IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
UNICHEM LABORATORIES, LIMITED,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

H. Lundbeck A/S ("Lundbeck"), Takeda Pharmaceutical Company Ltd. ("Takeda Japan"), Takeda Pharmaceuticals U.S.A., Inc. ("Takeda USA"), Takeda Pharmaceuticals International AG ("Takeda International"), and Takeda Pharmaceuticals America, Inc. ("Takeda America") (collectively, "Lundbeck and Takeda" or "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Unichem Laboratories, Limited ("Unichem" or "Defendant"), and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendant's recent submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 211131 (hereinafter, "Defendant's ANDA"). Through Defendant's ANDA, Defendant seeks approval to market generic versions of Plaintiffs' pharmaceutical product TRINTELLIX®, prior to the expiration of United States Patent No. 8,722,684 ("the '684

Patent"); United States Patent No. 8,969,355 ("the '355 Patent"); and United States Patent No. 9,227,946 ("the '946 Patent").

THE PARTIES

2. Plaintiff H. Lundbeck A/S ("Lundbeck") is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Lundbeck is the assignee and owner of the '684 Patent, the '355 Patent, and the '946 Patent.

3. Plaintiff Takeda Pharmaceutical Company Ltd. is a corporation organized and existing under the laws of Japan, with a place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan. Lundbeck has granted Takeda Japan an exclusive license to the '684, '355, and '946 Patents in connection with the use, importation, distribution, marketing, promotion, and sale of Trintellix® in the United States.

4. Plaintiff Takeda Pharmaceuticals International AG is a corporation organized and existing under the laws of Switzerland, with a place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland. Takeda International is an indirect wholly owned subsidiary of Takeda Japan. Takeda International has an exclusive sublicense to the '684, '355, and '946 Patents from Takeda Japan in connection with the commercialization of Trintellix® in the United States.

5. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda International and Takeda Japan own Takeda USA. Takeda USA holds the New Drug Application ("NDA") No. 204447 for TRINTELLIX® and has an exclusive sublicense to the '684, '355, and '946 Patents from Takeda International,

which grants it the right to import, distribute, and sell TRINTELLIX® in the United States on behalf of Takeda.

6. Plaintiff Takeda Pharmaceuticals America, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Takeda Parkway, Deerfield, IL 60015. Takeda America is a wholly owned subsidiary of Takeda USA. Takeda America distributes and markets TRINTELLIX® in the United States on behalf of Takeda USA.

7. Lundbeck and Takeda are engaged in the business of creating, researching, developing, and bringing to market revolutionary pharmaceutical products to help treat serious diseases, including major depressive disorder.

8. On information and belief, Defendant Unichem Laboratories, Limited is a limited liability company organized and existing under the laws of the Republic of India, with a principal place of business at Unichem Bhavan, Prabhat Estate, Off S V Road, Jogeshwari (West), Mumbai 400102 Maharashtra, India.

9. On information and belief, Defendant prepared and caused ANDA No. 211131 to be submitted to FDA and seeks FDA approval of ANDA No. 211131.

10. On information and belief, Defendant intends to commercially manufacture, market, offer for sale, and sell the vortioxetine hydrobromide tablets described in Defendant's ANDA (hereinafter, "Defendant's ANDA Products") throughout the United States, including in the State of Delaware, in the event FDA approves Defendant's ANDA.

JURISDICTION AND VENUE

11. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '684, '355, and '946 Patents.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

13. This Court has personal jurisdiction over Defendant because, on information and belief, Defendant, *inter alia*, has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell its ANDA Products in the State of Delaware upon approval of ANDA No. 211131.

14. On information and belief, Defendant is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through its subsidiaries, agents, and/or alter-egos, which Defendant manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

15. Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture TRINTELLIX® for sale and use throughout the United States, including this judicial district. On information and belief and as indicated by a letter dated November 29, 2017 sent by Defendant to H. Lundbeck and Takeda USA pursuant to 21 U.S.C. § 355(j)(2)(B) (hereinafter, the "Notice Letter"), Defendant prepared and filed Defendant's ANDA with the intention of seeking to market Defendant's ANDA Products nationwide, including within this judicial district.

