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

DEXCEL PHARMA TECHNOLOGIES LTD.'S SECOND AMENDED ANSWER TO THE AMENDED COMPLAINT AND AMENDED COUNTERCLAIMS

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 Israel and its U.S. office 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 Aktiebolaget 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. admits that its principal place of business at the Southern Industrial Zone, Or-Akiva, Israel 30600. 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. DPT 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 Aktiebolaget 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. DPT Ltd. denies that DPT Ltd.'s First Notice of Certification fails to comply with the law and FDA rules and regulations. DPT 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. DPT 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.

Fourth Affirmative Defense

(Inequitable Conduct)

68. All claims of the '380 patent are unenforceable because of Astra's inequitable conduct before the U.S. Patent and Trademark Office (USPTO) in the procurement of the '380 patent.

69. As set forth below with particularity, while the application that led to the '380 patent was being examined in the USPTO, Astra intentionally withheld from the Patent Examiner information that it knew to be material to patentability, and did so in order to deceive the Examiner. Moreover, Astra made material misrepresentations (including misrepresentations through omission) about information that it did provide to the Patent Examiner, also with an intent to deceive.

70. On December 10, 1998, Astra Aktiebolag ("Astra") filed U.S. Application No. 09/202,251 ("the '251 application").

71. The '251 application issued as the '380 patent.

72. On information and belief, the '380 patent is currently assigned to Plaintiff AstraZeneca AB.

73. During prosecution of the '251 application, the Patent Examiner rejected the claims of the '251 application under 35 U.S.C. § 103 for being obvious over various prior art references. In making the obviousness rejection, the Patent Examiner advised "that a new form of an old known compound is unpatenable (*sic*-unpatentable) unless side by side comparable are done to demonstrate some unexpected advantages."

74. During prosecution of the '251 application, representatives of Astra attended, in April 2000, an in person Examiner Interview during which they argued that the claimed form A omeprazole demonstrates "unexpected advantages" over prior art form B omeprazole. During the meeting, the Examiner and Astra representatives agreed that Astra would submit a declaration showing the "unexpected advantages" of form A over form B.

75. The representatives of Astra present at the Examiner Interview included Dr. Frans Langkilde, an analytical chemist who worked in the Solid State Analysis division of AstraZeneca in Mölndal, Sweden during the development of the invention recited by the '380 patent.

76. In 1998, 37 CFR § § 1.51, 1.56, 1.97 and 1.98 imposed a "duty of candor and good faith" in dealing with the USPTO upon each person who is substantively involved in the prosecution of a patent application and is associated with an inventor, and "encouraged" all persons substantively involved in the prosecution of the patent to file an Information Disclosure Statement ("IDS") containing "...a listing of patents, publications or other information..." known to the person and "[a] concise explanation of the relevance of each listed item..." as means of complying with that duty.

77. Because Dr. Langkilde was substantively involved in the prosecution of the '251 application and associated with the lead inventor of the '251 application, Dr. Karin Lovqvist, Dr. Langkilde was bound by the duty of candor and good faith in dealing with the USPTO.

78. Following the Examiner Interview and in response to the outstanding Office Action, on April 28, 2000 Astra filed three papers with the USPTO: (1) an Amendment, (2) an Information Disclosure Statement ("IDS"), and (3) a Declaration under 37 C.F.R. §1.132 of Frans W. Langkilde ("the Langkilde Declaration").

79. The Langkilde Declaration included a side by side comparison of certain physical chemical properties of "form A" omeprazole and omeprazole of the "prior art". Dr. Langkilde, in his declaration, identified the prior art as being the omeprazole described by Ohishi et al. Acta. Cryst. (1989), 1921-1923 ("Ohishi") which Dr. Langkilde referred to as "omeprazole form B." Dr. Langkilde further stated in his Declaration before the USPTO that the samples of "form A" omeprazole and "form B" omeprazole used for the comparative study were prepared in accordance with Examples 1 and 2, respectively, of the '251 application.

80. Dr. Langkilde in his declaration presented comparative data on thermodynamic stability and hygroscopicity. Dr. Langkilde asserted based on that comparative data that omeprazole "form A" was more thermodynamically stable than omeprazole "form B," and that unlike "form B" omeprazole, "form A" omeprazole was "essentially non-hygroscopic."

