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SANDOZ INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiff, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **SANDOZ INC.'S ANSWER TO PLAINTIFFS' 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 Complaint for Patent Infringement, Conversion, and Unfair Competition (Cal. Bus. & Prof. Code § 17200) ("Complaint") filed by Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Plaintiffs" or "Amgen") dated October 24, 2014.

The 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, have not yet been served, and whose time to respond to the Complaint has not yet begun to run. 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' Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. Sandoz denies the allegations contained in Paragraph 1. 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. Sandoz's subsequent decision to use the flexibilities of the BPCIA, for example by triggering Amgen's right to immediately commence patent infringement litigation by not disclosing its application, is not only both lawful and specifically provided for in the BPCIA, but also is directed to achieving the objective of the BPCIA to provide access to cost-effective biosimilar medicines as soon as possible. It is Amgen's act of asserting extra-BPCIA state law claims that fails to follow Congress' rules. Further, there is no link in the BPCIA between patent dispute resolution and regulatory approval of a product. Consequently, Sandoz's decision not to provide the application to Amgen without a protective order has no link to whether the product can be approved or legally sold.

2. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 2, and on that basis denies these allegations.

3. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 3, and on that basis denies these allegations.

4. Sandoz admits that in 2010, Congress enacted the BPCIA. The remaining allegations concerning the BPCIA contained in Paragraph 4 are allegations of law that require no response from Sandoz, and Sandoz therefore denies these allegations.

5. Sandoz denies the allegations contained in Paragraph 5. 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 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.

6. Sandoz admits that it has filed an application for FDA approval of biosimilar filgrastim, 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 any patent that claims the biological product or a use of the biological product, which Amgen has done here. Sandoz denies the remaining allegations contained in Paragraph 6.

7. Sandoz has complied with the BPCIA in all respects and denies the allegations contained in Paragraph 7. 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. 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). Any other interpretation would also render superfluous 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 and manufacturing information, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (l)(9)(C).

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 be Sando's primary competitor on this product. Despite Sandoz designating its correspondence on this matter as confidential, Amgen's public allegations about the content of that correspondence are unbalanced and should be addressed. 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, allowed additional Amgen employees and agents to review the application and it made such an offer of access at an even earlier time than would have been the case under the disclosure mechanism of the BPCIA. In a response letter dated July 18, 2014, Amgen itself admitted that the confidentiality provisions of the statute "may not be ideal." Amgen, however, refused to agree to Sandoz's proposed conditions. Sandoz acted within its rights not to share its BLA, in order to both only provide its application under the protection of a court order and to use the mechanisms of the BPCIA to bring forward the resolution of any potential patent disputes. The consequence is, as the BPCIA specifically provides, that the reference product sponsors may bring a declaratory judgment action for patent infringement in relation to patents that claim the biological product or a use of the

biological product. Amgen has in fact taken the benefit of this option here.

In addition to ignoring that the BPCIA expressly contemplates a subsection (k) applicant's election not to provide its application to the reference product sponsor, Amgen disregards the BPCIA statutory framework by asserting claims and remedies found nowhere in the BPCIA, including California state unfair competition and conversion claims seeking restitution and punitive damages.

THE PARTIES

8. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 8, and on that basis denies these allegations.

9. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 9, and on that basis denies these allegations.

10. 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 10 as stated.

11. 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 11 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

12. 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 12 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

13. The allegations contained in Paragraph 13 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

14. Sandoz denies the allegations contained in Paragraph 14.

15. Sandoz admits that upon FDA approval it will sell its biosimilar in the United States, and otherwise denies the allegations contained in Paragraph 15.

JURISDICTION AND VENUE

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

17. Sandoz denies the allegations contained in Paragraph 17.

18. Sandoz denies the allegations contained in Paragraph 18.

19. Sandoz denies the allegations contained in Paragraph 19, but for purposes of this action only will not challenge venue over Amgen's patent claims and Sandoz's counterclaim for a declaratory judgment that the BPCIA means what it says.

