

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

ASTRAZENECA AB; AKTIEBOLAGET
HÄSSLE; ASTRAZENECA LP; KBI INC.;
and KBI-E INC.,

Plaintiffs,

v.

SUN PHARMA GLOBAL FZE, SUN
PHARMACEUTICAL INDUSTRIES, INC.,
SUN PHARMA GLOBAL INC., SUN
PHARMACEUTICAL INDUSTRIES, LTD.,
and CARACO PHARMACEUTICAL
LABORATORIES, LTD.,

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC.,
and KB Plaintiffs I-E INC.; for their Complaint against Defendants SUN PHARMA GLOBAL
FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., SUN PHARMA GLOBAL INC., SUN
PHARMACEUTICAL INDUSTRIES, LTD., and CARACO PHARMACEUTICAL
LABORATORIES, LTD. state:

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, Sun Pharma Global FZE, Sun Pharmaceutical
Industries, Inc., Sun Pharma Global Inc., Sun Pharmaceutical Industries, Ltd., and Caraco

Pharmaceutical Laboratories, Ltd. (collectively “Sun”) have been and are engaging in activities directed toward infringement of United States Patent Nos. 5,877,192 (the “’192 patent”) and 6,143,771 (the “’771 patent”), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 20-882 and by submitting a Drug Master File (“DMF”) seeking FDA’s approval to manufacture commercially its proposed product called “Esomeprazole Sodium for Injection, 20 mg/vial and 40 mg/vial” (hereinafter referred to as “Esomeprazole Sodium I.V. Product”) containing the active ingredient esomeprazole sodium.

3. In Sun’s notice letter entitled “Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.S. 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95” (hereinafter referred to as the “January 15, 2010 Letter”), Sun has indicated that it intends to market its Esomeprazole Sodium I.V. Product before the expiration of the ’192 and ’771 patents.

4. Sun’s submission of ANDA No. 20-882 and the DMF, in addition to service of its January 15, 2010 Letter, indicates a refusal to change its current course of action.

5. There has been and is now an actual controversy between Sun and Plaintiffs as to whether Sun infringes the ’192 and ’771 patents.

6. Plaintiffs have filed a substantively identical action against the defendants in the United States District Court for the District of New Jersey. This action is being filed in the event that one or more of the defendants challenge personal jurisdiction over them or venue in the New Jersey court. If the defendants do not challenge personal jurisdiction over them or venue in the New Jersey court, plaintiffs plan to dismiss the Michigan action without prejudice.

THE PARTIES

7. 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 was a corporate name change from Astra Aktiebolaget.

8. Plaintiff Aktiebolaget Hässle (“Hässle”) is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

9. 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 New Drug Application from the United States Food and Drug Administration (“FDA”) for an esomeprazole magnesium formulation which it sells under the name NEXIUM[®].

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

11. Plaintiff KBI-E Inc. (“KBI-E”) is a Delaware corporation, having its principal place of business at Wilmington, Delaware. KBI and KBI-E have exclusive rights in the United States to patents-in-suit.

12. On information and belief, defendant Sun Pharma Global FZE is a company organized and existing under the laws of the United Arab Emirates having a principal place of business at Office #43, SAIF Zone, P.O. Box 122304, Shariah, United Arab Emirates. On information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharma Global Inc. which is in turn a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun Pharma Global FZE manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

13. On information and belief, defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of Michigan having a headquarters at 29714 Orion Ct., Farmington Hills, MI 48334. Based on information provided in Sun's January 15, 2010 Letter, Sun Pharmaceutical Industries, Inc. is authorized to accept service of process on behalf of Sun. On information and belief, Sun Pharmaceutical Industries, Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun Pharmaceutical Industries, Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

14. On information and belief, defendant Sun Pharma Global Inc. is a company organized and existing under the laws of British Virgin Islands having a place of business at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun Pharma Global Inc. is a wholly-owned subsidiary of Sun Pharmaceutical Industries, Ltd. On information and belief, Sun Pharma Global Inc. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

15. On information and belief, defendant Sun Pharmaceutical Industries, Ltd. is a company organized and existing under the laws of India having a principal place of business at Acme Plaza, Andheri – Kurla Rd., Andheri (E), Mumbai, India 400059. On information and belief, Sun Pharmaceutical Industries, Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

16. On information and belief, defendant Caraco Pharmaceutical Laboratories, Ltd. is a company organized and existing under the laws of Michigan having a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. On information and belief, Caraco

Pharmaceutical Laboratories, Ltd. is a subsidiary of Sun Pharmaceutical Industries, Ltd. and a majority of Caraco Pharmaceutical Laboratories, Ltd.'s stock is owned by Sun Pharmaceutical Industries, Ltd. On information and belief, Caraco Pharmaceutical Laboratories, Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including this judicial district.

17. On information and belief, Sun is doing business in Michigan, has continuous and systematic contacts with Michigan, has engaged in activities related to the subject matter of this action and is subject to personal jurisdiction in this judicial district.