REDACTED

REDACTED

REDACTED

88. The Amendment dated April 28, 2000, which accompanied Dr. Langkilde's declaration, asserted that the thermodynamic stability and hygroscopicity data presented in Dr. Langkilde's declaration represented "a ***greater than expected result***" (emphasis in original) and that "[i]n view of these advantageous properties, the claimed omeprazole form A is particularly suitable as the active ingredient in pharmaceutical formulations for treating gastric acid related conditions."

89. In response to the three papers submitted to the USPTO on April 28, 2000, the USPTO issued a Notice of Allowability and Notice of Allowance of the '251 application.

90. On November 21, 2000, the USPTO issued the '251 application as the '380 patent.

91. Astra benefited from the submission of the Langkilde Declaration, because Dr. Langkilde's conclusions resulted in allowance of the '251 application and issuance of the '380 patent.

REDACTED

93. Astra's misrepresentation of material information regarding the comparative data presented by Dr. Langkilde in his declaration was intentional and amounts to inequitable conduct.

94. As a result of Astra's inequitable conduct, and at least specifically Dr. Langkilde's inequitable conduct, in conjunction with the prosecution of the '251 application, the '380 patent is unenforceable.

* * *

REDACTED

REDACTED

97. **REDACTED**

98. **REDACTED**

99. **REDACTED**

REDACTED

REDACTED

105. In the IDS dated April 28, 2000 submitted to the USPTO following the Examiner Interview, the Astra attorney prosecuting the '251 application stated that upon the discovery of omeprazole form A, Astra performed analyses of batch samples of omeprazole prepared by "Applicants" as a bulk substance prior to the discovery of omeprazole form A, which analyses revealed the presence of both omeprazole form A omeprazole and omeprazole form B in the bulk substance. The prosecuting attorney further stated that Astra believed that the claimed omeprazole form A may be present in prior art pharmaceutical formulations comprising omeprazole which were in public use or on sale prior to the filing of the '251 application, but that Astra was not able to measure or determine the weight percentage of Form A omeprazole in the commercial formulations of omeprazole, so could not verify the prior sale of Form A omeprazole.

106. In the IDS, the Astra attorney prosecuting the '251 application characterized prior art omeprazole (omeprazole form B) as being represented by the

omeprazole disclosed in Ohishi, consistent with the Langkilde Declaration.

REDACTED

REDACTED

REDACTED

113. As a result of Astra's inequitable conduct, and specifically Dr. Langkilde's inequitable conduct, in conjunction with the prosecution of the '251 application, the '380 patent is unenforceable.

* * *

REDACTED

REDACTED

121. Astra benefited from the submission of the Langkilde Declaration, because Dr. Langkilde's conclusions resulted in allowance of the '251 application and issuance of the '380 patent.

REDACTED

123. As a result of Astra's inequitable conduct, and specifically Dr. Langkilde's inequitable conduct, in conjunction with the prosecution of the '251 application, the '380 patent is unenforceable.

REQUESTED RELIEF

WHEREFORE, DPT 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 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. A judgment and order declaring that the '380 patent is unenforceable as a result of Plaintiffs' inequitable conduct;

E. Costs and expenses in this action;

F. Attorneys fees as allowed by law; and

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

DEXCEL PHARMA TECHNOLOGIES LTD.'S FIRST AMENDED COUNTERCLAIM

Counterclaim-Plaintiff Dexcel Pharma Technologies Ltd. ("DPT Ltd."), by and through its attorneys, for its counterclaims against Counterclaim-Defendants, AstraZeneca AB, Aktiebolaget Hässle, KBI-E, INC., KBI INC. and AstraZeneca LP (collectively "AstraZeneca"), hereby alleges as follows.

NATURE OF THE ACTION

124. This counterclaim arises out of AstraZeneca's unlawful scheme to monopolize and attempt to monopolize the United States market for over-the-counter omeprazole products. Upon information and belief, AstraZeneca's sales of its branded over-the-counter omeprazole product, Prilosec OTC® tablets, exceed $800,000,000 per year, and AstraZeneca has protected its monopoly power in the market by illegally excluding competition from DPT Ltd.'s generic over-the-counter omeprazole product.

