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 LTD.'S
ANSWER TO THE AMENDED COMPLAINT AND COUNTERCLAIM

Defendant Dexcel Pharma Technologies Ltd. ("DPT 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. DPT 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). DPT Ltd. denies personal jurisdiction and venue in this district and division under 28 U.S.C. §§1391(b) (c), and 1400(b). DPT Ltd.'s principal place of business is in Norfolk, Virginia. However, for the purposes of this litigation only, DPT Ltd. waives any

objections to personal jurisdiction in this judicial district. DPT Ltd. admits that Plaintiffs purport to base remedies and relief on 28 U.S.C. §§ 2201, 2202 and 35 U.S.C. § 271.

2. DPT Ltd. admits that it 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"). DPT 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. DPT Ltd. otherwise denies the allegations in paragraph 2.

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

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

5. DPT Ltd. admits that it intends to act in a manner consistent with its First and Second Notice of Certification. DPT Ltd. otherwise denies the allegations of paragraph 5.

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

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

8. DPT 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, DPT Ltd. waives any objections to personal jurisdiction in this judicial district.

9. DPT 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. DPT Ltd. admits that the '505 patent and the '230 patent are assigned on their face to Aktibolaget Hässle ("Hässle"). DPT 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. DPT Ltd. admits that the entity identified as Astrazeneca has listed patents in the FDA Orange Book for PRILOSEC® and PRILOSEC OTC®. DPT 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. DPT 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. DPT 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. DPT Ltd. 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. DPT Ltd. denies the remaining allegations in paragraph 14.

15. DPT 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. DPT Ltd. denies the remaining allegations in paragraph 15.

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

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

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

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

22. DPT 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. DPT 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, DPT Ltd. denies the remaining allegations in paragraph 23.

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

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

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

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

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

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

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

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

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

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

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

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

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

37. DPT 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. DPT Ltd. admits that pursuant to 21 U.S.C. § 355(b) it 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, DPT Ltd. denies the remaining allegations in paragraph 38.

39. DPT Ltd. denies the allegations of paragraph 39.

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

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

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

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

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

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

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

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

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

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

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

51. DPT 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. Dexcel 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. DPT Ltd. denies the remaining allegations in paragraph 51.

52. DPT 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. DPT Ltd. admits that pursuant to 21 U.S.C. § 355(b) it 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, DPT Ltd. denies the remaining allegations in paragraph 53.

54. DPT Ltd. denies the allegations in paragraph 54.

55. DPT Ltd. admits that allegation that it has certified that the '230 patent is not infringed by DPT Ltd.'s Tablets.

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

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

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

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

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

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

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

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

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

AFFIRMATIVE DEFENSES

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

First Affirmative Defense

(Lack of Standing)

65. 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.

Second Affirmative Defense

(Non-Infringement and Absence of Liability for Infringement)

66. 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.

Third Affirmative Defense

(Patent Invalidity)

67. 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, DPT Ltd. prays for the following:

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

COUNTERCLAIM

THE PARTIES

1. Counterclaim-Plaintiff Dexcel Pharma Technologies Ltd. ("DPT Ltd.") is a corporation organized and existing under the laws of the United States, with a principal place of business at Wainwright Building, 229 West Bute Street, Suite 407, Norfolk, Virginia 23510.

2. Based upon the allegations in the Amended Complaint in this case, Counterclaim-Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden.

3. Based upon the allegations in the Amended Complaint in this case, Counterclaim-Defendant Aktiebolaget Hässle ("Hässle) is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

4. Based upon the allegations in the Amended Complaint in this case, Counterclaim-Defendant AstraZeneca LP is a company organized and existing under the laws of Delaware, having its principal place of business at Wilmington, DE.

JURISDICTION AND VENUE

5. This counterclaim is an action for a declaratory judgment of patent invalidity and non-infringement arising under the patent laws of the United States, Title 35 of the United States Code.

6. The Court has jurisdiction over the subject matter of this counterclaim under the Declaratory Judgment Act and the Patent Laws of the United States based on 28 U.S.C. §§1331, 1338(a), 1391(b) and 1400(b), and 28 U.S.C. §§ 2201 and 2202.

7. Venue properly lies within the District of Delaware under 28 U.S.C. §§ 1391(c) and 1400(b).

8. On May 30, 2006, Plaintiffs sued DPT Ltd. in this District alleging infringement of the '380 '505, and '230 patents.

9. On January 5, 2007, Plaintiffs filed an Amended Complaint in this District alleging infringement of the '380 '505, and '230 patents.

