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.	)	C.A. No. 06-358-SLR
DEXCEL, LTD., DEXXON, LTD., DEXCEL PHARMA TECHNOLOGIES LTD., and CIPLA, LTD.,	)	
Defendants.	)	

AMENDED COMPLAINT

SUBJECT MATTER JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202 and 35 U.S.C. § 271.

2. On information and belief, Dexcel, Ltd., Dexxon, Ltd., and Dexcel Pharma Technologies Ltd. (jointly and severally "DEXCEL") have infringed and are engaging in activities directed toward the further infringement of United States Patent Nos. 6,150,380 (the "'380 patent"); 4,786,505 (the "'505 patent"); and 4,853,230 (the "'230 patent"), by, *inter alia*, submitting a New Drug Application ("NDA") designated NDA No. 22-032 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, and sell its proposed 20 mg omeprazole delayed-release tablets ("DEXCEL's Tablets").

3. In addition, on information and belief, Cipla, Ltd. ("CIPLA") has and will continue to aid, abet, induce, contribute to and otherwise participate in the infringement of said

patents by, inter alia, supplying the bulk omeprazole to be used as the active ingredient in DEXCEL's Tablets and has otherwise aided and abetted DEXCEL in the preparation and submission of the NDA and aided and abetted DEXCEL in its further preparations to commercialize DEXCEL's Tablets upon FDA approval of the NDA.

4. DEXCEL indicated in its notification letter dated April 17, 2006, entitled "Omeprazole Delayed Release Tablets, 20 mg" ("First Notice of Certification"), and in a supplemental letter of the same title dated May 4, 2006 ("Second Notice of Certification"), that it intends to market DEXCEL's Tablets before the expiration of the '380, '505, and '230 patents. The earliest such expiration occurs on April 20, 2007.

5. DEXCEL's submission of NDA No. 22-032, and its service of the First and Second Notices of Certification, indicates that DEXCEL intends to continue its current course of action. DEXCEL has alleged that approval by the FDA to market DEXCEL's Tablets is expected within the first quarter of 2007.

6. There has been and is now an actual, justiciable controversy between DEXCEL and CIPLA on the one hand, and Plaintiffs on the other hand, as to whether DEXCEL has infringed and will infringe the '380, '505, and '230 patents and as to whether CIPLA has and will continue to induce, contribute to, or otherwise aid and abet said infringement.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331, 1338(a), 2201 and 2202.

8. Venue is proper in this Court pursuant to 28 U.S.C. §§1391(b), 1391(c), 1391(d) and 1400(b).

THE PARTIES AND PERSONAL JURISDICTION

9. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB is the assignee of the '380 patent.

10. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden. Hässle is the assignee of the '505 and '230 patents.

11. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved NDA from the FDA for an omeprazole formulation which it sold under the name PRILOSEC®. AstraZeneca LP also holds an approved NDA from the FDA for an omeprazole formulation which is sold under the name PRILOSEC OTC®. AstraZeneca gives notice to the public that PRILOSEC® and PRILOSEC OTC® are protected by patents listed, inter alia, in the FDA Orange Book, by appropriately marking the patented products.

12. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

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

14. On information and belief, defendant Dexcel, Ltd. is an Israeli entity, having its headquarters and principal place of business at Southern Industrial Zone, Or Akiva, Israel 30600. On information and belief, Dexcel, Ltd. has developed, manufactures and distributes DEXCEL's Tablets through its affiliates.

15. On information and belief, defendant Dexxon, Ltd. is an Israeli entity, having its headquarters and principal place of business at Southern Industrial Zone, Or Akiva, Israel 30600. On information and belief, Dexxon, Ltd. has developed and manufactures DEXCEL's Tablets.

16. On information and belief, defendant Dexcel Pharma Technologies, Ltd. is an Israeli entity having a principal place of business at Southern Industrial Zone, Or Akiva, Israel, 30600. On information and belief, Dexcel Pharma Technologies, Inc. is the nominal owner and applicant of NDA No. 22-032.

17. On information and belief, defendant Cipla, Ltd. is an Indian entity having a place of business at Mumbai Central, Mumbai 400 008, India.

18. On information and belief, DEXCEL regularly does or solicits business in Delaware, has continuous and systematic contacts with Delaware, and through its various entities has engaged in activities related to the subject matter of this action and thus is subject to personal jurisdiction in this judicial district.

19. On information and belief, CIPLA is an alien corporation subject to service in any judicial district in the United States and is thus subject to personal jurisdiction in this judicial district. On information and belief, CIPLA has consented to personal jurisdiction in this district on at least one prior occasion.