20. The allegations contained in Paragraph 20 are allegations of law that require no response from Sandoz, and Sandoz therefore denies these allegations.

21. Sandoz denies the allegations contained in Paragraph 21, but for purposes of this action only will not challenge personal jurisdiction over Amgen's patent claims and Sandoz's counterclaim for a declaratory judgment that the BPCIA means what it says. Sandoz expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Amgen.

A. Sandoz Inc.

22. 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 22 are relevant to personal jurisdiction in this case.

23. Sandoz denies the allegations contained in Paragraph 23, which attempt to set forth a basis for specific personal jurisdiction that does not exist as a matter of law.

24. Sandoz denies the allegations contained in Paragraph 24, 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)

25. The allegations contained in Paragraph 25 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

26. Sandoz denies the allegations contained in Paragraph 26 directed at it. The remaining allegations in Paragraph 26 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

27. Sandoz denies the allegations contained in Paragraph 27 directed at it. The remaining allegations contained in Paragraph 27 are directed to another Defendant and therefore require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

28. 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 28 that are directed to Sandoz. To the extent that the allegations contained in Paragraph 28 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

29. Sandoz denies the allegations contained in Paragraph 29 directed at it. Sandoz denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 29 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

30. Sandoz denies the allegations contained in Paragraph 30 directed at it. Sandoz denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 30 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

31. Sandoz denies the allegations contained in Paragraph 31 that are directed to Sandoz. To the extent that the allegations in Paragraph 31 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

32. The allegations contained in Paragraph 32 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 32 contains factual

allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

33. The allegations contained in Paragraph 33 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 33 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

C. Sandoz GmbH (Austria)

34. Sandoz denies the allegations contained in Paragraph 34.

35. Sandoz denies the allegations contained in Paragraph 35.

36. 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 36 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 36 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

37. Sandoz denies the allegations contained in Paragraph 37 directed at it, and denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 37 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

38. Sandoz denies the factual allegations contained in Paragraph 38 directed to it and denies all allegations of law, which require no response from Sandoz. To the extent that the allegations in Paragraph 38 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

39. Sandoz denies the allegations contained in Paragraph 39 that are directed to it. To the extent that the allegations contained in Paragraph 39 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

40. The allegations contained in Paragraph 40 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 40 contains factual allegations directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

41. The allegations contained in Paragraph 41 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 41 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]

42. The allegations contained in Paragraph 42 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 42.

43. The allegations contained in Paragraph 43 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.

44. The allegations contained in Paragraph 44 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.

45. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 45.

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

46. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 46.

47. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 47.

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

48. Sandoz admits that the BPCIA was enacted into law on March 23, 2010. The remaining allegations contained in Paragraph 48 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

49. The allegations contained in Paragraph 49 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

50. Sandoz admits the allegation in the first sentence of Paragraph 50. The other allegations contained in Paragraph 50 are allegations of law or characterizations of the BPCIA or PPACA that require no response from Sandoz, and Sandoz therefore denies these allegations.

51. The allegations contained in Paragraph 51 are allegations of law or characterizations of the BPCIA that require no response from Sandoz, and Sandoz therefore denies these allegations.

52. Sandoz denies the allegations contained in Paragraph 52. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. 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. 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). 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 to agree to these conditions. Thus, Sandoz acted within its rights not to share its BLA. Indeed, Amgen has here used the option specifically provided to reference product sponsors in this circumstance: a declaratory judgment action for patent infringement in relation to patents that claim the biological product or a use of the biological product. Only the declaratory judgment action pathway would allow the possibility of resolution of any patent disputes prior to the expected date of FDA approval and subsequent launch.

53. Sandoz denies the allegations contained in Paragraph 53. See Sandoz's response to Paragraph 52.

54. Sandoz denies the allegations contained in Paragraph 54. These time limits are not mandatory since the biosimilar applicant has the option to provide or not provide its biosimilar BLA to the reference product sponsor. See Sandoz's response to Paragraph 52.

