IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E, INC., KBI, INC. and ASTRAZENECA LP, Plaintiffs, v. DEXCEL LTD., DEXXON LTD., DEXCEL PHARMA TECHNOLOGIES LTD. and DEXCEL PHARMA TECHNOLOGIES, Defendants.	)	Civil Action No. 06-358 (SLR)
DEXCEL PHARMA TECHNOLOGIES LTD., Counterclaim-Plaintiff, v. ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, and ASTRAZENECA LP, Counterclaim-Defendants.	)	

DEXXON LTD.'S ANSWER TO AMENDED COMPLAINT

Defendant Dexxon Ltd. hereby responds to the Amended Complaint of Plaintiffs, Astrazeneca AB, Aktiebolaget Hässle, KBI-E, Inc., KBI Inc., and Astrazeneca LP ("Plaintiffs") as follows:

1. Dexxon Ltd. admits that Plaintiffs purport to bring this action under Titles 35 and 21, United States Code and that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). Dexxon Ltd. denies personal jurisdiction and venue in this district and division under 28 U.S.C. §§1391(b) (c), and 1400(b). Dexxon Ltd. is an Israeli entity and is not subject to personal jurisdiction in this district. However, for the purposes of this litigation only, Dexxon Ltd. waives any objections to personal jurisdiction in this judicial district.

Dexxon Ltd. admits that Plaintiffs purport to base remedies and relief on 28 U.S.C. §§ 2201, 2202 and 35 U.S.C. § 271.

2. Dexxon Ltd. admits that Dexcel Pharma Technologies Ltd. ("DPT Ltd.") submitted NDA No. 22-032 to the FDA pursuant to 21 U.S.C. § 355(b) seeking approval to market its 20 mg delayed-release omeprazole tablets ("DPT Ltd.'s Tablets"). Dexxon Ltd. further admits that pursuant to 35 U.S.C. § 355(b)(2)(A)(iv), DPT Ltd. certified that U.S. Patent Nos. 6,150,380 ("the '380 patent"), 4,786,505 ("the '505 patent") and 4,853,230 ("the '230 patent"), are invalid, unenforceable, and/or not infringed by DPT Ltd.'s Tablets. Dexxon Ltd. otherwise denies the allegations in paragraph 2.

3. Dexxon Ltd. denies the allegations of paragraph 3.

4. Dexxon Ltd. admits that DPT Ltd. indicated through its notification letters of April 17, 2006 and May 4, 2006, that DPT Ltd. intends to market DPT Ltd.'s Tablets before the expiration of the '505, '230, and'380 patents.

5. Dexxon Ltd. admits that DPT Ltd. submitted NDA No. 22-032 and provided a First and Second Notice of Certification. Dexxon Ltd. otherwise denies the allegations of paragraph 5.

6. Dexxon Ltd. denies the allegations of paragraph 6.

7. Dexxon Ltd. admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. Dexxon Ltd. denies personal jurisdiction and venue in this district under 28 U.S.C. §§1391(b) (c) (d), and 1400(b). However, for the purposes of this litigation only, Dexxon Ltd. waives any objections to personal jurisdiction in this judicial district.

9. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9 and therefore denies such allegations.

10. Dexxon Ltd. admits that the '505 patent and the '230 patent are assigned on their face to Aktibolaget Hässle ("Hässle"). Dexxon Ltd. is without knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in paragraph 10 and therefore denies such allegations.

11. Dexxon Ltd. admits that the entity identified as Astrazeneca has listed patents in the FDA Orange Book for PRILOSEC® and PRILOSEC OTC®. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 11 and therefore denies such allegations.

12. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 and therefore denies such allegations.

13. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 13 and therefore denies such allegations.

14. Dexxon Ltd. admits that Dexxon Ltd. is an Israeli entity having its headquarters and principal place of business at the Southern Industrial Zone, Or-Akiva, Israel 30600. Dexxon Ltd. denies the remaining allegations in paragraph 14.

15. Dexxon Ltd. admits that it is an Israeli entity having its headquarters and principal place of business at the Southern Industrial Zone, Or-Akiva, Israel 30600. Dexxon Ltd. denies the remaining allegations in paragraph 15.

16. Dexxon Ltd. admits that DPT Ltd. is the owner and applicant of NDA No. 22-032. Dexxon Ltd. denies the remaining allegations in paragraph 16.

17. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 17 and therefore denies such allegations.