10. There is an actual, substantial, and continuing justiciable case or controversy between DPT Ltd. and the Counterclaim-Defendants regarding the non-infringement and alleged validity of the '380 '505, and '230 patents.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY)

11. Counterclaim-Plaintiff DPT Ltd. repeats and realleges paragraphs 1 through 10 of the Counterclaim, inclusive, as though fully set forth herein and incorporates them by reference.

12. On November 21, 2000, the United States Patent and Trademark Office ("PTO") issued United States Patent No. 6,150,380 ("the '380 patent"), entitled "Crystalline Form of Omeprazole," to Karin Lövqvist, Funnel Sundén, David Noreland and Ingvar Ymén.

13. Based upon the allegations in the Amended Complaint in this case, Counterclaim-Defendant AstraZeneca AB owns and has the right to enforce the '380 patent.

14. On November 22, 1988, and August 1, 1989, the PTO issued United States Patent Nos. 4,786,505 ("the '505 patent") and 4,853,230 ("the '230 patent"), respectively. The '505 patent is entitled "New Pharmaceutical Preparation For Oral Use," and the '230 patent is entitled "Pharmaceutical Formulations of Acid Labile Substances For Oral Use." The '505 and '230 patents were issued to Kurt Lövgren, Ake Pilbrant, Mitsura Yasumura, Satoshi Morigaki, Miaora Oda, and Naohiro Ohishi.

15. Based upon the allegations in the Amended Complaint in this case, Counterclaim-Defendant Hässle owns and has the right to enforce, the '505 and '230 patents.

16. DPT Ltd., has not infringed, does not infringe, and would not infringe any valid and/or enforceable claim of the '380 '505, and '230 patent through the manufacture, use, sales, offer for sale, marketing, or importation of the 20 mg delayed-release omeprazole tablets ("DPT Ltd.'s Tablets") that are the subject of DPT Ltd.'s NDA No. 22-032.

17. DPT Ltd. is entitled to a judicial declaration that it has not infringed, does not infringe, and would not infringe any valid and/or enforceable claim of '380 '505, and '230 patents through the manufacture, use, sale, offer for sale, and/or importation of DPT Ltd.'s Tablets that are the subject of DPT Ltd.'s NDA No. 22-032.

18. The claims of the '380 patent are invalid for failure to comply with one or more of the applicable statutory requirement as conditions for patentability set forth in Part II of Title 35 of the United States Patent Code.

19. Unless DPT Ltd.'s Tablets are found not to infringe the claims of the '380, '505, and '230 patents, or unless said patent claims are adjudged invalid, DPT Ltd. will be prohibited from commercially marketing its Tablets to the detriment of DPT Ltd. and the public. As such, DPT Ltd. is entitled to a judicial decision that the claims of the '380, '505, and '230 patents are invalid or non-infringed.

PRAYER FOR RELIEF

WHEREFORE, DPT Ltd. prays for the following:

A. Judgment and order dismissing the Amended Complaint with prejudice; (and judgment entered in favor of DPT Ltd.;

B. A judgment and order declaring that the manufacture, use, sale, offer for sale, or importation of DPT Ltd.'s Tablets that are the subject of DPT Ltd.'s NDA No. 22-032 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

/s/ Richard D. Kirk (rk0922)
Richard D. Kirk (#922)
Ashley B. Stitzer (#3891)
222 Delaware Avenue, Suite 900
Wilmington, DE 19899-5130
(302) 655-5000
Counsel for Defendants

OF COUNSEL:
Robert F. Green, Esquire
David M. Airan, Esquire
Saumil S. Mehta, Esquire
LEYDIG, VOIT & MAYER
Two Prudential Plaza
180 N. Stetson Avenue, Suite 4900
Chicago, IL 60601
(312) 616-5000

Edgar H. Haug, Esquire
Dillon Kim, Esquire
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Michael F. Brockmeyer, Esquire
Elizabeth A. Leff, Esquire
FROMMER LAWRENCE & HAUG LLP
1667 K Street, NW
Washington, D.C. 20006
(202) 292-1530

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:

Jack B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19801

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:

Errol B. Taylor, Esq.
Robert J. Koch, Esq.
Jay I. Alexander, Esq.
Enrique D. Longton, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1850 K Street NW
Washington, DC 20006

/s/ Richard D. Kirk (rk0922)
Richard D. Kirk