16. On information and belief, Defendant plans to sell Defendant's ANDA Products in the State of Delaware, list Defendant's ANDA Products on the State of Delaware's

prescription drug formulary, and seek Medicaid reimbursements for sales of Defendant's ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

17. On information and belief, Defendant knows and intends that its proposed ANDA Products will be distributed and sold in Delaware and will thereby displace sales of TRINTELLIX®, causing injury to Lundbeck and Takeda. Defendant intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed ANDA Products.

18. Defendant has engaged and continues to engage in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See Bristol-Myers Squibb Company et al v. Unichem Laboratories, Ltd.*, 17-cv-00382 (D. Del.).

19. Alternatively, this Court has personal jurisdiction over Defendant because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Defendant is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Defendant has sufficient contacts in the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Defendant satisfies due process.

20. Venue is proper in this district for Defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Defendant is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

PLAINTIFFS' APPROVED TRINTELLIX® DRUG PRODUCT AND PATENTS

21. Takeda USA is the holder of New Drug Application ("NDA") No. 204447 for TRINTELLIX® tablets (5 mg, 10 mg, 15 mg, and 20 mg dosage strengths).[1] The active ingredient in TRINTELLIX® is vortioxetine hydrobromide. FDA approved NDA No. 204447 on September 30, 2013.

22. TRINTELLIX® is an oral antidepressant indicated for the treatment of Major Depressive Disorder (MDD). It is an inhibitor of serotonin (5-HT) reuptake, an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors, and an antagonist at 5-HT3, 5-HT1D and 5-HT7 receptors. It is considered to be the first and only drug with this combination of pharmacodynamic activity. It represents a major advancement in the treatment of depression.

23. The '684, '355, and '946 Patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for TRINTELLIX®.

24. The '684 Patent, entitled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment," was duly and lawfully issued by the USPTO on May 13, 2014. A true and correct copy of the '684 Patent is attached hereto as Exhibit A.

25. The '355 Patent, entitled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the

[1] Plaintiffs do not sell 15 mg TRINTELLIX® tablets in the United States.

Treatment of Cognitive Impairment," was duly and lawfully issued by the USPTO on March 3, 2015. A true and correct copy of the '355 Patent is attached hereto as Exhibit B.

26. The '946 Patent, entitled "1-[2-(2,4-dimethylphenylsulfanyl)-phenyl] piperazine as a Compound with Combined Serotonin Reuptake, 5-HT3 and 5-HT1A Activity for the Treatment of Cognitive Impairment," was duly and lawfully issued by the USPTO on January 5, 2016. A true and correct copy of the '946 Patent is attached hereto as Exhibit C.

DEFENDANT'S ANDA NO. 211131

27. On information and belief, Defendant has submitted ANDA No. 211131 to FDA, or caused ANDA No. 211131 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of vortioxetine hydrobromide tablets as purported generic versions of TRINTELLIX® tablets prior to the expiration of the '684, '355, and '946 Patents.

28. On information and belief, FDA has not approved Defendant's ANDA.

29. On information and belief, Defendant sent Lundbeck and Takeda USA a Notice Letter dated November 29, 2017. The Notice Letter represented that Defendant had submitted to FDA ANDA No. 211131 and a purported Paragraph IV certification for the '684, '355, and '946 Patents. Plaintiffs reserve all rights to challenge the sufficiency of Defendant's ANDA and Notice Letter.

30. On information and belief, the purpose of an ANDA and Paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Products before expiration of the '684, '355, and '946 Patents. Hence, Defendant's purpose in submitting ANDA No. 211131 is to market the products described therein before the expiration of the '684, '355, and '946 Patents.

31. According to applicable regulations, Notice Letters such as Defendant's must contain 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 which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 CFR § 314.95(c)(7); *see also* 21 CFR § 314.52.

32. For at least one claim of each of the '684, '355, and '946 Patents, Defendant's Notice Letter failed to allege that its ANDA Products do not meet the limitations of that claim. Accordingly, Defendant's Notice Letter did not assert a non-infringement position for at least one claim of each of the '684, '355, and '946 Patents.

33. On information and belief, if approved, the ANDA Products will have the same indication as TRINTELLIX®. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 211131 for Defendant's ANDA Products is the treatment of major depressive disorder (MDD).

34. On information and belief, if FDA approves Defendant's ANDA, Defendant will manufacture, offer for sale, or sell Defendant's ANDA Products, within the United States, including within the State of Delaware, or will import Defendant's ANDA Products into the United States, including the State of Delaware.

