IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

AMGEN INC., AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., MYLAN GMBH, and MYLAN N.V. Defendants.	)	C.A. No. 2:17-cv-01235 **JURY TRIAL DEMANDED** ***Electronically Filed***

FIRST AMENDED AND SUPPLEMENTAL COMPLAINT

Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendants Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. (collectively, "Defendants") hereby allege as follows:

THE PARTIES

1. Amgen Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen Inc. discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen Inc. is a pioneer in the development of biological human therapeutics. Today, Amgen Inc. is the largest biotechnology company in the world, fueled in part by the success of NEULASTA® (pegfilgrastim).

2. Amgen Manufacturing, Limited ("AML") is a corporation 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. AML manufactures and sells biologic medicines for treating particular diseases in humans. AML is a wholly-owned subsidiary of Amgen Inc.

3. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business in Canonsburg, Pennsylvania at 1000 Mylan Boulevard Canonsburg, Pennsylvania 15317. Upon information and belief, acting in concert with the other Defendants, Mylan Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

4. Upon information and belief, Mylan Inc. is a United States agent for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with the Food and Drug Administration ("FDA").

5. Upon information and belief, Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, with its principal place of business in Morgantown, West Virginia at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, acting in concert with the other Defendants, Mylan Pharmaceuticals Inc. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

6. Upon information and belief, Mylan Pharmaceuticals Inc. is a United States agent for Mylan GmbH and Mylan N.V. for purposes including, but not limited to, corresponding with FDA.

7. Upon information and belief, Mylan GmbH is a corporation existing under the laws of the Republic of Switzerland with its principal place of business at Thurgauerstrasse 40

Zurich, 8050 Switzerland. Upon information and belief, acting in concert with each of the other Defendants, Mylan GmbH is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

8. Upon information and belief, Mylan N.V. is a corporation existing under the laws of the Republic of Netherlands with its global headquarters and principal offices located in Canonsburg, Pennsylvania, and its principal executive offices located Hatfield, Hertfordshire, England. Upon information and belief, acting in concert with each of the other Defendants, Mylan N.V. is in the business of developing, manufacturing, and marketing biopharmaceutical products that are distributed and sold in the Commonwealth of Pennsylvania and throughout the United States.

9. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH are wholly owned subsidiaries of Mylan N.V.

10. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc.

11. Upon information and belief, Defendants collaborate to develop, manufacture, seek regulatory approval for, import, market, distribute, and sell biopharmaceutical products (including products intended to be sold as biosimilar versions of successful biopharmaceutical products developed by others) in the Commonwealth of Pennsylvania and throughout the United States.

NATURE OF THE ACTION

12. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act of 2009 ("the

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).

13. The asserted patents are U.S. Patent No. 8,273,707 ("the '707 Patent") and U.S. Patent No. 9,643,997 ("the '997 Patent"). Amgen Inc. is the owner of all rights, title, and interest in the '707 and '997 Patents. The '707 and '997 Patents claim methods of purifying proteins used in the manufacture of a biological product.

14. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. 42 U.S.C. § 262(k). The abbreviated pathway (also known as "the subsection (k) pathway") allows a biosimilar applicant (here, Mylan GmbH, acting in concert with the other Defendants) to rely on the prior licensure and approval status of the innovative biological product (here, NEULASTA® (pegfilgrastim)) that the biosimilar purports to copy. Amgen Inc. is the sponsor of the reference product ("reference product sponsor" or "RPS"), NEULASTA® (pegfilgrastim), which is approved by FDA to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. Under the subsection (k) pathway, the biosimilar applicant may rely on its reference product's data rather than demonstrating that a biological product is safe, pure, and potent, as Amgen Inc. was required to do to obtain FDA licensure of its reference product under 42 U.S.C. § 262(a).

15. To avoid burdening the courts and parties with unnecessary disputes, the BPCIA also creates an intricate and carefully orchestrated set of procedures for the biosimilar applicant and the RPS to engage in a series of information exchanges and good-faith negotiations between parties prior to the filing of a patent infringement lawsuit. These exchanges are set forth in 42 U.S.C. § 262(*l*)(2)-(*l*)(5) and culminate in an "immediate patent infringement action" pursuant to 42 U.S.C. § 262(*l*)(6).

16. Seeking the benefits of the subsection (k) pathway, Mylan GmbH, acting in concert with the other Defendants, submitted Defendants' abbreviated Biologics License Application No. 761075 (the "Mylan aBLA") to FDA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k), requesting that its biological product ("the Mylan Pegfilgrastim Product") be licensed by relying on Amgen Inc.'s demonstration that NEULASTA® (pegfilgrastim) is "safe, pure, and potent."

17. Upon information and belief, Mylan GmbH, acting in concert with the other Defendants, submitted the Mylan aBLA to FDA prior to February 2017, and thus before the expirations of the '707 Patent and the '997 Patent.

18. Defendants received FDA acceptance of the Mylan aBLA for review on or about February 7, 2017.

19. In March 2017, the parties began exchanging information as required by the BPCIA.

20. The '707 Patent was included on Amgen Inc.'s May 1, 2017 disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pursuant to 42 U.S.C. § 262(*l*)(7), the '997 Patent was included on Amgen Inc.'s June 7, 2017 supplement to its 42 U.S.C. § 262(*l*)(3)(A) list.

21. The submission of the Mylan aBLA, including on information and belief, any amendments thereto, is an act or acts of infringement of one or more claims of each of the '707 and '997 Patents under 35 U.S.C. § 271(e)(2)(C)(i). Here, Defendants committed an act or acts of infringement with respect to each of the '707 and '997 Patents under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

22. On June 4, 2018, Mylan received FDA approval for Fulphila™. Mylan N.V.'s 10-Q dated August 8, 2018 and filed with the U.S. Securities and Exchange Commission, attached hereto as Exhibit 1, states: "On June 4, 2018, the FDA approved Mylan's Fulphila® (pegfilgrastim-jmdb), a biosimilar to Neulasta® (pegfilgrastim), co-developed with Biocon." Exhibit 1, Mylan N.V.'s Form 10-Q, at 66.

