IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COHERUS BIOSCIENCES, INC., Plaintiff, v. AMGEN INC., Defendant.	Civil Action No. 19-139 (RGA) **JURY TRIAL DEMANDED**

PLAINTIFF COHERUS BIOSCIENCES, INC.'S FIRST AMENDED COMPLAINT

For its First Amended Complaint against Defendant Amgen Inc. ("Defendant" or "Amgen"), Plaintiff Coherus Biosciences, Inc., ("Plaintiff" or "Coherus"), by its attorneys, alleges as follows:

NATURE OF ACTION

1. This is an action for infringement of United States Patent Nos. 10,155,039 ("the '039 patent"), 10,159,732 ("the '732 patent"), 10,159,733 ("the '733 patent"), and 10,207,000 ("the '000 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

THE PARTIES

2. Plaintiff Coherus Biosciences, Inc. is a company 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, California 94065.

3. Upon information and belief, 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.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States of America, United States Code, Title 35, Section 1, *et seq.,* including 35 U.S.C. § 271. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

5. This Court has personal jurisdiction over Amgen Inc. because Amgen Inc. is incorporated in the State of Delaware and is, thus, a resident of the State.

6. Upon information and belief, Amgen Inc. is registered to do business in Delaware, has availed itself of the rights and benefits of Delaware law, conducts business in Delaware, derives substantial revenue from business conducted in Delaware, and has engaged in purposeful systematic and continuous contacts with the State of Delaware.

7. Venue as to Amgen Inc. is proper in this District under 28 U.S.C. § 1400(b) at least because Amgen Inc. resides in this District.

FACTUAL BACKGROUND

8. The ’039 patent, entitled “Stable Aqueous Formulations of Adalimumab,” issued on December 18, 2018, and names Mark Manning and Robert W. Payne as the inventors. A true and accurate copy of the ’039 patent is attached hereto as Exhibit A.

9. The ’039 patent claims recite stable aqueous compositions comprising adalimumab as the active ingredient and other components as inactive ingredients. For example, claim 1 of the ’039 patent recites a stable aqueous pharmaceutical composition comprising adalimumab, a buffer, polysorbate 80, and a sugar, wherein the composition is free of mannitol, citrate and phosphate buffer, and sodium chloride, and wherein the composition has a pH of about 5 to about 6.

10. The ’732 patent, entitled “Stable Aqueous Formulations of Adalimumab,” issued on December 25, 2018, and names Mark Manning and Robert W. Payne as the inventors. A true and accurate copy of the ’732 patent is attached hereto as Exhibit B.

11. The ’732 patent claims recite stable aqueous compositions comprising adalimumab as the active ingredient and other components as inactive ingredients. For example, claim 1 of the ’732 patent recites a stable aqueous pharmaceutical composition comprising adalimumab, a buffer, and a stabilizer wherein the composition is free of mannitol and has a pH of about 5 to about 6.

12. The ’733 patent, entitled “Stable Aqueous Formulations of Adalimumab,” issued on December 25, 2018, and names Mark Manning and Robert W. Payne as the inventors. A true and accurate copy of the ’733 patent is attached hereto as Exhibit C.

13. The ’733 patent claims recite stable aqueous compositions comprising adalimumab as the active ingredient and other components as inactive ingredients. For example, claim 1 of the ’733 patent recites a stable aqueous pharmaceutical composition comprising adalimumab, a single buffer, a surfactant, and a sugar, wherein the composition is free of mannitol and has a pH of about 5 to about 6.

14. The ’000 patent, entitled “Stable Aqueous Formulations of Adalimumab,” issued on February 19, 2019, and names Mark Manning and Robert Payne as inventors. A true and accurate copy of the ’000 patent is attached hereto as Exhibit D.

15. The ’000 patent claims recite stable aqueous compositions comprising adalimumab as the active ingredient and other components as inactive ingredients. For example, claim 1 of the ’000 patent recites a stable aqueous pharmaceutical composition comprising

adalimumab, a single buffer, a surfactant, and a tonicity modifier, wherein the composition is free of mannitol and has a pH of about 5 to about 6.

16. Coherus, as assignee, owns the entire right, title and interest in the '039, '732, '733, and '000 patents.

17. On October 15, 2016, Amgen announced that it would launch Amgevita™, an adalimumab biosimilar, in markets across Europe beginning on October 16, 2018. (*See* Exhibit E.)

18. Amgevita™ is approved by the European Commission for the treatment of inflammatory diseases, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, axial spondyloarthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis. (Exhibit E.)

