of Paragraph 14.

15. Plaintiffs deny the allegations of Paragraph 15.

16. Plaintiffs deny the allegations of Paragraph 16.

17. Plaintiffs admit that Defendant's quotation is an excerpt from 42 U.S.C. § 262(l)(9). Plaintiffs deny any remaining allegations of Paragraph 17.

18. Plaintiffs admit that 42 U.S.C. § 262(l)(9)(A) states that if a biosimilar applicant provides the application and manufacturing information required under the statute, neither party may bring an action for declaratory judgment for infringement, validity, or enforceability of any patent described by 42 U.S.C. § 262(l)(8)(B) before the biosimilar applicant provides its notice of commercial marketing under § 262(l)(8)(A). Plaintiffs deny any remaining allegations of Paragraph 18.

19. Plaintiffs deny that a biosimilar applicant may "elect" not to provide the information required under § 262(l)(2)(A). Plaintiffs admit that § 262(l)(9)(C) provides that

"if the subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product."

20. Plaintiffs deny that a biosimilar applicant may "elect" not to provide the information required under § 262(l)(2)(A) and therefore deny Paragraph 20.

21. Plaintiffs deny the allegations of Paragraph 21.

22. Plaintiffs deny the allegations of Paragraph 22.

23. Plaintiffs deny the allegations of Paragraph 23. Neither the BPCIA nor 35 U.S.C. § 271(e)(4) precludes or preempts the state-law claims pleaded in Plaintiffs' Complaint.

24. Plaintiffs deny the allegations of Paragraph 24.

25. Plaintiffs admit that Amgen filed a Citizen Petition with the FDA on October 29, 2014, in which Amgen requested that before accepting an application for review under § 351(k), the FDA should require that biosimilar applications contain a certification that the biosimilar applicant will comply with subsection (l)(2)(A) by providing the reference product sponsor a copy of the application accepted for review and manufacturing information within 20 days after being informed by the FDA that its biosimilar application has been accepted for review. Plaintiffs deny any remaining allegations of Paragraph 25.

26. Plaintiffs deny the allegations of Paragraph 26.

27. Plaintiffs admit that § 262(l)(1) of the BPCIA provides confidentiality provisions and that § 262(l)(1)(A) states "[u]nless otherwise agreed to by" a biosimilar applicant and a reference product sponsor "the provisions of this paragraph shall apply." Plaintiffs admit that Sandoz purported to only offer a copy of its BLA under conditions that: (1) attempted to limit the exchange of information; (2) failed to include information "describ[ing] the process or processes used to manufacture" its biological product as required by § 262(l)(2)(A); and (3)

attempted to limit Amgen's causes of actions for patent infringement to exclude process patents. Plaintiffs deny any remaining allegations of Paragraph 27.

28. Plaintiffs admit that there is a substantial controversy between Amgen and Sandoz regarding Sandoz's obligations under § 262(l)(2)(A) and (l)(8)(A). Plaintiffs deny any remaining allegations of Paragraph 28.

29. Plaintiffs admit that this controversy is at the core of this lawsuit, although it is properly before the Court only through Plaintiffs' claims. Plaintiffs deny that interpretation of the BPCIA would automatically resolve Amgen's claims for conversion and violation of California's Unfair Competition Law, but admit that the meaning and interpretation of the BPCIA is a core element of those claims. Plaintiffs deny the allegations of Paragraph 29.

30. Plaintiffs admit that there is a judiciable controversy regarding Sandoz's obligations under the BPCIA as pled in Plaintiffs' Complaint but deny that Sandoz's counterclaims present a justiciable controversy.

FIRST COUNTERCLAIM

31. Plaintiffs reassert their responses to Paragraphs 1 through 30 and incorporate them by reference herein.

32. Plaintiffs deny that a biosimilar applicant may "elect" not to provide the information required under § 262(l)(2)(A). Plaintiffs admit that § 262(l)(9)(C) provides that "if the subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product," and deny that § 262(l)(9)(C) provides the only remedy available for failure to comply with § 262(l)(2)(A).

33. Plaintiffs deny the allegations of Paragraph 33.

34. Plaintiffs deny the allegations of Paragraph 34.

35. Plaintiffs deny the allegations of Paragraph 35.

SECOND COUNTERCLAIM

36. Plaintiffs reassert their responses to Paragraphs 1 through 35 and incorporate them by reference herein.

37. Plaintiffs deny this paragraph to the extent it suggests that compliance with § 262(l)(2)(A) is optional for the subsection (k) applicant.

38. Plaintiffs deny the allegations of Paragraph 38.

39. Plaintiffs deny the allegations of Paragraph 39.

40. Plaintiffs deny the allegations of Paragraph 40.

41. Plaintiffs deny the allegations of Paragraph 41.

THIRD COUNTERCLAIM

42. Plaintiffs reassert their responses to Paragraphs 1 through 41 and incorporate them by reference herein.

43. Plaintiffs admit that § 262(l)(9)(C) provides that "if the subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product." Plaintiffs deny any remaining allegations of Paragraph 43.