125. As part of its unlawful scheme, AstraZeneca procured a patent by fraud and filed objectively baseless patent infringement lawsuits against DPT Ltd. (and parties related to DPT Ltd.) despite the underlying patents in these lawsuits being invalid, unenforceable or not infringed by DPT Ltd. AstraZeneca filed these baseless lawsuits solely for the purpose of delaying and obstructing DPT Ltd.'s legitimate and lawful launch of a generic over-the-counter omeprazole product in competition with AstraZeneca's Prilosec OTC® tablets.

126. AstraZeneca furthered its illegal scheme by conducting the present lawsuit in such a manner to prevent the Court from timely adjudicating AstraZeneca's own claims of patent infringement. As detailed below, AstraZeneca deliberately failed to abide by its discovery obligations and interfered with discovery sought by DPT Ltd., including third-party discovery directed to AstraZeneca's business partners, aaiPharma Inc. ("aaiPharma") and Merck & Co., Inc. ("Merck").

127. AstraZeneca's assertion of a patent procured by fraud and its baseless infringement actions against DPT Ltd. and the delay in advancing them to trial benefited AstraZeneca to the detriment of competition by delaying the entry of DPT Ltd.'s over-the-counter omeprazole product into the United States market. As a result of AstraZeneca's illegal activity, United States consumers have been improperly denied the benefits that competition by DPT Ltd.'s over-the-counter omeprazole product would provide.

THE PARTIES

128. Counterclaim-Plaintiff Dexcel Pharma Technologies Ltd. is a corporation organized and existing under the laws of the State of Israel, having its principal place of business in the State of Israel and its United States office at the Wainwright Building, 229 West Bute Street, Suite 407, Norfolk, Virginia 23510.

129. Counterclaim-Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden.

130. 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.

131. Counterclaim-Defendant KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

132. Counterclaim-Defendant KBI-E Inc. ("KBI-E") is a Delaware corporation having its principal place of business at Wilmington, Delaware.

133. 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

134. 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, and for damages, injunctive relief and other remedies as available for violations of the Sherman Act, 15 U.S.C. § 2 and violations of the Lanham Act, 15 U.S.C. § 1125(a).

135. 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. This Court has jurisdiction over the antitrust claims for relief under section 2 of the Sherman Act, 15 U.S.C. § 2, sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337, and for claims arising under the Lanham Act 15 U.S.C. §§ 1051 et seq. pursuant to 15 U.S.C. § 1121. This Court further has supplemental

jurisdiction over the remaining claim for relief under state and common law pursuant to 28 U.S.C. § 1367.

136. Venue properly lies within the District of Delaware under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391 and 1400(b).

137. On May 30, 2006, AstraZeneca sued DPT Ltd. in this District alleging infringement of U.S. Patent Nos. 6,150,380 ("the '380 patent"), 4,786,505 ("the '505 patent") and 4,853,230 ("the '230 patent") (collectively the "patents in suit").

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

139. There is an actual, substantial, and continuing justiciable case or controversy between DPT Ltd. and AstraZeneca regarding the non-infringement and alleged validity of the patents in suit.

ASTRAZENECA'S SCHEME TO IMPEDE GENERIC COMPETITION

140. AstraZeneca has engaged in a pattern of predatory conduct in order to prevent generic competition to its various product offerings. In particular, upon information and belief, AstraZeneca and its business partners have sold over $2,000,000 per day for every day that generic competition has been kept out of the United States market for over-the-counter omeprazole products.

141. Because, upon information and belief, DPT Ltd. is the first and only entity that has sought and received tentative approval from the FDA to market a generic version of an over-the-counter omeprazole product, AstraZeneca has a particular interest in preventing DPT Ltd. from launching its generic over-the-counter omeprazole product in the United States.

142. On January 27, 2000, AstraZeneca and its marketing partner, Procter & Gamble, jointly applied to the FDA for approval to market Prilosec OTC. On June 20, 2003, the FDA approved the sale of Prilosec OTC. The FDA awarded AstraZeneca three years of exclusivity in the over-the-counter omeprazole market because of safety studies

performed and submitted by AstraZeneca. AstraZeneca (through its distributor Procter & Gamble) began selling Prilosec OTC tablets in September 2003.