19. Upon information and belief, Amgen is actively offering for sale and selling Amgevita™ throughout Europe.

20. Upon information and belief, Amgen manufactures Amgevita™ in the United States. The European Medicines Agency ("EMA")'s Assessment Report on Amgevita™ indicates that "Amgen Thousand Oaks (ATO), USA, is responsible for active substance manufacture." (Exhibit F at 13.) Annex I to the EMA Assessment Report lists the manufacturer of the active substance as Amgen Inc., One Amgen Center Drive, Thousand Oaks, California 91320, United States. (Exhibit G at 48.)

21. The EMA Assessment Report indicates that "[t]he active substance and finished product have an identical formulation. The formulation is not modified during finished product manufacturing." (Exhibit F at 18.) The EMA Assessment Report also indicates "[t]he finished product has the same formulation and concentration as the active substance. Therefore, no

dilution is required for finished product manufacturing and the concentrations of active and excipients remain the same." (Exhibit F at 18.)

22. Upon information and belief, Amgen is actively manufacturing Amgevita™ in the United States for sale in Europe.

23. The active ingredient in Amgevita™ is adalimumab. The inactive ingredients in Amgevita™ include glacial acetic acid, sucrose, polysorbate 80, sodium hydroxide, and water for injection. (Exhibit G at 44, 52.)

24. Upon information and belief, glacial acetic acid, or one of its constituent ions, acts as a buffer in the Amgevita™ formulation. Sucrose is a sugar, and can function as a stabilizer and tonicity modifier. Polysorbate 80 is a surfactant. Sodium hydroxide is identified as "for pH adjustment" in the EMA Assessment Report Annex. (Exhibit G at 44.) Mannitol is not identified as a component in the Amgevita™ formulation. (Exhibit G at 44, 52.) No citrate or phosphate buffers, or sodium chloride, are identified as components in the Amgevita™ formulation. (*Id*.) Upon information and belief, the pH of the Amgevita™ formulation is between 5 and 6.

25. This is an action to stop Amgen from manufacturing and using its infringing Amgevita™ product in the United States for sale in Europe without a license, and to recover damages for Amgen's infringement of the '039, '732, '733, and '000 patents.

COUNT I

Infringement of the '039 Patent Under 35 U.S.C. § 271(a) by Amgen's Amgevita™ Product

26. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

27. Amgen, through its affiliate Amgen Europe B.V., has offered for sale and sold Amgevita™, and is actively offering for sale and selling Amgevita™, in markets throughout Europe since October 16, 2018.

28. Upon information and belief, Amgen has engaged in the commercial manufacture of Amgevita™ at its facility in Thousand Oaks, California at least since Amgen began marketing Amgevita™ in Europe on October 16, 2018, and is actively manufacturing Amgevita™ in the United States.

29. Upon information and belief, Amgevita™ is an aqueous composition comprising adalimumab, glacial acetic acid, sucrose, sodium hydroxide, polysorbate 80, and water for injection at a pH between about 5 to about 6.

30. The commercial manufacture of Amgevita™ constitutes an act of direct infringement of at least one claim of the '039 patent under 35 U.S.C. § 271(a).

31. Upon information and belief, Amgen became aware of the '039 patent no later than December 18, 2018, when it was issued by the Patent Office.

32. The commercial manufacture of Amgevita™ in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

33. Unless and until Amgen is enjoined from infringing the '039 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

34. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia,* damages adequate to compensate Plaintiff for the infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '039 patent by Amgen, together with interest and costs.

35. Upon information and belief, despite having actual notice of the '039 patent, Amgen continues to actively infringe the '039 patent in disregard of Plaintiff's rights, making this case exceptional and entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II

Infringement of the '732 Patent Under 35 U.S.C. § 271(a) by Amgen's Amgevita™ Product

36. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

37. Amgen, through its affiliate Amgen Europe B.V., has offered for sale and sold Amgevita™, and is actively offering for sale and selling Amgevita™, in markets throughout Europe since October 16, 2018.

38. Upon information and belief, Amgen has engaged in the commercial manufacture of Amgevita™ at its facility in Thousand Oaks, California at least since Amgen began marketing Amgevita™ in Europe on October 16, 2018, and is actively manufacturing Amgevita™ in the United States.

39. Upon information and belief, Amgevita™ is an aqueous composition comprising adalimumab, glacial acetic acid, sucrose, sodium hydroxide, polysorbate 80, and water for injection at a pH between about 5 to about 6.

40. The commercial manufacture of Amgevita™ constitutes an act of direct infringement of at least one claim of the '732 patent under 35 U.S.C. § 271(a).

41. Upon information and belief, Amgen became aware of the '732 patent no later than December 25, 2018, when it was issued by the Patent Office.

42. The commercial manufacture of Amgevita™ in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

43. Unless and until Amgen is enjoined from infringing the '732 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

44. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia,* damages adequate to compensate Plaintiff for the infringement, but not less than a reasonable

royalty and/or lost profits for the use made of the invention of the ’732 patent by Amgen, together with interest and costs.