18. Dexxon Ltd. admits that for the purposes of this litigation only, Dexxon Ltd. waives any objections to personal jurisdiction in this judicial district. Dexxon Ltd. otherwise denies the allegations of paragraph 18.

19. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 19 and therefore denies such allegations.

20. Dexxon Ltd. re-asserts its responses to paragraphs 1-19 as if fully set forth herein.

21. Dexxon Ltd. admits that a copy of the '380 patent, entitled "Crystalline Form of Omeprazole," was attached to the Amended Complaint as Exhibit A. Dexxon Ltd. further admits that the issue date set forth on the '380 patent is November 21, 2000, and that the '380 patent is assigned on its face to Astra Aktiebolag from inventors Lövqvist, Sundén, Noreland and Ymén. Dexxon Ltd. denies the remaining allegations in paragraph 21.

22. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 22 of the Amended Complaint and, therefore, denies them.

23. Dexxon Ltd. admits that pursuant to 21 U.S.C. § 355(b) DPT Ltd. sent a letter to Plaintiffs Astrazeneca AB, Astrazeneca LP, and Aktiebolaget Hässle, providing notice that DPT Ltd. filed NDA No. 22-032. This letter speaks for itself and, on that basis, Dexxon Ltd. denies the remaining allegations in paragraph 23.

24. Dexxon Ltd. denies that DPT Ltd.'s First Notice of Certification fails to comply with the law and FDA rules and regulations. Dexxon Ltd. denies the remaining allegations in paragraph 24.

25. Dexxon Ltd. denies the allegations of paragraph 25.

26. Dexxon Ltd. denies the allegations of paragraph 26.

27. Dexxon Ltd. admits that DPT Ltd. is subject to 35 U.S.C. § 271(e)(2) as a result of filing NDA 22-031. Dexxon Ltd. denies the remaining allegations of paragraph 27.

28. Dexxon Ltd. denies the allegations of paragraph 28.

29. Dexxon Ltd. denies the allegations of paragraph 29.

30. Dexxon Ltd. denies the allegations of paragraph 30.

31. Dexxon Ltd. denies the allegations of paragraph 31.

32. Dexxon Ltd. denies the allegations of paragraph 32.

33. Dexxon Ltd. denies the allegations of paragraph 33.

34. Dexxon Ltd. denies the allegations of paragraph 34.

35. Dexxon Ltd. re-asserts its responses to paragraphs 1-19 as if fully set forth herein.

36. Dexxon Ltd. admits that a copy of the '505 patent, entitled "New Pharmaceutical Preparation For Oral Use," was attached to the Complaint as Exhibit B. Dexxon Ltd. further admits that the issue date set forth on the '505 patent is November 22, 1988, and that the '505 patent is assigned on its face to Aktiebolaget Hässle from inventors Lövgren, Pilbrant, Yasumura, Morigaki, Oda, and Ohishi. Dexxon Ltd. denies the remaining allegations in paragraph 36.

37. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 37 of the Amended Complaint and, therefore, denies such allegations.

38. Dexxon Ltd. admits that pursuant to 21 U.S.C. § 355(b) DPT Ltd. sent a letter to Plaintiffs Astrazeneca AB, Astrazeneca LP, and Aktiebolaget Hässle providing notice that DPT Ltd. filed NDA No. 22-032. This letter speaks for itself and, on that basis, Dexxon Ltd. denies the remaining allegations in paragraph 38.

39. Dexxon Ltd. denies that DPT Ltd.'s Second Notice of Certification fails to comply with the law and FDA rules and regulations. Dexxon Ltd. denies the remaining allegations in paragraph 39.

40. Dexxon Ltd. admits that DPT Ltd. certified that the '505 patent is not infringed by DPT Ltd.'s Tablets. Dexxon Ltd. denies the remaining allegations in paragraph 40.

41. Dexxon Ltd. denies the allegations of paragraph 41.

42. Dexxon Ltd. admits that DPT Ltd. is subject to 35 U.S.C. § 271(e)(2) as a result of filing NDA 22-031. Dexxon Ltd. denies the remaining allegations of paragraph 42.

