

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, Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) have been and are 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. 91-324 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)” (hereinafter referred to as “Esomeprazole Magnesium Capsules”) containing the active ingredient esomeprazole magnesium.

3. In Lupin’s notice letter entitled “Notice of Paragraph IV Certification” (hereinafter referred to as the “Notice of Certification”), Lupin has indicated that it intends to market its Esomeprazole Magnesium Capsules before the expiration of the ’504, ’192, ’872, ’085 and ’070 patents.

4. Lupin’s submission of ANDA No. 91-324 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 Lupin and Plaintiffs as to whether Lupin infringes the ’504, ’192, ’872, ’085 and ’070 patents.

6. On October 21, 2009, Lupin Pharmaceuticals, Inc. and Lupin Ltd. stated that, for purposes of this action, they would not contest personal jurisdiction or venue in the District of New Jersey.

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 Lupin, Ltd. is a company incorporated under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai 400 051, India.

13. On information and belief, defendant Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd. On information and belief, defendant Lupin Pharmaceuticals, Inc. is a company incorporated under the laws of the state of Virginia, having a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, MD. On information and belief, Lupin Pharmaceuticals, Inc. is registered to do business in New Jersey and maintains a registered agent in New Jersey.

14. On information and belief, Lupin 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

15. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, “Plaintiffs”) reallege paragraphs 1-14, above, as if set forth specifically here.

16. 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.

17. 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.

18. Lupin'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 Lupin's Esomeprazole Magnesium Capsules as a generic version of the NEXIUM[®] product.

19. In the Notice of Certification, Lupin 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."

20. On information and belief, at the time Lupin's Notice of Certification was served, Lupin was aware of the statutory provisions and regulations referred to in paragraph 19, above.

21. Lupin's Notice of Certification 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 '504 patent.

22. Accordingly, Lupin'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. Lupin 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, Lupin'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 Lupin's active behest and with its intent, knowledge and encouragement. On information and belief, Lupin 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, Lupin'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, Lupin is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information

and belief, Lupin is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

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

27. To further investigate whether Lupin will infringe AstraZeneca's patents, in a letter dated September 25, 2009, AstraZeneca requested access to certain documents, information and samples, as well as access to Lupin's ANDA No. 91-324 and the DMF.

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

29. 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 Lupin's Esomeprazole Magnesium Capsules infringe the '504 patent claims.

SECOND CLAIM FOR RELIEF: '192 PATENT

30. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-14 and 18, above, as if set forth specifically here.

31. 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.

32. 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.

33. In the Notice of Certification, Lupin 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.”

34. On information and belief, at the time Lupin’s Notice of Certification was served, Lupin was aware of the statutory provisions and regulations referred to in paragraph 33, above.

35. Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 33 above), does not allege non-infringement of claims 12-19 or 21-23 of the '192 patent.

36. Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 33 above), does not address invalidity of claims 8, 9, or 20 of the '192 patent.

37. In addition, even where asserted, Lupin's Notice of Certification 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.

38. Accordingly, Lupin'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.

39. Lupin 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.

40. On information and belief, Lupin'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 Lupin's active behest and with its intent, knowledge and encouragement. On information and belief, Lupin will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

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

42. Lupin's Notice of Certification does not allege and does not address non-infringement of claims 12-19 or 21-23 of the '192 patent. By not addressing non-infringement of claims 12-19 or 21-23 of the '192 patent in its Notice of Certification, Lupin admits that its Esomeprazole Magnesium Capsules meet all limitations of claims 12-19 or 21-23 of the '192 patent.

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

44. To further investigate whether Lupin will infringe AstraZeneca's patents, in a letter dated September 25, 2009, AstraZeneca requested access to certain documents, information and samples, as well as access to Lupin's ANDA No. 91-324 and the DMF.

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

46. 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 Lupin's Esomeprazole Magnesium Capsules infringe the '192 patent claims.

THIRD CLAIM FOR RELIEF: '872 PATENT

47. Plaintiffs reallege paragraphs 1-14 and 18, above, as if set forth specifically here.

48. 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.