35. On information and belief, if FDA approves Defendant's ANDA, Defendant will actively induce or contribute to the manufacture, use, offer for sale, or sale of Defendant's ANDA Products in a manner that infringes the '684, '355, and '946 Patents.

36. This action is being brought within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

COUNT I
INFRINGEMENT OF THE '684 PATENT

37. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–36 as if fully set forth herein.

38. On information and belief, Defendant submitted or caused the submission of ANDA No. 211131 to FDA, and thereby seeks FDA approval of Defendant's ANDA.

39. Plaintiffs own all rights, title, and interest in and to the '684 Patent.

40. Defendant's ANDA Products fall within one or more claims of the '684 patent.

41. Defendant does not contest infringement of at least claims 2 and 5 of the '684 Patent in its Notice Letter. If Defendant had a factual or legal basis to contest infringement of claims 2 and 5 of the '684 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

42. Defendant has infringed at least one claim of the '684 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendant's ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '684 Patent.

43. If approved, the importation, manufacture, sale, offer for sale, or use of Defendant's ANDA Products will infringe one or more claims of the '684 Patent under 35 U.S.C. § 271(a).

44. Unless enjoined by this Court, upon FDA approval, Defendant will actively induce infringement of the '684 Patent under 35 U.S.C. § 271(b). On information and belief,

upon FDA approval of Defendant's ANDA, Defendant will make, use, offer to sell, or sell Defendant's ANDA Products within the United States, or will import Defendant's ANDA Products into the United States, and will thereby induce infringement of one or more claims of the '684 Patent. On information and belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '684 Patent and knowledge that its acts are encouraging infringement.

45. Unless enjoined by this Court, upon FDA approval, Defendant will contributorily infringe the '684 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendant's ANDA, Defendant will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the '684 Patent. On information and belief, Defendant has had and continues to have knowledge of the '684 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Defendant has had and continues to have knowledge that the ANDA Products are especially made or especially adapted for a use that infringes the '684 Patent and that there are no substantial non-infringing uses for the ANDA Products.

46. Defendant had actual and constructive notice of the '684 Patent prior to filing Defendant's ANDA, and was aware that the filing of Defendant's ANDA with the request for FDA approval prior to the expiration of the '684 Patent would constitute an act of infringement of the '684 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendant's ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '684 Patent.

47. Defendant filed Defendant's ANDA without adequate justification for asserting the '684 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendant's ANDA Products. Defendant's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '684 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

48. Plaintiffs will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '684 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II
INFRINGEMENT OF THE '355 PATENT

49. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–48 as if fully set forth herein.

50. On information and belief, Defendant submitted or caused the submission of ANDA No. 211131 to FDA, and thereby seeks FDA approval of Defendant's ANDA.

51. Plaintiffs own all rights, title, and interest in and to the '355 Patent.

52. Defendant's ANDA Products fall within one or more claims of the '355 patent.

53. On information and belief, Defendant's ANDA Products will be indicated for the treatment of major depressive disorder.

54. Defendant does not contest infringement of at least claims 1 and 4 of the '355 Patent in its Notice Letter. If Defendant had a factual or legal basis to contest infringement of

claims 1 and 4 of the ’355 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

55. Defendant has infringed at least one claim of the ’355 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendant’s ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the ’355 Patent.

56. If approved, use of Defendant’s ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the ’355 Patent.

57. Unless enjoined by this Court, upon FDA approval, Defendant will actively induce infringement of the ’355 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendant’s ANDA, Defendant will make, use, offer to sell, or sell Defendant’s ANDA Products within the United States, or will import Defendant’s ANDA Products into the United States, and will thereby induce the infringement of one or more claims of the ’355 Patent. On information and belief, upon FDA approval, Defendant will intentionally encourage acts of direct infringement with knowledge of the ’355 Patent and knowledge that its acts are encouraging infringement.

58. Unless enjoined by this Court, upon FDA approval, Defendant will contributorily infringe the ’355 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendant’s ANDA, Defendant will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’355 Patent. On information and belief, Defendant has had and continues to have knowledge of the ’355 Patent and knowledge that its acts will lead to infringement of the patent. On information and belief, Defendant has

had and continues to have knowledge that Defendant's ANDA Products are especially made or especially adapted for a use that infringes the '355 Patent and that there are no substantial non-infringing uses for the ANDA Products.