23. At least by July 9, 2018, Defendants began to import the Mylan Pegfilgrastim Product into the United States, and Defendants began to offer to sell, sell, or use the Mylan Pegfilgrastim Product within the United States. For example, Mylan N.V.'s Form 10-Q states that "[i]n July 2018, Mylan began selling Fulphila®," and FDA's National Drug Code Directory says that Fulphila®'s "Start Marketing Date" is July 9, 2018. *See* Exhibit 2, FDA's Nat'l Drug Code Directory search results for "fulphila," https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm (last visited Sept. 12, 2018); Exhibit 1, Mylan N.V.'s Form 10-Q, at 66.

24. Defendants' importation of the Mylan Pegfilgrastim Product into the United States, or offer to sell, sell, or use the Mylan Pegfilgrastim Product within the United States, has infringed and/or will infringe one or more claims of the '707 and '997 Patents under 35 U.S.C. § 271(g).

JURISDICTION AND VENUE

25. This action arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and under the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202), Title 28 of the United States Code.

26. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

28. Upon information and belief, Mylan Pharmaceuticals Inc. has a regular and established place of business in Pennsylvania. Upon information and belief, Mylan Pharmaceuticals Inc. is licensed to do business in Pennsylvania as a foreign business corporation.

29. This Court has personal jurisdiction over each of the Defendants for the reasons set forth below.

A. Mylan Inc.

30. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

31. This Court has personal jurisdiction over Mylan Inc. by virtue of, among other things, Mylan Inc. being a Pennsylvania corporation; having its principal place of business in Canonsburg, Pennsylvania; having availed itself of the rights and benefits of Pennsylvania law; and having engaged in substantial and continuing contacts with Pennsylvania.

B. Mylan Pharmaceuticals Inc.

32. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

33. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc., which exercises considerable control over Mylan Pharmaceuticals Inc.

34. Upon information and belief, Mylan Pharmaceuticals Inc. develops, manufactures, seeks regulatory approval for, markets, distributes, and sells biopharmaceuticals

for sale and use throughout the United States, including in Pennsylvania and this federal judicial District.

35. This Court has personal specific jurisdiction over Mylan Pharmaceuticals Inc. because, upon information and belief, following any FDA approval of the Mylan Pegfilgrastim Product, Mylan Pharmaceuticals Inc. will sell the Mylan Pegfilgrastim Product that is the subject of the patent infringement claims in this action in Pennsylvania and throughout the United States.

36. This Court has personal general jurisdiction over Mylan Pharmaceuticals Inc. by virtue of, inter alia, its having conducted business in this District, having availed itself of the rights and benefits of Pennsylvania law, and having engaged in substantial and continuing contacts with Pennsylvania. Upon information and belief, Mylan Pharmaceuticals Inc. has regular and continuous commercial business dealings with representatives, agents, distributors, and customers located in Pennsylvania and this District. In addition, Mylan Pharmaceuticals Inc. has availed itself of this Court by asserting claims in this District, *see, e.g.*, *Mylan Inc., Mylan Pharmaceuticals, Inc. v. Boehringer Ingelheim International GmbH, et al.*, Case No. 09-00990-GLL (W.D. Pa. complaint filed July 7, 2009), and by asserting counterclaims against plaintiffs in this judicial District and by consenting to this Court as a patent infringement defendant, *see, e.g.*, *Takeda Pharmaceutical Company Limited, et al. v. Mylan Inc., Mylan Pharmaceuticals Inc.*, Case No. 12-00026-AJS (W.D. Pa. answer and counterclaims filed Jan. 23, 2012).

C. Mylan GmbH

37. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

38. Upon information and belief, Mylan GmbH collaborates with Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan N.V. to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in Pennsylvania and in the United States.

39. Upon information and belief, Mylan GmbH operates as a subsidiary of Mylan N.V., which exercises considerable control over Mylan GmbH.

40. This Court has personal specific jurisdiction over Mylan GmbH because, upon information and belief, Mylan GmbH submitted the Mylan aBLA seeking approval from FDA to market and sell the Mylan Pegfilgrastim Product in the Commonwealth of Pennsylvania and throughout the United States, which directly gives rise to Plaintiffs' claims of patent infringement.

41. Further, upon information and belief, Mylan GmbH has or will directly or indirectly manufacture, import into the United States, and/or sell the Mylan Pegfilgrastim Product that is the subject of the infringement claim in this action in Pennsylvania and throughout the United States.

42. Additionally, upon information and belief, Mylan GmbH exercises considerable control over Mylan Inc. and Mylan Pharmaceuticals Inc. with respect to biosimilar products, and approves significant decisions of Mylan Inc. and Mylan Pharmaceuticals Inc. such as allowing Mylan Inc. and Mylan Pharmaceuticals Inc. to act as United States agents in connection with preparing and submitting the Mylan aBLA.

43. Additionally, and in the alternative, Plaintiffs allege that to the extent Mylan GmbH is not subject to the jurisdiction of the courts of general jurisdiction of the Commonwealth of Pennsylvania, Mylan GmbH likewise is not subject to the jurisdiction of the

courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

D. Mylan N.V.

44. Upon information and belief, Mylan Inc., Mylan Pharmaceuticals Inc., Mylan GmbH, and Mylan N.V. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

45. Upon information and belief, Mylan N.V. collaborates with Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH to develop, manufacture, seek approval for, and sell FDA-approved biopharmaceutical drugs, which are being marketed, distributed, and sold in Pennsylvania and in the United States.

46. Upon information and belief, Mylan GmbH operates as a subsidiary of Mylan N.V., which exercises considerable control over Mylan GmbH.

47. Mylan N.V. has issued press releases regarding the Mylan Pegfilgrastim Product and its regulatory status. *See* Press Release, Mylan N.V., "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" (Feb. 16, 2017), http://newsroom.mylan.com/2017-02-16-U-S-FDA-Accepts-Biologics-License-Application-BLA-for-Mylan-and-Biocons-Proposed-Biosimilar-Pegfilgrastim-for-Review, attached hereto as Exhibit 3; Press Release, Mylan N.V., "U.S. FDA Approves Mylan and Biocon's Fulphila™ (pegfilgrastim-jmdb), the First Biosimilar to Neulasta®" (June 4, 2018), http://newsroom.mylan.com/2018-06-04-U-S-FDA-Approves-Mylan-and-Biocons-Fulphila-TM-pegfilgrastim-jmdb-the-First-Biosimilar-to-Neulasta-R, attached hereto as Exhibit 4. In addition, Mylan N.V.'s Chief Executive Officer has made public statements regarding the pricing of the Mylan Pegfilgrastim Product. *See* CBS News, Mylan CEO promises Neulasta

biosimilar will offer "significant savings" for patients (June 12, 2018), https://www.cbsnews.com/news/mylan-ceo-fda-approval-biosimilar-neulasta-trumps-plan-to-lower-drug-prices/, attached hereto as Exhibit 5.

