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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **SANDOZ INC.'S ANSWER TO PLAINTIFFS' FIRST AMENDED AND SUPPLEMENTAL COMPLAINT AND AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** **DEMAND FOR JURY TRIAL**

Defendant Sandoz Inc. ("Sandoz"), by and through its undersigned attorneys, hereby submits this Answer and Affirmative Defenses and Counterclaim ("Answer") to the First Amended and Supplemental Complaint ("First Amended Complaint") filed by Amgen Inc. and

Amgen Manufacturing, Limited (collectively, "Plaintiffs" or "Amgen") dated October 15, 2015.

The First Amended Complaint improperly refers to "Sandoz" to include co-defendants Sandoz International GmbH and Sandoz GmbH, which are separate companies based in Germany and Austria respectively. All responses below are made solely on behalf of Sandoz Inc., and no response is made to any allegation that is properly directed at any defendant other than Sandoz Inc., because none is required. *See* Fed. R. Civ. P. 8(b)(1)(B). To the extent a response is required, Sandoz Inc. denies all allegations properly directed at other defendants.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Sandoz denies each and every allegation in Plaintiffs' First Amended Complaint except those expressly admitted below.

PROCEDURAL POSTURE

1. Sandoz admits Plaintiffs filed their original complaint against Sandoz in this Court on October 24, 2014, asserting unfair competition under California Business & Professions Code § 17200 et seq., conversion, and infringement of U.S. Patent 6,162,427 ("the '427 patent"). Sandoz admits Plaintiffs alleged that Sandoz refused to comply with the statutory requirements of the Biosimilars Price Competition and Innovation Act ("BPCIA"). Sandoz admits Plaintiffs purported to reserve the right to seek leave to assert additional patents. Sandoz denies the remaining allegations contained in Paragraph 1.

2. Sandoz admits that an Answer was submitted only on behalf of Sandoz Inc. but further states that Sandoz International GmbH and Sandoz GmbH also filed answers to the Complaint. Sandoz admits the remaining allegations contained in Paragraph 2.

3. Sandoz admits the allegations contained in Paragraph 3.

4. Sandoz admits the allegations contained in Paragraph 4.

5. Sandoz admits the allegations contained in Paragraph 5.

6. Sandoz admits the allegations contained in Paragraph 6.

7. Sandoz admits the allegations contained in Paragraph 7.

8. Sandoz admits the allegations contained in Paragraph 8.

9. The allegations contained in Paragraph 9 are allegations of law that require no

response from Sandoz and Sandoz therefore denies these allegations. Sandoz further states that, on October 16, 2015, the Federal Circuit denied Plaintiffs' petition for rehearing *en banc*.

NATURE OF THE ACTION

10. Sandoz denies the allegations contained in Paragraph 10. As part of its initiative to make high-quality biosimilars accessible to patients in the U.S. as early as possible, Sandoz has spent millions of dollars and devoted thousands of hours to develop a biosimilar filgrastim product. Sandoz submitted a Biologics License Application ("BLA") for filgrastim to the U.S. Food and Drug Administration ("FDA") pursuant to the procedures set forth in the Biosimilars Price Competition and Innovation Act ("BPCIA"), the intent of which is to provide a "biosimilars pathway balancing innovation and consumer interest." *See* Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010). FDA accepted Sandoz's BLA in July 2014, bringing a more affordable version of this drug one step closer for U.S. patients. As has already been determined in this action, Sandoz fully complied with the BPCIA. FDA approved Sandoz's BLA on March 6, 2015, and U.S. patients are currently enjoying the benefits of Sandoz's ZARXIO®.

11. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 11, and on that basis denies these allegations.

12. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 12, and on that basis denies these allegations.

13. Sandoz admits that in 2010, Congress enacted the BPCIA. The remaining allegations concerning the BPCIA contained in Paragraph 13 are allegations of law that require no response from Sandoz, and Sandoz therefore denies these allegations.

14. Sandoz denies the allegations contained in Paragraph 14. The law, including the BPCIA, gives those applying to market a biosimilar product options in how to resolve patent issues before that biosimilar product comes to market. The law provides a pathway for biosimilars to come to market after 12 years of exclusivity has expired. Amgen has enjoyed exclusivity far longer than that statutory period; in fact since 1991. The California state claims of unfair competition and conversion of the First Amended Complaint ignore the BPCIA's language

and intent, and instead Amgen seeks an improper delay in the resolution of any patent disputes, which could, if accepted, result in a delay in affordable filgrastim reaching consumers. Because Amgen's position in this case attempts to re-write the BPCIA and seeks relief found nowhere in the BPCIA, it is Amgen, and not Sandoz, that is operating contrary to law.

15. Sandoz admits that it filed an application for FDA approval of biosimilar filgrastim in May 2014, that it received notification from FDA that it had accepted Defendants' BLA for review on July 7, 2014, that Sandoz offered early access to its BLA to Amgen under conditions more generous than provided by the BPCIA that Amgen refused, that the BPCIA permits Sandoz not to submit its BLA or manufacturing information to Amgen, and that the BPCIA accordingly provides Amgen an option if it does not receive Sandoz's BLA: the immediate right to bring a declaratory judgment action for infringement of allegedly relevant patents, which Amgen has done here. Sandoz further states that following entry of a protective order in this case, Sandoz produced its BLA to Amgen on February 9, 2015. Sandoz denies the remaining allegations contained in Paragraph 15.

16. Sandoz has complied with the BPCIA in all respects and denies the allegations contained in Paragraph 16. The BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor within twenty days of acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Any other interpretation would render superfluous BPCIA subsection (*l*)(9)(C), which states:

> If a 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 a use of the biological product.

42 U.S.C. § 262(*l*)(9)(C), as well as the very provision on which Amgen relies to bring this action, 35 U.S.C. § 271(e)(2)(C)(ii), which is a conforming amendment contained in the BPCIA that expressly contemplates and provides for this situation—*i.e.*, where an applicant declines to

turn over its FDA application.

The BPCIA permits the reference product sponsor and biosimilar applicant to agree on confidentiality protections not set forth in the BPCIA. See 42 U.S.C. § 262(*l*)(1)(A). Sandoz has a legitimate interest in the confidentiality of its BLA, as Amgen is also entering the biosimilars field and will compete with Sandoz.

