

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Västra Mälarehamnen 9, Södertälje, S-151 85, Sweden.

4. Upon information and belief, Defendant TPM is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 19 Hughes, Irvine, California. Upon information and belief, TPM is a wholly-owned subsidiary of Teva USA and acts as an agent of Teva USA.

5. Upon information and belief, Defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

6. Upon information and belief, Defendant Teva Ltd. is a corporation organized and existing under the laws of Israel, with its principal place of business at 5 Basel Street, Petah Tikva, Israel.

7. Upon information and belief, TPM's preparation and submission of ANDA No. 200479 was done collaboratively with, and at least in part for the benefit of, Teva USA and Teva Ltd.

8. Teva manufactures and sells various generic pharmaceutical products and regularly conducts business throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America and this court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

11. TPM and Teva USA are subject to personal jurisdiction in Delaware because, among other things, they are residents and citizens of the State of Delaware and have submitted themselves to the jurisdiction of courts in Delaware by virtue of their incorporation under Delaware law. Teva Ltd. is also subject to personal jurisdiction in Delaware because, among other things, Teva Ltd. directly and/or through its wholly-owned subsidiaries, manufactures, markets, and sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware.

NATURE OF THE ACTION

12. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant TPM of Abbreviated New Drug Application ("ANDA") No. 200479 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of FASLODEX[®] prior to the expiration of U.S. Patent Nos. 6,774,122 and 7,456,160 ("the '122 and '160 patents"), which expire on January 9, 2021.

BACKGROUND

13. FASLODEX[®] (fulvestrant) injection is an antioestrogen breast cancer drug approved by the FDA for the treatment of hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antioestrogen therapy.

14. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX[®], in 50 mg/ml dosage forms. AstraZeneca Pharmaceuticals LP is the United States authorized agent for matters related to NDA No. 21-344.

15. The use of FASLODEX[®] is covered by one or more claims of the ‘122 and ‘160 patents, and the ‘122 and ‘160 patents have been listed for NDA No. 21-344 in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the “Orange Book.”

16. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX[®] in the United States pursuant to NDA No. 21-344.

17. United States Patent No. 4,774,122 (“the ‘122 patent”), entitled “Formulation” (Exhibit A hereto), was duly and legally issued on August 10, 2004 and will expire on January 9, 2021. AstraZeneca AB is the legal owner of the ‘122 patent. AstraZeneca UK Limited is the beneficial owner of the ‘122 patent.

18. United States Patent No. 7,456,160 (“the ‘160 patent”), entitled “Formulation” (Exhibit B hereto), was duly and legally issued on November 25, 2008 and will expire on January 9, 2021. AstraZeneca AB is the legal owner of the ‘160 patent. AstraZeneca UK Limited is the beneficial owner of the ‘160 patent.

19. By letter dated November 25, 2009 (the “Notice Letter”), Teva notified AstraZeneca that it had submitted to the FDA ANDA No. 200479 for Fulvestrant Injection, 50 mg/ml (“Teva’s ANDA Product”) seeking approval to engage in the commercial manufacture, use or sale of Teva’s ANDA Product prior to the expiration of the ‘122 and ‘160 patents, and was providing information to AstraZeneca pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). AstraZeneca received this Notice Letter on or about November 27, 2009.

20. The Notice Letter included allegations of invalidity with respect to the ‘122 patent and ‘160 patent, but contained no allegations of non-infringement of one or more claims of the ‘120 and ‘160 patents.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 6,774,122

21. Plaintiffs incorporate each of the preceding paragraphs 1 – 20 as if fully set forth herein.

22. The use of Teva's ANDA Product is covered by one or more claims of the '122 patent.

23. Teva's submission of ANDA No. 200479 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '122 patent constitutes infringement of one or more claims of the '122 patent under 35 U.S.C. § 271(e)(2).

24. Upon information and belief, Teva Ltd. and Teva USA, acting in concert with TPM, have actively supported, participated in, encouraged, and induced TPM's filing of ANDA No. 200479, and the preparation to sell Teva's ANDA Product in the United States.

25. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product imminently upon approval of ANDA No. 200479 and will direct physicians and patients on the use of Teva's ANDA Product through product labeling.