FIRST CLAIM FOR RELIEF: '380 PATENT

20. AstraZeneca AB, Aktiebolaget Hässle, KBI, KBI-E and AstraZeneca LP (collectively, "Plaintiffs") reallege paragraphs 1-19, above, as if set forth specifically here.

21. The '380 patent (Exhibit A), entitled "Crystalline Form of Omeprazole", issued on November 21, 2000 to Astra Aktiebolag upon assignment from the inventors Karin Lövqvist, Gunnel Sundén, David Noreland, and Ingvar Ymén. The patent was subsequently assigned to AstraZeneca AB. The '380 patent claims, inter alia, a novel crystalline form of omeprazole, pharmaceutical compositions of this novel crystalline form of omeprazole, and methods of using omeprazole for the treatment of gastrointestinal disorders.

22. Plaintiff AstraZeneca AB has been and is still the owner of the '380 patent. The '380 patent will expire on November 10, 2018, and pediatric exclusivity relating to the '380 patent expires on May 10, 2019.

23. By the First Notice of Certification, DEXCEL notified Plaintiffs that it had submitted a NDA under 21 U.S.C. §355(b), seeking FDA approval to manufacture, use, and sell DEXCEL's Tablets and identifying 20 mg tablets of PRILOSEC OTC® and 10 mg, 20 mg, and 40 mg capsules of PRILOSEC® products in its NDA.

24. DEXCEL's First Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(b), and FDA rules and regulations, as specified in 21 C.F.R. § 314.52(c).

25. DEXCEL's First Notice of Certification does not allege and does not address non-infringement of claims 1-4 of the '380 patent. DEXCEL thus concedes that DEXCEL's Tablets meet all limitations of claims 1-4 of the '380 patent.

26. DEXCEL's First Notice of Certification does not address the validity or enforceability of claims 5 or 6 of the '380 patent. DEXCEL concedes that these claims are valid and enforceable.

27. DEXCEL has infringed the '380 patent under 35 U.S.C. § 271(e)(2) by filing its NDA, seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a drug claimed in this patent, or the use of which is claimed in the this patent, prior to the expiration of the '380 patent.

28. On information and belief, DEXCEL's Tablets, if approved, will be administered to human patients in a therapeutically effective amount for the treatment of gastrointestinal disorders. On information and belief, this administration will occur at DEXCEL's active behest and with its intent, knowledge, and encouragement. On information and belief, DEXCEL will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '380 patent.

29. On information and belief, DEXCEL's Tablets are especially made or especially adapted for use in the treatment of gastrointestinal disorders via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed omeprazole. On information and belief, DEXCEL is aware that DEXCEL's Tablets are so made or so adapted. On information and belief, DEXCEL is aware that DEXCEL's Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '380 patent.

30. On information and belief, the manufacture, use and sale of DEXCEL's Tablets, if approved, will infringe one or more claims of the '380 patent.

31. CIPLA is jointly and severally liable for any infringement of the '380 patent. This is so because, upon information and belief, CIPLA participated in, contributed to,

aided, abetted, and/or induced the submission of NDA 22-032 by providing material information and physical product, including omeprazole product, to DEXCEL in connection with the preparation and submission of NDA 22-032, which information was relied upon and used by DEXCEL in the submission of NDA 22-032. If NDA 22-032 is approved by the United States Food & Frug Administration ("FDA"), the importation into the United States and commercial sale and offer for sale within the United States of DEXCEL's Tablets pursuant to NDA 22-032, and made using omperazole product supplied by CIPLA, will constitute infringement of the '380 patent.

32. In addition, on information and belief, CIPLA will, without authority, supply further material information and physical product, including omeprazole product, to DEXCEL for formulation into DEXCEL's Tablets for subsequent commercial importation into the United States, and commercial sale and offer for sale within the United States under NDA 22-032, in violation of the '380 patent.

33. By supplying further material information and physical product, including omeprazole product, to DEXCEL for formulation into DEXCEL's Tablets as stated above, CIPLA will knowingly and intentionally contribute to, aid, abet and/or induce the infringement of the '380 patent. Such acts constitute patent infringement under 35 U.S.C. §§271(a), 271(b), 271(c), 271(g) and/or 271(e)(2).

34. There therefore has been and is now an actual justiciable controversy between DEXCEL and CIPLA on the one hand, and Plaintiffs on the other hand, as to whether DEXCEL has infringed and will infringe, and as to whether CIPLA has infringed and will infringe, or has contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of, the '380 patent by the acts stated above. This is so

because DEXCEL has and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above and because CIPLA has and will continue to, without altering course, engage in and make meaningful preparation to engage in the infringing acts stated above.