Sandoz further states that following entry of a protective order in this case, Sandoz produced its BLA to Amgen on February 9, 2015.

17. Sandoz admits that on March 6, 2015, FDA approved Sandoz's application for its biosimilar filgrastim product. Sandoz further admits that on September 3, 2015, it launched ZARXIO®. Sandoz denies the remaining allegations contained in Paragraph 17.

18. Sandoz admits that Amgen seeks relief from this Court. Sandoz denies that Amgen is entitled to any relief. Sandoz denies the remaining allegations contained in Paragraph 18.

THE PARTIES

19. On information and belief, Sandoz admits that Amgen Inc. ("Amgen") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business One Amgen Center Drive, Thousand Oaks, California 91320. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 19, and on that basis denies these allegations.

20. On information and belief, Sandoz admits that Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in Paragraph 20, and on that basis denies these allegations.

21. Sandoz denies that it is a corporation organized and existing under the laws of New Jersey, with a principal place of business at 506 Carnegie Drive, Suite 500, Princeton, New Jersey 08540. Sandoz is a corporation organized and existing under the laws of Colorado, with a principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz denies the

remaining allegations contained in Paragraph 21 as stated.

22. On information and belief, Sandoz admits that Sandoz International GmbH has its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany. The remaining allegations contained in Paragraph 22 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

23. On information and belief, Sandoz admits that Sandoz GmbH has its principal place of business at Biochemiestraße 10, 6250 Kundl, Austria. The remaining allegations contained in Paragraph 23 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

24. The allegations contained in Paragraph 24 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

25. Sandoz denies the allegations contained in Paragraph 25.

26. Sandoz admits that FDA approved its biosimilar on March 6, 2015, and that Sandoz began sales of its biosimilar in the United States on September 3, 2015. Sandoz otherwise denies the allegations contained in Paragraph 26.

JURISDICTION AND VENUE

27. Sandoz admits that this Court has subject matter jurisdiction over Plaintiffs' patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

28. Sandoz denies the allegations contained in Paragraph 28.

29. Sandoz denies the allegations contained in Paragraph 29.

30. Sandoz denies the allegations contained in Paragraph 30, but for purposes of this action only will not challenge venue over Amgen's patent claims and Sandoz's counterclaims.

31. The allegations contained in Paragraph 31 are allegations of law that require no response from Sandoz, and Sandoz therefore denies these allegations.

32. The allegations contained in Paragraph 32 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

33. Sandoz denies the allegations contained in Paragraph 33, but for purposes of this action only will not challenge personal jurisdiction over Amgen's patent claims and Sandoz's

counterclaims. Sandoz expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Amgen.

A. Sandoz Inc.

34. Sandoz admits it is in the business of developing, manufacturing, seeking regulatory approval for, marketing, distributing, and selling generic drug products and that it does business in this district. Sandoz denies that the allegations contained in Paragraph 34 are relevant to personal jurisdiction in this case.

35. Sandoz denies the allegations contained in Paragraph 35, which attempt to set forth a basis for specific personal jurisdiction that does not exist as a matter of law.

36. Sandoz denies the allegations contained in Paragraph 36, which attempt to set forth a basis for general personal jurisdiction that does not exist as a matter of law.

B. Sandoz International GmbH (Germany)

37. The allegations contained in Paragraph 37 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

38. Sandoz denies the allegations contained in Paragraph 38 directed at it. The remaining allegations in Paragraph 38 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

39. Sandoz denies the allegations contained in Paragraph 39 directed at it. The remaining allegations contained in Paragraph 39 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

40. Sandoz admits that Peter Goldschmidt is the President of Sandoz Inc. as well as the Head of North American Operations at Sandoz. Sandoz denies the remaining allegations contained in Paragraph 40 that are directed to Sandoz. To the extent that the allegations contained in Paragraph 40 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

41. Sandoz denies the allegations contained in Paragraph 41 directed at it. Sandoz denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 41 are directed to another Defendant, such allegations require no

response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

42. Sandoz admits that Exhibit C to the First Amended Complaint appears to be the label for ZARXIO®. Sandoz avers that the ZARXIO® label speaks for itself.

43. Sandoz denies the allegations contained in Paragraph 43 directed at it. Sandoz denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 43 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

44. Sandoz denies the allegations contained in Paragraph 44 that are directed to Sandoz. To the extent that the allegations in Paragraph 44 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

45. The allegations contained in Paragraph 45 are allegations of law that require no response from Sandoz, but because they purport to be a basis of personal jurisdiction that does not exist as a matter of law, Sandoz denies them. To the extent that Paragraph 45 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

46. The allegations contained in Paragraph 46 are allegations of law that require no response from Sandoz, but because they purport to be a basis of personal jurisdiction that does not exist as a matter of law, Sandoz denies them. To the extent that Paragraph 46 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

B. Sandoz GmbH (Austria)

47. Sandoz denies the allegations contained in Paragraph 47.

48. Sandoz denies the allegations contained in Paragraph 48.

49. Sandoz admits that the active pharmaceutical ingredient ("API") of its biosimilar filgrastim that is the subject of Sandoz's BLA is manufactured at Sandoz GmbH's facilities. Sandoz denies the remaining allegations contained in Paragraph 49 directed to Sandoz and allegations of law, including those concerning 42 U.S.C. § 262(k)(2)(A)(V). To the extent that the allegations contained in Paragraph 49 are directed to another Defendant, such allegations

require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

50. Sandoz denies the allegations contained in Paragraph 50 directed at it, and denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 50 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

51. Sandoz denies the factual allegations contained in Paragraph 51 directed to it and denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 51 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

52. Sandoz admits that Exhibit F to the First Amended Complaint appears to be the March 6, 2015, BLA Approval Letter sent from FDA to Sandoz. Sandoz avers that the March 6, 2015, BLA Approval Letter speaks for itself.

