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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVEN PHARMACEUTICALS, INC. Plaintiff, v. WATSON LABORATORIES, INC. and WATSON PHARMACEUTICALS, INC. Defendants.	)	Civil Action No. _____

COMPLAINT

Plaintiff Noven Pharmaceuticals, Inc. ("Noven") for its Complaint against Defendants Watson Laboratories, Inc. ("Watson Labs.") and Watson Pharmaceuticals, Inc. ("Watson Pharms.") (collectively, "Watson") hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100, *et seq*. This action relates to Watson Labs.' Abbreviated New Drug Application ("ANDA") No. 200147 submitted to the United States Food and Drug Administration (the "FDA") seeking approval to market a generic version of Noven's Daytrana® methylphenidate transdermal system, which is indicated for the treatment of Attention Deficit Hyperactivity Disorder.

THE PARTIES

2. Plaintiff Noven is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 11960 Southwest 144th Street, Miami, FL 33186.

3. Upon information and belief, Defendant Watson Labs. is a corporation organized and existing under the laws of the State of Nevada, and has places of business at 311 Bonnie Circle, Corona, CA 92880 and at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

4. Upon information and belief, Defendant Watson Pharms. is a corporation organized and existing under the laws of the State of Nevada, having places of business at 311 Bonnie Circle, Corona, CA 92880 and 360 Mount Kemble Avenue, Morristown, NJ 07962, and corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

5. Upon information and belief, Watson Labs. and Watson Pharms. are engaged in the manufacture for sale of pharmaceutical products, including transdermal pharmaceutical products.

6. Upon information and belief, Watson Labs. is a wholly owned subsidiary of Watson Pharms.

7. Upon information and belief, Watson Labs.' preparation and submission of ANDA No. 200147 was done collaboratively with, and for the benefit of, Watson Pharms.

8. Watson Labs. and Watson Pharms. hereinafter are referred to collectively as "Watson."

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201 and 2202.

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

11. Upon information and belief, Watson Labs. is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States. Upon information and belief, Watson Labs. maintains a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054. Upon information and belief, Watson Labs. engages in continuous and systemic contacts in New Jersey and has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction.

12. Upon information and belief, Watson Pharms. is an integrated pharmaceutical company engaged in the development, manufacturing, marketing, sale and distribution of generic pharmaceutical products, whose largest commercial market is the United States. Upon information and belief, Watson Pharms. operates and manages its business as three operating segments, including Global Generics, which markets approximately 160 generic pharmaceutical

product families primarily under the Watson Labs. and Watson Pharms. labels. Upon information and belief, Watson Pharms.' generic business in the U.S. provides the dominant source of its revenue. Upon information and belief, Watson Pharms. maintains its corporate headquarters at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054, and a place of business at 360 Mount Kemble Avenue, Morristown, NJ 07962. Upon information and belief, Watson Pharms. is registered to do business in New Jersey and has appointed The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for process in New Jersey. Upon information and belief, Watson Pharms. engages in continuous and systemic contacts in New Jersey, including, but not limited to, Watson Pharms.' direction of the operations and management of Watson Labs.

13. Upon information and belief, Watson Labs. acts under the direction, control, and influence of Watson Pharms. with respect to, at least, the acts and conduct alleged in this Complaint.

14. Watson Labs.' acts and continuous and systematic contacts with the State of New Jersey, as an agent of Watson Pharms., are also attributable to Watson Pharms. for jurisdictional purposes.

15. This Court has personal jurisdiction over Watson Labs. by virtue of, among other things, (1) its presence in New Jersey; (2) its sale of a substantial volume of prescription drugs in New Jersey; (3) its continuous and systematic contacts with New Jersey; and (4) its conduct by and through, and in concert with and under the direction of, Watson Pharms.

16. This Court has personal jurisdiction over Watson Pharms. by virtue of, among other things, (1) its presence in New Jersey; (2) its registration to do business in New Jersey, including its appointment of a registered agent in New Jersey for the receipt of service of

process; (3) its sale of a substantial volume of prescription drugs in New Jersey; (4) its continuous and systematic contacts with New Jersey; and (5) its conduct by and through, and in concert with, Watson Labs.

THE PATENTS-IN-SUIT

17. United States Patent No. 6,210,705, entitled "Compositions and Methods For Treatment of Attention Deficit Disorder and Attention Deficit/Hyperactivity Disorder With Methylphenidate" (the " '705 patent"), a copy of which is attached hereto as **Exhibit A**, was duly issued by the United States Patent and Trademark Office ("USPTO") on April 3, 2001.

18. Noven is the lawful owner of the '705 patent by assignment of all rights, title and interest in and to the '705 patent, including all rights needed to bring this action in Plaintiff's own name.

19. United States Patent No. 6,348,211, entitled "Compositions and Methods For Treatment of Attention Deficit Disorder and Attention Deficit/Hyperactivity Disorder With Methylphenidate" (the " '211 patent"), a copy of which is attached hereto as **Exhibit B**, was duly issued by the USPTO on February 19, 2002.

20. Noven is the lawful owner of the '211 patent by assignment of all rights, title and interest in and to the '211 patent, including all rights needed to bring this action in Plaintiff's own name.

21. The '705 and '211 patents claim, *inter alia*, compositions and methods for treatment of attention deficit disorder and attention deficit/hyperactivity disorder (collectively "ADHD") with transdermal methylphenidate delivery systems.

NOVEN'S DAYTRANA® DRUG PRODUCT

22. Noven holds an approved New Drug Application (NDA No. 021514) for Daytrana® methylphenidate transdermal system, which is marketed and sold by Noven under the registered trademark Daytrana®.