SECOND CLAIM FOR RELIEF: '505 PATENT

35. Plaintiffs reallege paragraphs 1-19, above, as if set forth specifically here.

36. The '505 patent (Exhibit B), entitled "New Pharmaceutical Preparation For Oral Use," issued on November 22, 1988 to Hässle upon assignment from the inventors Kurt I. Lövgren, Åke G. Pilbrant, Mitsuru Yasumura, Satoshi Morigaki, Minoru Oda and Naohiro Ohishi. The '505 patent claims, inter alia, pharmaceutical preparations of omeprazole.

37. Plaintiff Hässle has been and is still the owner of the '505 patent. The '505 patent will expire on April 20, 2007, and pediatric exclusivity relating to the '505 patent expires on October 20, 2007.

38. By the Second Notice of Certification, DEXCEL notified Plaintiffs that it had submitted a NDA under 21 U.S.C. §355(b), seeking FDA approval to manufacture, use, and sell DEXCEL's Tablets and identifying 20 mg tablets of PRILOSEC OTC® and 10 mg, 20 mg, and 40 mg capsules of PRILOSEC® products in its NDA.

39. DEXCEL's Second Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(b), and FDA rules and regulations, as specified in 21 C.F.R. § 314.52(c).

40. DEXCEL alleged in the Second Notice of Certification that the '505 patent is not infringed by DEXCEL's Tablets.

41. DEXCEL's Second Notice of Certification does not address the validity or enforceability of any claim of the '505 patent. DEXCEL thus concedes that these claims are valid and enforceable.

42. DEXCEL has infringed the '505 patent under 35 U.S.C. § 271(e)(2) by filing its NDA, seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a drug claimed in this patent or the use of which is claimed in this patent, prior to the expiration of the '505 patent.

43. On information and belief, DEXCEL's Tablets, if approved, will be administered to human patients in a therapeutically effective amount for the treatment of gastrointestinal disease. On information and belief, this administration will occur at DEXCEL's active behest and with its intent, knowledge and encouragement. On information and belief, DEXCEL will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '505 patent.

44. On information and belief, DEXCEL's Tablets are especially made or especially adapted for use in the treatment of gastrointestinal disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed omeprazole. On information and belief, DEXCEL is aware that DEXCEL's Tablets are so made or so adapted. On information and belief, DEXCEL is aware that DEXCEL's Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '505 patent.

45. On information and belief, the manufacture, use, or sale of DEXCEL's Tablets, if approved, will infringe one or more claims of the '505 patent.

46. CIPLA is jointly and severally liable for any infringement of the '505 patent. This is so because, upon information and belief, CIPLA participated in, contributed to,

aided, abetted and/or induced the submission of NDA 22-032 by providing material information and physical product, including omeprazole product, to DEXCEL in connection with the preparation and submission of NDA 22-032, which information was relied upon and used by DEXCEL in the submission of NDA 22-032. If NDA 22-032 is approved by the United States Food & Frug Administration ("FDA"), the importation into the United States and commercial sale and offer for sale within the United States of DEXCEL's Tablets pursuant to NDA 22-032, and made using omperazole product supplied by CIPLA, will constitute infringement of the '505 patent.

47. In addition, on information and belief, CIPLA will, without authority, supply further material information and physical product, including omeprazole product, to DEXCEL for formulation into DEXCEL's Tablets for subsequent commercial importation into the United States, and commercial sale and offer for sale within the United States under NDA 22-032, in violation of the '505 patent.

48. By supplying further material information and physical product, including omeprazole product, to DEXCEL for formulation into DEXCEL's Tablets as stated above, CIPLA will knowingly and intentionally contribute to, aid, abet and/or induce the infringement of the '505 patent. Such acts constitute patent infringement under 35 U.S.C. §§271(a), 271(b), 271(c), 271(g) and/or 271(e)(2).

49. There therefore has been and is now an actual justiciable controversy between DEXCEL and CIPLA on the one hand, and Plaintiffs on the other hand, as to whether DEXCEL has infringed and will infringe, and as to whether CIPLA has infringed and will infringe, or has contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of, the '505 patent by the acts stated above. This is so

because DEXCEL has and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above and because CIPLA has and will continue to, without altering course, engage in and make meaningful preparation to engage in the infringing acts stated above.

THIRD CLAIM FOR RELIEF: '230 PATENT

50. Plaintiffs reallege paragraphs 1-19, above, as if set forth specifically here.

51. The '230 patent (Exhibit C), entitled "Pharmaceutical Formulations of Acid Labile Substances For Oral Use," issued on August 1, 1989 to Hässle, upon assignment from the inventors Kurt I. Lövgren, Åke G. Pilbrant, Mitsuru Yasumura, Satoshi Morigaki, Minoru Oda and Naohiro Ohishi. The '230 patent claims, *inter alia*, pharmaceutical preparations of acid labile pharmaceutically active substances, including omeprazole.

