

Andrew T. Berry
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
AstraZeneca AB, Aktiebolaget Hässle,
AstraZeneca LP, KBI Inc. and KBI-E Inc.

Of Counsel:
Errol B. Taylor
Fredrick M. Zullo
MILBANK, TWEED, HADLEY &
& McCLOY LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
(212) 530-5000

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

<hr/>		
ASTRAZENECA AB; AKTIEBOLAGET	:	Civil Action No. _____
HÄSSLE; ASTRAZENECA LP; KBI INC.;	:	
and KBI-E INC.,	:	
	:	COMPLAINT FOR PATENT
Plaintiffs,	:	INFRINGEMENT
	:	AND CERTIFICATION PURSUANT TO
v.	:	LOCAL RULE 11.2
	:	
SANDOZ, INC.	:	
	:	
Defendants.	:	
	:	
<hr/>		

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, Sandoz, Inc. (“Sandoz”) has been and is engaging in activities directed toward infringement of United States Patent Nos. 5,714,504 (the “’504 patent”), 5,877,192 (the “’192 patent”), 6,875,872 (the “’872 patent”), 6,369,085 (the “’085 patent”), and 7,411,070 (the “’070 patent”), by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 90-841 and by submitting Drug Master Files (DMF) seeking FDA’s approval to manufacture commercially its proposed 20 mg and 40 mg product called “Esomeprazole Magnesium Delayed Release Capsules, 20 mg Base, and 40 mg Base” (hereinafter referred to as “Esomeprazole Magnesium Capsules”) containing the active ingredient esomeprazole magnesium.

3. In Sandoz’s notice letter entitled “Notice of Certification Under 21 U.S.C. § 355(j)(2)(B) (§ 505(j)(2)(B)) of Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95 Sandoz Inc.’s Esomeprazole Magnesium Delayed Release Capsules, 20 mg Base, and 40 mg Base Sandoz Inc.’s ANDA 90-841” (hereinafter referred to as the “Notice of Certification”), Sandoz has indicated that it intends to market its Esomeprazole Magnesium Capsules before the expiration of the ’504, ’192, ’872, ’085 and ’070 patents.

4. Sandoz’s submission of ANDA No. 90-841 and the DMF, in addition to service of its Notice of Certification, indicates a refusal to change its current course of action.

5. There has been and is now an actual controversy between Sandoz and Plaintiffs as to whether Sandoz infringes the '504, '192, '872, '085 and '070 patents.

THE PARTIES

6. 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.

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

8. 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[®].

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

10. 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.

11. On information and belief, defendant Sandoz, Inc. is a company incorporated under the laws of the state of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

12. On information and belief, Sandoz is doing business in New Jersey, has continuous and systematic contacts with New Jersey, 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: '504 PATENT

13. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-12, above, as if set forth specifically here.

14. The '504 patent (copy attached as Exhibit "A"), entitled "Compositions," was issued on February 3, 1998 to Astra Aktiebolag upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The patent was subsequently assigned to AstraZeneca AB. The '504 patent claims, *inter alia*, pharmaceutical formulations comprising alkaline salts of esomeprazole (including esomeprazole magnesium) and methods of using esomeprazole magnesium.

15. Plaintiff AstraZeneca AB has been and is still the owner of the '504 patent. The '504 patent will expire on February 3, 2015 and pediatric exclusivity relating to the '504 patent expires on August 3, 2015.

16. Sandoz's Notice of Certification notified Plaintiffs that it had submitted an Abbreviated New Drug Application ("ANDA") to the FDA under 21 U.S.C. § 355(j), seeking the FDA's approval to manufacture, use, offer to sell and sell Sandoz's Eesomeprazole Magnesium Capsules as a generic version of the NEXIUM[®] product.

17. In the Notice of Certification, Sandoz 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 '504 patent. This statutory section requires, *inter alia*,

certification by the ANDA applicant that the subject patent, here the '504 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."

18. On information and belief, at the time Sandoz's Notice of Certification was served, Sandoz was aware of the statutory provisions and regulations referred to in paragraph 17, above.

19. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 17 above), does not allege non-infringement of any of the claims of the '504 patent.

20. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 17 above), does not address unenforceability or inequitable conduct of the '504 patent.

21. In the Notice of Certification, Sandoz did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 17, above, as to the '504 patent.

22. Sandoz's Notice of Certification 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.

23. Sandoz has infringed the '504 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 '504 patent.

24. On information and belief, Sandoz's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Sandoz's active behest and with its intent, knowledge and encouragement. On information and belief, Sandoz will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '504 patent.

25. On information and belief, Sandoz's Esomeprazole Magnesium Capsules 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 claimed esomeprazole magnesium and a pharmaceutically acceptable carrier. On information and belief, Sandoz is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Sandoz is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

26. Sandoz's Notice of Certification does not allege and does not address non-infringement of any claims of the '504 patent. By not addressing non-infringement of any claims of the '504 patent in its Notice of Certification, Sandoz admits that its Esomeprazole Magnesium Capsules meet all limitations of all claims of the '504 patent.