143. DPT Ltd.'s affiliates currently sell generic over-the-counter omeprazole products in several jurisdictions throughout the world. In an effort to stop these sales in Israel, AstraZeneca filed a patent infringement lawsuit in Israel. AstraZeneca ultimately conceded that the Israeli omeprazole tablet formulation did not infringe any Israeli patents owned or controlled by AstraZeneca, including the Israeli patent counterparts to the '505 and '230 patents that AstraZeneca accused DPT Ltd. of infringing in this action.

144. Notwithstanding its litigation outcome in Israel, AstraZeneca nevertheless filed two baseless patent infringement lawsuits against DPT Ltd. in the United States to delay DPT Ltd.'s introduction of a generic over-the-counter omeprazole product in the United States market. AstraZeneca filed and conducted these lawsuits with the purpose of delaying DPT Ltd. from offering its over-the-counter omeprazole product in the United States.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT, INVALIDITY, AND INEQUITABLE CONDUCT)

145. Counterclaim-Plaintiff DPT Ltd. repeats and realleges paragraphs 1 through 144, inclusive, as though fully set forth herein and incorporates them by reference.

146. On November 21, 2000, the United States Patent and Trademark Office ("PTO") issued the '380 patent, entitled "Crystalline Form of Omeprazole," to Karin Lövqvist, Funnel Sundén, David Noreland and Ingvar Ymén.

147. Counterclaim-Defendant AstraZeneca AB owns and has the right to enforce the '380 patent.

148. On November 22, 1988 and August 1, 1989, the PTO issued the '505 patent and 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.

149. 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.

150. DPT Ltd. has not infringed, does not infringe, and would not infringe any valid and/or enforceable claim of the patents in suit through the manufacture, use, sale, offer for sale, marketing, and/or importation of generic 20 mg delayed-release over-the-counter omeprazole tablets ("DPT Ltd.'s Tablets") that are the subject of DPT Ltd.'s NDA No. 22-032.

151. 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 the patents in suit through the manufacture, use, sale, offer for sale, marketing, and/or importation of DPT Ltd.'s Tablets that are the subject of DPT Ltd.'s NDA No. 22-032.

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

REDACTED

154. Unless DPT Ltd.'s Tablets are found not to infringe the claims of the patents in suit, or unless said patent claims are adjudged invalid, DPT Ltd. will be prohibited from commercially marketing DPT Ltd.'s 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 patents in suit are invalid or non-infringed.

COUNT II

(MONOPOLIZATION IN VIOLATION OF THE SHERMAN ACT 15 U.S.C. § 2)

155. DPT Ltd. repeats and realleges paragraphs 1 through 154, inclusive, as though fully set forth herein and incorporates them by reference.

156. This Counterclaim seeks treble damages and other relief arising out of AstraZeneca's unlawful monopolization of the market for over-the-counter omeprazole products. AstraZeneca's continuing anticompetitive and exclusionary conduct has delayed and hindered entry of generic drugs capable of competing with AstraZeneca's lucrative branded monopoly for Prilosec OTC® tablets.

157. Among other things, AstraZeneca has: (1) improperly obtained a patent through fraudulent and inequitable conduct; (2) abused FDA regulations to block generic entry into the market for over-the-counter omeprazole products by improperly listing a patent in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book;" (3) unlawfully failed to delist the improperly listed patent from the Orange Book; and (4) filed and pursued in bad faith a patent infringement action based on a patent that AstraZeneca knew to be invalid and unenforceable due to invalidating prior art and to fraud and inequitable conduct in the PTO; (5) filed, and pursued in bad faith and in a dilatory fashion, objectively baseless patent infringement lawsuits in federal court against DPT with the subjective intent to maintain its monopoly of the market for over-the-counter omeprazole products.

158. The pharmaceutical products at issue in this case are sold in interstate commerce, and the unlawful activities alleged in this Counterclaim have occurred in, and have had a substantial effect upon, interstate commerce.

159. Counterclaim Defendant AstraZeneca AB submitted and has at all relevant times maintained a listing of U.S. Patent Nos. 6,150,380 ("the '380 patent"), 4,786,505 ("the '505 patent") and 4,853,230 ("the '230 patent") patents in the Orange Book for Prilosec OTC® in 20 mg dosage strengths.