53. Sandoz denies the allegations contained in Paragraph 53 that are directed to it. To the extent that the allegations contained in Paragraph 53 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

54. The allegations contained in Paragraph 54 are allegations of law that require no response from Sandoz, but because they purport to be a basis of personal jurisdiction that does not exist as a matter of law, Sandoz denies them. To the extent that Paragraph 54 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

55. The allegations contained in Paragraph 55 are allegations of law that require no response from Sandoz, but because they purport to be a basis of personal jurisdiction that does not exist as a matter of law, Sandoz denies them. To the extent that Paragraph 55 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

AMGEN OBTAINS FDA APPROVAL FOR ITS INNOVATIVE G-CSF BIOLOGICAL PRODUCT, NEUPOGEN®, UNDER 42 U.S.C. § 262(a)[1]

56. The allegations contained in Paragraph 56 are either allegations of law that require no response from Sandoz, or allegations on which Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations. Sandoz therefore denies the allegations contained in Paragraph 56.

57. The allegations contained in Paragraph 57 are either allegations of law that require no response from Sandoz, or allegations on which Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations. Sandoz therefore denies the allegations contained in Paragraph 57.

58. The allegations contained in Paragraph 58 are either allegations of law that require no response from Sandoz, or allegations on which Sandoz lacks knowledge or information sufficient to form a belief about the truth of such allegations. Sandoz therefore denies the allegations contained in Paragraph 58.

59. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 59, and on that basis denies these allegations.

60. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 60, and on that basis denies these allegations.

61. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 61, and on that basis denies these allegations.

THE BPCIA REFLECTS A CONGRESSIONAL BALANCE OF THE INTERESTS OF INNOVATORS AND BIOSIMILAR APPLICANTS UNDER THE 262(k) PATHWAY

62. Sandoz admits that the BPCIA was enacted into law on March 23, 2010. The remaining allegations contained in Paragraph 62 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

63. The allegations contained in Paragraph 63 are allegations of law or

[1] Headings in this Answer are used solely to mirror the headings in the First Amended Complaint for the sake of organization and should not be construed as an admission or denial by Sandoz on any issue.

characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

64. Sandoz admits the allegation in the first sentence of Paragraph 64. The other allegations contained in Paragraph 64 are allegations of law or characterizations of the BPCIA or PPACA that require no response from Sandoz, and Sandoz therefore denies these allegations.

65. The allegations contained in Paragraph 65 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

66. The allegations contained in Paragraph 66 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations. As has already been briefed and ruled upon, there is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. And providing the biosimilar application to the reference product sponsor is an option, not a requirement. Any other interpretation would render superfluous BPCIA subsection (*l*)(9)(C), which states:

> If a 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 a use of the biological product.

42 U.S.C. § 262(*l*)(9)(C). Further, the BPCIA permits the reference product sponsor and biosimilar applicant to agree on confidentiality protections not set forth in the BPCIA. *See* 42 U.S.C. § 262(l)(1)(A). Sandoz had a legitimate interest in the confidentiality of its BLA. Sandoz further states that following entry of a protective order in this case, Sandoz produced its BLA to Amgen on February 9, 2015.

67. The allegations contained in Paragraph 67 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

68. The allegations contained in Paragraph 68 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations. Sandoz has provided Amgen notice of commercial marketing as required by the BPCIA.

69. The allegations contained in Paragraph 69 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations. Sandoz has provided Amgen notice of commercial marketing as required by the BPCIA.

70. The allegations contained in Paragraph 70 are allegations of law that require no response from Sandoz, and Sandoz therefore denies these allegations.

71. The allegations contained in Paragraph 71 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations. Sandoz has provided Amgen notice of commercial marketing as required by the BPCIA.

DEFENDANTS' BIOSIMILAR APPLICATION UNDER 42 U.S.C. 262(k)

72. Sandoz denies the allegations contained in Paragraph 72, except it admits that it filed a § 262(k) application seeking FDA approval of a biosimilar filgrastim for sale in the United States and that FDA approved that application on March 6, 2015.

73. Sandoz denies the allegations contained in Paragraph 73, except it admits that Amgen's NEUPOGEN® is the reference product and further avers that the ZARXIO® label speaks for itself.

74. Sandoz admits that Sandoz's BLA is the first application that the FDA has accepted under the § 262(k) pathway.

75. Sandoz denies the allegations contained in Paragraph 75, except admits that it complied with the BPCIA.

76. Sandoz admits that it received notification from the FDA on July 7, 2014 that the FDA had accepted the BLA for Sandoz's biosimilar filgrastim and that FDA approved Sandoz's

BLA on March 6, 2015. Sandoz admits it sent a letter to Amgen dated July 8, 2014 and one dated July 25, 2014. Sandoz denies the remaining allegations contained in Paragraph 76 that are directed to Sandoz. To the extent that the allegations in Paragraph 76 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

77. The allegations contained in Paragraph 77 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

78. Sandoz incorporates its response to Paragraph 66. Answering further, Sandoz denies the allegations contained in Paragraph 78, especially that any defendant other than Sandoz has any obligation under the BPCIA, and to the extent this paragraph tries to read subsection (*l*)(9)(C) out of the BPCIA. The BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. Sandoz admits that if the parties had decided to use the patent exchange process in the BPCIA to resolve any potential patent disputes, Amgen may have only been in a position to even start patent litigation under this mechanism until after the date on which Sandoz expects (under the BSUFA guidelines) that it may receive approval for its biosimilar filgrastim product, thereby undermining one of the purposes of the BPCIA. In a letter dated August 22, 2014, Amgen acknowledged that resolution under the statutory patent exchange and litigation procedures could not be completed prior to Sandoz's expected launch date.

79. Sandoz denies the allegations contained in Paragraph 79. Sandoz incorporates its responses to Paragraphs 69 and 70.

80. Sandoz denies the allegations contained in Paragraph 80. Sandoz incorporates its response to Paragraph 71.

81. Sandoz denies the allegations contained in Paragraph 81. FDA review and approval under § 262(k) in no part turns on the patent-related provisions of § 262(*l*). Further, under § 262(*l*), providing the BLA is an option, not a requirement. The BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with

the reference product sponsor immediately after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. The BPCIA permits the reference product sponsor and biosimilar applicant to agree on confidentiality protections not set forth in the BPCIA. *See* 42 U.S.C. § 262(*l*)(1)(A).

Sandoz Inc. has a legitimate interest in the confidentiality of its BLA, as Amgen is also entering the biosimilars field and will compete with Sandoz. Sandoz further states that following entry of a protective order in this case, Sandoz produced its BLA to Amgen on February 9, 2015.