55. The allegations contained in Paragraph 55 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.

56. The allegations contained in Paragraph 56 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.

57. Sandoz admits that it has appealed the November 12, 2013 decision in *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904.

58. The allegations contained in Paragraph 58 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)

59. Sandoz denies the allegations contained in Paragraph 59, except admits that it is a § 262(k) applicant that is seeking FDA approval of a Sandoz biosimilar filgrastim for sale in the United States as soon as legally permissible after approval of Sandoz's application.

60. Sandoz denies the allegations contained in Paragraph 60, except it admits that Amgen's NEUPOGEN® is the reference product.

61. On information and belief, Sandoz's BLA is the first application that the FDA has accepted under the § 262(k) pathway.

62. Sandoz denies the allegations contained in Paragraph 62, except admits that it complied with the BPCIA.

63. 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 admits that in accordance with BSUFA guidelines, FDA may approve the BLA by as early as March 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 63 that are directed to Sandoz. To the extent that the allegations in Paragraph 63 are directed to another Defendant, such allegations require no response from Sandoz. *See* Fed. R. Civ. P. 8(b)(1)(B).

64. Sandoz incorporates its response to Paragraph 52. Answering further, Sandoz denies the allegations contained in Paragraph 64, especially that any defendant other than Sandoz Inc. 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.

65. Sandoz denies the allegations contained in Paragraph 65. Sandoz incorporates its responses to Paragraphs 56 and 57.

66. Sandoz denies the allegations contained in Paragraph 66. Sandoz incorporates its response to Paragraph 58.

67. Sandoz denies the allegations contained in Paragraph 67. 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 has a legitimate interest in the confidentiality of its BLA, as Amgen is also entering the biosimilars field and will be Sandoz's primary competitor on this product. 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, allowed additional Amgen employees and agents to review the application, and it made such an offer of access at an even earlier time than would have been the case under the disclosure mechanism of

the BPCIA. Amgen, however, refused to agree to Sandoz's proposed conditions. Sandoz acted within its rights not to share its BLA, in order to both only provide its application under the protection of a court order and to use the mechanisms of the BPCIA to bring forward the resolution of any potential patent disputes. Amgen, in turn, thus has the option specifically provided to reference product sponsors in this circumstance: a declaratory judgment action for patent infringement in relation to patents that claim the biological product or a use of the biological product. As noted, Amgen has in fact taken the benefit of this option here.

The California state claims of unfair competition and conversion of the 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.

68. Sandoz denies the allegations contained in Paragraph 68, 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. 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 to agree to these conditions. Thus, 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 patents that claim the biological product or a use of the biological product, which option it has used here.

69. Sandoz denies the allegations contained in Paragraph 69, 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.

70. Sandoz denies the allegations contained in Paragraph 70. See response to Paragraph 69.

71. Sandoz denies the allegations contained in Paragraph 71.

72. Sandoz denies the allegations contained in Paragraph 72. 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 patents that cover the biological product or a method of using that product. 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 remains prepared to provide our biosimilar application under a protective order.

73. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 73, 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. Further, to the extent that Paragraph 73 purports to reserve legal rights that Amgen may or may not have, they are allegations of law that require no response from Sandoz, and Sandoz therefore denies these allegations.

74. Sandoz denies the allegations contained in Paragraph 74, 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.

75. Sandoz denies the allegations contained in Paragraph 75. Sandoz provided the required notice of commercial marketing, and complied with the BPCIA. Sandoz has appealed the November 12, 2013 decision in *Sandoz Inc. v. Amgen Inc.*, No. C-13-2904. Sandoz's notice of commercial marketing complies with the BPCIA.