160. Upon information and belief, AstraZeneca knew at the time of the listing that the '380 patent was invalid and unenforceable due to fraud and inequitable conduct, and AstraZeneca in bad faith caused the listing of the '380 patent in the Orange Book. Despite AstraZeneca's knowledge that the '380 patent is invalid and unenforceable due to fraud and inequitable conduct, it has not withdrawn the Orange Book listing for the '380 patent.

161. DPT Ltd. developed its omeprazole NDA and submitted NDA No. 22-032 to the FDA pursuant to 21 U.S.C. § 355(b) seeking approval to market DPT Ltd.'s Tablets. DPT Ltd. certified that the patents in suit are invalid, unenforceable, and/or not infringed by DPT Ltd.'s Tablets ("the Paragraph IV certification"). The title to and beneficial ownership of that NDA and any FDA approval thereof vests in DPT Ltd.

162. In notification letters dated April 17, 2006 and May 4, 2006, DPT Ltd. provided notice to AstraZeneca of the filing of the Paragraph IV certification and that DPT Ltd. intended to market DPT Ltd.'s Tablets before the expiration of the patents in suit.

163. In response to DPT Ltd.'s Paragraph IV certification, AstraZeneca filed the present patent infringement action on May 30, 2006, which it amended on January 5, 2007. In the Complaint and Amended Complaint, AstraZeneca alleged that DPT Ltd.'s Tablets, if approved by the FDA, will infringe the patents in suit.

164. At the time it filed the present action and at the time it filed the Amended Complaint, AstraZeneca knew that it could not reasonably succeed on the merits in a litigation to enforce the patents in suit. At such times, among other things, AstraZeneca knew:

a. DPT Ltd.'s Tablets did not infringe the '505 and '230 patents because DPT Ltd.'s Tablets lack the "subcoating" layer required by each claim of these patents; and

b. The '380 patent was invalid due to commercial activities occurring in the United States prior to November 10, 1997; and

c. The '380 patent was unenforceable due to fraud and inequitable conduct as a result of AstraZeneca's failure to disclose and present prior art, misrepresentation of prior art and submission of false and misleading data.

The discovery that AstraZeneca obtained from DPT Ltd. and others further confirmed its knowledge that it could not reasonably succeed on the merits of its litigation against DPT Ltd.

165. AstraZeneca commenced and continues to prosecute the predatory, anticompetitive, and objectively baseless litigation in bad faith, and with the subjective intent to interfere with the business of DPT Ltd., by improperly barring DPT Ltd. from entering the relevant market. For example, DPT Ltd. offered AstraZeneca samples of DPT Ltd.'s Tablets for testing, but AstraZeneca deliberately avoided testing the samples to determine if they had a subcoating. AstraZeneca directed its lawsuit in such a way as to perpetuate its unlawful monopoly of the relevant market in violation of section 2 of the Sherman Act, 15 U.S.C. § 2, and not for the legitimate purpose of enforcing its respective patents.

166. AstraZeneca caused the predatory and anticompetitive listing and continued listing of the '380 patent in the Orange Book in bad faith and with the intent and subjective motivation of causing its generic competitors, including DPT Ltd., to file paragraph IV certifications with the FDA, in response to which AstraZeneca would commence sham litigation to obtain an automatic 30-month stay barring generic competitors, including DPT Ltd., from entering the relevant market and not for the legitimate purpose of enforcing a valid patent.

167. By its sham Orange Book listing and continued listing of the '380 patent, AstraZeneca has engaged in anticompetitive and exclusionary conduct to maintain its monopoly in the relevant market in violation of section 2 of the Sherman Act, 15 U.S.C. § 2.

168. AstraZeneca obtained the '380 patent by intentionally defrauding the U.S. Patent and Trademark Office.

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But for AstraZeneca's improper and intentional conduct, the U.S. Patent and Trademark Office would not have issued the '380 patent.

169. AstraZeneca commenced and continues to prosecute this predatory, anti-competitive, and objectively baseless litigation in bad faith because AstraZeneca knew that it procured the '380 patent by fraud. In pursuing this litigation, AstraZeneca had the specific intent and subjective motivation of interfering with the business of DPT Ltd. by improperly obtaining the automatic 30-month injunction barring DPT Ltd. from entering the relevant market. AstraZeneca has done so to perpetuate its unlawful monopoly of the relevant market in violation of 15 U.S.C. § 2 and not for the legitimate purpose of enforcing a valid and enforceable patent.