49. 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.

50. In the Notice of Certification, Lupin 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.”

51. On information and belief, at the time Lupin’s Notice of Certification was served, Lupin was aware of the statutory provisions and regulations referred to in paragraph 50, above.

52. Lupin’s Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 50 above), does not allege non-infringement of claims 1, 2, 4, 5, 7, 8, 10, or 11 of the ’872 patent.

53. In addition, even where asserted, Lupin’s Notice of Certification 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 ’872 patent.

54. Accordingly, Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 50 above), does not address invalidity of claims of 3, 6, 9, or 12 of the '872 patent.

55. In the Notice of Certification, Lupin 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 50, above, as to the '872 patent.

56. Lupin'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.

57. Lupin 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.

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

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

60. Lupin's Notice of Certification does not allege and does not address non-infringement of claims 1, 2, 4, 5, 7, 8, 10, or 11 of the '872 patent. By not addressing non-

infringement of claims 1, 2, 4, 5, 7, 8, 10, or 11 of the '872 patent in its Notice of Certification, Lupin admits that its Esomeprazole Magnesium Capsules meet all limitations in claims 1, 2, 4, 5, 7, 8, 10, or 11 of the '872 patent.

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

62. To further investigate whether Lupin will infringe AstraZeneca's patents, in a letter dated September 25, 2009, AstraZeneca requested access to certain documents, information and samples, as well as access to Lupin's ANDA No. 91-324 and the DMF.

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

64. 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 Lupin's Esomeprazole Magnesium Capsules infringe the '872 patent claims.

FOURTH CLAIM FOR RELIEF: '085 PATENT

65. Plaintiffs reallege paragraphs 1-14 and 18, above, as if set forth specifically here.

66. 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.

67. 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.

68. In the Notice of Certification, Lupin 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.”

69. On information and belief, at the time Lupin’s Notice of Certification was served, Lupin was aware of the statutory provisions and regulations referred to in paragraph 68, above.

70. Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 68 above), does not allege non-infringement of dependent claims 2-12 of the '085 patent.

71. Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 68 above), does not allege invalidity of any claims of the '085 patent.

72. In addition, even where asserted, Lupin's Notice of Certification 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 '085 patent.

73. Accordingly, Lupin'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.

74. Lupin 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.

75. On information and belief, Lupin'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 Lupin's active behest and with its intent, knowledge and encouragement. On information and belief, Lupin will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

76. On information and belief, Lupin'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, Lupin is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Lupin is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

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

78. To further investigate whether Lupin will infringe AstraZeneca's patents, in a letter dated September 25, 2009, AstraZeneca requested access to certain documents, information and samples, as well as access to Lupin's ANDA No. 91-324 and the DMF.

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

80. 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 Lupin's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

FIFTH CLAIM FOR RELIEF: '070 PATENT

81. Plaintiffs reallege paragraphs 1-14 and 18, above, as if set forth specifically here.

82. 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.

83. 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.

84. In the Notice of Certification, Lupin 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.”

85. On information and belief, at the time Lupin’s Notice of Certification was served, Lupin was aware of the statutory provisions and regulations referred to in paragraph 84, above.

86. Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 84 above), does not allege non-infringement of dependent claims 2-4 of the '070 patent.

87. Lupin's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 84 above), does not allege invalidity of any claims of the '070 patent.

88. In addition, even where asserted, Lupin's Notice of Certification 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 '070 patent.

89. Lupin'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.

90. Lupin 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.

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

92. 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.

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

94. To further investigate whether Lupin will infringe AstraZeneca's patents, in a letter dated September 25, 2009, AstraZeneca requested access to certain documents, information and samples, as well as access to Lupin's ANDA No. 91-324 and the DMF.

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

96. 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 Lupin's Eesomeprazole 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 Lupin's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Eesomeprazole 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 Lupin;

(c) A judgment declaring that Lupin 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 Lupin of the '504, '192, '872, '085 and '070 patents;
- (e) A judgment that Lupin'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,

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