76. Sandoz denies the allegations contained in Paragraph 76. Each of Sandoz's acts was lawful. The plain language of the BPCIA (and the patent laws) allows for the situation where the biosimilar applicant does not provide the application to the originator and gives the originator the right to file a declaratory judgment action as a consequence. The plain language of the BPCIA also allows for provision of the notice of commercial marketing before FDA approval; Amgen's contrary assertion frustrates Congress' intent to permit biosimilars to launch on approval (despite ongoing patent disputes).

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

77. Sandoz incorporates its responses to Paragraphs 1 to 76 as if fully set forth herein.

78. Sandoz denies the allegations contained in Paragraph 78, denies that there is jurisdiction over a Section 17200 claim, and further states that Section 17200 does not apply to this dispute.

79. Sandoz incorporates its responses to Paragraphs 50-58 and 64, and denies the allegations contained in Paragraph 79. These time limits are not mandatory since the biosimilar applicant has the option of providing its biosimilar BLA to the reference product sponsor. See response to Paragraph 78.

80. Sandoz denies the allegations contained in Paragraph 80. See responses to Paragraphs 75 and 78.

81. Sandoz incorporates its responses to Paragraphs 56, 57, 64-76, and denies the allegations contained in Paragraph 81. 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. See response to Paragraph 78.

82. Sandoz denies the allegations contained in Paragraph 82. See response to Paragraph 78.

83. Sandoz denies the allegations contained in Paragraph 83. See response to Paragraph 78.

84. Sandoz denies the allegations contained in Paragraph 84. See response to Paragraph 78.

85. Sandoz denies the allegations contained in Paragraph 85. See response to Paragraph 78.

86. Sandoz denies the allegations contained in Paragraph 86. See response to Paragraph 78.

SECOND CAUSE OF ACTION
(CONVERSION)

87. Sandoz incorporates its responses to Paragraphs 1 to 86 as if fully set forth herein.

88. Sandoz admits that one function of the FDA is to prescribe standards and measure compliance with a multistep process for approval for drugs and biological products. The remaining allegations contained in Paragraph 88 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.

89. Sandoz denies the allegations contained in Paragraph 89. There is no linkage in the BPCIA between the patent exchange provisions and the regulatory approval pathway. Sandoz incorporates its response to Paragraph 43.

90. The allegations contained in Paragraph 90 are allegations of law to which no response is required or allegations about which Sandoz lacks knowledge or information sufficient to form a belief and therefore denies.

91. Sandoz denies the allegations contained in Paragraph 91, denies that there is jurisdiction over a conversion claim, and further states that a common law claim conversion has no place in this dispute.

92. Sandoz denies the allegations contained in Paragraph 92. See response to Paragraph 91.

93. Sandoz denies the allegations contained in Paragraph 93. See response to Paragraph 91.

94. Sandoz denies the allegations contained in Paragraph 94. See response to Paragraph 91.

95. Sandoz denies the allegations contained in Paragraph 95, and reserves all rights to seek appropriate relief after discovery on the supposed information and belief for this allegation. See response to Paragraph 91.

96. Sandoz denies the allegations contained in Paragraph 96. See response to Paragraph 91.

97. Sandoz denies the allegations contained in Paragraph 97, incorporates by reference its response to Paragraph 91, and denies that there is any basis for the relief requested by Amgen. Amgen filed a Citizen Petition with the FDA on October 29, 2014. In its Citizen Petition, Amgen requested that the FDA require BLA applicants to certify that they will provide the reference product sponsor a copy of their BLA and manufacturing process information, which presumably would force BLA applicants into the patent exchange process of the BPCIA. *See* Citizen Petition at 5.[2] In its Complaint, however, Amgen alleges that the BPCIA itself mandates that a biosimilar applicant share this information with the reference product sponsor, at the risk of facing causes of action not contemplated by the BPCIA, such as state unfair competition and conversion claims. There would be no need to ask the FDA to force applicants into the patent exchange process if the BPCIA itself mandated such a result.

