IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

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)-(c), 1400(b), 2201-02 and 35 U.S.C. §§ 271(a),(b), (c) and (e).

2. On information and belief, Teva Parenteral Medicines, Inc. ("TPM"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Ltd. ("Teva Israel") (jointly and severally "Teva") have been and are engaging in activities directed toward infringement of United States Patent No. 5,877,192 (the "'192 patent"), by, *inter alia*, assembling and submitting pursuant to 21 U.S.C. § 355(b) New Drug Application ("NDA") No. 22-322 seeking FDA approval to manufacture commercially its proposed 20 mg/Vial and 40 mg/Vial products called "Esomeprazole For Injection" (hereinafter referred to as "NDA Products") containing the active ingredient esomeprazole.

3. In Teva's notice letter entitled "Patent Certification Notice – U.S. Patent No. 5,877,192" (hereinafter referred to as the "Notice of Certification"), Teva has indicated that it intends to market its NDA Products before the expiration of the '192 patent.

4. Teva's submission of NDA No. 22-322, 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 Plaintiffs and Teva as to whether Teva infringes the '192 patent.

6. On information and belief, Teva is in the business of developing, manufacturing, marketing, and distributing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

7. On information and belief, Teva USA, Inc. and/or Teva Israel, acting alone or in concert, have caused, actively encouraged and/or directed TPM to file NDA No. 22-322 with the United States Food and Drug Administration ("FDA"), and/or participated in the work related to the submission of NDA 22-322.

8. On information and belief, the Teva defendants are incorporated in Delaware, doing business in Delaware, have continuous and systematic contacts with Delaware, sell various products through the United States, including within Delaware, manufacture pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within Delaware, and/or are engaged in activities together related to the subject matter of this action.

9. The Teva defendants are subject to personal jurisdiction in this judicial district.

THE PARTIES

10. 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 formerly known as Astra Aktiebolaget.

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

12. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved NDA from FDA for intravenous esomeprazole sodium which it sells under the name NEXIUM I.V.®.

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

14. 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 '192 patent.

15. On information and belief, defendant Teva Parenteral Medicines, Inc. is a Delaware corporation having an office and conducting business at 2050 Springdale Rd., Cherry Hill, NJ 08003. On information and belief, defendant Teva Parenteral Medicines, Inc. is a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.

16. 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. 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.

17. 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.

INFRINGEMENT OF U.S. PATENT NO. 5,877,192

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

19. The '192 patent ("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 '192 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. The '192 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

21. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent.

22. Teva's Notice of Certification notified Plaintiffs that Teva had submitted an NDA to the FDA under 21 U.S.C. § 355(b), seeking the FDA's approval to manufacture, use, offer to sell and sell Teva's NDA Products as a generic version of the NEXIUM I.V.® product.

23. In the Notice of Certification, Teva notified Plaintiffs that as part of its NDA it had filed a certification of the type described in 21 U.S.C. § 355(b)(2)(A)(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(b)(3)(D)(ii)) also requires that the notice "include a detailed statement of the factual and legal basis of the opinion that of the applicant that the patent is invalid or will not be infringed." FDA Rules and Regulations (21 C.F.R. § 314.52(c)(6)) specify, *inter alia*, that such notification must include "[a] detailed statement of the factual and legal basis of the 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."

24. 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 23 above.

25. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 23 above), does not allege and does not address non-infringement of the '192 patent claims. By not addressing non-infringement of '192 patent claims in its Notice of Certification, Teva admits that the commercial manufacture, use or sale of its NDA Products prior to the expiration of the '192 patent will infringe the '192 patent.

26. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 23 above), does not address unenforceability or inequitable conduct of the '192 patent. By not addressing unenforceability or inequitable conduct of the '192 patent in its Notice of Certification, Teva admits that the '192 is enforceable and that there was no inequitable conduct concerning the '192 patent.

27. Teva's Notice of Certification did not provide the full and detailed statement regarding the '192 patent as required by, and therefore fails to comply with, the law, as specified in 21 U.S.C. § 355(b), and FDA rules and regulations, as specified in 21 C.F.R. § 314.52.

28. The commercial manufacture, use or sale of Teva's NDA Products will meet the limitations of one or more claims of the '192 patent and thus will infringe one or more of the '192 patent claims.

29. Teva has infringed the '192 patent under 35 U.S.C. § 271(e)(2) by filing an NDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '192 patent.

30. On information and belief, Teva's NDA 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, administration of esomeprazole in Teva's NDA Products when compared to omeprazole decreases interindividual variation in plasma levels (AUC) during treatment of gastric acid related diseases.

32. On information and belief, administration of the esomeprazole in Teva's NDA Products when compared to omeprazole will increase average plasma levels (AUC) per dosage unit.

33. On information and belief, administration of the esomeprazole in Teva's NDA Products when compared to omeprazole will effect a pronounced increase in gastrin levels in slow metabolizers during treatment of gastric acid related diseases.

34. On information and belief, administration of the esomeprazole in Teva's NDA Products when compared to omeprazole will effect decreased CYP1A induction in slow metabolizers during treatment of gastric acid related diseases.

35. On information and belief, administration of the esomeprazole in Teva's NDA Products when compared to omeprazole will elicit an improved antisecretory effect during treatment of gastric acid related diseases, as further indicated by the proposed labeling submitted with Teva's NDA.

36. On information and belief, administration of the esomeprazole in Teva's NDA Products when compared to omeprazole will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during treatment of gastric acid related diseases.

37. On information and belief, the amount of esomeprazole to be administered in Teva's 20 mg/Vial NDA Products will be about 20 mg total daily dose.

38. On information and belief the amount of esomeprazole to be administered in Teva's 40 mg/Vial NDA Products will be about 40 mg total daily dose.

39. On information and belief, Teva's NDA Products will be essentially devoid of (+)-omeprazole enantiomeric contaminant.

40. On information and belief, administration of Teva's NDA Products will occur at Teva's active behest and with its intent, knowledge and encouragement.

41. On information and belief, Teva will actively encourage, aid and abet administration of Teva's NDA Products with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

42. On information and belief, Teva's NDA 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 esomeprazole. On information and belief, Teva is aware that its NDA Products are so made or so adapted. On information and belief, Teva is aware that its NDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

43. In a letter dated April 7, 2008 and in order to further investigate whether Teva's NDA Products infringe the '192 patent claims, Plaintiffs requested access to certain documents, information and samples, as well as access to Teva's NDA No. 22-322 and the DMF.

44. Teva refused to provide Plaintiffs with access to any of the requested documents, information and samples.

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

46. There has been and is now an actual justiciable controversy between Plaintiffs and Teva as to whether Teva has infringed, will infringe, or has contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet

infringement of the '192 patent by the acts stated above. This is so because Teva has engaged in and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

47. Plaintiffs have a 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 this action without prejudice.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment that the '192 patent has been and will be infringed by the Teva defendants;

(b) A judgment declaring that the effective date of any approval of Teva's NDA under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)) for the drug product "Esomeprazole For Injection" be no earlier than November 27, 2014, the expiration date of the last patent in suit, including pediatric exclusivity relating to the patent, that is infringed;

(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(b)(2), 21 C.F.R. § 314.50 and 21 U.S.C. § 314.52;

(d) A permanent injunction against any infringement of the '192 patent by Teva;

(e) A judgment that this is an exceptional case;

(f) An award of 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.

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