48. According to the Defendants' website (page attached hereto as Exhibit 6) "[t]he Chief Executive Officer and other executive officers of Mylan N.V. carry out the day-to-day conduct of Mylan N.V.'s worldwide businesses at the company's principal offices in Canonsburg, Pennsylvania."

49. This Court has personal jurisdiction over Mylan N.V. by virtue of, among other things, Mylan N.V. having its global headquarters and principal offices in Canonsburg, Pennsylvania; having availed itself of the rights and benefits of Pennsylvania law; and having engaged in substantial and continuing contacts with Pennsylvania.

50. Additionally, this Court has personal specific jurisdiction over Mylan N.V. because, upon information and belief, the acts of Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan GmbH complained of herein were done, in part, for the benefit of Mylan N.V. Further, upon information and belief, Mylan N.V. has or will directly or indirectly manufacture, import into the United States, and/or sell the Mylan Pegfilgrastim Product that is the subject of the infringement claim in this action in Pennsylvania and throughout the United States.

51. Additionally, upon information and belief, Mylan N.V. exercises considerable control over Mylan Inc. and Mylan Pharmaceuticals Inc. with respect to biosimilar products, and approves significant decisions of Mylan Inc. and Mylan Pharmaceuticals Inc. such as allowing Mylan Inc. and Mylan Pharmaceuticals Inc. to act as United States agents in connection with preparing and submitting the Mylan aBLA.

52. Additionally, and in the alternative, Plaintiffs allege that to the extent Mylan N.V. is not subject to the jurisdiction of the courts of general jurisdiction of the Commonwealth of Pennsylvania, Mylan N.V. likewise is not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

BACKGROUND

A. Amgen Inc.'s Innovative Biological Product: NEULASTA® (pegfilgrastim)

53. Amgen Inc. is one of the world's leading biopharmaceutical companies and is dedicated to using discoveries in human biology to invent, develop, manufacture, and sell new therapeutic products for the benefit of patients suffering from serious illnesses. Toward that end, Amgen Inc. has invested billions of dollars into its research and development efforts.

54. In 2002, Amgen Inc. introduced NEULASTA® (pegfilgrastim), an innovative biologic medicine which has benefited millions of cancer patients as a treatment of side effects of certain forms of cancer therapy. Amgen Inc. conducted extensive clinical trials and submitted the results of those trials to FDA in order to prove that NEULASTA® (pegfilgrastim) is safe, pure, and potent.

55. The active ingredient in Amgen Inc.'s innovative NEULASTA® (pegfilgrastim) product is a recombinantly expressed, 175-amino acid form of a protein known as human granulocyte-colony stimulating factor ("G-CSF") conjugated to a 20 kD monomethoxypolyethylene glycol (m-PEG) at the N-terminus of G-CSF.

56. NEULASTA® (pegfilgrastim) is indicated to decrease the incidence of infection in patients receiving myelosuppressive anti-cancer drugs. By binding to specific receptors on

the surface of certain types of cells, NEULASTA® (pegfilgrastim) stimulates the production of a type of white blood cells known as neutrophils. Neutrophils are the most abundant type of white blood cells and form a vital part of the human immune system. A deficiency in neutrophils is known as neutropenia, a condition which makes the individual highly susceptible to infection. Neutropenia can result from a number of causes; it is a common side effect of chemotherapeutic drugs used to treat certain forms of cancer. NEULASTA® (pegfilgrastim) counteracts neutropenia.

57. NEULASTA® (pegfilgrastim) represented a major advance in cancer treatment by protecting chemotherapy patients from the harmful effects of neutropenia and by facilitating more effective chemotherapy regimens.

58. Prior to 2010, any other company wishing to sell its own version of NEULASTA® (pegfilgrastim) would have had to undertake the same extensive effort to conduct clinical trials to prove to FDA that its proposed version was also safe, pure, and potent.

59. Developing a new therapeutic product from scratch is extremely expensive: studies estimate the cost of obtaining FDA approval of a new biologic product at more than $2.5 billion. *See* DiMasi J.A. *et al*., Innovation in the pharmaceutical industry: New estimates of R&D costs, 47 J. Health Econ. 20, 25-26 (2016), attached hereto as Exhibit 7.

60. Amgen Inc. is the sponsor of the BLA for NEULASTA® (pegfilgrastim).

61. AML is a wholly-owned subsidiary of Amgen Inc. AML manufactures NEULASTA® (pegfilgrastim).

62. Amgen USA Inc. is a wholly-owned subsidiary of Amgen Inc. Amgen USA Inc. purchases NEULASTA® (pegfilgrastim) from AML, and is the distributor of NEULASTA® (pegfilgrastim) in the United States.

63. Plaintiffs profit from each sale of NEULASTA® (pegfilgrastim) in the United States.

B. Defendants Sought Approval To Market a Proposed Biosimilar Version of NEULASTA® (pegfilgrastim) by Taking Advantage of the Abbreviated Subsection (k) Pathway of the BPCIA

64. Upon information and belief, Mylan GmbH, acting in concert with the other Defendants, submitted the Mylan aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Mylan Pegfilgrastim Product, a biosimilar version of Amgen Inc.'s NEULASTA® (pegfilgrastim) product.

65. Upon information and belief, the Mylan aBLA references and relies on the approval and licensure of Amgen Inc.'s NEULASTA® (pegfilgrastim) product in support of Defendants' request for FDA approval.

66. Upon information and belief, the Mylan Pegfilgrastim Product is designed to copy and compete with Amgen Inc.'s NEULASTA® (pegfilgrastim).

67. Defendants did not seek to independently demonstrate to FDA that their biological product is "safe, pure, and potent" pursuant to 42 U.S.C. § 262(a), as Amgen Inc. did in its BLA for its innovative biological product NEULASTA® (pegfilgrastim). Rather, upon information and belief, Defendants requested that FDA evaluate the suitability of their biological product for licensure, expressly electing and seeking reliance on Amgen Inc.'s FDA license for NEULASTA® (pegfilgrastim). Accordingly, Defendants submitted to FDA publicly available information regarding FDA's previous licensure determination that NEULASTA® (pegfilgrastim) is "safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I).