170. AstraZeneca further has purposefully engaged in dilatory tactics to delay resolution of the present litigation, including, inter alia, the following:

a. improperly filing duplicative lawsuits, including this action, *AstraZeneca AB et al. v. Dexcel, Ltd. et al.*, Civil Case No. 1:06-358, pending in the United States District Court for the District of Delaware ("the Delaware action") and another identical action, *AstraZeneca AB et al. v. Dexcel, Ltd. et al.*, Civil Case No. 1:06-634, pending in the U.S. District Court for Eastern District of Virginia ("the Virginia action");

b. seeking to assign and consolidate both the Delaware action and the Virginia action with much more advanced multidistrict litigation pending in the Southern District of New York, MDL-1291;

c. misrepresenting to the Judicial Panel on Multidistrict Litigation that its Delaware and Virginia actions were tag-along actions to MDL-1291, when in fact these litigations were not;

d. refusing to comply with discovery deadlines and obligations in the Virginia action and seeking a stay of the Virginia action after filing it;

e. refusing to comply with court orders, including a court order to schedule the Astra 30(b)(6) deposition taken through Dr. Langkilde, discovery deadlines and obligations in this action and delaying production and inspection of key documents, including a New Drug Application and Drug Master File ("NDA/DMF") that AstraZeneca agreed to produce and which the Court in this action ordered to be produced;

f. asserting in bad faith that the NDA/DMF contained no "relevant" information to disputed issues in this action when in fact such documents contain highly relevant information;

g. interfering with and inhibiting third-party discovery, including discovery directed to its partners, licensees and attorneys; and

h. refusing to comply with a court order to provide DPT Ltd. with its contentions regarding the alleged infringement of the '380 patent.

171. AstraZeneca further willfully obstructed DPT Ltd.'s ability to access documents even after their production. In particular, AstraZeneca belatedly produced the NDA/DMF in an electronic form that integrated multiple different documents and volumes into a single file spanning more than one hundred and seventy thousand pages. On information and belief, AstraZeneca created this large and unwieldy electronic file

with the intent of causing DPT Ltd. undue expense and delay of the review of the information therein.

172. AstraZeneca continually insisted on the production of many irrelevant documents, while at the same time refusing to produce even basic information, for the sole purpose of delaying the trial, in the knowledge that the two formulation patents would not then be litigated due to their expiry.

173. The relevant product market in which to assess the anticompetitive effects of AstraZeneca's conduct is the market for over-the-counter omeprazole products, including Prilosec OTC® tablets and generic bioequivalent over-the-counter omeprazole products. There is cross-elasticity of demand between Prilosec OTC® and generic over-the-counter omeprazole products, including DPT Ltd.'s Tablets, because consumers would substitute generic over-the-counter omeprazole products for Prilosec OTC® tablets.

174. Over-the-counter omeprazole products constitute a distinct relevant product market because, unlike other over-the-counter heartburn medications, over-the-counter omeprazole products directly shut down many active acid pumps and they work for up to 24 hours with one pill per day. Other over-the-counter heartburn medications are not reasonably interchangeable with over-the-counter omeprazole products due to price, use, qualities, characteristics, and/or distinct end users.

175. Over-the-counter omeprazole products constitute a distinct relevant product market from prescription omeprazole products because a consumer can readily and immediately purchase over-the-counter omeprazole products. As a matter of law, a consumer cannot purchase prescription omeprazole products without an authorized person prescribing and dispensing the drug.

176. The relevant geographic market is the United States.

177. At all times relevant to this Counterclaim, AstraZeneca's share of the relevant market has been 100%.

178. There are high entry barriers to participating in the relevant market due to regulation by the FDA. Further, AstraZeneca's exclusionary acts restricted entry into the relevant market to protect its monopoly.

179. AstraZeneca has monopoly power in the market for over-the-counter omeprazole products and has used anticompetitive, exclusionary conduct as alleged herein to maintain that power.

180. AstraZeneca's actions were intended to suppress rather than promote competition on the merits, and have had precisely the intended effect.