27. On information and belief, the manufacture, use and sale of Sandoz's Esomeprazole Magnesium Capsules infringe the '504 patent claims.

SECOND CLAIM FOR RELIEF: '192 PATENT

28. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-12 and 16, above, as if set forth specifically here.

29. The '192 patent, (copy attached as Exhibit "B"), 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.

30. 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.

31. In the Notice of Certification, Sandoz 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.”

32. On information and belief, at the time Sandoz’s Notice of Certification was served, Sandoz was aware of the statutory provisions and regulations referred to in paragraph 31, above.

33. Sandoz’s Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 31 above), does not allege non-infringement of any of the claims of the ’192 patent.

34. Sandoz’s Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 31 above), does not address unenforceability or inequitable conduct of the ’192 patent.

35. In the Notice of Certification, Sandoz did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 31, above, as to the '192 patent.

36. Sandoz's Notice of Certification 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.

37. Sandoz has 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.

38. On information and belief, Sandoz's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion. On information and belief, such administration will decrease interindividual variation in plasma levels (AUC) during such treatment. On information and belief, such treatment will increase average plasma levels (AUC) per dosage unit. On information and belief, such treatment will effect a pronounced increase in gastrin levels in slow metabolizers during such treatment. On information and belief, such treatment will effect decreased CYP1A induction in slow metabolizers during such treatment. On information and belief, such treatment will elicit an improved antisecretory effect during such treatment. 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. 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. On information and belief, this administration will occur at Sandoz's active behest and with its intent, knowledge and encouragement. On information and belief, Sandoz will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

39. On information and belief, Sandoz's Esomeprazole Magnesium Capsules 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, Sandoz is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Sandoz is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

40. Sandoz's Notice of Certification does not allege and does not address non-infringement of any claims of the '192 patent. By not addressing non-infringement of any claims of the '192 patent in its Notice of Certification, Sandoz admits that its Esomeprazole Magnesium Capsules meet all limitations of all claims of the '192 patent.

41. On information and belief, the manufacture, use and sale of Sandoz's Esomeprazole Magnesium Capsules infringe the '192 patent claims.

THIRD CLAIM FOR RELIEF: '872 PATENT

42. Plaintiffs reallege paragraphs 1-12 and 16, above, as if set forth specifically here.

43. The '872 patent, (copy attached as Exhibit "C"), entitled "Compounds," was issued on April 5, 2005 to AstraZeneca AB, upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The '872 patent claims, *inter alia*,esomeprazole magnesium salts.

44. Plaintiff AstraZeneca AB has been and still is the owner of the '872 patent. The '872 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '872 patent expires on November 27, 2014.

45. In the Notice of Certification, Sandoz 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 '872 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '872 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."

46. On information and belief, at the time Sandoz's Notice of Certification was served, Sandoz was aware of the statutory provisions and regulations referred to in paragraph 45, above.

47. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 45 above), does not allege non-infringement of any of the claims of the '872 patent.

48. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 45 above), does not address unenforceability or inequitable conduct of the '872 patent.

49. In the Notice of Certification, Sandoz did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 45, above, as to the '872 patent.

50. Sandoz's Notice of Certification 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.

51. Sandoz has infringed the '872 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, prior to the expiration of the '872 patent.

52. On information and belief, Sandoz's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients at Sandoz's active behest and with its intent, knowledge and encouragement. On information and belief, Sandoz will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '872 patent.

53. On information and belief, Sandoz's Esomeprazole Magnesium Capsules are especially made or especially adapted for treatment of humans. On information and belief, Sandoz is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Sandoz is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '872 patent.

54. Sandoz's Notice of Certification does not allege and does not address non-infringement of any claims of the '872 patent. By not addressing non-infringement of any claims of the '872 patent in its Notice of Certification, Sandoz admits that its Esomeprazole Magnesium Capsules meet all limitations in all claims of the '872 patent.

55. On information and belief, the manufacture, use and sale of Sandoz's Esomeprazole Magnesium Capsules infringe the '872 patent claims.

FOURTH CLAIM FOR RELIEF: '085 PATENT

56. Plaintiffs reallege paragraphs 1-12 and 16, above, as if set forth specifically here.

57. The '085 patent, (copy attached as Exhibit "D"), entitled "Form of S-Omeprazole," was issued on April 9, 2002 to AstraZeneca AB, upon assignment from the inventors Hanna Cotton, Anders Kronström, Anders Mattson and Eva Möller. The '085 patent claims, *inter alia*, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts.

