

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN)	
MANUFACTURING LIMITED,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
COHERUS BIOSCIENCES INC.,)	DEMAND FOR JURY TRIAL
)	
Defendant.)	

COMPLAINT

Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively “Amgen”), by and through their undersigned attorneys, for their Complaint against Defendant Coherus Biosciences Inc. (“Coherus”), hereby allege:

THE PARTIES

1. 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.
2. Amgen Manufacturing Limited is a corporation organized and existing under the laws of Bermuda, with its principal place of business in Juncos, Puerto Rico.
3. Amgen discovers, develops, manufactures, and sells innovative therapeutic products based on advances in molecular biology, recombinant DNA technology, and chemistry. Founded in 1980, Amgen is a pioneer in the development of biological human therapeutics. Today, Amgen is the largest biotechnology company in the world, fueled in part by the success of NEULASTA® (pegfilgrastim). Amgen Manufacturing Limited manufactures and sells

biologic medicines for treating particular diseases in humans. Amgen Manufacturing Limited is a wholly-owned subsidiary of Amgen Inc.

4. Upon information and belief, Coherus is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 333 Twin Dolphin Drive, Suite 600, Redwood City, CA 94065.

5. Upon information and belief, Coherus, founded in 2010, is in the business of developing and commercializing “biosimilar” products based on successful biologic medicines developed by others.

NATURE OF THE ACTION

6. This action arises under 35 U.S.C. § 271(e)(2)(C)(i), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act (“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).

7. The asserted patent is Amgen’s U.S. Patent No. 8,273,707 (“the ’707 Patent”). The ’707 Patent is directed to a process for purifying proteins.

8. By amendment to the Public Health Service Act, the BPCIA created a new, abbreviated pathway for the approval of biological products that are highly similar to previously-licensed innovative biological products. The abbreviated pathway (42 U.S.C. § 262(k), often referred to as “the subsection (k) pathway”) allows a biosimilar applicant to secure a license from the Food and Drug Administration (“FDA”) by designating an innovative biological product (“the reference product”) with an existing license granted to the innovator company (“the reference product sponsor” or “RPS”) under the innovator pathway (42 U.S.C. § 262(a), often referred to as “the subsection (a) pathway”), which has traditionally required proof of safety and efficacy through a series of phased clinical trials.

9. Amgen is the sponsor of the reference product, NEULASTA® (pegfilgrastim), which is approved by FDA to decrease the incidence of infection in patients receiving myelosuppressive chemotherapy. Seeking the benefits of the subsection (k) pathway, Coherus submitted its abbreviated Biologic License Application No. 761039 (the “Coherus aBLA”) to FDA, requesting that its biological product (“the Coherus Pegfilgrastim Product”) be licensed by relying on Amgen’s demonstration that NEULASTA® is “safe, pure, and potent.”

10. Upon information and belief, Coherus submitted the Coherus aBLA to FDA on or about August 9, 2016, and thus before the September 24, 2024 expiration date of the ’707 Patent.

11. Upon information and belief, on or about October 6, 2016, Coherus received notification from FDA that the Coherus aBLA had been accepted for review.

12. On October 11, 2016, and, upon information and belief, within 20 days after FDA notified Coherus that the Coherus aBLA had been accepted for review, the exchange of information under the provisions of the BPCIA began.

13. This information exchange culminated in the parties’ agreement in April 2017 that the ’707 Patent should be included in an immediate infringement action to be filed by Amgen under 42 U.S.C. § 262(l)(6)(A). The ’707 Patent was identified in the process provided in 42 U.S.C. § 262(l)(3).

14. This immediate infringement action now follows, as provided by 42 U.S.C. § 262(l)(6)(A).

15. Coherus committed an act of infringement with respect to the ’707 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when it submitted its aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Coherus Pegfilgrastim Product.

16. Upon information and belief, Coherus has a manufacturing agreement with KBI BioPharma, Inc. (“KBI”) for “long-term manufacturing” of the Coherus Pegfilgrastim Product, such that KBI “will manufacture and deliver production quantities” of the Coherus Pegfilgrastim Product for Coherus’s “planned commercial launch” of the Coherus Pegfilgrastim Product and “multiple years of commercial product sales” following FDA approval. *See* Dec. 21, 2015 Press Release, *available at* <http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2124381>.