68. Defendants are piggybacking on the fruits of Amgen Inc.'s trailblazing efforts. Defendants have publicly announced that they submitted the Mylan aBLA under the subsection

(k) pathway to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Mylan Pegfilgrastim Product that they assert is a biosimilar version of Amgen Inc.'s NEULASTA® (pegfilgrastim). *See* Press Release, Mylan N.V., "U.S. FDA Accepts Biologics License Application (BLA) for Mylan and Biocon's Proposed Biosimilar Pegfilgrastim for Review" (Feb. 16, 2017), http://newsroom.mylan.com/2017-02-16-U-S-FDA-Accepts-Biologics-License-Application-BLA-for-Mylan-and-Biocons-Proposed-Biosimilar-Pegfilgrastim-for-Review, attached hereto as Exhibit 3.

69. On or about October 10, 2017, FDA issued a Complete Response Letter ("CRL") for the Mylan aBLA. *See* Biocon's Press Release, "US FDA Issues Complete Response Letter for Proposed Biosimilar Pegfilgrastim" (Oct. 10, 2017), available at http://biocon.com/biocon_press_releases_101017.asp, attached hereto as Exhibit 17.

70. Upon information and belief, Mylan GmbH, acting in concert with the other Defendants, resubmitted the Mylan aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to commercially manufacture, use, offer to sell, and sell, and import into the United States the Mylan Pegfilgrastim Product.

C. Information Exchange Under 42 U.S.C. § 262(*l*)

71. In March 2017, the exchange of information between Amgen Inc. and Mylan GbmH, as required by the BPCIA, began.

72. On March 2, 2017, pursuant to 42 U.S.C. § 262(*l*)(2)(A), Mylan GmbH provided Amgen Inc.'s counsel with access to the Mylan aBLA.

73. Upon information and belief, the Mylan aBLA provided to Amgen Inc. was in a format different than and less complete than the format provided to FDA.

74. Upon information and belief, the Mylan aBLA was provided to FDA in Electronic Common Technical Document (eCTD) format with fully working hyperlinks and without restrictions on, inter alia, viewing, copying, and printing.

75. Mylan GmbH's failure to provide "a copy of the application submitted to the Secretary under subsection (k)" as required by 42 U.S.C. § 262(*l*)(2)(A) materially prejudiced and impeded Amgen Inc.'s ability to review the Mylan aBLA. For example: Mylan GmbH uploaded the Mylan aBLA to a virtual data room (the "ShareVault data room") and provided Amgen Inc.'s counsel with credentials to access the documents and data on the ShareVault data room. Mylan GmbH configured the ShareVault data room to prohibit Amgen Inc. from, inter alia, saving, copying, annotating, or printing any documents or data on the ShareVault data room. The ShareVault data room is also slow and cumbersome, and lacks fully working hyperlinks. In addition, Amgen Inc. was and, in some cases, continues to be unable to view many of the documents and data on the ShareVault data room, including many of the xml, xsl, sas, xpt, jpeg, and txt files. Additionally, the ShareVault data room suffered periodic technological failures, preventing Amgen Inc. from accessing or viewing the documents and data on the ShareVault data room.

76. Mylan GmbH also failed to provide "other information that describes the process or processes used to manufacture the biological product that is the subject of" the Mylan aBLA, pursuant to 42 U.S.C. § 262(*l*)(2)(A). In April and May 2017, Amgen Inc. requested certain specific categories of documents that it believes exist and describe the Defendants' process for manufacturing the Mylan Pegfilgrastim Product. Mylan GmbH undertook to consider Amgen's request but, to date, has failed to provide such documents.

77. On May 1, 2017, Amgen Inc. provided Mylan GmbH with Amgen Inc.'s list of patents under 42 U.S.C. § 262(*l*)(3)(A). That list included the '707 Patent and U.S. Patent No. 8,940,878 ("the '878 Patent"). On June 5, 2017, Mylan GmbH provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases of Mylan GmbH's opinions that the '707 and '878 Patents are invalid, are unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA.

78. On June 7, 2017, pursuant to 42 U.S.C. § 262(*l*)(7) Amgen Inc. supplemented its 42 U.S.C. § 262(*l*)(3)(A) list to include the '997 Patent. On June 9, 2017, Mylan GmbH provided a detailed statement pursuant to 42 U.S.C. § 262(*l*)(7) describing the factual and legal bases of Mylan GmbH's opinions that the '997 Patent is invalid, is unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA.

79. On August 4, 2017, Amgen Inc. provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) describing the factual and legal bases of Amgen Inc.'s opinion that certain claims of the '707 and '878 Patents will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA, and Amgen Inc.'s responses to the invalidity and unenforceability assertions against the '707 and '878 Patents in Mylan GmbH's statement under 42 U.S.C. § 262(*l*)(3)(B).

80. On August 8, 2017, Amgen Inc. provided Mylan GmbH with the factual and legal bases of Amgen Inc.'s opinion that certain claims of the '997 will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA and responses to the invalidity and unenforceability assertions against the '997 Patent in Mylan GmbH's June 9, 2017 statement.

81. Amgen Inc. and Mylan GmbH then negotiated under 42 U.S.C. § 262(*l*)(4) as to "which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6)." Failing to reach agreement, Amgen Inc. and Mylan GmbH exchanged lists pursuant to the procedures of 42 U.S.C. § 262(*l*)(5) on August 25, 2017. Amgen Inc. asserted that there should be an immediate patent infringement action on the '707 and '997 Patents, but not on the '878 Patent.

82. Accordingly, on September 22, 2017, Plaintiffs filed an immediate patent infringement action against Defendants pursuant to 42 U.S.C. § 262(*l*)(6)(B) on the '707 and '997 Patents, which followed "not later than 30 days after the exchange of lists under paragraph (5)(B)."

D. Defendants Receive FDA Approval for and Launch Fulphila™

83. On June 4, 2018, Defendants received FDA approval for Fulphila™. Mylan N.V.'s Form 10-Q states: "On June 4, 2018, the FDA approved Mylan's Fulphila® (pegfilgrastim-jmdb), a biosimilar to Neulasta® (pegfilgrastim), co-developed with Biocon." Exhibit 1, Mylan N.V.'s Form 10-Q, at 66.