The California state claims of unfair competition and conversion of the First Amended Complaint ignore the BPCIA's language and intent, instead seeking an improper delay in the resolution of any patent disputes, which could, if accepted, result in a delay in affordable filgrastim reaching consumers. Because Amgen's position in this case attempts to rewrite the BPCIA and seeks relief found nowhere in the BPCIA, it is Amgen, and not Sandoz, that is operating contrary to law. Additionally, Amgen is seeking to create a link between the patent information exchange provisions and the regulatory review where one does not exist in the BPCIA.

82. Sandoz denies the allegations contained in Paragraph 82, except admits that correspondence was exchanged. Sandoz further states that the BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor immediately after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. The BPCIA permits the reference product sponsor and biosimilar applicant to agree on confidentiality protections not set forth in the BPCIA. *See* 42 U.S.C. § 262(*l*)(1)(A). Sandoz has fully complied with the BPCIA. Sandoz has a legitimate interest in the confidentiality of its BLA. Sandoz acted within its rights not to share its BLA. Amgen thus has the option specifically provided to reference product sponsors in this circumstance: a declaratory judgment action for patent infringement in relation to allegedly relevant patents, which option it has used here.

83. Sandoz denies the allegations contained in Paragraph 83, except admits that the BPCIA contemplates that Amgen and Sandoz could try and agree on confidentiality protections

other than those set forth in the BPCIA, that Sandoz and Amgen tried to but did not reach an agreement, and that Sandoz then elected not to provide Amgen with its BLA in the absence of confidentiality protections. The BPCIA provides as a sole consequence that Amgen can bring a declaratory judgment action on any patent it believes claims the biologic or a use of that biologic, which Amgen has now done. The interpretation Amgen seeks would even limit the parties' ability to amicably resolve their disputes outside of the BPCIA.

84. Sandoz denies the allegations contained in Paragraph 84. See response to Paragraph 83.

85. Sandoz denies the allegations contained in Paragraph 85.

86. Sandoz denies the allegations contained in Paragraph 86. The BPCIA gives biosimilar applicants the right not to disclose their biosimilar application under the BPCIA. The consequence is that the reference product sponsor may immediately start patent infringement proceedings in those cases where it holds allegedly relevant patents. This process is clearly the intention of the BPCIA: to allow the parties to resolve patent disputes prior to the launch of the biosimilar product. As previously advised to Amgen, Sandoz was prepared to provide its biosimilar application under a protective order, and following entry of a protective order in this case, Sandoz produced its BLA to Amgen on February 9, 2015.

87. Sandoz admits that FDA approved Sandoz's BLA for its biosimilar filgrastim on March 6, 2015 and that U.S. patients are currently enjoying the benefits of ZARXIO®. Sandoz denies the remaining allegations contained in Paragraph 87 directed to it. To the extent that the allegations in Paragraph 87 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

88. Sandoz denies the allegations contained in Paragraph 88.

89. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 89, and on that basis denies these allegations, but notes that Amgen has information regarding filgrastim, its uses, and its formulation, and has elected to proceed on the U.S. Patent No. 6,162,427 ("the '427 patent"), which it is permitted to do under the BPCIA.

90. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 90, and on that basis denies these allegations.

91. Sandoz denies the allegations contained in Paragraph 91, because Sandoz has complied with the BPCIA. Sandoz lacks knowledge or information sufficient to form a belief as to what Amgen believes or could have done. Amgen has offered no reason for waiting until October 24, 2014, to file an action that would provide the opportunity for discovery of Sandoz's biosimilar application.

92. Sandoz denies the allegations contained in Paragraph 92.

FIRST CAUSE OF ACTION
(UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE § 17200 et seq.)

93. Sandoz understands that Amgen purports to preserve claims that have already been rejected by this Court and the Federal Circuit. Sandoz preserves and incorporates its prior arguments against such claims. Sandoz further states that, on October 16, 2015, the Federal Circuit denied Plaintiffs' petition for rehearing *en banc*.

94. Sandoz incorporates its responses to Paragraphs 1 to 92 as if fully set forth herein.

95. Sandoz denies the allegations contained in Paragraph 95, denies that there is jurisdiction over a Section 17200 claim, and further states that Section 17200 does not apply to this dispute.

96. Sandoz incorporates its responses to Paragraphs 64-71 and 78, and denies the allegations contained in Paragraph 96.

97. Sandoz denies the allegations contained in Paragraph 97.

98. Sandoz incorporates its responses to Paragraphs 69, 70, 78-92, and denies the allegations contained in Paragraph 98. Sandoz notes that Amgen has information regarding filgrastim, its uses, and its formulation, and has elected to proceed on the '427 patent, which it is permitted to do under the BPCIA.

99. Sandoz denies the allegations contained in Paragraph 99.

100. Sandoz denies the allegations contained in Paragraph 100.

101. Sandoz denies the allegations contained in Paragraph 101.

102. Sandoz denies the allegations contained in Paragraph 102.

103. Sandoz denies the allegations contained in Paragraph 103.

SECOND CAUSE OF ACTION
(CONVERSION)

104. Sandoz understands that Amgen purports to preserve claims that have already been rejected by this Court and the Federal Circuit. Sandoz preserves and incorporates its prior arguments against such claims. Sandoz further states that, on October 16, 2015, the Federal Circuit denied Plaintiffs' petition for rehearing *en banc*.

105. Sandoz incorporates its responses to Paragraphs 1 to 103 as if fully set forth herein.

106. The allegations contained in Paragraph 106 are allegations of law to which no response is required or are allegations about which Sandoz lacks knowledge or information sufficient to form a belief, and Sandoz therefore denies them.

107. Sandoz denies the allegations contained in Paragraph 107. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. Sandoz incorporates its response to Paragraph 57.

108. The allegations contained in Paragraph 108 are allegations of law to which no response is required or allegations about which Sandoz lacks knowledge or information sufficient to form a belief. Sandoz therefore denies the allegations contained in Paragraph 108.

109. Sandoz denies the allegations contained in Paragraph 109, denies that there is jurisdiction over a conversion claim, and further states that a common law claim conversion has no place in this dispute.