17. Upon information and belief, KBI acts at the direction, under the control, and for the benefit of Coherus with respect to the Coherus Pegfilgrastim Product.

18. Unless enjoined by this Court, following FDA approval of the Coherus aBLA, Coherus will infringe one or more claims of the ’707 Patent under 35 U.S.C. § 271(a) by making the Coherus Pegfilgrastim Product within the United States or having the Coherus Pegfilgrastim Product made at the direction, under the control, and for the benefit of Coherus within the United States, before the expiration of the ’707 Patent.

19. Unless enjoined by this Court, following FDA approval of the Coherus aBLA, Coherus will induce infringement of one or more claims of the ’707 Patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting KBI’s acts of direct infringement in manufacturing the Coherus Pegfilgrastim Product, with knowledge of the ’707 Patent, and with knowledge that its acts are encouraging infringement, before the expiration of the ’707 Patent.

20. Unless enjoined by this Court, following FDA approval of the Coherus aBLA, Coherus will infringe one or more claims of the ’707 Patent under 35 U.S.C. § 271(g) by offering to sell, selling, or using within the United States the Coherus Pegfilgrastim Product, which

Coherus and/or KBI makes by a process patented in the '707 Patent, before the expiration of the '707 Patent.

JURISDICTION AND VENUE

21. 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 the Declaratory Judgment Act of 1934 (28 U.S.C. §§ 2201-2202). This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

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

23. This Court has personal jurisdiction over Coherus by virtue of, among other things, Coherus being a Delaware corporation, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with Delaware.

BACKGROUND

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

24. Amgen 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 has invested billions of dollars into its research and development efforts.

25. In 2002, Amgen 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 conducted extensive clinical trials and submitted the results of those trials to FDA in order to prove that NEULASTA® is safe, pure, and potent.

26. The active ingredient in Amgen's innovative NEULASTA® product is pegfilgrastim, 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.

27. NEULASTA® 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® 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® counteracts neutropenia.

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

29. Prior to 2010, any other company wishing to sell its own version of NEULASTA® 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. 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).

B. Coherus Seeks Approval to Market a Proposed Biosimilar Version of NEULASTA® (pegfilgrastim) by Taking Advantage of the Abbreviated Subsection (k) Pathway of the BPCIA

30. Upon information and belief, Coherus submitted the Coherus aBLA with FDA pursuant to Section 351(k) of the Public Health Service Act in order to obtain approval to engage

in the commercial manufacture, use, or sale of the Coherus Pegfilgrastim Product. The Coherus Pegfilgrastim Product is a proposed biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

31. Upon information and belief, the Coherus aBLA references and relies on the approval and licensure of Amgen's NEULASTA® product in support of the request Coherus made for FDA licensure of the Coherus aBLA.

32. Upon information and belief, the Coherus Pegfilgrastim Product is designed to copy and compete with Amgen's NEULASTA®.

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

34. Coherus is piggybacking on the fruits of Amgen's trailblazing efforts. Coherus has publicly announced that it submitted the Coherus aBLA under the subsection (k) pathway to obtain approval to engage in the commercial manufacture, use, or sale of the Coherus Pegfilgrastim Product that Coherus asserts is a biosimilar version of Amgen's NEULASTA®. *See* October 6, 2016 Press Release, FDA Acceptance of 351(k) Biologics License Application for CHS-1701 (Pegfilgrastim Biosimilar Candidate), *available at* <http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2210016>.

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

35. In October 2016, the exchange of information between Amgen and Coherus, as required by the BPCIA, began.

36. As part of this exchange, Amgen provided Coherus with Amgen's list of patents under 42 U.S.C. § 262(l)(3)(A). That list included the '707 Patent. Coherus then provided Amgen with Coherus's list of patents and detailed statement under 42 U.S.C. § 262(l)(3)(B). Amgen then provided Coherus with Amgen's detailed statement under 42 U.S.C. § 262(l)(3)(C).

37. Amgen and Coherus 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)." Amgen and Coherus agreed that the '707 Patent would be included in the action for patent infringement under 42 U.S.C. § 262(l)(6).

38. Amgen now files this immediate patent infringement action against Coherus pursuant to 42 U.S.C. § 262(l)(6)(A). This action follows "not later than 30 days after" the parties' agreement under 42 U.S.C. § 262(l)(4) with respect to the '707 Patent.