84. Mylan N.V. stated in a press release the same day that "Fulphila is the first FDA-approved biosimilar to Neulasta and the second biosimilar from Mylan and Biocon's joint portfolio approved in the U.S. ***Mylan anticipates launching Fulphila in the coming weeks,*** representing the first alternative, more affordable treatment option to Neulasta for oncology patients." Exhibit 4, Mylan N.V. Press Release, U.S. FDA Approves Mylan and Biocon's Fulphila™ (pegfilgrastim-jmdb), the First Biosimilar to Neulasta® (June 4, 2018), http://newsroom.mylan.com/2018-06-04-U-S-FDA-Approves-Mylan-and-Biocons-Fulphila-TM-pegfilgrastim-jmdb-the-First-Biosimilar-to-Neulasta-R ("Mylan Press Release"), at 1

(emphasis added). Mylan N.V.'s President also stated, "Today's approval of Fulphila represents a meaningful step forward in the affordability and accessibility of cancer care in the U.S." *See id.*

85. In an interview with "CBS This Morning," Mylan N.V.'s CEO stated, "We'll be launching our biosimilar to Neulasta in the coming weeks at a significant reduction. Double-digits reduction." Exhibit 5, CBS News, Mylan CEO promises Neulasta biosimilar will offer "significant savings" for patients (June 12, 2018), https://www.cbsnews.com/news/mylan-ceo-fda-approval-biosimilar-neulasta-trumps-plan-to-lower-drug-prices/.

86. These public statements evidence both price erosion and Defendants' intent to cause price erosion by infringing each of the '707 Patent and the '997 Patent.

87. The actions of Mylan N.V. and other Defendants are evidence of Defendants' infringement, including without limitation Defendants' offering for sale, sale, and marketing of infringing products.

88. Defendants' infringement has already injured and will continue to injure Plaintiffs including without limitation by offering for sale, selling, and marketing infringing products.

89. At least by July 9, 2018, Defendants began to sell Fulphila™ in the United States. Mylan N.V.'s Form 10-Q states: "In July 2018, Mylan began selling Fulphila®." Exhibit 1, Mylan N.V.'s Form Q-10, at 66. The FDA's National Drug Code Directory shows the "Start Marketing Date" for Fulphila™ as "07/09/2018." *See* Exhibit 2, FDA's Nat'l Drug Code Directory search results for "fulphila," https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm (last visited Aug. 24, 2018).

90. Prior to launch, upon information and belief, Mylan N.V. informed The Center for Biosimilars® that Fulphila™'s wholesale price would undercut Plaintiffs' wholesale price by more than 30%. Specifically, The Center for Biosimilars® stated that "Mylan confirmed that it will launch its biosimilar pegfilgrastim at a wholesale acquisition cost (WAC) of $4175 per syringe, a price that reflects a 33% discount to the WAC of Amgen's reference product, Neulasta." *See* Exhibit 8, Ctr. for Biosimilars, Mylan to Launch Fulphila at 33% Discount to Neulasta (July 17, 2018), https://www.centerforbiosimilars.com/news/mylan-to-launch-fulphila-at-33-discount-to-neulasta. Upon information and belief, this is a deeper discount to a reference product than any other first biosimilar launched in the United States. *See id.*; *see also* Exhibit 9, FiercePharma, Amgen's $3.9B Neulasta to face U.S. biosim 'in the coming weeks' with Mylan approval (June 5, 2018), https://www.fiercepharma.com/pharma/amgen-s-neulasta-to-face-u-s-biosim-competition-coming-weeks-mylan-approval.

91. Upon information and belief, Fulphila launched at a 33% discount to Neulasta's wholesale acquisition cost. Upon information and belief, this is an "aggressively lower discount relative to the first biosimilars that launched in the US." *See* Exhibit 12, Scrip, Mylan Head Of Biologics Chrys Kokino On Fulphila Launch And US Biosimilars (Oct. 8, 2018).

92. Following launch and during Mylan N.V.'s Earnings Conference Call for Q2 2018, Rajiv Malik, Mylan N.V.'s Chief Commercial Officer, stated: "We launched the product [Fulphila] in July and are very proud to lead the first wave of biosimilar introduction in US. Our launch has included a suite of services to further support patients and caregivers with the treatment. We expect a gradual, but sustainable uptake with the product and we continue to ramp up our capacity as we expand our launch. So far, the launch has been in line with our expectations, which have been recalibrated based on our experience with other complex product

launches." *See* Exhibit 10, Mylan N.V.'s Q2 2018 Earnings Conference Call Transcript by The Motley Fool at 6-7 (Aug. 8, 2018). In addition, Mr. Malik stated: "And Ronny, I think you asked a question around our Fulphila launch, and what I would say, first and foremost is we're very happy with this launch. We're on track with our expectations. We are partnering with clinics, with payers, especially oncology distributors and GPOs. Yes, it's very surgical as you commented, but we have great confidence in terms of how we launched and we are really monitoring and happy with where this uptake has been here in the first month of launch." *See id.* at 15.

93. Mylan N.V. and other biosimilar companies seek to increase the use of biosimilar products in the United States: "'Education, education, education,' Chrys Kokino, head of biologics for North America at Mylan NV said Sept. 6 when asked what specifically biosimilar sponsors can be doing better to help facilitate update of their products in the US." *See* Exhibit 11, Biosimilar Sponsors: We Need To Do A Better Job Educating Physicians And Patients (Sept. 17, 2018).

94. In an October 8, 2018 article published by the pharmaceutical news service Scrip, Mr. Kokino stated: "Do I believe Fulphila has been a success? I would say absolutely yes." Mr. Kokino "credited Mylan's pricing strategy with helping to secure market access for Fulphila, which is covered by 50%-60% of US payers"; he said that Fulphila is doing well "because the price was favorable when it came to the comparison between our price and the average selling price of the originator price." Additionally, he said "One reason I believe Fulphila is successful today is because we did what the originator did," and "We have the hub services, patient services, benefits verification for patients, patient assistance programs, copay cards." Mr. Kokino also said that Mylan established a "specialty sales organization" with an

emphasis in oncology to educate patients and physicians about Fulphila to support its launch. *See* Exhibit 12, Scrip, Mylan Head Of Biologics Chrys Kokino On Fulphila Launch And US Biosimilars (Oct. 8, 2018).