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

THIRD CAUSE OF ACTION
(PATENT INFRINGEMENT)

98. Sandoz incorporates its responses to Paragraphs 1 to 97 as if fully set forth herein.

99. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in Paragraph 99.

100. Sandoz admits that the U.S. Patent and Trademark Office ("PTO") issued U.S. the '427 patent on December 19, 2000. Sandoz admits that Exhibit H to the 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 100.

101. Sandoz admits that it is seeking approval from the FDA to sell biosimilar filgrastim in the United States as soon as legally permissible after approval of Sandoz's application. Sandoz denies the remaining allegations contained in Paragraph 101.

102. Sandoz denies the allegations contained in Paragraph 102, and notes that 35 U.S.C. § 271(e)(2)(C)(ii), which was enacted as part of the BPCIA, confirms that Amgen's reading of BPCIA subsection (l)(2)(A) is wrong.

103. Sandoz denies the allegations contained in Paragraph 103.

104. Sandoz denies the allegations contained in Paragraph 104.

105. Sandoz denies the allegations contained in Paragraph 105.

106. Sandoz incorporates its responses to Paragraphs 72-73, and denies the allegations contained in Paragraph 106.

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 counterclaim for a declaratory judgment that the BPCIA means what it says.

SECOND AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

3. The '427 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.

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.

SIXTH AFFIRMATIVE DEFENSE
(Preemption)

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

SEVENTH AFFIRMATIVE DEFENSE

(No Recovery of Costs)

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

EIGHTH AFFIRMATIVE DEFENSE
(Standing)

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

NINTH AFFIRMATIVE DEFENSE
(Legitimate Business Interest)

8. 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)

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

ELEVENTH AFFIRMATIVE DEFENSE
(Laches, Waiver, Estoppel)

10. The 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)

11. 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, 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"):

THE PARTIES

1. 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.

2. As pled in Amgen's 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.

3. As pled in Amgen's 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

4. 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").

5. 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).

6. 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.

7. 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)

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

9. 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).

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

11. The BPCIA provides 12 years of exclusivity to the reference product. According to Amgen's 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.

12. Now, more than ten years after its exclusivity period expired, Amgen seeks to delay Sandoz's BLA application for 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.

13. 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.*

14. 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.

15. 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.

16. 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.

17. 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).

18. 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.

19. 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).

20. 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.

21. 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).

22. 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).

23. 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.

24. 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)).

25. 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.[3]

26. 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.

27. 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.

28. 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).

29. 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.

30. 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. Furthermore, resolution of this controversy will directly affect Sandoz's conduct with regard to its pending BLA application for biosimilar filgrastim, and will affect the timing of Sandoz's ability to commercially market biosimilar filgrastim upon FDA's grant of the BLA license.

[3] 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).

31. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 30 of these Counterclaims above.

32. 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.

33. 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.

34. 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).

35. 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)

36. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 35 of these Counterclaims above.

37. 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.

38. 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).

39. 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.

40. 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.

41. 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)

42. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 41 of these Counterclaims above.

43. 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.

44. 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).

45. 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)

46. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 45 of these Counterclaims above.

47. 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.

48. 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).

49. 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.

50. 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.

51. 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.

52. 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)

53. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 52 of these Counterclaims above.

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

55. 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.

56. 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.

57. 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®.

58. 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)

59. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 58 of these Counterclaims above.

60. 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.

61. 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).

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

63. 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)

64. Sandoz hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the Complaint and Paragraphs 1 through 63 of these Counterclaims above.

65. 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.

66. 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.

67. 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.

68. 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 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. 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;

10. Granting Sandoz judgment in its favor on Plaintiffs' Complaint;

11. Denying Plaintiffs' request for injunctive relief;

12. Dismissing Plaintiffs' Complaint with prejudice;

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

14. 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.

Dated: November 20, 2014

MORRISON & FOERSTER LLP

By: /s/David C. Doyle
David C. Doyle

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