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.	

DEXCEL PHARMA TECHNOLOGIES'S ANSWER TO THE AMENDED COMPLAINT

Defendant Dexcel Pharma Technologies ("DP Tech.") hereby responds to the Amended Complaint of Plaintiffs, Astrazeneca AB, Aktiebolaget Hässle, KBI-E, Inc., KBI Inc., and Astrazeneca LP ("Plaintiffs") as follows. The following Answer is provided on the basis of information held by Dexcel Pharma Technologies Ltd. ("DPT Ltd.") and applies only to the extent that the Court determines that DP Tech. independently has the capacity to be sued.

1. DP Tech. admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a). DP Tech. denies personal jurisdiction and venue in this district and division under 28 U.S.C. §§1391(b) (c), and 1400(b), inasmuch as DP Tech. is not a

legal entity and lacks capacity to be sued. DP Tech. admits that Plaintiffs purport to base remedies and relief on 28 U.S.C. §§ 2201, 2202 and 35 U.S.C. § 271.

2. DP Tech. admits that 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"). DP Tech. 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. DP Tech. otherwise denies the allegations in paragraph 2.

3. DP Tech. denies the allegations of paragraph 3.

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

6. DP Tech. denies the allegations of paragraph 6.

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

8. DP Tech. denies personal jurisdiction and venue in this district under 28 U.S.C. §§1391(b) (c) (d), and 1400(b), inasmuch as DP Tech. is not a legal entity and lacks capacity to be sued.

9. DP Tech. 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. DP Tech. admits that the '505 patent and the '230 patent are assigned on their face to Aktibolaget Hässle ("Hässle"). DP Tech. 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. DP Tech. admits that the entity identified as Astrazeneca has listed patents in the FDA Orange Book for PRILOSEC® and PRILOSEC OTC®. DP Tech. 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. DP Tech. 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. DP Tech. 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. DP Tech. admits that Dexcel, Ltd. is an Israeli entity having its headquarters and principal place of business at the Southern Industrial Zone, Or-Akiva, Israel 30600. DP Tech. denies the remaining allegations in paragraph 14.

15. DP Tech. 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. DP Tech. denies the remaining allegations in paragraph 15.

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

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

19. DP Tech. 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. DP Tech. re-asserts its responses to paragraphs 1-19 as if fully set forth herein.

21. DP Tech. admits that a copy of the '380 patent, entitled "Crystalline Form of Omeprazole," was attached to the Amended Complaint as Exhibit A. DP Tech. 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. DP Tech. denies the remaining allegations in paragraph 21.

22. DP Tech. 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. DP Tech. 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, DP Tech. denies the remaining allegations in paragraph 23.

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

25. DP Tech. denies the allegations of paragraph 25.

26. DP Tech. denies the allegations of paragraph 26.

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

28. DP Tech. denies the allegations of paragraph 28.

29. DP Tech. denies the allegations of paragraph 29.

30. DP Tech. denies the allegations of paragraph 30.

31. DP Tech. denies the allegations of paragraph 31.

32. DP Tech. denies the allegations of paragraph 32.

33. DP Tech. denies the allegations of paragraph 33.

34. DP Tech. denies the allegations of paragraph 34.

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

36. DP Tech. admits that a copy of the '505 patent, entitled "New Pharmaceutical Preparation For Oral Use," was attached to the Complaint as Exhibit B. DP Tech. 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. DP Tech. denies the remaining allegations in paragraph 36.

37. DP Tech. 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. DP Tech. 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, DP Tech. denies the remaining allegations in paragraph 38.

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

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

41. DP Tech. denies the allegations of paragraph 41.

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

43. DP Tech. denies the allegations of paragraph 43.

44. DP Tech. denies the allegations of paragraph 44.

45. DP Tech. denies the allegations of paragraph 45.

46. DP Tech. denies the allegations of paragraph 46.

47. DP Tech. denies the allegations of paragraph 47.

48. DP Tech. denies the allegations of paragraph 48.

49. DP Tech. denies the allegations of paragraph 49.

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

51. DP Tech. 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. DP Tech. 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. DP Tech. denies the remaining allegations in paragraph 51.

52. DP Tech. 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. DP Tech. 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, DP Tech. denies the remaining allegations in paragraph 53.

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

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

56. DP Tech. denies the allegations of paragraph 56.

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

58. DP Tech. denies the allegations of paragraph 58.

59. DP Tech. denies the allegations of paragraph 59.

60. DP Tech. denies the allegations of paragraph 60.

61. DP Tech. denies the allegations of paragraph 61.

62. DP Tech. denies the allegations of paragraph 62.

63. DP Tech. denies the allegations of paragraph 63.

64. DP Tech. denies the allegations of paragraph 64.

AFFIRMATIVE DEFENSES

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

First Affirmative Defense

(Lack of Capacity to be Sued)

65. DP Tech. is not a legal entity and lacks capacity to be sued.

Second Affirmative Defense

(Failure to State a Claim)

66. The complaint against DP Tech. fails to state a claim upon which relief can be granted.

Third Affirmative Defense

(Lack of Personal Jurisdiction)

67. DP Tech. is not subject to personal jurisdiction in the District of Delaware.

Fourth Affirmative Defense

(Lack of Standing)

68. 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.

Fifth Affirmative Defense

(Non-Infringement and Absence of Liability for Infringement)

69. 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.

Sixth Affirmative Defense

(Patent Invalidity)

70. 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, DP Tech. prays for the following:

A. Judgment that Plaintiffs are entitled to none of the relief it requested in its Amended Complaint and judgment for DP Tech., 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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