Andrew T. Berry
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 (ET 6742)
Fredrick M. Zullow (FZ 0350)
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

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs, v. IVAX CORPORATION, IVAX PHARMACEUTICALS, INC., IVAX PHARMACEUTICALS NV, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC. and CIPLA, LTD. Defendants.	Civil Action No. _____ **COMPLAINT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

JURISDICTION AND VENUE

1. This is an action for patent infringement and a declaratory judgment 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, IVAX Corporation, IVAX Pharmaceuticals, Inc., IVAX Pharmaceuticals NV, Inc., Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. (jointly and severally "Teva") have been and are engaging in activities directed toward infringement of United States Patent No. 7,411,070 ("the '070 patent") by, *inter alia*, submitting an abbreviated new drug application designated ANDA No. 78-003 seeking FDA's approval to commercially manufacture, use and sell in the U.S. its proposed 20 mg and 40 mg Esomeprazole Magnesium Delayed-Release Capsules (hereinafter referred to as "Esomeprazole Magnesium Capsules") containing the active ingredient esomeprazole magnesium.

3. On information and belief, Cipla, Ltd. ("Cipla") has and will continue to aid, abet, induce, contribute to, engage in activities directed towards and otherwise participate in the infringement of the '070 patent by, *inter alia*, submitting a Drug Master File (DMF) seeking FDA approval to commercially manufacture, use and sell esomeprazole magnesium, supplying the bulk esomeprazole magnesium to be used in Teva's Esomeprazole Magnesium Capsules, importing and supplying the final Esomeprazole Magnesium Capsules to be marketed by Teva under ANDA No. 78-003, and otherwise aiding and abetting Teva in the preparation and submission of ANDA No. 78-003 and in its further preparations to commercialize Teva's Esomeprazole Magnesium Capsules upon FDA approval of ANDA No. 78-003.

4. In Teva's notice letter entitled "Notice of ANDA No. 78-003 Concerning Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and 40 mg, With Paragraph IV Certification Concerning U.S. Patent No. 7,411,070" (hereinafter referred to as the "Notice of Certification"), Teva has indicated that it intends to market its Esomeprazole Magnesium Capsules before the expiration of the '070 patent.

5. Teva's submission of ANDA No. 78-003, Cipla's submission of the DMF, Cipla's supply of the active ingredient and drug product that is the subject oof Teva's ANDA , and service of Teva's Notice of Certification, indicates a refusal to change their current course of action.

6. There has been and is now an actual, justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, have and will continue to induce, contribute to, engage in activities directed toward or otherwise aid and abet said infringement of the '070 patent.

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 the '070 patent.

12. On information and belief, defendant Ivax Corporation is a Florida corporation, having a principal place of business at 4400 Biscayne Blvd., Miami, Florida and having a place of business at 140 Legrand Avenue, Northvale, New Jersey. On information and belief, defendant Ivax Corporation is a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.

13. On information and belief, defendant Ivax Pharmaceuticals, Inc. is a wholly owned subsidiary of Ivax Corporation, having places of business at 4400 Biscayne Blvd., Miami, Florida and 140 Legrand Avenue, Northvale, New Jersey.

14. On information and belief, defendant Ivax Pharmaceuticals NV, Inc. is a wholly owned subsidiary of Ivax Pharmaceuticals, Inc., which in turn is a wholly owned subsidiary of Ivax Corporation, having a place of business at 140 Legrand Avenue, Northvale, New Jersey.

15. On information and belief, defendant Teva Pharmaceutical Industries Ltd. acquired Ivax Corporation, Ivax Pharmaceuticals, Inc. and Ivax Pharmaceuticals NV, Inc. on January 26, 2005.

16. On information and belief, defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation having a principal place of business at 5 Basel St., P.O. Box 3190, Petach Tikva 49131, Israel.

17. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a Delaware corporation, having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454 and having places of business at 8 Gloria Lane, Fairfield, New Jersey 07004 and Two University Plaza, Suite 220, Hackensack, New Jersey 07601. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Orvet UK, which is a wholly-owned subsidiary of Teva Pharmaceuticals Europe, which is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd.

18. On information and belief, defendants Teva are doing business in New Jersey, have continuous and systematic contacts with New Jersey, have engaged in activities together related to the subject matter of this action and are subject to personal jurisdiction in this judicial district.

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

20. On information and belief, defendants Cipla are doing business in New Jersey, have continuous and systematic contacts with New Jersey, have engaged in activities together related to the subject matter of this action and are subject to personal jurisdiction in this judicial district.

21. On information and belief Cipla supplies the active ingredient and the final product for Esomeprazole Magnesium Capsules that Teva intends to market prior to expiration of the ’070 patent.

CLAIM FOR RELIEF: ’070 PATENT

22. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, “Plaintiffs”) reallege paragraphs 1-21, above, as if set forth specifically here.

23. The ’070 patent (copy attached as Exhibit “A”), 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.

24. 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.

25. Teva’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 Teva’s Esomeprazole Magnesium Capsules as a generic version of the NEXIUM® product.

26. In the Notice of Certification, Teva 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, 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."

27. On information and belief, at the time Teva's Notice of Certification was served, Teva was aware of the statutory provisions and regulations referred to in paragraph 26, above.

28. Teva's Notice of Certification does not provide a full and detailed explanation regarding non-infringement of the '070 patent claims, as is required by statute and regulation (see paragraph 26 above).

29. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 26 above), does not allege invalidity of all claims of the '070 patent

30. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 26 above), does not address unenforceability or inequitable conduct of the '070 patent.

31. Teva'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.

32. Teva 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, or the use of which is claimed in the this patent, prior to the expiration of the '070 patent.

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

34. 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.

35. On information and belief, the manufacture, use and sale of Teva's Esomeprazole Magnesium Capsules infringes the '070 patent claims.

36. On information and belief, Cipla has and will, without authority, manufacture and import into the United States and/or use, offer to sell or sell within the United States the Esomeprazole Magnesium Capsules, or a material part thereof, which Teva then intends to offer for sale under ANDA No. 78-003, if approved, in violation of the '070 patent.

37. On information and belief, Cipla has and will continue to provide material information and physical product to Teva in connection with the preparation and submission of ANDA No. 78-003, which seeks approval to offer the Esomeprazole Magnesium Capsules for commercial sale in violation of the '070 patent. On information and belief, the information and product supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 78-003. By so doing, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '070 patent.

38. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '070 patent. Therefore, Cipla is jointly and severally liable for any infringement of the '070 patent.

39. There has been and is now an actual justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, or have contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of the '070 patent by the acts stated

above. This is so because Teva and Cipla have and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Teva'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 Capsules" must be later than November 25, 2018, the expiration date of the '070 patent, including pediatric exclusivity relating to the patent, that is infringed;

(b) A judgment declaring that the '070 patent remains valid, remains enforceable and has been infringed by Teva and/or Cipla if the Esomeprazole Magnesium Capsules are imported into, made, used, offered for sale or sold in the United States prior to the expiration of the '070 patent;

(c) A judgment declaring that Teva 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 Teva and/or Cipla of the '070 patent;

(e) A judgment that Teva's and/or Cipla's conduct is exceptional;

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

(g) Costs and expenses in this action; and

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

Respectfully Submitted,

Date: October 9, 2008

By: S/Andrew T. Berry

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

Attorneys for Plaintiffs
ASTRAZENECA AB,
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AND KBI-E INC.

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