IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and LES LABORATORIES SERVIER, Plaintiffs, v. BIONPHARMA INC., Defendant.	C.A. No. 20-cv-00105 -CFC

DEFENDANT BIONPHARMA INC.'S
AMENDED ANSWER TO COMPLAINT

Defendant Bionpharma Inc. ("Bionpharma"), by its counsel, hereby responds to the allegations set forth in the Complaint of Plaintiffs, Amgen Inc. and Les Laboratories Servier (collectively, "Amgen," or "Plaintiffs"), for patent infringement against Defendant under 35 U.S.C. § 271(e)(2). This response is based on Defendant's current knowledge as to its own activities. If an allegation within the Complaint is not specifically admitted herein, the allegation is denied.

NATURE OF THE ACTION

1. Bionpharma admits that Plaintiffs allege that this action arises under the patent laws of the United States. Bionpharma further admits that Plaintiffs purport to seek relief from alleged infringement by Bionpharma of U.S. Patent Nos. 7,361,649 ("the '649 patent"); 7,361,650 ("the '650 patent"); 7,867,996 ("the '996 patent") and 7,879,842 ("the '842 patent") (collectively, "Patents-in-Suit"). Bionpharma admits that ANDA No. 213276 includes a certification, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), with respect to the Patents-in-Suit alleging that, in

Bionpharma's opinion, the relevant claims are invalid or will not be infringed by the commercial manufacture, importation, use or sale of ivabradine hydrochloride tablets (eq. to 5 mg and 7.5 mg ivabradine) that are the subject of ANDA No. 213276. Bionpharma denies the remaining allegations in Paragraph 1.

THE PARTIES

2. Bionpharma is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and therefore denies them.

3. Bionpharma is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint, and therefore denies them.

4. Admitted.

5. Bionpharma admits that it submitted ANDA No. 213276 to the U.S. Food and Drug Administration ("FDA"). Bionpharma denies the remaining allegations in Paragraph 5.

6. Bionpharma admits that ANDA No. 213276 seeks approval for the commercial manufacture, importation, use or sale of ivabradine hydrochloride tablets (eq. to 5 mg and 7.5 mg ivabradine prior to the expiration of the Patent-in-Suit. Bionpharma denies the remaining allegations in Paragraph 6.

7. Bionpharma admits that ANDA No. 213276 seeks approval from FDA for the commercial manufacture, importation, use or sale of ivabradine hydrochloride tablets (eq. to 5 mg and 7.5 mg ivabradine.

JURISDICTION AND VENUE

8. Bionpharma admits that the Complaint purports to assert an action for patent infringement pursuant to the patent laws of the United States based on Defendant's submission of ANDA No. 213276.

9. Paragraph 9 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Bionpharma will not contest subject matter jurisdiction for the limited purpose of this action.

10. Paragraph 10 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest personal jurisdiction in this District for the limited purpose of this action.

11. Bionpharma is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 of the Complaint, and therefore denies them.

12. Paragraph 12 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Bionpharma does not contest personal jurisdiction in this District for the limited purpose of this action.

13. Paragraph 13 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Bionpharma does not contest venue in this District for the limited purpose of this action.

THE PATENTS-IN-SUIT

14. Bionpharma is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 14 of the Complaint, and therefore denies them.

15. Bionpharma admits that, based on its face, the ’649 Patent is entitled “β-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It” and issued on April 22, 2008. Bionpharma denies that the ’649 Patent was duly and legally issued. Bionpharma admits that what purports to be a true and correct copy of the ’649 Patent is attached as Exhibit A.

16. Bionpharma admits that, based on its face, the '650 Patent is entitled "γ-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and issued on April 22, 2008. Bionpharma denies that the '650 Patent was duly and legally issued. Bionpharma admits that what purports to be a true and correct copy of the '650 Patent is attached as Exhibit B.

17. Bionpharma admits that, based on its face, the '996 Patent is entitled "γ - Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and issued on January 11, 2011. Bionpharma denies that the '996 Patent was duly and legally issued. Bionpharma admits that what purports to be a true and correct copy of the '996 Patent is attached as Exhibit C.

18. Bionpharma admits that, based on its face, the '842 Patent is entitled "γ Beta-Crystalline Form of Ivabradine Hydrochloride, a Process for Its Preparation and Pharmaceutical Compositions Containing It," and issued on February 1, 2011. Bionpharma denies that the '842 Patent was duly and legally issued. Bionpharma admits that what purports to be a true and correct copy of the '842 Patent is attached as Exhibit D.

FACTUAL BACKGROUND

Corlanor® (Ivabradine)

19. Bionpharma is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19 of the Complaint, and therefore denies them.

20. Bionpharma admits that according to FDA, Amgen is listed as the holder of NDA 20-6143, which is sold under the trade name Corlanor®. Bionpharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 20 of the Complaint, and therefore denies them.

21. Paragraph 21 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Bionpharma admits that the ’649 patent, the ’650 patent, the ’996 patent, and the ’842 patent are listed in the FDA’s Orange Book for Corlanor®.

Bionpharma’s ANDA No. 213276

22. Bionpharma admits that, on December 11, 2019, it sent a Notice Letter pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application (“ANDA”). Bionpharma denies the remaining allegations in this paragraph.

23. Bionpharma admits that it was aware of the Patents-in-Suit when it submitted its ANDA No. 213276.

24. Bionpharma admits that the proposed ANDA product contains the hydrochloride salt form of ivabradine. Bionpharma denies the remaining allegations in this paragraph.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Bionpharma admits that ANDA No. 213276 was submitted with bioequivalence data and information required by law.