45. Upon information and belief, despite having actual notice of the ’732 patent, Amgen continues to actively infringe the ’732 patent in disregard of Plaintiff’s rights, making this case exceptional and entitling Plaintiff to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT III

Infringement of the ’733 Patent Under 35 U.S.C. § 271(a) by Amgen’s Amgevita™ Product

46. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

47. Amgen, through its affiliate Amgen Europe B.V., has offered for sale and sold Amgevita™, and is actively offering for sale and selling Amgevita™, in markets throughout Europe since October 16, 2018.

48. Upon information and belief, Amgen has engaged in the commercial manufacture of Amgevita™ at its facility in Thousand Oaks, California at least since Amgen began marketing Amgevita™ in Europe on October 16, 2018, and is actively manufacturing Amgevita™ in the United States.

49. Upon information and belief, Amgevita™ is an aqueous composition comprising adalimumab, glacial acetic acid, sucrose, sodium hydroxide, polysorbate 80, and water for injection at a pH between about 5 to about 6.

50. The commercial manufacture of Amgevita™ constitutes an act of direct infringement of at least one claim of the ’733 patent under 35 U.S.C. § 271(a).

51. Upon information and belief, Amgen became aware of the ’733 patent no later than December 25, 2018, when it was issued by the Patent Office.

52. The commercial manufacture of Amgevita™ in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

53. Unless and until Amgen is enjoined from infringing the '733 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

54. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia,* damages adequate to compensate Plaintiff for the infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '733 patent by Amgen, together with interest and costs.

55. Upon information and belief, despite having actual notice of the '733 patent, Amgen continues to actively infringe the '733 patent in disregard of Plaintiff's rights, making this case exceptional and entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV

Infringement of the '000 Patent Under 35 U.S.C. § 271(a) by Amgen's Amgevita™ Product

56. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

57. Amgen, through its affiliate Amgen Europe B.V., has offered for sale and sold Amgevita™, and is actively offering for sale and selling Amgevita™, in markets throughout Europe since October 16, 2018.

58. Upon information and belief, Amgen has engaged in the commercial manufacture of Amgevita™ at its facility in Thousand Oaks, California at least since Amgen began marketing Amgevita™ in Europe on October 16, 2018, and is actively manufacturing Amgevita™ in the United States.

59. Upon information and belief, Amgevita™ is an aqueous composition comprising adalimumab, glacial acetic acid, sucrose, sodium hydroxide, polysorbate 80, and water for injection at a pH between about 5 to about 6.

60. The commercial manufacture of Amgevita™ constitutes an act of direct infringement of at least one claim of the ’000 patent under 35 U.S.C. § 271(a).

61. Upon information and belief, Amgen became aware of the ’000 patent no later than February 19, 2019, when it was issued by the Patent Office.

62. The commercial manufacture of Amgevita™ in violation of Plaintiff’s patent rights will cause harm to Plaintiff for which damages are inadequate.

63. Unless and until Amgen is enjoined from infringing the ’000 patent, Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

64. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for the infringement, but not less than a reasonable royalty and/or lost profits for the used made of the invention of the ’000 patent by Amgen, together with interest and costs.

65. Upon information and belief, despite having actual notice of the ’000 patent, Amgen continues to actively infringe the ’000 patent in disregard of Plaintiff’s rights, making this case exceptional and entitling Plaintiff to reasonable attorney’s fees pursuant to 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby requests a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiff respectfully requests the following relief:

A) A judgment that Amgen has infringed, either literally or under the doctrine of equivalents, and continues to infringe the ’039 patent, ’732 patent, ’733 patent, and ’000 patent;

B) A judgment permanently enjoining Amgen and its respective officers, agents, servants, employees, affiliates, representatives, successors and assigns, attorneys, and any others acting in concert with Amgen, from further infringement of the ’039 patent, ’732 patent, ’733 patent, and ’000 patent;

C) A judgment awarding Plaintiff damages adequate to compensate for past, present, and future infringement, said damages being no less than a reasonable royalty and/or lost profits, and any pre- and post-judgement interest as allowed by law, costs, and other damages permitted by 35 U.S.C. § 284;

D) A judgment finding that Amgen’s infringement of the ’039 patent, ’732 patent, ’733 patent, and ’000 patent was deliberate and willful;

E) A judgment awarding Plaintiff enhanced damages up to three times their amount pursuant to 35 U.S.C. § 284, together with interest and costs;

F) A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys’ fees and costs;

G) An accounting to determine the damages to be awarded to Plaintiff as a result of Amgen’s infringement, including an accounting for infringing sales not presented at trial and an award of additional damages for any such infringing sales;

H) An award to Plaintiff of costs and expenses that it incurs in prosecuting this action; and

I) Such other and further relief as the Court may deem just and proper.

Dated: March 5, 2019

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