26. Upon information and belief, Teva's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one or more claims of the '122 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

27. Upon FDA approval of ANDA No. 200479, Teva will infringe the '122 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling,

and/or importing Teva's ANDA Product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. § 271(b) and (c).

28. Upon information and belief, Teva Ltd., Teva USA and TPM will actively participate in the production, importation, sale, offer for sale, and use of Teva's ANDA Product.

29. Upon information and belief, Teva had knowledge of the '122 patent when it submitted its ANDA to the FDA and knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '122 patent literally or under the doctrine of equivalents.

30. Upon information and belief, the offer to sell, sale, and/or importation of Teva's ANDA Product would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the '122 patent, either literally or under the doctrine of equivalents.

31. The Notice Letter lacks any legal or factual basis for non-infringement of any claims of the '122 patent.

32. Teva has knowledge of the '122 patent and is knowingly and willfully infringing the '122 patent.

33. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 7,456,160

34. Plaintiffs incorporate each of the preceding paragraphs 1 – 33 as if fully set forth herein.

35. The use of Teva's ANDA Product is covered by one or more claims of the '160 patent.

36. Teva's submission of ANDA No. 200479 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '160 patent constitutes infringement of one or more claims of the '160 patent under 35 U.S.C. § 271(e)(2).

37. Upon information and belief, Teva Ltd. and Teva USA, acting in concert with TPM, have actively supported, participated in, encouraged, and induced TPM's filing of ANDA No. 200479, and the preparation to sell Teva's ANDA Product in the United States.

38. Upon information and belief, Teva intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Teva's ANDA Product imminently upon approval of ANDA No. 200479 and will direct physicians and patients on the use of Teva's ANDA Product through product labeling.

39. Upon information and belief, Teva's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one or more claims of the '160 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

40. Upon FDA approval of ANDA No. 200479, Teva will infringe the '160 patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Teva's ANDA Product in the United States, and by actively inducing and contributing to infringement by others under 35 U.S.C. § 271(b) and (c).

41. Upon information and belief, Teva Ltd., Teva USA and TPM will actively participate in the production, importation, sale, offer for sale, and use of Teva's ANDA Product.

42. Upon information and belief, Teva had knowledge of the '160 patent when it submitted its ANDA to the FDA and knows or should know that it will aid and abet another's

direct infringement of at least one of the claims of the '160 patent literally or under the doctrine of equivalents.

43. Upon information and belief, the offer to sell, sale, and/or importation of Teva's ANDA Product would contributorily infringe under 35 U.S.C. § 271(c) at least one of the claims of the '160 patent, either literally or under the doctrine of equivalents.

44. The Notice Letter lacks any legal or factual basis for non-infringement of any claims of the '160 patent.

45. Teva has knowledge of the '160 patent and is knowingly and willfully infringing the '122 patent.

46. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

- (a) A judgment that the '122 and '160 patents are valid and enforceable;
- (b) A judgment that Teva's submission of ANDA No. 200479 was an act of infringement of one or more claims of the '122 and '160 patents under 35 U.S.C. § 271(e)(2);
- (c) A judgment that Teva's making, using, offering to sell, selling, or importing into the United States Teva's ANDA Product prior to the expiration of the '122 and '160 patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of the '122 and/or '160 patents;
- (d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Teva's ANDA No. 200479, or any product or compound that infringes one

or more claims of the '122 or '160 patents, shall be a date that is not earlier than the expiration of the '122 and '160 patents;

(e) An Order permanently enjoining Teva, its affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Teva, from making, using, offering to sell, selling, marketing, distributing, or importing into the United States Teva's ANDA Product, or any product or compound that infringes one or more claims of the '122 or '160 patents, or inducing or contributing to the infringement of the '122 and '160 patents until after the expiration of the '122 and '160 patents;

(f) A judgment declaring that infringement of the '122 and '160 patents is willful if Teva commercially manufactures, uses, offers to sell, sells, or imports into the United States Teva's ANDA Product, or any product or compound that infringes one or more claims of the '122 or '160 patents, or the inducement or contribution of the foregoing;

(g) A declaration that this is an exceptional case and an award of attorneys' fees to plaintiff pursuant to 35 U.S.C. § 285;

(h) Plaintiffs reasonable costs and expenses in this action; and

(i) Such further and other relief as this Court deems proper and just.