110. Sandoz denies the allegations contained in Paragraph 110.

111. Sandoz denies the allegations contained in Paragraph 111.

112. Sandoz denies the allegations contained in Paragraph 112.

113. Sandoz denies the allegations contained in Paragraph 113, and reserves all rights to seek appropriate relief after discovery on the supposed information and belief for this allegation.

114. Sandoz denies the allegations contained in Paragraph 114.

115. Sandoz denies the allegations contained in Paragraph 115, incorporates by reference its response to Paragraph 109, and denies that there is any basis for the relief requested by Amgen.

THIRD CAUSE OF ACTION
(PATENT INFRINGEMENT OF THE '427 PATENT)

116. Sandoz incorporates its responses to Paragraphs 1 to 115 as if fully set forth herein.

117. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 117, and on that basis denies these allegations.

118. Sandoz admits that the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,162,427 (the "'427 patent") on December 19, 2000. Sandoz admits that Exhibit K to the First Amended Complaint appears to be a copy of the '427 patent. Sandoz admits that the face of the '427 patent lists Matthias Baumann and Peter-Paul Ochlich as inventors. Sandoz denies that the '427 patent was duly and legally issued. Sandoz denies the remaining allegations contained in Paragraph 118.

119. Sandoz denies the allegations contained in Paragraph 119.

120. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 120, and on that basis denies these allegations.

121. Sandoz denies it has infringed the '427 patent but admits that 35 U.S.C. § 271(e)(2)(C)(ii) provides a jurisdictional basis for this litigation. Sandoz denies the remaining allegations contained in Paragraph 121.

122. Sandoz denies the allegations contained in Paragraph 122.

123. Sandoz denies the allegations contained in Paragraph 123.

124. Sandoz admits that it is currently selling ZARXIO® in the United States. Sandoz denies the remaining allegations contained in Paragraph 124 directed to it. To the extent that the allegations in Paragraph 124 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

125. Sandoz denies the allegations contained in Paragraph 125.

126. Sandoz admits that it was aware of the existence of the '427 patent prior to the filing of Amgen's First Amended Complaint. Sandoz denies the remaining allegations contained in Paragraph 126 directed to it. To the extent that the allegations in Paragraph 126 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

127. Sandoz denies the allegations contained in Paragraph 127.

128. Sandoz denies the allegations contained in Paragraph 128.

129. Sandoz denies the allegations contained in Paragraph 129.

130. Sandoz denies the allegations contained in Paragraph 130.

131. Sandoz denies the allegations contained in Paragraph 131.

132. Sandoz denies the allegations contained in Paragraph 132.

133. Sandoz denies the allegations contained in Paragraph 133.

FOURTH CAUSE OF ACTION
(PATENT INFRINGEMENT OF THE '878 PATENT)

134. Sandoz incorporates its responses to Paragraphs 1 to 133 as if fully set forth herein.

135. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 135, and on that basis denies these allegations.

136. Sandoz admits that the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 8,940,878 (the "'878 patent") on January 27, 2015. Sandoz admits that Exhibit L to the First Amended Complaint appears to be a copy of the '878 patent. Sandoz admits that the face of the '878 patent lists Joseph Edward Shultz and Roger Hart as inventors. Sandoz denies that the '878 patent was duly and legally issued. Sandoz denies the remaining allegations contained in Paragraph 136.

137. Sandoz denies the allegations contained in Paragraph 137.

138. Sandoz denies the allegations contained in Paragraph 138.

139. Sandoz lacks knowledge or information sufficient to form a belief about the truth

of the allegations contained in Paragraph 139, and on that basis denies these allegations.

140. Sandoz denies it has infringed the '878 patent but admits that 35 U.S.C. § 271(e)(2)(C)(ii) provides a jurisdictional basis for this litigation. Sandoz denies the remaining allegations contained in Paragraph 140.

141. Sandoz denies the allegations contained in Paragraph 141.

142. Sandoz denies the allegations contained in Paragraph 142.

143. Sandoz admits that it was aware of the existence of the '878 patent prior to the filing of Amgen's First Amended Complaint. Amgen, through counsel, identified its intent to assert the '878 patent on September 21, 2015, before the First Amended Complaint was filed. Sandoz denies the remaining allegations contained in Paragraph 143 directed to it. To the extent that the allegations in Paragraph 143 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

144. Sandoz denies the allegations contained in Paragraph 144.

145. Sandoz denies the allegations contained in Paragraph 145.

146. Sandoz denies the allegations contained in Paragraph 146.

147. Sandoz denies the allegations contained in Paragraph 147.

ANSWER TO PRAYER FOR RELIEF

Sandoz denies that Plaintiffs are entitled to any of the relief requested.

AFFIRMATIVE DEFENSES

Without admitting or implying that Sandoz bears the burden of proof as to any of them, Sandoz, on information and belief, asserts the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Lack of Personal Jurisdiction)

1. Plaintiffs do not and cannot establish that sufficient grounds exist for this Court to exercise personal jurisdiction over Sandoz in this action. For purposes of this action only, Sandoz will not challenge personal jurisdiction over Amgen's patent claims and Sandoz's counterclaims.

SECOND AFFIRMATIVE DEFENSE
(Failure to State a Claim)

2. Plaintiffs' First Amended Complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

3. The '427 patent and the '878 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(No Direct Infringement)

4. Sandoz has not, does not, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '427 patent or the '878 patent.

FIFTH AFFIRMATIVE DEFENSE
(No Indirect Infringement)

5. Sandoz has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '427 patent or the '878 patent.

SIXTH AFFIRMATIVE DEFENSE
(Preemption)

6. Plaintiffs' claims of Unfair Competition and Conversion are preempted by federal law.

SEVENTH AFFIRMATIVE DEFENSE
(No Recovery of Costs)

7. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

EIGHTH AFFIRMATIVE DEFENSE
(Standing)

8. Plaintiffs have not suffered injury in fact and have not lost money or property as a result of any alleged unfair competition, and therefore lack standing under Cal. Bus. Prof. Code § 17200, *et seq*.

NINTH AFFIRMATIVE DEFENSE
(Legitimate Business Interest)

9. Plaintiffs' claims of Unfair Competition and Conversion are barred because the acts about which Plaintiffs complain were undertaken for legitimate business purposes.