THE PATENT-IN-SUIT

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

40. Amgen Manufacturing Limited is the exclusive licensee under the '707 Patent.

41. 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 A.

42. The '707 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)

43. Amgen incorporates by reference paragraphs 1-42 as if fully set forth herein.

44. Upon information and belief, Coherus seeks FDA approval under Section 351(k) of the Public Health Service Act to engage in the commercial manufacture, use, or sale of the Coherus Pegfilgrastim Product, a proposed biosimilar version of Amgen's NEULASTA® (pegfilgrastim) product.

45. Under the BPCIA exchange provisions, Amgen and Coherus agreed that the '707 Patent would be included in the action for patent infringement under 42 U.S.C. § 262(l)(6).

46. Coherus committed an act of infringement with respect to the '707 Patent under 35 U.S.C. § 271(e)(2)(C)(i) when it submitted the Coherus aBLA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of the Coherus Pegfilgrastim Product.

47. Upon information and belief, Coherus intends to make the Coherus Pegfilgrastim Product within the United States or have the Coherus Pegfilgrastim Product made at the direction, under the control, and for the benefit of Coherus within the United States, before the expiration of the '707 Patent. Upon information and belief, Coherus also intends to offer to sell, sell, or use within the United States the Coherus Pegfilgrastim Product, before the expiration of the '707 Patent.

48. Upon information and belief, the manufacture, offer for sale, sale, and/or use of the Coherus Pegfilgrastim Product will infringe, either literally or under the doctrine of equivalents, one or more claims of the '707 Patent.

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

50. 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 Coherus manufactures the Coherus Pegfilgrastim Product satisfies each limitation of at least claim 1 and also dependent claims 2, 3, 4, and 7. With respect to the requirement that the protein is purified on a hydrophobic interaction chromatography column, Coherus practices a process for purifying a protein on a hydrophobic interaction chromatography column as defined in the '707 patent or,

alternatively, an equivalent of such column. With respect to the use of dual salts, in the Coherus process, a preparation containing protein is mixed with a combination of a first salt and a second salt, which combination is the equivalent of one or more of the recited salt pairs. With respect to the salt concentration, the concentration of each salt in the Coherus mixture falls within the claimed range and/or is equivalent to a concentration within the claimed range. With respect to elution, the Coherus mixture containing protein and dual salts is loaded onto a hydrophobic interaction chromatography column and protein is eluted.

51. Amgen does not have an adequate remedy at law and is entitled to injunctive relief preventing Coherus from any further infringement under 35 U.S.C. § 271(e)(4)(B).

52. The manufacture, offer for sale, sale, and/or use of the Coherus Pegfilgrastim Product before the expiration of the '707 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

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

53. Amgen incorporates by reference paragraphs 1-52 as if fully set forth herein.

54. Upon information and belief, FDA may act upon the Coherus aBLA as soon as August 2017. FDA has stated publicly that the agency's goal is to act upon 90% of aBLA applications within 10 months of the 60-day-filing-review period that begins on the date of FDA receipt of the original aBLA submission. *See Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, available at* <https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf>.

55. Upon information and belief, Coherus believes that FDA may act upon the Coherus aBLA as soon as June 9, 2017, and that Coherus will be able to pay the user fee prescribed under the Biosimilar User Fee Act by that time. *See* March 6, 2017 Coherus

Presentation, *available at* <http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-presentations>. Coherus has publicly stated that it anticipates “commercial launch mid-second half of 2017 depending on Supreme Court decision on 180-day notice of commercialization and other litigation matters.” *See* May 8, 2017 Press Release, *available at* <http://investors.coherus.com/phoenix.zhtml?c=253655&p=irol-newsArticle&ID=2270950>.

56. Unless enjoined by this Court, following FDA approval of the Coherus aBLA, Coherus will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(a) by making the Coherus Pegfilgrastim Product within the United States or having the Coherus Pegfilgrastim Product made at the direction, under the control, and for the benefit of Coherus within the United States, before the expiration of the '707 Patent.

57. An actual controversy has arisen and now exists between the parties concerning whether Coherus has infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(a). Coherus has denied infringement of the '707 Patent in its detailed statement under 42 U.S.C. § 262(l)(3)(B).