44. Plaintiffs deny the allegations of Paragraph 44.

45. Plaintiffs deny the allegations of Paragraph 45.

FOURTH COUNTERCLAIM

46. Plaintiffs reassert their responses to Paragraphs 1 through 45 and incorporate them by reference herein.

47. Plaintiffs deny this paragraph to the extent it suggests that compliance with § 262(l)(2)(A) is optional for the subsection (k) applicant.

48. Plaintiffs admit that § 262(l)(9)(C) provides that "if the subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference

product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product." Plaintiffs deny any remaining allegations of Paragraph 48.

49. Plaintiffs deny the allegations of Paragraph 49.

50. Plaintiffs admit that § 262(l)(9)(C) provides that "if the subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product." Plaintiffs deny any remaining allegations of Paragraph 50.

51. Plaintiffs deny the allegations of Paragraph 51.

52. Plaintiffs deny the allegations of Paragraph 52.

FIFTH COUNTERCLAIM

53. Plaintiffs reassert their responses to Paragraphs 1 through 52 and incorporate them by reference herein.

54. Plaintiffs deny the allegations of Paragraph 54. The BPCIA creates an abbreviated approval pathway for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). By following the provisions of the BPCIA, biosimilar applicants may make use of the FDA's prior determinations as to the safety, purity, and potency of the reference product that was already approved by the FDA. Under the BPCIA, the FDA reviews the biosimilar application to determine if the information submitted is sufficient to show that the biological product is "biosimilar" to the reference product—i.e. (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences between the biological product and the

reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(k)(3)(A), (i)(2).

55. Plaintiffs deny the allegations of Paragraph 55.

56. Plaintiffs deny the allegations of Paragraph 56.

57. Plaintiffs deny the allegations of Paragraph 57.

58. Plaintiffs deny the allegations of Paragraph 58.

SIXTH COUNTERCLAIM

59. Plaintiffs reassert their responses to Paragraphs 1 through 58 and incorporate them by reference herein.

60. Plaintiffs admit that their Complaint asserts Defendants have committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by virtue of their submission of the BLA.

61. Plaintiffs admit that Paragraph 61 states that "Sandoz asserts that the manufacture, use, offer for sale, and sale of biosimilar filgrastim do not and will not infringe any valid claim of the '427 patent under 35 U.S.C. § 271(a), (b), (c), or (e)(2)(C)(ii)," but deny the veracity and merit of these assertions.

62. Plaintiffs deny the allegations of Paragraph 62.

63. Plaintiffs deny the allegations of Paragraph 63.

SEVENTH COUNTERCLAIM

64. Plaintiffs reassert their responses to Paragraphs 1 through 63 and incorporate them by reference herein.

65. Plaintiffs admit that their Complaint asserts Defendants have committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by virtue of their submission of the BLA.

66. Plaintiffs admit that Paragraph 66 states that "Sandoz asserts that the claims of the '427 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or

112, or other judicially created bases for invalidation" but deny the veracity and merit of these assertions.

67. Plaintiffs deny the allegations of Paragraph 67.

68. Plaintiffs deny the allegations of Paragraph 68.

RESPONSE TO PRAYER FOR RELIEF

Plaintiffs deny all remaining allegations not specifically admitted herein and deny that Defendant is entitled to any of the relief it has requested.

AFFIRMATIVE DEFENSES

By characterizing these as "Affirmative Defenses," as Defendants do in their Answer, Plaintiffs are not taking on any burden of proof beyond that which the law applies to them. Thus, without admitting or implying that Plaintiffs bear the burden of proof as to any of them, Plaintiffs, on information and belief, assert the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE

(Lack of Subject Matter Jurisdiction)

1. The Court lacks subject matter jurisdiction over Sandoz's Sixth and Seventh Counterclaims, because 42 U.S.C. § 262(l)(9)(C) provides that where, as here, the subsection (k) applicant fails to provide the materials called for by subsection (l), only the reference product sponsor—and not the subsection (k) applicant—may seek a declaratory judgment relating to patent validity, infringement or enforceability.

SECOND AFFIRMATIVE DEFENSE

(Failure to State a Claim)

2. Sandoz's First, Second, Third, Fourth, and Fifth Counterclaims fail to state a claim for which relief can be granted because they are merely defenses directed at an element of Plaintiffs' claims, and are not proper counterclaims.

THIRD AFFIRMATIVE DEFENSE

(Failure to State a Claim)

3. Sandoz's First, Second, Third, Fourth, and Fifth Counterclaims fail to state a claim for which relief can be granted because they are, as a matter of law, based on an incorrect reading of the BPCIA. As set forth in the statute and in the Complaint, the exchanges called for by subsection (l) are mandatory, and subsection (l)(9)(C) is not the exclusive remedy for a breach of subsection (l).

FOURTH AFFIRMATIVE DEFENSE

(Failure to State a Claim)

4. Sandoz's Sixth and Seventh Counterclaims fail to state a claim for which relief can be granted because 42 U.S.C. § 262(l)(9)(C) provides that where, as here, the subsection (k) applicant fails to provide the materials called for by subsection (l), only the reference product sponsor—and not the subsection (k) applicant—may seek a declaratory judgment relating to patent validity, infringement or enforceability.

DEMAND FOR A JURY TRIAL

Plaintiffs hereby demand a jury trial on all issues so triable.

Date: December 15, 2014

/s/ Vernon M. Winters

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