TENTH AFFIRMATIVE DEFENSE
(Unclean Hands)

10. The First Amended Complaint, and each of its purported causes of action, is barred by Plaintiffs' unclean hands.

ELEVENTH AFFIRMATIVE DEFENSE
(Laches, Waiver, Estoppel)

11. The First Amended Complaint, and each of its purported causes of action, is barred in whole or in part by the doctrines of laches, waiver, or estoppel.

TWELFTH AFFIRMATIVE DEFENSE
(Failure to Mitigate)

12. Plaintiffs have failed to mitigate the harm they claim to have sustained, if any.

OTHER AFFIRMATIVE DEFENSES RESERVED

Sandoz reserves the right to assert any other defenses that discovery may reveal.

RESERVATION OF RIGHTS

As Sandoz's investigation is ongoing and discovery has not yet taken place, Sandoz is without sufficient information regarding the existence or non-existence of other facts or acts that would constitute a defense to Plaintiffs' claims of patent infringement or that would establish the invalidity and/or unenforceability of the '427 patent or the '878 patent, including additional prior art or related patents. Sandoz hereby gives notice that it may assert facts or acts which tend to

establish noninfringement, invalidity, unenforceability or which otherwise constitute a defense under Title 35 of the United States Code as information becomes available to Sandoz in sufficient detail to assert such a defense.

SANDOZ'S COUNTERCLAIMS

Sandoz submits these counterclaims against Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen"):

PROCEDURAL POSTURE

1. Certain portions of paragraphs of these Counterclaims address claims previously adjudicated by this Court and by the Federal Circuit. Those portions are restated to preserve those claims, in light of corresponding claims set forth in Amgen's First Amended Complaint and pending any subsequent proceedings.

THE PARTIES

2. Sandoz is a corporation organized and existing under the laws of Colorado with its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

3. As pled in Amgen's First Amended Complaint, Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business One Amgen Center Drive, Thousand Oaks, California 91320.

4. As pled in Amgen's First Amended Complaint, Amgen Manufacturing, Limited ("AML") is a corporation existing under the laws of Bermuda with its principal place of business in Juncos, Puerto Rico.

JURISDICTION AND VENUE

5. These counterclaims are for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for determining questions of actual controversy between the parties regarding the rights and other legal relations of the parties with respect to the Biosimilars Price Competition and Innovation Act ("BPCIA").

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 42 U.S.C. § 262(k)-(*l*), 28 U.S.C. §§ 1331, 1338(a) and 1367(a), and 35 U.S.C. § 271(e)(2)(C)(ii).

7. This Court has personal jurisdiction over each of Amgen Inc. and Amgen Manufacturing, Limited at least because they have subjected themselves to the jurisdiction of this Court in this case by filing the Complaint.

8. Venue in this case is proper in this judicial district pursuant to 28 U.S.C. § 1391 and by virtue of Amgen's filing of this action in this Court.

THE CONTROVERSY RELATING TO BPCIA SUBSECTION (*l*)(9)(C)

9. Filgrastim is a biological product used to avoid the side effects of certain forms of cancer therapy. As pled in Amgen's First Amended Complaint, the biological product license to NEUPOGEN® (filgrastim) is owned by Amgen Inc. and exclusively licensed to AML.

10. Sandoz submitted a Biologics License Application ("BLA") for filgrastim to FDA pursuant to the procedures set forth in the BPCIA, the intent of which is to provide a "biosimilars pathway balancing innovation and consumer interest." *See* Biologics Price Competition and Innovation Act, § 7001(b), Pub. L. No. 111-148, 124 Stat 804 (2010).

11. The BPCIA provides for FDA's reliance on the approval of the reference product sponsor's biological product to approve the biosimilar application.

12. The BPCIA provides 12 years of exclusivity to the reference product. According to Amgen's First Amended Complaint, FDA licensed NEUPOGEN® in 1991. Therefore, Amgen's exclusivity period expired in 2003. Indeed, a biosimilar filgrastim has been marketed in Europe since 2008.

13. Now, more than ten years after its exclusivity period expired, Amgen seeks to suspend the regulatory approval of biosimilar filgrastim, extend its exclusivity even farther beyond the 12 years contemplated by Congress in the BPCIA, and delay patient access to a more affordable version of this drug.

14. The BPCIA sets forth a procedure by which the biosimilar applicant and reference product sponsor may exchange information relating to potential patent disputes. *See* 42 U.S.C. § 262(*l*). These exchanges occur after the biosimilar BLA has been submitted to FDA but before any court-enforced confidentiality protections are in place. *Id.*

15. According to the timing of the procedures set forth in the BPCIA, the information exchanges necessarily occur ***after*** the biosimilar applicant has filed the biosimilar application.

16. The BPCIA clearly and cleanly separates the FDA review and approval process described in 42 U.S.C. § 262(k) from the patent exchange process described in 42 U.S.C. § 262(*l*). Amgen wrongly seeks to create a link between the patent information exchange provisions and the regulatory review where one does not exist in the BPCIA.

17. This separation demonstrates and implements Congress' intent that the patent exchange process is ***not*** a mandatory prerequisite to FDA review and approval of a biosimilar applicant's subsection (k) application.

18. In addition, 42 U.S.C. § 262(*l*)(9)(C) governs and provides the sole consequence if the biosimilar applicant elects not to share its subsection (k) application with the reference product sponsor:

> **(9) Limitation on declaratory judgment action**
>
> **(A) Subsection (k) application provided**
>
> If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).
>
> **(B) Subsequent failure to act by subsection (k) applicant**
>
> If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(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 included in the list described in paragraph (3)(A), including as provided under paragraph (7).
>
> **(C) Subsection (k) application not provided**
>
> If a 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 a use of the biological product.

42 U.S.C. § 262(*l*)(9).

19. Under the language of subsection (*l*)(9)(A), if the biosimilar applicant elects to share its subsection (k) application, neither party may bring an action for declaratory judgment for infringement, validity, or enforceability of a patent at issue before the biosimilar applicant provides its notice of commercial marketing.