52. Plaintiff Hässle has been and still is the owner of the '230 patent. The '230 patent will expire on April 20, 2007, and pediatric exclusivity relating to the '230 patent expires on October 20, 2007.

53. By the Second Notice of Certification, DEXCEL notified Plaintiffs that it had submitted a NDA under 21 U.S.C. §355(b), seeking FDA approval to manufacture, use, and sell DEXCEL's Tablets and identifying 20 mg tablets of PRILOSEC OTC® and 10 mg, 20 mg, and 40 mg capsules of PRILOSEC® products in its NDA.

54. DEXCEL's Second Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(b), and FDA rules and regulations, as specified in 21 C.F.R. § 314.52(c).

55. DEXCEL alleged in the Second Notice of Certification that the '230 patent is not infringed by DEXCEL's Tablets.

56. DEXCEL's Second Notice of Certification does not address the validity or unenforceability of any claim of the '230 patent. DEXCEL thus concedes that these claims are valid and enforceable.

57. DEXCEL has infringed the '230 patent under 35 U.S.C. § 271(e)(2) by filing its NDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent or the use of which is claimed in this patent, prior to the expiration of the '230 patent.

58. On information and belief, DEXCEL's Tablets, if approved, will be administered to human patients in a therapeutically effective amount for the treatment of gastrointestinal disorders. On information and belief, this administration will occur at DEXCEL's active behest and with its intent, knowledge, and encouragement. On information and belief, DEXCEL will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '230 patent.

59. On information and belief, DEXCEL's Tablets are especially made or especially adapted for use in the treatment of gastrointestinal disorders via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed omeprazole. On information and belief, DEXCEL is aware that DEXCEL's Tablets are so made or so adapted. On information and belief, DEXCEL is aware that DEXCEL's Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '230 patent.

60. On information and belief, the manufacture, use, or sale of DEXCEL's Tablets, if approved, will infringe one or more claims of the '230 patent.

61. CIPLA is jointly and severally liable for any infringement of the '230 patent. This is so because, upon information and belief, CIPLA participated in, contributed to,

aided, abetted and/or induced the submission of NDA 22-032 by providing material information and physical product, including omeprazole product, to DEXCEL in connection with the preparation and submission of NDA 22-032, which information was relied upon and used by DEXCEL in the submission of NDA 22-032. If NDA 22-032 is approved by the United States Food & Frug Administration ("FDA"), the importation into the United States and commercial sale and offer for sale within the United States of DEXCEL's Tablets pursuant to NDA 22-032, and made using omperazole product supplied by CIPLA, will constitute infringement of the '230 patent.

62. In addition, on information and belief, CIPLA will, without authority, supply further material information and physical product, including omeprazole product, to DEXCEL for formulation into DEXCEL's Tablets for subsequent commercial importation into the United States, and commercial sale and offer for sale within the United States under NDA 22-032, in violation of the '230 patent.

63. By supplying further material information and physical product, including omeprazole product, to DEXCEL for formulation into DEXCEL's Tablets as stated above, CIPLA will knowingly and intentionally contribute to, aid, abet and/or induce the infringement of the '230 patent. Such acts constitute patent infringement under 35 U.S.C. §§271(a), 271(b), 271(c), 271(g) and/or 271(e)(2).

64. There therefore has been and is now an actual justiciable controversy between DEXCEL and CIPLA on the one hand, and Plaintiffs on the other hand, as to whether DEXCEL has infringed and will infringe, and as to whether CIPLA has infringed and will infringe, or has contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of, the '230 patent by the acts stated above. This is so

because DEXCEL has and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above and because CIPLA has and will continue to, without altering course, engage in and make meaningful preparation to engage in the infringing acts stated above.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of DEXCEL's NDA under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)) for DEXCEL's Tablets must be no earlier than the latest expiration date of the infringed patents-in-suit, including pediatric exclusivity;

(b) A judgment declaring that the '380, '505, and '230 patents will be infringed by defendants DEXCEL and CIPLA if DEXCEL's Tablets are made, used, offered for sale or sold in the United States prior to the expiration of said patents;

(c) A judgment declaring that DEXCEL has not complied with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(b)(2)(A)(iv), 21 U.S.C. § 355(b)(3)(D)(ii), 21 C.F.R. § 314.50 and 21 U.S.C. § 314.52;

(d) A permanent injunction against any infringement by DEXCEL and/or CIPLA of the '380, '505, and '230 patents;

(e) A judgment that DEXCEL's and CIPLA's conduct is exceptional;

(f) Attorneys' fees in this action under 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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January 5, 2007

CERTIFICATE OF SERVICE

I hereby certify that on January 5, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to Richard D. Kirk.

I further certify that I caused to be served copies of the foregoing document on January 5, 2007 upon the following in the manner indicated:

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