43. Dexxon Ltd. denies the allegations of paragraph 43.

44. Dexxon Ltd. denies the allegations of paragraph 44.

45. Dexxon Ltd. denies the allegations of paragraph 45.

46. Dexxon Ltd. denies the allegations of paragraph 46.

47. Dexxon Ltd. denies the allegations of paragraph 47.

48. Dexxon Ltd. denies the allegations of paragraph 48.

49. Dexxon Ltd. denies the allegations of paragraph 49.

50. Dexxon Ltd. re-asserts its responses to paragraphs 1-19 as if fully set forth herein.

51. Dexxon Ltd. admits that a copy of the '230 patent, entitled "Pharmaceutical Formulations of Acid Labile Substances For Oral Use," was attached to the Complaint as Exhibit C. Dexxon Ltd. further admits that the issue date set forth on the '230 patent is August 1, 1989, and that the '230 patent is assigned on its face to Aktiebolaget Hässle from inventors Lövgren, Pilbrant, Yasumura, Morigaki, Oda, and Ohishi. Dexxon Ltd. denies the remaining allegations in paragraph 51.

52. Dexxon Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 52 of the Amended Complaint and, therefore, denies such allegations.

53. Dexxon Ltd. admits that pursuant to 21 U.S.C. § 355(b) DPT Ltd. sent a letter to Plaintiffs Astrazeneca AB, Astrazeneca LP, and Aktiebolaget Hässle providing notice that DPT Ltd. filed NDA No. 22-032. This letter speaks for itself and, on that basis, Dexxon Ltd. denies the remaining allegations in paragraph 53.

54. Dexxon Ltd. denies that DPT Ltd.'s Second Notice of Certification fails to comply with the law and FDA rules and regulations. Dexxon Ltd. denies the remaining allegations in paragraph 54.

55. Dexxon Ltd. admits that DPT Ltd. certified that the '230 patent is not infringed by DPT Ltd.'s Tablets. Dexxon Ltd. denies the remaining allegations in paragraph 55.

56. Dexxon Ltd. denies the allegations of paragraph 56.

57. Dexxon Ltd. admits that DPT Ltd. is subject to 35 U.S.C. § 271(e)(2) as a result of filing NDA 22-031. Dexxon Ltd. denies the remaining allegations of paragraph 57.

58. Dexxon Ltd. denies the allegations of paragraph 58.

59. Dexxon Ltd. denies the allegations of paragraph 59.

60. Dexxon Ltd. denies the allegations of paragraph 60.

61. Dexxon Ltd. denies the allegations of paragraph 61.

62. Dexxon Ltd. denies the allegations of paragraph 62.

63. Dexxon Ltd. denies the allegations of paragraph 63.

64. Dexxon Ltd. denies the allegations of paragraph 64.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, Dexxon Ltd. alleges the following affirmative defenses to the Complaint.

First Affirmative Defense

(Failure to State a Claim)

65. The complaint against Dexxon Ltd. fails to state a claim upon which relief can be granted.

Second Affirmative Defense

(Lack of Standing)

66. One or more of the Plaintiffs, including on information and belief KBI-E, Inc. and KBI Inc., lack standing to assert the claims in the Complaint.

Third Affirmative Defense

(Non-Infringement and Absence of Liability for Infringement)

67. The commercial manufacture, use, sale, offer for sale or importation of DPT Ltd.'s Tablets as set forth in DPT Ltd. NDA No. 22-032 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '380, '505, and/or '230 patents.

Fourth Affirmative Defense

(Patent Invalidity)

68. The claims of the '380 patent are invalid for failing to meet all applicable statutory requirements as conditions for patentability set forth in Part II of Title 35 of the United States Code.

REQUESTED RELIEF

WHEREFORE, Dexxon Ltd. prays for the following:

A. Judgment that Plaintiffs are entitled to none of the relief it requested in its Amended Complaint and judgment for Dexxon Ltd., and an order dismissing the complaint with prejudice;

B. A judgment and order declaring that the manufacture, use, sale, offer for sale, or importation of DPT Ltd.'s Tablets have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claims of the '380, '505, and '230 patents;

C. A judgment and order declaring that the claims of the '380 patent are invalid;

D. Costs and expenses in this action;

E. Attorneys fees as allowed by law; and

F. Such further relief as this Court may deem just and proper.

January 25, 2007

THE BAYARD FIRM

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CERTIFICATE OF SERVICE

The undersigned counsel certifies that, on January 25, 2007, he electronically filed the foregoing document with the Clerk of the Court using CM/ECF, which will send automatic notification of the filing to the following:

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The undersigned counsel further certifies that, on January 25, 2007, copies of the foregoing document were sent by email and hand to the above local counsel and by email and first class mail to the following non-registered participant:

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