20. However, if the biosimilar applicant elects not to share the application, then the reference product sponsor—but ***not*** the biosimilar applicant—may seek a declaration of infringement, validity, or enforceability before the biosimilar applicant provides it notice of commercial marketing. 42 U.S.C. § 262(*l*)(9)(C).

21. Notably, subsection (*l*) does not prohibit FDA from reviewing or approving the biosimilar BLA if the biosimilar applicant elects not to provide the subsection (k) application to the reference product sponsor.

22. Reading subsections (k) and (*l*) together, the BPCIA gives a biosimilar applicant the option either to share its biosimilar application and manufacturing information with the reference product sponsor promptly after acceptance of the BLA by FDA or to face an action under 28 U.S.C. § 2201 for a declaration of patent infringement. And even if the subsection (*l*)(2)(A) disclosures were "mandatory" as Amgen contends, Congress has provided the sole consequence for any violation in subsection (*l*)(9)(C).

23. Any other interpretation would render superfluous both BPCIA subsection (*l*)(9)(C) and the BPCIA conforming amendment codified at 35 U.S.C. § 271(e)(2)(C)(ii).

24. The BPCIA does not provide for relief under state statutes or common law claims, including conversion or unfair competition claims. Nor does the BPCIA provide for injunctive relief, restitution, or damages. Instead, the BPCIA and/or 35 U.S.C. § 271(e)(4) precludes and preempts any and all such claims and remedies.

25. The BPCIA demonstrates Congress' intent not to allow a reference product sponsor to delay FDA approval of a biosimilar BLA by omitting injunctive relief and by

completely separating provisions related to patents (in subsection (*l*)) from those related to FDA approval (in subsection (k)).

26. Amgen filed a Citizen Petition with FDA on October 29, 2014. In its Citizen Petition, Amgen requested that FDA require BLA applicants to certify that they will provide the reference product sponsor a copy of their BLA and manufacturing process information. *See* Citizen Petition at 5.[2]

27. If the BPCIA mandated that applicants provide this information to reference product sponsors, there would be no need for Amgen to request FDA to take this action.

28. The BPCIA permits the reference product sponsor and biosimilar applicant to agree on confidentiality protections not set forth in the BPCIA. *See* 42 U.S.C. § 262(*l*)(1)(A). Sandoz has a legitimate interest in the confidentiality of its BLA. In a letter dated July 8, 2014, Sandoz offered to share its BLA with Amgen under conditions that would adequately protect the confidential and proprietary nature of the information in the BLA. Amgen, however, refused.

29. There is a substantial controversy between Amgen and Sandoz as to whether, if a biosimilar applicant does not provide the subsection (k) application to the reference product sponsor, the BPCIA allows the reference product sponsor to obtain relief other than "a declaration of infringement, validity, or enforceability of any patent that claims the biological product or use of the biological product." 42 U.S.C. § 262(*l*)(9)(C).

30. This disagreement between Amgen and Sandoz over the meaning of the BPCIA is at the core of this lawsuit. Interpretation of the BPCIA would resolve Amgen's claims for conversion and violation of California's Unfair Competition Law.

31. The controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment, as evidenced by Amgen's commencement of the instant action in this Court seeking injunctive relief, restitution, and damages in contradiction of the clear statutory language of the BPCIA.

[2] http://www.regulations.gov/#!documentDetail;D=FDA-2014-P-1771-0001

FIRST COUNTERCLAIM

(Declaratory Judgment That Subsection (k) Applicants May Elect Not to Provide the Subsection (k) Application to the Reference Product Sponsor, Subject to the Consequences Set Forth in 42 U.S.C. § 262(*l*)(9)(C).

32. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 31 of these Counterclaims above.

33. As codified at 42 U.S.C. § 262(*l*)(9)(C), the BPCIA dictates the consequences if the biosimilar applicant elects not to provide its subsection (k) application and/or manufacturing process information.

34. The BPCIA contemplates at least two pathways for the biosimilar applicant under subsection (*l*)—either the biosimilar applicant provides the reference product sponsor with the subsection (k) application and such other information that describes the manufacturing processes or it does not.

35. Sandoz is entitled to a judgment declaring that the BPCIA allows the biosimilar applicant to elect to not provide the reference product sponsor with the subsection (k) application, subject only to the consequences set forth in 42 U.S.C. § 262(*l*)(9)(C).

36. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SECOND COUNTERCLAIM

(Declaratory Judgment of No Injunctive Relief, Restitution, or Damages Under BPCIA)

37. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 36 of these Counterclaims above.

38. The BPCIA contemplates at least two pathways for the biosimilar applicant under subsection (*l*)—either the biosimilar applicant provides the reference product sponsor with the subsection (k) application and such other information that describes the manufacturing processes or it does not.

39. Even if the subsection (*l*)(2)(A) disclosures were "mandatory" as Amgen contends, the BPCIA places limits on actions available to the reference product sponsor if the biosimilar applicant elects not to provide the subsection (k) application. 42 U.S.C. § 262(*l*)(9)(C).

40. The BPCIA does not allow the reference product sponsor to obtain an injunction, nor does the BPCIA entitle the reference product sponsor to an award of restitution or damages if the biosimilar applicant chooses not to provide the reference product sponsor with the subsection (k) application.

41. Sandoz is entitled to a judgment declaring that Amgen cannot obtain damages, restitution, or injunctive relief, including enjoining Sandoz from continuing to seek FDA review of its subsection (k) application for filgrastim, for Sandoz electing not to provide the reference product sponsor with the subsection (k) application.

42. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

THIRD COUNTERCLAIM

(Declaratory Judgment of Exclusive Consequence Under BPCIA)

43. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 42 of these Counterclaims above.

44. If the biosimilar applicant does not provide the reference product sponsor with the subsection (k) application and information related to its manufacturing process, the BPCIA removes the biosimilar applicant's right to bring a declaratory judgment action regarding patents for the biological product or for use of the biological product, while authorizing the reference product sponsor to bring such an action immediately.

45. Sandoz is entitled to a judgment declaring that the exclusive consequence of the BPCIA for a biosimilar applicant that does not choose to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process is for the applicant to lose its right to file a declaratory judgment action regarding patents for the biological

product while authorizing the reference product sponsor to bring such an action immediately, or for use of the biological product as set forth in 42 U.S.C. § 262(*l*)(9)(C).

46. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Improper Remedies Under BPCIA – No Unfair Competition or Conversion)

47. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 46 of these Counterclaims above.

48. The BPCIA contemplates at least two pathways for the biosimilar applicant under subsection (*l*)—either the biosimilar applicant provides the reference product sponsor with the subsection (k) application and such other information that describes the manufacturing processes or it does not.

49. If the biosimilar applicant does not provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process, the BPCIA provides the reference product sponsor a right to bring an action for "a declaration of infringement, validity, or enforceability of a patent that claims the biological product or use of the biological product." 42 U.S.C. § 262(*l*)(9)(C).

50. The BPCIA does not allow the reference product sponsor to obtain an injunction, nor does the BPCIA entitle the reference product sponsor to an award of restitution or damages if the biosimilar applicant does not choose to provide the reference product sponsor with the subsection (k) application.

51. If the biosimilar applicant does not provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process, the BPCIA removes the biosimilar applicant's right to bring a declaratory judgment action regarding patents for the biological product or for use of the biological product.

52. Sandoz is entitled to a judgment declaring that Amgen's claims for violation of California's Unfair Competition Law and conversion cannot state a claim for relief as they seek remedies that are improper, unlawful, and/or preempted—including injunction, restitution, and damages—for a biosimilar applicant's decision not to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process.

53. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

FIFTH COUNTERCLAIM

(Declaratory Judgment that Reference Product Sponsor Does Not Have Exclusive Possession or Control over the Biological Product License)

54. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 53 of these Counterclaims above.

55. The BPCIA allows FDA to rely on the approval of the reference product sponsor's biological product in reviewing and approving a (k) application.

56. By allowing FDA to rely on the reference product's license, the BPCIA makes the reference product sponsor's property right in the reference product license non-exclusive.

57. Sandoz is entitled to a judgment declaring that the BPCIA necessarily renders a reference product sponsor's property interest in a biological product license non-exclusive.

58. Sandoz is further entitled to a judgment declaring that Amgen's cause of action for conversion fails to state a claim due to the non-exclusive property right Amgen possesses in its license for NEUPOGEN®.

59. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SIXTH COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the '427 Patent)

60. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 59 of these Counterclaims above.

61. Amgen asserts that Sandoz committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting a BLA for biosimilar filgrastim and has induced infringement of the '427 patent under 35 U.S.C. § 271(b).

62. 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), (e)(2)(C)(ii), or (g).

63. Sandoz is entitled to a declaration 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), (e)(2)(C)(ii), or (g).

64. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

SEVENTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '427 Patent)

65. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 64 of these Counterclaims above.

66. Amgen asserts that Sandoz committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting a BLA for biosimilar filgrastim and has induced infringement of the '427 patent under 35 U.S.C. § 271(b).

67. 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.

68. Sandoz is entitled to a declaration 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.

69. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

EIGHTH COUNTERCLAIM

(Declaratory Judgment of Noninfringement of the '878 Patent)

70. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 69 of these Counterclaims above.

71. Amgen asserts that Sandoz committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting a BLA for biosimilar filgrastim and has infringed the '878 patent under 35 U.S.C. § 271(g).

72. 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 '878 patent under 35 U.S.C. § 271(a), (b), (c), (e)(2)(C)(ii), or (g).

73. Sandoz is entitled to a declaration that the manufacture, use, offer for sale, and sale of biosimilar filgrastim do not and will not infringe any valid claim of the '878 patent under 35 U.S.C. § 271(a), (b), (c), (e)(2)(C)(ii), or (g).

74. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

NINTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '878 Patent)

75. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to Amgen's First Amended Complaint and Paragraphs 1 through 74 of these Counterclaims above.

76. Amgen asserts that Sandoz committed a statutory act of infringement under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting a BLA for biosimilar filgrastim and has infringed the '878 patent under 35 U.S.C. § 271(g).

77. Sandoz asserts that the claims of the '878 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.

78. Sandoz is entitled to a declaration that the claims of the '878 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.

79. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Sandoz prays that the Court enter judgment in its favor and against Plaintiffs as follows:

1. Adjudging and decreeing that Plaintiffs be denied all relief requested under its First Amended Complaint;

2. Declaring that a subsection (k) applicant may elect not to provide the subsection (k) application or information related to its manufacturing process to the reference product sponsor, subject only to the consequences set forth under 42 U.S.C. § 262(*l*)(9)(C);

3. Declaring that Plaintiffs cannot obtain damages, restitution, or injunctive relief, including enjoining Sandoz from continuing to seek FDA review of its subsection (k) application for filgrastim, for Sandoz electing not to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process;

4. Declaring that the exclusive consequences of the BPCIA for a biosimilar applicant that does not choose to provide the reference product sponsor with the subsection (k) application or information related to its manufacturing process is for the applicant to lose its right to file a declaratory judgment action regarding patents for the biological product or for use of the biological product, and for the reference product sponsor to be entitled to file a declaratory relief

action regarding patents for the biological product or for use of the biological product, as set forth in 42 U.S.C. § 262(*l*)(9)(C);

5. Declaring that Plaintiffs fail to state a claim for conversion or violation of California's Business & Professions Code § 17200 *et seq.*;

6. Declaring that Plaintiffs' property interest in the biological product license is non-exclusive and that Plaintiffs cannot state a claim for conversion;

7. Declaring that Sandoz has not and will not infringe the '427 patent;

8. Declaring that the '427 patent is invalid;

9. Declaring that Sandoz has not and will not infringe the '878 patent;

10. Declaring that the '878 patent is invalid;

11. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Sandoz or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Sandoz, or charging them either orally or in writing with infringement of any patent asserted herein against Sandoz;

12. Granting Sandoz judgment in its favor on Plaintiffs' First Amended Complaint;

13. Denying Plaintiffs' request for injunctive relief;

14. Dismissing Plaintiffs' First Amended Complaint with prejudice;

15. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Sandoz its costs and reasonable attorneys' fees; and

16. Awarding any other such relief as is just and proper.

DEMAND FOR A JURY TRIAL

Sandoz hereby demands a jury trial on all issues so triable.

November 2, 2015

/s/ Rachel Krevans

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