59. Defendant had actual and constructive notice of the '355 Patent prior to filing Defendant's ANDA, and was aware that the filing of Defendant's ANDA with the request for FDA approval prior to the expiration of the '355 Patent would constitute an act of infringement of the '355 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendant's ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '355 Patent.

60. Defendant filed Defendant's ANDA without adequate justification for asserting the '355 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendant's ANDA Products. Defendant's conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the '355 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

61. Plaintiffs will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '355 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III
INFRINGEMENT OF THE '946 PATENT

62. Plaintiffs restate, reallege, and incorporate by reference paragraphs 1–61 as if fully set forth herein.

63. On information and belief, Defendant has submitted or caused the submission of ANDA No. 211131 to FDA, and thereby seeks FDA approval of Defendant's ANDA.

64. Plaintiffs own all rights, title, and interest in and to the '946 Patent.

65. Defendant's ANDA Products fall within one or more claims of the '946 patent.

66. On information and belief, Defendant's ANDA Products will be indicated for the treatment of major depressive disorder.

67. Defendant does not contest infringement of at least claims 1, 2, 4, and 5 of the '946 Patent in its Notice Letter. If Defendant had a factual or legal basis to contest infringement of claims 1, 2, 4, and 5 of the '946 patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

68. Defendant has infringed at least one claim of the '946 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendant's ANDA with a Paragraph IV certification and thereby seeking FDA approval of generic versions of TRINTELLIX® prior to the expiration of the '946 Patent.

69. If approved, use of Defendant's ANDA Products in accordance with the proposed labeling will directly infringe one or more claims of the '946 Patent.

70. Unless enjoined by this Court, upon FDA approval, Defendant will actively induce infringement of the '946 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendant's ANDA, Defendant will make, use, offer to sell, or sell Defendant's ANDA Products within the United States, or will import Defendant's ANDA Products into the United States, and will thereby induce the infringement of one or more claims of the '946 Patent. On information and belief, upon FDA approval, Defendant will intentionally

encourage acts of direct infringement with knowledge of the ’946 Patent and knowledge that its acts are encouraging infringement.

71. Unless enjoined by this Court, upon FDA approval, Defendant will contributorily infringe the ’946 Patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendant’s ANDA, Defendant will offer to sell or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby contribute to the infringement of one or more claims of the ’946 Patent. On information and belief, Defendant has had and continues to have knowledge of the ’946 Patent and knowledge that its acts will lead to infringement of the patent. Upon information and belief, Defendant has had and continues to have knowledge that Defendant’s ANDA Products are especially made or especially adapted for a use that infringes the ’946 Patent and that there are no substantial non-infringing uses for the ANDA Products.

72. Defendant had actual and constructive notice of the ’946 Patent prior to filing Defendant’s ANDA, and was aware that the filing of Defendant’s ANDA with the request for FDA approval prior to the expiration of the ’946 Patent would constitute an act of infringement of the ’946 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendant’s ANDA Products will not infringe, contribute to the infringement of, and/or induce the infringement of the ’946 Patent.

73. In addition, Defendant filed Defendant’s ANDA without adequate justification for asserting the ’946 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of Defendant’s ANDA Products. Defendant’s conduct in certifying invalidity, unenforceability, and/or non-infringement with respect to the ’946 Patent

renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitle Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

74. Plaintiffs will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '946 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Defendant has infringed the '684, '355, and '946 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendant's ANDA shall be no earlier than the last expiration date of any of the '684, '355, or '946 Patents, or any later expiration of exclusivity for any of the '684, '355, or '946 Patents, including any extensions or regulatory exclusivities;

(C) Entry of a permanent injunction enjoining Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf from commercially manufacturing, using, offering for sale, or selling Defendant's ANDA Products within the United States, or importing Defendant's ANDA Products into the United States, until the expiration of the '684, '355, and '946 Patents;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Defendant's ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the '684, '355, and '946 Patents pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf, engages in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Products, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Products, or any product that infringes the '684, '355, or '946 Patents, or induces or contributes to such conduct, prior to the expiration of the patents;

(G) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such other and further relief as the Court deems just and proper.

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