26. Denied.

27. Bionpharma admits that it filed ANDA No. 213276 with the FDA, seeking regulatory approval to make and sell ivabradine hydrochloride tablets throughout the United States. Bionpharma is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

28. Admitted.

29. Defendant lacks knowledge or information sufficient to confirm or deny the allegations of Paragraph 29 and therefore denies the same.

30. Admitted.

31. Admitted.

32. Admitted.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,361,649

33. Bionpharma repeats and incorporates by reference all of the answers in prior paragraphs.

34. Denied.

35. Denied.

36. Paragraph 36 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Bionpharma admits that it filed ANDA No. 213276 with the FDA, seeking regulatory approval to make and sell ivabradine hydrochloride tablets throughout the United States. Bionpharma is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

37. Denied.

38. Denied.

39. Denied.

40. Paragraph 40 of the Complaint states a legal conclusion to which no response is required. To the extent a response a required, the allegations are denied.

41. Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 7,361,650

42. Bionpharma repeats and incorporates by reference all of the answers in prior paragraphs.

43. Denied.

44. Denied.

45. Paragraph 45 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Bionpharma admits that it filed ANDA No. 213276 with the FDA, seeking regulatory approval to make and sell ivabradine hydrochloride tablets throughout the United States. Bionpharma is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

46. Denied.

47. Denied.

48. Denied.

49. Paragraph 49 of the Complaint states a legal conclusion to which no response is required. To the extent a response a required, the allegations are denied.

50. Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,867,996

51. Bionpharma repeats and incorporates by reference all of the answers in prior paragraphs.

52. Denied.

53. Denied.

54. Paragraph 54 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, Bionpharma admits that it filed ANDA No. 213276 with the FDA, seeking regulatory approval to make and sell ivabradine hydrochloride tablets throughout the United States. Bionpharma is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

55. Denied.

56. Denied.

57. Denied.

58. Paragraph 58 of the Complaint states a legal conclusion to which no response is required. To the extent a response a required, the allegations are denied.

59. Denied.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 7,879,842

60. Bionpharma repeats and incorporates by reference all of the answers in prior paragraphs.

61. Denied.

62. Denied.

63. Paragraph 63 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Bionpharma admits that it filed ANDA No. 213276 with the FDA, seeking regulatory approval to make and sell ivabradine hydrochloride tablets throughout the United States. Bionpharma is without information sufficient to admit or deny the remaining allegations in this paragraph and therefore denies the allegations.

64. Denied.

65. Denied.

66. Denied.

67. Paragraph 67 of the Complaint states a legal conclusion to which no response is required. To the extent a response a required, the allegations are denied.

68. Denied.

REQUESTED RELIEF

Bionpharma denies that Plaintiffs are entitled to any of the relief sought in their Prayer for Relief in the Complaint.

AFFIRMATIVE DEFENSES

Pursuant to Fed. R. Civ. P. 8(b) and (c), Bionpharma asserts the following defenses to the Complaint. An allegation of any defense below is not an admission that Bionpharma bears the burden of proof or persuasion on any claim or issue.

FIRST AFFIRMATIVE DEFENSE – NON-INFRINGEMENT OF THE CLAIMS OF PATENTS-IN-SUIT

Bionpharma has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claims of the patents-in-suit against Bionpharma.

SECOND AFFIRMATIVE DEFENSE – INVALIDITY OF THE CLAIMS OF PATENTS-IN-SUIT

The claims of the patents-in-suit against Bionpharma are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or for double patenting.

THIRD AFFIRMATIVE DEFENSE – FAILURE TO STATE A CLAIM

The Complaint fails to state a claim upon which relief can be granted and fails to state any facts to support any claim upon which relief can be granted.

FOURTH AFFIRMATIVE DEFENSE – NO INJUNCTIVE RELIEF

Plaintiffs are not entitled to seek injunctive relief against Bionpharma because the alleged harm is not immediate or irreparable, and therefore Plaintiff has an adequate remedy at law.

FIFTH AFFIRMATIVE DEFENSE – NO ATTORNEYS FEES AND COSTS

Plaintiffs are not entitled to attorney's fees against Bionpharma because Plaintiffs have not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285. Moreover, because the claims of the Patents-in-Suit are invalid, Plaintiffs cannot recover costs associated with this action pursuant to 35 U.S.C. § 288.

RESERVATION OF ADDITIONAL DEFENSES

Bionpharma reserves the right to assert such other defenses, if such defenses are discovered during the course of this litigation.

PRAYER FOR RELIEF

WHEREFORE, Bionpharma respectfully prays that this Court enter judgment in Bionpharma's favor and grant the following relief:

A. Dismiss Plaintiffs' Complaint with prejudice and deny each and every prayer for relief alleged against Bionpharma contained therein;

B. A declaration that Bionpharma does not infringe the claims of the Patents-in-Suit against Bionpharma;

C. A declaration that the claims of the Patents-in-Suit against Bionpharma are invalid;

D. That the Court permanently enjoin Plaintiffs or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products

which are the subject of Bionpharma's ANDA No. 213276 infringes or will infringe any claim of the Patents-in-Suit;

E. Assess the costs of this action against Plaintiffs;

F. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Bionpharma is entitled to recover its reasonable attorney fees and costs upon prevailing in this action;

G. An award to Bionpharma of such further and other relief as this Court deems necessary, just, and proper.

Respectfully submitted,

/s/ Gregory B. Williams

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