58. Amgen is entitled to a declaratory judgment that Coherus has infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(a).

59. Amgen will be irreparably harmed if Coherus is not enjoined from infringing the '707 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Coherus from making the Coherus Pegfilgrastim Product within the United States or having the Coherus Pegfilgrastim Product made at the direction, under the control, and for the benefit of Coherus before the expiration of the '707 Patent.

60. Infringement of the '707 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 284.

**THIRD COUNT:
DECLARATORY JUDGMENT OF INFRINGEMENT OF
THE '707 PATENT UNDER 35 U.S.C. § 271(b)**

61. Amgen incorporates by reference paragraphs 1-60 as if fully set forth herein.

62. Unless enjoined by this Court, following FDA approval of the Coherus aBLA, Coherus will induce infringement of one or more claims of the '707 Patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting KBI's acts of direct infringement in manufacturing the Coherus Pegfilgrastim Product, with knowledge of the '707 Patent, and with knowledge that its acts are encouraging infringement, before the expiration of the '707 Patent.

63. An actual controversy has arisen and now exists between the parties concerning whether Coherus has induced infringement or will induce infringement of one or more claims of the '707 Patent under 35 U.S.C. § 271(b). Coherus has denied infringement of the '707 Patent in its detailed statement under 42 U.S.C. § 262(l)(3)(B).

64. Amgen is entitled to a declaratory judgment that Coherus has induced infringement or will induce infringement of one or more claims of the '707 Patent under 35 U.S.C. § 271(b).

65. Amgen will be irreparably harmed if Coherus is not enjoined from infringing the '707 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Coherus from inducing infringement of the '707 Patent by intentionally encouraging, aiding and abetting KBI to manufacture the Coherus Pegfilgrastim Product using the patented process before expiration of the '707 Patent.

66. Infringement of the '707 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 284.

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

67. Amgen incorporates by reference paragraphs 1-66 as if fully set forth herein.

68. Unless enjoined by this Court, following FDA approval of the Coherus aBLA, Coherus will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g) by offering to sell, selling, or using within the United States the Coherus Pegfilgrastim Product, which Coherus and/or KBI makes by a process patented in the '707 Patent, before the expiration of the '707 Patent.

69. An actual controversy has arisen and now exists between the parties concerning whether Coherus has infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g). Coherus has denied infringement of the '707 Patent in its detailed statement under 42 U.S.C. § 262(l)(3)(B).

70. Amgen is entitled to a declaratory judgment that Coherus has infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g).

71. Amgen will be irreparably harmed if Coherus is not enjoined from infringing the '707 Patent. Amgen does not have an adequate remedy at law and is entitled to injunctive relief under 35 U.S.C. § 283 prohibiting Coherus from offering to sell, selling, or using within the United States the Coherus Pegfilgrastim Product which Coherus and/or KBI makes by a process patented in the '707 Patent, before the expiration of the '707 Patent.

72. Infringement of the '707 Patent will cause injury to Amgen, entitling it to damages or other monetary relief under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Amgen respectfully requests that this Court enter judgment in its favor against Coherus and grant the following relief:

- A. A judgment that Coherus has infringed one or more claims of the '707 Patent under 35 U.S.C. § 271(e)(2)(C)(i);
- B. A judgment that Coherus has infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(a);
- C. A judgment that Coherus has induced infringement or will induce infringement of one or more claims of the '707 Patent under 35 U.S.C. § 271(b);
- D. A judgment that Coherus has infringed or will infringe one or more claims of the '707 Patent under 35 U.S.C. § 271(g);
- E. A judgment directing Coherus to pay to Amgen damages adequate to compensate for its infringement of the '707 Patent;
- F. An order enjoining Coherus and its officers, employees, agents, representatives, affiliates, assignees, successors, and affiliates, and all persons acting on behalf of or at the direction of, or in concert with Coherus, from infringing the '707 Patent, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;
- G. A declaration that this is an exceptional case and awarding to Amgen its attorneys' fees and costs pursuant to 35 U.S.C. § 285, and expenses; and
- H. Such other relief as this Court may deem just and proper.

DEMAND FOR A JURY TRIAL

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

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/s/ Maryellen Noreika

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