95. There is a market and demand for pegfilgrastim in the United States.

96. Plaintiffs are capable of meeting the demand for pegfilgrastim in the United States.

97. Fulphila™ (pegfilgrastim-jmdb) competes with Plaintiffs' innovative product, NEULASTA® (pegfilgrastim) because Fulphila™ (pegfilgrastim-jmdb) shares the same indication as NEULASTA® (pegfilgrastim). The FDA label for NEULASTA® (pegfilgrastim) states that "Neulasta is a leukocyte growth factor indicated to [d]ecrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia." *See* Exhibit 13 (FDA label for NEULASTA® (pegfilgrastim)). Likewise, the FDA label for Fulphila™ (pegfilgrastim-jmdb) states that "Fulphila is a leukocyte growth factor indicated to [d]ecrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia." *See* Exhibit 14 (FDA label for Fulphila™ (pegfilgrastim-jmdb)).

98. Including Plaintiffs and Defendants, there are very few suppliers of FDA-approved pegfilgrastim product to consumers in the United States.

99. Defendants' sales of Fulphila™ (pegfilgrastim-jmdb) are sales that, but for Defendants' infringement, would have been sales of NEULASTA® (pegfilgrastim).

100. Additionally, Defendants' offer for sale or sale of Fulphila™ (pegfilgrastim-jmdb) at prices below that of NEULASTA® (pegfilgrastim) erode the price of NEULASTA® (pegfilgrastim).

101. Defendants' sales and marketing of FULPHILA™, including without limitation Mylan N.V.'s statements to the public such as the statements identified above and Defendants' confidential or non-confidential statements to market participants such as, without limitation, health care providers and formularies, cause Plaintiffs to lose sales of NEULASTA® (pegfilgrastim) and erode the price of NEULASTA® (pegfilgrastim), and Plaintiffs are entitled to recover lost profits to compensate for this damage.

102. But for Defendants' infringement, Plaintiffs would have made additional sales of its pegfilgrastim product, NEULASTA® (pegfilgrastim), and the price of NEULASTA® (pegfilgrastim) would not have been eroded by competition with Defendants' substantially-lower-priced infringing product for which Defendants did not shoulder any of the cost or burden of the years of research and development that Plaintiffs undertook to make NEULASTA® (pegfilgrastim) available to patients and doctors.

103. The profits lost by Plaintiffs as a result of lost sales and price erosion caused by Defendants' infringement of each of the '997 Patent and '707 Patent include at least the profits Plaintiffs would have made absent price erosion on sales of NEULASTA® (pegfilgrastim) that were lost as a result of Defendants' infringement; the profits Plaintiffs would have made absent price erosion on Amgen's own sales of NEULASTA® (pegfilgrastim); and Plaintiffs' other lost profits resulting from Defendants' infringement.

THE PATENTS-IN-SUIT: U.S. PATENT NOS. 8,273,707 AND 9,643,997

104. Amgen Inc. is the owner of all rights, title, and interest in the '707 Patent.

105. AML is an exclusive licensee under the '707 Patent.

106. The ’707 Patent, titled “Process For Purifying Proteins,” was duly and legally issued on September 25, 2012 by the U.S. Patent and Trademark Office. A true and correct copy of the ’707 Patent is attached to this Complaint as Exhibit 15.

107. The ’707 Patent is directed to a process for purifying proteins.

108. Amgen Inc. is the owner of all rights, title, and interest in the ’997 Patent.

109. AML is an exclusive licensee under the ’997 Patent.

110. The ’997 Patent, titled “Capture Purification Processes for Proteins Expressed in a Non-Mammalian System,” was duly and legally issued on May 9, 2017 by the U.S. Patent and Trademark Office. A true and correct copy of the ’997 Patent is attached to this Complaint as Exhibit 16.

111. The ’997 Patent is directed to a process for purifying proteins.

CAUSES OF ACTION

FIRST COUNT: INFRINGEMENT OF THE ’707 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(i)

112. Plaintiffs incorporate by reference paragraphs 1-111 as if fully set forth herein.

113. Defendants sought FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product, a proposed biosimilar version of Amgen Inc.’s NEULASTA® (pegfilgrastim) product.

114. Defendants committed an act or acts of infringement with respect to the ’707 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

115. Upon information and belief, Defendants intended to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

116. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '707 Patent.

117. Defendants have now manufactured, used, sold, and/or offered for sale within the United States, and/or imported into the United States, the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

118. The manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product infringes, literally or under the doctrine of equivalents, one or more claims of the '707 Patent.

119. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Amgen Inc. has provided Defendants with a detailed statement describing with respect to the '707 Patent, on a claim by claim basis, the factual and legal bases of Amgen Inc.'s opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA. Amgen Inc.'s detailed statement includes, refers to, and relies on confidential information that Mylan GmbH provided to Amgen Inc. pursuant to 42 U.S.C. § 262(*l*)(2). Plaintiffs do not repeat Amgen Inc.'s detailed statement here because under 42 U.S.C. § 262(*l*)(1), Plaintiffs are not permitted to include confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

120. Representative claim 1 of the '707 Patent recites:

> A process for purifying a protein on a hydrophobic interaction chromatography column such that the dynamic capacity of the column is increased for the protein comprising
>
> > mixing a preparation containing the protein with a combination of a first salt and a second salt,
> >
> > loading the mixture onto a hydrophobic interaction chromatography column, and
> >
> > eluting the protein,
> >
> > wherein the first and second salts are selected from the group consisting of citrate and sulfate, citrate and acetate, and sulfate and acetate, respectively, and wherein the concentration of each of the first salt and the second salt in the mixture is between about 0.1 M and about 1.0.

'707 Patent at col. 15:8-18. Upon information and belief, the process by which Defendants manufacture the Mylan Pegfilgrastim Product satisfies each limitation of at least claims 1, 2, 6, 8, 10, and 11, literally or equivalently. With respect to the requirement that the protein is purified on a hydrophobic interaction chromatography column, Defendants practice a process for purifying a protein on a hydrophobic interaction chromatography column as defined in the '707 patent. With respect to the use of a combination of a first salt and a second salt, in the Defendants' process, a preparation containing protein becomes mixed with a first salt and a second salt as recited in the claim. With respect to the salt concentration, the concentration of the salts in the Defendants' process falls within the claimed range and/or is equivalent to a concentration within the claimed range. In the Defendants' process, after the protein is loaded onto the hydrophobic interaction chromatography column in the presence of the combination of salts, the protein is eluted. Amgen incorporates Amgen's Second Amended Disclosure of Asserted Claims and Infringement Contentions, ECF No. 183-1, by reference as if fully set forth herein.

121. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '707 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

122. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '707 Patent will cause and has caused injury to Plaintiffs, entitling them to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C). For example, Amgen Inc. has suffered lost profits of its NEULASTA® (pegfilgrastim) product because of Defendants' infringing acts with respect to FULPHILA™ (pegfilgrastim-jmdb) product, including sales of NEULASTA® (pegfilgrastim) that would have been made by Plaintiffs—such as sales to and through Amgen Inc.'s wholly-owned subsidiary Amgen USA Inc.—that were either lost as a result of Defendants' infringement or were made at eroded prices because of Defendants' infringement. But for Defendants' infringement, Plaintiffs would not have suffered injury, entitling Plaintiffs to damages in the form of lost profits resulting from at least diverted sales and price erosion, and in no event less than a reasonable royalty under 35 U.S.C. § 284.

SECOND COUNT:
INFRINGEMENT OF THE '707 PATENT UNDER 35 U.S.C. 35 U.S.C. § 271(g) AND DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '707 PATENT UNDER 35 U.S.C. § 271(g)

123. Plaintiffs incorporate by reference paragraphs 1-122 as if fully set forth herein.

124. Defendants sought FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Mylan Pegfilgrastim Product, a biosimilar version of Amgen Inc.'s NEULASTA® (pegfilgrastim) product.

125. Upon information and belief, Defendants obtained approval to import into the United States, or offer to sell, sell, or use within the United States, the Mylan Pegfilgrastim Product (Fulphila™) before the expiration of the '707 Patent.

126. Defendants have now manufactured, used, sold, and/or offered for sale within the United States, and/or imported into the United States, the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

127. The manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product infringes, literally or under the doctrine of equivalents, one or more claims of the '707 Patent. Thus, Plaintiffs are entitled to judgment that Defendants have infringed one or more claims of the '707 Patent by using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

128. In addition, an actual controversy has arisen and now exists between the parties concerning whether the Mylan Pegfilgrastim Product has or will infringe one or more claims of the '707 Patent.

129. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '707 Patent by using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

130. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '707 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from using, offering to sell, or

selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '707 Patent.

131. Defendants' use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '707 Patent has caused or will cause injury to Plaintiffs, entitling Plaintiffs to damages under 35 U.S.C. § 284. For example, Amgen Inc. has suffered lost profits of its NEULASTA® (pegfilgrastim) product because of Defendants' infringing acts with respect to FULPHILA™ (pegfilgrastim-jmdb) product, including sales of NEULASTA® (pegfilgrastim) that would have been made by Plaintiffs—such as sales to and through Amgen Inc.'s wholly-owned subsidiary Amgen USA Inc.—that were either lost as a result of Defendants' infringement or were made at eroded prices because of Defendants' infringement. But for Defendants' infringement, Plaintiffs would not have suffered injury, entitling Plaintiffs to damages in the form of lost profits resulting from at least diverted sales and price erosion, and in no event less than a reasonable royalty under 35 U.S.C. § 284.

132. On information and belief, Defendants' infringement of the '707 Patent is exceptional and entitles Amgen to attorneys' fees and costs incurred in prosecuting this action in accordance with 35 U.S.C. § 285.

THIRD COUNT:
INFRINGEMENT OF THE '997 PATENT UNDER 35 U.S.C. § 271(e)(2)(C)(i)

133. Plaintiffs incorporate by reference paragraphs 1-131 as if fully set forth herein.

134. Upon information and belief, Defendants seek FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product, a proposed biosimilar version of Plaintiffs' NEULASTA® (pegfilgrastim) product.

135. Defendants committed an act or acts of infringement with respect to the '997 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when they caused Mylan GmbH to submit the Mylan aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Mylan Pegfilgrastim Product.

136. Upon information and belief, Defendants intended to manufacture, use, sell, and/or offer for sale within the United States, and/or import into the United States, the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

137. Defendants have now manufactured, used, sold, and/or offered for sale within the United States, and/or imported into the United States, the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

138. The manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product infringes, literally or under the doctrine of equivalents, one or more claims of the '997 Patent.

139. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product will infringe, literally or under the doctrine of equivalents, one or more claims of the '997 Patent.

140. Plaintiffs have provided Defendants with a statement describing with respect to the '997 Patent the factual and legal bases of Plaintiffs' opinion that such patent will be infringed by the commercial marketing of the biological product that is the subject of the Mylan aBLA. Plaintiffs' statement includes, refers to, and relies on confidential information that Mylan GmbH provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2). Plaintiffs do not repeat their statement here because under 42 U.S.C. § 262(*l*)(1), Plaintiffs are not permitted to include

confidential information provided by Mylan GmbH "in any publicly-available complaint or other pleading." *See* 42 U.S.C. § 262(*l*)(1)(F).

141. Representative claim 9 of the '997 Patent recites:

> A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
>
> (a) solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) a reductant; and
>
> (iii) a surfactant;
>
> (b) forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
>
> (i) a denaturant;
>
> (ii) an aggregation suppressor;
>
> (iii) a protein stabilizer; and
>
> (iv) a redox component;
>
> (c) applying the refold solution to a separation matrix under conditions suitable for the protein to associate with the matrix;
>
> (d) washing the separation matrix; and
>
> (e) eluting the protein from the separation matrix.

'997 Patent at col. 22:36-55. Upon information and belief, the process by which Defendants manufacture the Mylan Pegfilgrastim Product satisfies each limitation of one or more claims, literally or equivalently. With respect to the requirement that the protein is expressed in a non-native limited solubility form in a non-mammalian expression system, Defendants practice a process for purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system. With respect to the requirement of the "solubilizing" step, in the Defendants' process, protein is solubilized in a solubilization solution comprising one or more of a denaturant, reductant, and surfactant. With respect to the requirement of the "forming" step, in the Defendants' process, a refold solution is formed comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of a denaturant, aggregation suppressor, protein stabilizer, and redox component. With respect to the requirement of the "applying" step,

the Defendants' refold solution is applied to a separation matrix under conditions suitable for the protein to associate with the matrix. With respect to the requirement of the "washing" step, the Defendants' separation matrix is washed. With respect to the requirement of the "eluting" step, Defendants' protein is eluted from the separation matrix. Amgen incorporates Amgen's Second Amended Disclosure of Asserted Claims and Infringement Contentions, ECF No. 183-1, by reference as if fully set forth herein.

142. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '997 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief preventing Defendants from any further infringement under 35 U.S.C. § 271(e)(4)(B).

143. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '997 Patent will cause and has caused injury to Plaintiffs, entitling them to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C). For example, Amgen Inc. has suffered lost profits of its NEULASTA® (pegfilgrastim) product because of Defendants' infringing acts with respect to FULPHILA™ (pegfilgrastim-jmdb) product, including sales of NEULASTA® (pegfilgrastim) that would have been made by Plaintiffs—such as sales to and through Amgen Inc.'s wholly-owned subsidiary Amgen USA Inc.—that were either lost as a result of Defendants' infringement or were made at eroded prices because of Defendants' infringement. But for Defendants' infringement, Plaintiffs would not have suffered injury, entitling Plaintiffs to damages in the form of lost profits resulting from at least diverted sales and price erosion, and in no event less than a reasonable royalty under 35 U.S.C. § 284.

FOURTH COUNT:
INFRINGEMENT OF THE '997 PATENT UNDER 35 U.S.C. 35 U.S.C. § 271(g) AND DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '997 PATENT UNDER 35 U.S.C. § 271(g)

144. Plaintiffs incorporate by reference paragraphs 1-143 as if fully set forth herein.

145. Defendants sought FDA approval under Section 351(k) of the Public Health Service Act to manufacture and sell the Mylan Pegfilgrastim Product, a biosimilar version of Amgen Inc.'s NEULASTA® (pegfilgrastim) product.

146. Upon information and belief, Defendants obtained approval to import into the United States, or offer to sell, sell, or use within the United States, the Mylan Pegfilgrastim Product (Fulphila™) before the expiration of the '997 Patent.

147. Defendants have now manufactured, used, sold, and/or offered for sale within the United States, and/or imported into the United States, the Mylan Pegfilgrastim Product before the expiration of the '997 Patent

148. The manufacture, use, sale, and/or offer for sale within the United States, and/or the importation into the United States, of the Mylan Pegfilgrastim Product infringes, literally or under the doctrine of equivalents, one or more claims of the '997 Patent. Thus, Plaintiffs are entitled to judgment that Defendants have infringed one or more claims of the '997 Patent by using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

149. In addition, an actual controversy has arisen and now exists between the parties concerning whether the Mylan Pegfilgrastim Product has or will infringe one or more claims of the '997 Patent.

150. Plaintiffs are entitled to a declaratory judgment that Defendants have infringed or will infringe one or more claims of the '997 Patent by using, offering to sell, or selling within

the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

151. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '997 Patent. Plaintiffs do not have an adequate remedy at law and are entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Defendants from using, offering to sell, or selling within the United States, or importing into the United States the Mylan Pegfilgrastim Product before the expiration of the '997 Patent.

152. Defendants' use, offer for sale, or sale within the United States, or importation into the United States, of the Mylan Pegfilgrastim Product before the expiration of the '997 Patent will cause injury to Plaintiffs, entitling them to damages under 35 U.S.C. § 284. For example, Amgen Inc. has suffered lost profits of its NEULASTA® (pegfilgrastim) product because of Defendants' infringing acts with respect to FULPHILA™ (pegfilgrastim-jmdb) product, including sales of NEULASTA® (pegfilgrastim) that would have been made by Plaintiffs—such as sales to and through Amgen Inc.'s wholly-owned subsidiary Amgen USA Inc.—that were either lost as a result of Defendants' infringement or were made at eroded prices because of Defendants' infringement. But for Defendants' infringement, Plaintiffs would not have suffered injury, entitling Plaintiffs to damages in the form of lost profits resulting from at least diverted sales and price erosion, and in no event less than a reasonable royalty under 35 U.S.C. § 284.

153. On information and belief, Defendants' infringement of the '997 Patent is exceptional and entitles Amgen to attorneys' fees and costs incurred in prosecuting this action in accordance with 35 U.S.C. § 285.

DEMAND FOR A JURY TRIAL

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Defendants and grant the following relief:

A. a judgment that Defendants have infringed one or more claims of the '707 Patent under 35 U.S.C. § 271(e)(2)(C)(i);

B. a judgment that Defendants have infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g);

C. a judgment that Defendants have infringed one or more claims of the '997 Patent under 35 U.S.C. § 271(e)(2)(C)(i);

D. a judgment that Defendants have infringed or will infringe one or more claims of the '997 Patent under 35 U.S.C. § 271(g);

E. a judgment compelling Defendants to pay to Plaintiffs damages or other monetary relief adequate to compensate for Defendants' infringement in accordance with 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284, in an amount to be ascertained at trial, including without limitation lost profits resulting from at least diverted sales and price erosion, and in no event less than a reasonable royalty;

F. an order enjoining Defendants, as well as all officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates of Defendants, and all persons acting on behalf of or at the direction of, or in concert with Defendants, from infringing the '707 Patent, or contributing to or inducing anyone to do the same, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

G. an order enjoining Defendants, as well as all officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates of Defendants, and all persons acting on behalf of or at the direction of, or in concert with Defendants, from infringing the '997

Patent, or contributing to or inducing anyone to do the same, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

H. a declaration that this is an exceptional case and awarding to Plaintiffs their attorneys' fees and costs pursuant to 35 U.S.C. § 285, and expenses; and

I. such other relief as this Court may deem just and proper.

Respectfully submitted,

THE WEBB LAW FIRM

Dated: February 7, 2019

/s/ *Kent E. Baldauf, Jr.*

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CERTIFICATE OF SERVICE

I hereby certify that on the 7th day of February, 2019, I electronically filed the foregoing **FIRST AMENDED AND SUPPLEMENTAL COMPLAINT** with the Clerk of Court using the CM/ECF system which sent notification to all counsel of record.

THE WEBB LAW FIRM

s/ *Kent E. Baldauf, Jr.*
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