58. Plaintiff AstraZeneca AB has been and still is the owner of the '085 patent. The '085 patent will expire on May 25, 2018 and pediatric exclusivity relating to the '085 patent expires on November 25, 2018.

59. In the Notice of Certification, Sandoz 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 '085 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '085 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."

60. On information and belief, at the time Sandoz's Notice of Certification was served, Sandoz was aware of the statutory provisions and regulations referred to in paragraph 59, above.

61. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 59 above), does not allege invalidity of any claims of the '085 patent.

62. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 59 above), does not address unenforceability or inequitable conduct of the '085 patent.

63. In the Notice of Certification, Sandoz did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 59, above, as to the '085 patent.

64. Sandoz's Notice of Certification 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.

65. Sandoz has infringed the '085 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, prior to the expiration of the '085 patent.

66. On information and belief, Sandoz's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related conditions. On information and belief, this administration will occur at Sandoz's active behest and with its intent, knowledge and encouragement. On information and belief, Sandoz will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

67. On information and belief, Sandoz's Esomeprazole Magnesium Capsules are especially made or especially adapted to treat gastric acid related diseases via the administration of a therapeutically effective amount of a pharmaceutical formulation containing esomeprazole magnesium. On information and belief, Sandoz is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Sandoz is aware

that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

68. On information and belief, the manufacture, use and sale of Sandoz's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

69. To further investigate whether Sandoz will infringe AstraZeneca's patents, in a letter dated December 30, 2008, AstraZeneca requested access to certain documents, information and samples, as well as access to Sandoz's ANDA No. 90-841 and the DMF.

70. On January 7, 2009, Sandoz' outside attorney responded that it was still considering AstraZeneca requests. By the date of this Complaint, Sandoz had still not agreed to provide AstraZeneca access to any of the requested documents, information and samples.

71. 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 Sandoz's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

FIFTH CLAIM FOR RELIEF: '070 PATENT

72. Plaintiffs reallege paragraphs 1-12 and 16, above, as if set forth specifically here.

73. The '070 patent (copy attached as Exhibit "E"), entitled "Form of S-omeprazole," was issued on August 12, 2008 to AstraZeneca AB upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson and Eva Moller. The '070 patent is directed to, *inter alia*, magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts.

74. Plaintiff AstraZeneca AB has been and is still the owner of the '070 patent. The '070 patent will expire on May 25, 2018 and pediatric exclusivity relating to the '070 patent expires on November 25, 2018.

75. In the Notice of Certification, Sandoz 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 '070 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '070 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."

76. On information and belief, at the time Sandoz's Notice of Certification was served, Sandoz was aware of the statutory provisions and regulations referred to in paragraph 75, above.

77. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 75 above), does not allege invalidity of any claims of the '070 patent.

78. Sandoz's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 75 above), does not address unenforceability or inequitable conduct of the '070 patent.

79. In the Notice of Certification, Sandoz did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 75, above, as to the '070 patent.

80. Sandoz's Notice of Certification 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.

81. Sandoz has infringed the '070 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, prior to the expiration of the '070 patent.

82. On information and belief, Teva's Esomeprazole Magnesium Capsules contain a magnesium salt of esomeprazole trihydrate as claimed by the '070 patent.

83. On information and belief, Teva's Esomeprazole Magnesium Capsules are manufactured by a process comprised of treating a magnesium salt of esomeprazole of any form with water as claimed by the '070 patent.

84. On information and belief, the manufacture, use and sale of Sandoz's Esomeprazole Magnesium Capsules infringe the '070 patent claims.

85. To further investigate whether Sandoz will infringe AstraZeneca's patents, in a letter dated December 30, 2008, AstraZeneca requested access to certain documents, information and samples, as well as access to Sandoz's ANDA No. 90-841 and the DMF.

86. On January 7, 2009, Sandoz' outside attorney responded that it was still considering AstraZeneca requests. By the date of this Complaint, Sandoz had still not agreed to provide AstraZeneca access to any of the requested documents, information and samples.

87. 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 Sandoz's Esomeprazole Magnesium Capsules infringe the '070 patent claims.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Sandoz'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 magnesium" must be later than November 25, 2018, 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 '504, '192, '872, '085 and '070 patents remain valid, remain enforceable and have been infringed by defendant Sandoz;

(c) A judgment declaring that Sandoz 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 permanent injunction against any infringement by Sandoz of the '504, '192, '872, '085 and '070 patents;

(e) A judgment that Sandoz'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.

Respectfully Submitted,

Dated: January 14, 2009

By: s/ Andrew T. Berry
Andrew T. Berry
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
ASTRAZENECA AB,
AKTIEBOLAGET HÄSSLE,
ASTRAZENECA LP, KBI INC.
and KBI-E INC.

Of Counsel:
Errol B. Taylor
Fredrick M. Zullo
MILBANK, TWEED, HADLEY &
& McCLOY LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
(212) 530-5000