Todd Benoff (Bar No. 192983)
Todd.Benoff@alston.com
ALSTON & BIRD LLP
333 South Hope Street, 16th Floor
Los Angeles, CA 90071
Telephone: (213) 576-1000
Facsimile: (213) 576-1100

Natalie Clayton
ALSTON & BIRD LLP
90 Park Ave., 15th Floor
New York, NY 10016
Telephone: (214) 922-3400
Facsimile: (214) 922-3899
(*Additional counsel on signature page*)

Attorneys for Plaintiff Sandoz Inc.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

SANDOZ INC.,

Plaintiff,

vs.

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Defendants.

Case No. _____

COMPLAINT FOR:

i. False Advertising (in violation of the Lanham Act, Section 43(a), 15 U.S.C. § 1125 *et seq.*);

ii. False Advertising (in violation of Cal. Bus. & Prof. Code §§ 17500 *et seq.*);

iii. Unfair Competition (in violation of Cal. Bus. & Prof. Code §§ 17200 *et seq.*)

DEMAND FOR JURY TRIAL

PRELIMINARY STATEMENT

1. Plaintiff Sandoz Inc. ("Sandoz" or "Plaintiff") brings this action for false advertising, by and through its counsel, against Defendants Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen" or "Defendants").

2. Sandoz is a pioneer and global leader in providing affordable biosimilar products to patients. In particular, Sandoz has devoted significant resources to develop, manufacture, market and sell a pegfilgrastim prefilled syringe product, sold under the brand name Ziextenzo®, which is used to reduce the incidence of infections in patients with cancer receiving chemotherapy.

3. The Food and Drug Administration ("FDA") approved Sandoz's Ziextenzo® product as a biosimilar to Amgen's pegfilgrastim prefilled syringe named Neulasta®, only for Amgen to taint the marketplace shortly after Sandoz launched its product.

4. Amgen has engaged in a deliberate and audacious marketing campaign that falsely states that pegfilgrastim prefilled syringe products, which includes Sandoz's Ziextenzo® product, are less effective and thus, by implication, less safe as compared to Amgen's pegfilgrastim administered through its on-body device, named Neulasta® Onpro®. Relying on inadequately designed studies—for which Amgen has already been admonished once by the FDA—Amgen has made false and misleading statements to the medical and healthcare communities and public representing that its product is superior in safety and efficacy when it is not.

5. Amgen willfully disseminated erroneous scientific conclusions in a bold effort to undermine Sandoz's ability to provide patients more affordable medicine, competing unfairly to the detriment of Sandoz and others. The data do not support Amgen's erroneous claims that pegfilgrastim prefilled syringe products, including Sandoz's Ziextenzo®, are less effective than Neulasta® Onpro®. Amgen's comparative advertising claims are false and misleading.

6. Defendants' actions constitute false advertising in violation of Section

43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); false advertising in violation of California False Advertising Law, Cal. Bus. & Prof. Code § 17500 *et seq*.; and unfair competition in violation of California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200. Plaintiff seeks permanent injunctive relief, Plaintiff's damages, disgorged profits, corrective advertising, recovery of Plaintiff's costs and reasonable attorneys' fees incurred in connection with this action and such other, different, and additional relief as the Court deems just and proper.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338 and 15 U.S.C. § 1121(a) because this action arises under the Lanham Act, 15 U.S.C. §§ 1051, *et seq*.

8. This Court has jurisdiction over all state law claims pursuant to 28 U.S.C. §§ 1367 and 1338(b).

9. This Court has personal jurisdiction over Defendants because Defendants transact business within the State of California, contract to supply goods or services in the State of California, including but not limited to Neulasta®, have engaged in tortious acts within the State of California, and have engaged in tortious acts outside the State of California causing injury within the State. More specifically, Defendants market, promote, advertise, offer for sale, sell, and/or distribute their products, including Neulasta®, to customers and/or others throughout the United States, including in the Central District of California. Upon information and belief, Defendant Amgen Manufacturing Limited manufactures products, including Neulasta®, for and/or in coordination with Defendant Amgen, and each Defendant serves the market in this District. Defendant Amgen Manufacturing Limited's involvement with Neulasta® is further evidenced by the fact that it was a plaintiff along with Amgen Inc. in the patent suit brought in federal court in California regarding Sandoz's biosimilar version of Neulasta®. Defendants have purposefully and voluntarily placed their products, including Neulasta®, into the stream of commerce with the expectation that they will

be purchased by consumers in the Central District of California. Defendant Amgen Inc. also resides in this District, having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. As such, Defendants have established minimum contacts with the forum such that the exercise of jurisdiction over them would not offend traditional notions of fair play and substantial justice.

10. Venue is proper in this district under 28 U.S.C. § 1391(b) because Amgen Inc. resides in this District and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this District.

THE PARTIES

11. Sandoz Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz develops, manufactures and sells generic and biosimilar medicines, providing access to high-quality, affordable medicines to millions of patients.

12. Amgen Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

13. Amgen Inc. develops, manufactures, markets and sells medicines addressing various therapeutic areas throughout the United States, including in this District.

14. Amgen Manufacturing Limited is a corporation organized and existing under the laws of the Territory of Bermuda with its principal place of business at Road 31 km 24.6, Juncos, Puerto Rico 00777.

15. Amgen Manufacturing Limited, a wholly owned subsidiary of Amgen Inc., manufactures, markets and sells medicines addressing various therapeutic areas throughout the United States, including in this District.

16. Amgen Inc. controls, directs and supervises the activities of Amgen Manufacturing Limited, as well as its employees.

GENERAL FACTUAL ALLEGATIONS

A. Biologics and Regulatory Pathway for Biosimilars

17. The products at issue in this litigation are biologic products. Biologics, unlike conventional drugs, are isolated from a variety of natural sources: human, animal, or microorganism.

18. To market a new biologic product, a company must submit to the FDA a biologics license application ("BLA").

19. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (amending, *inter alia,* 35 U.S.C. § 271 and 42 U.S.C. § 262), created an abbreviated pathway for the approval of biologics that are biosimilar to an FDA-approved reference biologic product.

20. A biosimilar is "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and has "no clinically meaningful differences" from the reference product in terms of "safety, purity, and potency." 42 U.S.C. § 262(i)(2).

21. A biosimilar must have the same route of administration, dosage form, strength, mechanism of action, and conditions of use as the approved reference product. 42 U.S.C. § 262(k)(2)(A)(i)(II)–(IV).

22. Biosimilarity is based on analytical studies; animal studies, including toxicity assessments; and a clinical study or studies, including assessments of immunogenicity and pharmacokinetics or pharmacodynamics. 42 U.S.C. § 262(k)(2)(A)(i)(I).

23. Biosimilars undergo an extensive regulatory evaluation and approval process by the FDA to prove they match the quality, safety and efficacy of the reference product.

24. A company seeking approval of a biosimilar must submit to the FDA an abbreviated BLA ("aBLA"). An aBLA can rely on clinical studies that were performed by the reference biologic product sponsor.

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