181. On or about December 8, 2006, the FDA issued to DPT Ltd. an approvable letter to market generic versions of Prilosec OTC® tablets. The FDA's issuance of this approvable letter for DPT Ltd.'s Tablets means that the FDA has determined that DPT Ltd.'s Tablets are bioequivalent to Prilosec OTC® tablets of the same dosage strength, are indicated for use in the same circumstances as Prilosec OTC® tablets, and have the same FDA-approved end-use as Prilosec OTC® tablets.

182. By virtue of AstraZeneca's filing of the present action, DPT Ltd. has been subject to a 30-month stay preventing it from obtaining final approval to market generic versions of Prilosec OTC® tablets. Accordingly, to date, the pendency of the present litigation prevents DPT Ltd. from marketing generic versions of Prilosec OTC® tablets.

183. AstraZeneca's anticompetitive conduct prevented DPT Ltd. from entering the market with DPT Ltd.'s Tablets at a time when DPT Ltd. could have made substantial sales of such tablets as generics to Prilosec OTC® tablets. But for AstraZeneca's anticompetitive conduct, DPT Ltd. would have received final approval for DPT Ltd.'s Tablets and entered the market with such tablets soon after the FDA issued DPT Ltd. its approvable letter. But for the presently pending action, substantial demand for DPT Ltd.'s Tablets would have existed and DPT Ltd. would have realized substantial sales of those products. Thus, AstraZeneca's actions that precluded DPT Ltd.'s ability to enter into the market with DPT Ltd.'s Tablets have caused and continue to cause DPT Ltd. to

lose substantial sales and profits on sales of DPT Ltd.'s Tablets. Due to the competitive pricing of DPT Ltd.'s product, inter alia, DPT Ltd. would have successfully captured significant sales immediately upon its entry into the relevant market.

184. DPT Ltd. was and is ready, willing and able to manufacture and market DPT Ltd.'s Tablets as of the time when it could have entered into the market. DPT Ltd. has established lines of distribution and contacts with, inter alia, buyers of over-the-counter drugs.

185. DPT Ltd. has been injured in its business and property by reason of AstraZeneca's unlawful monopolization and has suffered damages, including but not limited to lost profits on lost sales and attorneys' fees and costs incurred to defend against AstraZeneca's sham litigation, as a direct and proximate result of AstraZeneca's wrongful conduct.

186. AstraZeneca's violations threaten continuing loss and injury to DPT Ltd. unless enjoined by the court.

187. The injury to DPT Ltd. resulting from AstraZeneca's wrongful conduct constitutes antitrust injury.

188. Upon entry into the relevant market, DPT Ltd. would have priced DPT Ltd.'s Tablets lower than the price of Prilosec OTC® tablets.

189. AstraZeneca's anticompetitive conduct deprived and continues to deprive consumers of lower-cost alternatives to Prilosec OTC® and effectively forecloses competition in the relevant markets, directly injuring competition in those relevant markets and costing consumers due to their inability to purchase a lower cost alternative to Prilosec OTC® tablets.

190. Unless enjoined by the court, AstraZeneca's anticompetitive conduct will continue to deprive customers of lower-cost alternatives to Prilosec OTC® and will effectively foreclose competition in the relevant market.

COUNT III

(ATTEMPTED MONOPOLIZATION IN VIOLATION OF 15 U.S.C. § 2)

191. DPT Ltd. repeats and realleges paragraphs 1 through 190, inclusive, as though fully set forth herein and incorporates them by reference.

192. AstraZeneca has attempted to monopolize the relevant market by the use of exclusionary, predatory, and anticompetitive conduct.

193. AstraZeneca has a specific intent to monopolize and have taken affirmative acts in furtherance of its attempt to monopolize.

194. There is a dangerous probability that AstraZeneca will succeed in its attempt to acquire or maintain monopoly power in the relevant market.

195. AstraZeneca's conduct has occurred in, and is having a substantial effect on, interstate commerce.

196. As a direct and proximate cause of AstraZeneca's exclusionary and anticompetitive conduct, DPT Ltd. has been injured and has sustained damages.

197. The injury to DPT Ltd. constitutes antitrust injury.

COUNT IV

(COMMON LAW UNFAIR COMPETITION)

198. DPT Ltd. repeats and realleges paragraphs 1 through 197, inclusive, as though fully set forth herein and incorporates them by reference.