FIRST CLAIM FOR RELIEF: '192 PATENT

18. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-17 above as if set forth specifically here.

19. The '192 patent, (copy attached as Exhibit A), entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-)-Enantiomer Of Omeprazole," was issued on March 2, 1999 to Astra Aktiebolag, upon assignment from the inventors Per Lindberg and Lars Weidolf. The patent was subsequently assigned to AstraZeneca AB. The '192 patent claims, *inter alia*, methods for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazole and pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

20. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent. The '192 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

21. In Sun's January 15, 2010 Letter, Sun notified Plaintiffs that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '192 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '192 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

22. On information and belief, at the time Sun's January 15, 2010 Letter was served, Sun was aware of the statutory provisions and regulations referred to in paragraph 21 above.

23. Sun's January 15, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 21 above), does not allege non-infringement of claims 1-6, 8-18 and 20-23 of the '192 patent.

24. Even where asserted, Sun's January 15, 2010 Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '192 patent.

25. Sun conceded in its January 15, 2010 Letter that it did not comply with the laws and regulations cited in paragraph 21 above by stating “We do not need or undertake here to exhaust all reasonable invalidity or non-infringement arguments for each of these claims, and we do not take the position that all such arguments are exhausted in this opinion.”

26. In a letter dated January 29, 2010, Sun’s outside litigation counsel further incorrectly stated that “there is no requirement that Sun’s detailed statement exhaust all invalidity or non-infringement arguments for each of the claims.”

27. Accordingly, Sun’s January 15, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

28. By not addressing non-infringement of claims 1-6, 8-18 and 20-23 of the ’192 patent in its January 15, 2010 Letter, Sun admits that its Esomeprazole Sodium I.V. Products meet all limitations of claims 1-6, 8-18 and 20-23 of the ’192 patent.

29. Sun infringed the ’192 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA 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 ’192 patent.

30. On information and belief, Sun’s Esomeprazole Sodium I.V. Products, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

31. On information and belief, such administration will decrease interindividual variation in plasma levels (AUC) during such treatment.

32. On information and belief, such treatment will increase average plasma levels (AUC) per dosage unit.

33. On information and belief, such treatment will effect a pronounced increase in gastrin levels in slow metabolizers during such treatment.

34. On information and belief, such treatment will effect decreased CYP1A induction in slow metabolizers during such treatment.

35. On information and belief, such treatment will elicit an improved antisecretory effect during such treatment.

36. On information and belief, such treatment will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during such treatment.

37. On information and belief the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment.

38. On information and belief, this administration will occur at Sun's active behest and with its intent, knowledge and encouragement.

39. On information and belief, Sun will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

40. On information and belief, Sun's Esomeprazole Sodium I.V. Products are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the magnesium salt of esomeprazole. On

information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products are so made or so adapted.

41. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

42. On information and belief, the manufacture, use and sale of Sun's Esomeprazole Sodium I.V. Products infringe the '192 patent claims.

43. To further investigate Sun's allegations of invalidity of the '192 patent, in a letter dated January 27, 2010, AstraZeneca requested access to certain documents and information.

44. Sun failed to timely provide all requested confidential documents and information, thereby preventing AstraZeneca from fully investigating Sun's allegations. These actions show that Sun failed to provide an offer of confidential access to the application pursuant to statute (21 U.S.C. § 355(j)(5)(C)(i)(III)).

45. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Sun's Esomeprazole Sodium I.V. Products infringe valid claims of the '192 patent.

SECOND CLAIM FOR RELIEF: '771 PATENT

46. Plaintiffs reallege paragraphs 1-17 above as if set forth specifically here.

47. The '771 patent, (copy attached as Exhibit B), entitled "Compounds," was issued on November 7, 2000 to AstraZeneca AB, upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The '771 patent claims, *inter alia*, esomeprazole sodium salts.

48. Plaintiff AstraZeneca AB has been and still is the owner of the '771 patent. The '771 patent will expire on May 27, 2014.

49. In Sun's January 15, 2010 Letter, Sun notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '771 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '771 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted" The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

50. On information and belief, at the time Sun's January 15, 2010 Letter was served, Sun was aware of the statutory provisions and regulations referred to in paragraph 49 above.

51. Sun's January 15, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 49 above), does not allege non-infringement of any '771 patent claims.

52. Even where asserted, Sun's January 15, 2010 Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '771 patent.

53. Sun conceded in its January 15, 2010 Letter that it did not comply with the laws and regulations cited in paragraph 49 above by stating "We do not need or undertake here to exhaust all reasonable invalidity or non-infringement arguments for each of these claims, and we do not take the position that all such arguments are exhausted in this opinion."

54. In a letter dated January 29, 2010, Sun's outside litigation counsel further incorrectly stated that "there is no requirement that Sun's detailed statement exhaust all invalidity or non-infringement arguments for each of the claims."

55. Accordingly, Sun's January 15, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

56. By not addressing non-infringement of the '771 patent claims in its January 15, 2010 Letter, Sun admits that its Esomeprazole Sodium I.V. Products meet all limitations of the '771 patent claims.

