**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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

**DEXCEL LTD.'S ANSWER TO AMENDED COMPLAINT**

Defendant Dexcel 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. Dexcel 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). Dexcel Ltd. denies personal jurisdiction and venue in this district and division under 28 U.S.C. §§1391(b) (c), and 1400(b). Dexcel Ltd. is an Israeli entity and is not subject to personal jurisdiction in this district. However, for the purposes of this litigation only, Dexcel Ltd. waives any objections to personal jurisdiction in this judicial district.

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

2. Dexcel 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"). Dexcel 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. Dexcel Ltd. otherwise denies the allegations in paragraph 2.

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

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

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

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

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

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

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

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

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

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

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

22. Dexcel 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. Dexcel Ltd. admits that pursuant to 21 U.S.C. § 355(b) DPT Ltd. sent a letter to Plaintiffs Astrazeneca AB and Aktiebolaget Hässle, providing notice that DPT Ltd. filed NDA No. 22-032. This letter speaks for itself and, on that basis, Dexcel 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. Dexcel Ltd. denies the allegations of paragraph 25.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**AFFIRMATIVE DEFENSES**

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

**First Affirmative Defense**

**(Failure to State a Claim)**

65. The complaint against Dexcel 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, Dexcel 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 Dexcel 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

/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