199. AstraZeneca's sham "Orange Book" listing, sham failure to withdraw the "Orange Book" listing, the present sham litigation and the delay tactics as set forth herein, constitute wrongful and bad faith unfair competition with the intent and improper purpose of delaying the sale of DPT Ltd.'s Tablets by DPT Ltd. in violation of the common law against unfair competition.

200. AstraZeneca's improper conduct threatens to delay the sale by DPT Ltd. of DPT Ltd.'s Tablets which will result in lost profits and the maintenance of substantially higher prices to consumers for Prilosec OTC® tablets.

201. AstraZeneca's conduct has caused DPT Ltd. to incur attorneys' fees and costs in defending the instant litigation and has improperly barred DPT Ltd. from the relevant market.

202. As a direct and proximate cause of AstraZeneca's improper conduct, DPT Ltd. has been injured and has sustained damages.

203. AstraZeneca's conduct constitutes an overall scheme by it to improperly restrain trade with the intent and improper purpose of delaying the sale of DPT Ltd.'s Tablets by DPT Ltd.

204. DPT Ltd. is entitled to recover for its damages.

COUNT V

(UNFAIR COMPETITION IN VIOLATION OF THE LANHAM ACT)

205. DPT Ltd. repeats and realleges paragraphs 1 through 204, inclusive, as though fully set forth herein and incorporates them by reference.

206. AstraZeneca's sham "Orange Book" listing, sham failure to withdraw the "Orange Book" listing, the present sham litigation and the delay tactics as set forth herein, constitute wrongful and bad faith unfair competition with the intent and improper purpose of delaying the sale of DPT Ltd.'s Tablets by DPT Ltd. in interstate commerce and in violation of Section 43 (a) of the Lanham Act, 15 U.S.C. § 1125(a).

207. AstraZeneca's submission of the '380 patent to the FDA and its statements in support of that listing constitute false and misleading statements of fact in commercial promotion. The listing of the '380 patent in the Orange Book deceives or is likely to deceive a substantial segment of the wholesale purchasers and distributors of omeprazole tablets and is likely to influence purchasing decisions.

208. By submitting the '380 patent for listing, AstraZeneca caused the improper and false listing of the '380 patent in the Orange Book to enter interstate commerce.

209. AstraZeneca's activities in listing the invalid '380 patent with the FDA in the Orange Book were undertaken in bad faith.

210. AstraZeneca's conduct threatens the sale by DPT Ltd. of DPT Ltd.'s Tablets in interstate commerce, which will result in lost profits and the maintenance of substantially higher supra-competitive prices to consumers for omeprazole OTC tablets. AstraZeneca's wrongful conduct has caused DPT Ltd. to incur attorneys' fees and costs in defending the present litigation and has barred DPT Ltd. from the relevant market.

211. Under 15 U.S.C. § 1117(a), DPT Ltd. is entitled to recover triple the amount of its lost profits, attorneys' fees and costs, and/or DPT Ltd. is entitled to an order providing for the return, by way of divestiture, restitution, disgorgement, or other equitable remedy, of illicit profits that were made by AstraZeneca, and those acting in concert therewith, by selling Prilosec OTC® tablets at the expense of DPT Ltd. Accordingly, DPT Ltd. is entitled to an order enjoining AstraZeneca from engaging in such unfair competition in the future.

PRAYER FOR RELIEF

WHEREFORE, DPT prays for the following:

A. 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 patents in suit;

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

D. A determination that, under 35 U.S.C. § 285, this is an "exceptional case" and an award to DPT Ltd. of its attorneys' fees in this action;

E. Costs and expenses in this action;

F. A declaration that Counterclaim-Defendants have violated the antitrust laws in the ways described herein;

G. A permanent injunction enjoining Counterclaim-Defendants from continuing their illegal conduct and requiring Counterclaim-Defendants to take affirmative action to dissipate the effects of their violations;

H. An award to DPT Ltd. on its counterclaims of three times the amount of its damages, attorneys' fees and costs and/or punitive damages;

I. Disgorgement of the illicit profits that Counterclaim-Defendants have obtained and are continuing to obtain as a result of their violation of the Lanham Act;

J. Disgorgement of all money Counterclaim-Defendants obtained from sales made at DPT Ltd.'s expense; and

K. Such other and further relief as this Court deems just and proper.

August 10, 2007

RESPECTFULLY SUBMITTED,

THE BAYARD FIRM

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