57. Sun infringed the '771 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA 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 '771 patent.

58. On information and belief, Sun's Esomeprazole Sodium I.V. Products, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

59. On information and belief, Sun's Esomeprazole Sodium I.V. Products, if approved, will be administered to human patients at Sun's active behest and with its intent, knowledge and encouragement. On information and belief, Sun will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '771 patent.

60. On information and belief, Sun's Esomeprazole Sodium I.V. Products are especially made or especially adapted for treatment of humans. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products are so made or so adapted. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products, if approved, will be used in contravention of Plaintiffs' rights under the '771 patent.

61. On information and belief, Sun is aware that its Esomeprazole Sodium I.V. Products, if approved, will be used in contravention of Plaintiffs' rights under the '771 patent.

62. On information and belief, the manufacture, use and sale of Sun's Esomeprazole Sodium I.V. Products infringe the '771 patent claims.

63. To further investigate Sun's allegations of invalidity of the '771 patent, in a letter dated January 27, 2010, AstraZeneca requested access to certain documents and information.

64. Sun failed to timely provide all requested confidential documents and information, thereby preventing AstraZeneca from fully investigating Sun's allegations. These actions show that Sun failed to provide an offer of confidential access to the application pursuant to statute (21 U.S.C. § 355(j)(5)(C)(i)(III)).

65. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain under appropriate judicial safeguards information to confirm that Sun's Eesomeprazole Sodium I.V. Products infringe valid claims of the '771 patent.

THIRD CLAIM FOR RELIEF:

WILLFUL INFRINGEMENT AND EXCEPTIONAL CASE

66. Plaintiffs reallege paragraphs 1-65 above as if set forth specifically here.

67. In Sun's January 15, 2010 Letter, Sun notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '771 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '771 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted" The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

68. On information and belief, at the time Sun's January 15, 2010 Letter was served, Sun was aware of the statutory provisions and regulations referred to in paragraph 67 above.

69. Sun's January 15, 2010 Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 67 above), does not allege non-infringement of any '771 patent claims or '192 patent claims 1-6, 8-18 and 20-23.

70. Even where asserted, Sun did not include a full and detailed statement of its factual and legal basis to support its non-infringement and/or invalidity allegations as to the '771 and '192 patents even though 21 C.F.R. § 314.95(c) requires that the January 15, 2010 Letter include "(i) ffor each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) ffor each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation" (emphasis added).

71. In addition, the invalidity bases alleged in Sun's January 15, 2010 Letter are speculative and without adequate foundation.

72. Sun conceded in its January 15, 2010 Letter that it did not provide a full and detailed explanation, as required by the laws and regulations cited in paragraph 67 above, by stating "[w]e do not need or undertake here to exhaust all reasonable invalidity or non-infringement arguments for each of these claims, and we do not take the position that all such arguments are exhausted in this opinion. "

73. In a letter dated January 29, 2010, Sun's outside litigation counsel further incorrectly stated that "there is no requirement that Sun's detailed statement exhaust all invalidity or non-infringement arguments for each of the claims."

74. Accordingly, Sun's January 15, 2010 Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

75. Sun's failure to provide a full and detailed explanation of non-infringement and invalidity positions for each claim of the '771 and '192 patents is willful.

76. Sun's conduct in certifying to non-infringement and invalidity in its ANDA, providing a deficient, baseless and incomplete January 15, 2010 Letter and thereafter failing to remedy this deficiency when notified by AstraZeneca constitutes willful infringement.

77. Sun's conduct in certifying to non-infringement and invalidity in its ANDA, providing a deficient, baseless and incomplete January 15, 2010 Letter and thereafter failing to remedy this deficiency when notified by AstraZeneca qualifies this case as exceptional.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Sun's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Esomeprazole Sodium For Injection" must be later than November 27, 2014, the expiration date of the last patent in suit, including pediatric exclusivity relating to the patent, that is infringed;

(b) A judgment declaring that the '192 and '771 patents remain valid, remain enforceable and have been infringed by defendant Sun;

(c) A judgment declaring that Sun has not complied with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(B)(iv), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95;

(d) A judgment that Sun's defenses and claims for relief are limited to those presented in Sun's January 15, 2010 Letter;

(e) A judgment that Sun admits to infringement of '192 claims 1-6, 8-18 and 20-23 and '771 claims 1-12 by failing to address non-infringement of those claims in its January 15, 2010 Letter;

(f) A judgment that Sun's intentional failure to comply with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(B)(iv), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95 by failing to present non-infringement defenses is exceptional and willful;

(g) A permanent injunction against any infringement by Sun of the '192 and '771 patents;

(h) A judgment that Sun's conduct is exceptional;

(i) A judgment that Sun's infringement is willful;

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

(k) Costs and expenses in this action; and

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

Dated: March 1, 2010

Respectfully Submitted,

CLARK HILL PLC

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