23. Daytrana® is covered by one or more claims of the '705 and '211 patents. Pursuant to 21 U.S.C. § 355(b)(1) and attendant regulations, the '705 and '211 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Daytrana®, as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Daytrana®.

ACTS GIVING RISE TO THIS ACTION

24. By letter dated August 31, 2011 (the "Notice Letter"), Watson Labs. notified Noven that it had filed ANDA No. 200147 with the FDA seeking approval to market methylphenidate transdermal systems containing methylphenidate 31.6 mg, 47.5 mg, 63.3 mg, and 94.9 mg, supplied as a 14.4 cm^2, 21.6 cm^2, 28.8 cm^2, and 43.1 cm^2 transdermal patch respectively (collectively, "Watson's ANDA Product"), generic versions of Daytrana®, prior to the expiration of the '705 and '211 patents. The Notice Letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the "factual and legal bases" for Watson Labs.' opinion that the '705 and '211 patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Product.

25. This action is being commenced before the expiration of forty-five days from the date Noven received the Notice letter.

26. Upon information and belief, pursuant to Section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)), Watson Labs. filed with the FDA ANDA No. 200147 seeking approval to engage in the commercial manufacture, use, and sale of Watson's ANDA Product. Upon information and belief, Watson Labs. stated to the FDA in its ANDA that Watson's ANDA Product is bioequivalent to Noven's Daytrana® product.

27. The use of Watson's ANDA product is covered by one or more claims of the '705 and '211 patents.

28. Upon information and belief, Watson's ANDA No. 200147 was submitted to obtain FDA approval to engage in the commercial manufacture, use, and sale of Watson's ANDA Product prior to the expiration of the '705 and '211 patents.

29. Upon information and belief, Watson's ANDA No. 200147 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating that in Watson Labs.' opinion the '705 and '211 patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Product.

30. Upon information and belief, Watson was aware of the '705 and '211 patents when ANDA No. 200147 was filed containing the Paragraph IV certification.

COUNT I: INFRINGEMENT OF THE '705 PATENT

31. Watson Labs.' filing of ANDA No. 200147 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Product before the expiration of the '705 patent constitutes infringement of one or more of the claims of the '705 patent under 35 U.S.C. § 271(e)(2).

32. Upon information and belief, Watson has also infringed, induced, or contributed to and will infringe, induce, or contribute to infringement of one or more claims of the '705

patent by acting in concert and actively aiding, abetting, encouraging, and inducing the (1) filing of ANDA No. 200147 for methylphenidate transdermal system and (2) manufacturing of Watson's ANDA Product pursuant to that ANDA.

33. Upon information and belief, upon FDA approval, Watson will sell and distribute Watson's ANDA Product which will result in direct infringement of one or more claims of the '705 patent.

34. Watson Labs.' ANDA and Watson's intention to engage in the commercial manufacture, use, offer to sell or sale of Watson's ANDA Product upon receiving FDA approval prior to expiration of the '705 patent creates an actual and justiciable controversy with respect to infringement of the '705 patent.

35. Upon FDA approval of Watson Labs.' ANDA, Watson will infringe the '705 patent by making, using, offering to sell, and selling Watson's ANDA Product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

36. Noven will be substantially and irreparably damaged and harmed if Watson's infringement of the '705 patent is not enjoined by this Court. Noven does not have an adequate remedy at law.

COUNT II: INFRINGEMENT OF THE '211 PATENT

37. Watson Labs.' filing of ANDA No. 200147 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Watson's ANDA Product before the expiration of the '211 patent constitutes infringement of one or more of the claims of the '211 patent under 35 U.S.C. § 271(e)(2).

38. Upon information and belief, Watson has also infringed, induced, or contributed to and will infringe, induce, or contribute to infringement of one or more claims of the '211 patent by acting in concert and actively aiding, abetting, encouraging, and inducing the (1) filing of ANDA No. 200147 for methylphenidate transdermal system and (2) manufacturing of Watson's ANDA Product pursuant to that ANDA.

39. Upon information and belief, upon FDA approval, Watson will sell and distribute Watson's ANDA Product which will result in direct infringement of one or more claims of the '211 patent.

40. Watson Labs.' ANDA and Watson's intention to engage in the commercial manufacture, use, offer to sell or sale of Watson's ANDA Product upon receiving FDA approval prior to expiration of the '211 patent create an actual and justiciable controversy with respect to infringement of the '211 patent.

41. Upon FDA approval of Watson Labs.' ANDA, Watson will infringe the '211 patent by making, using, offering to sell, and selling Watson's ANDA Product in the United States, and by actively inducing and contributing to infringement by others, unless enjoined by this Court.

42. Noven will be substantially and irreparably damaged and harmed if Watson's infringement of the '211 patent is not enjoined by this Court. Noven does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Noven requests the following relief:

A. A declaration that the '705 and '211 patents are valid and enforceable;

B. A judgment declaring that Watson has infringed, and that Watson's making, using, selling, offering to sell, marketing, distributing, or importing Watson's ANDA Product

described in ANDA No. 200147 will constitute infringement, contributory infringement, and actively inducing infringement of the '705 patent;

C. A judgment declaring that Watson has infringed, and that Watson's making, using, selling, offering to sell, marketing, distributing, or importing Watson's ANDA Product described in ANDA No. 200147 will constitute infringement, contributory infringement, and actively inducing infringement of the '211 patent;

D. An Order providing that the effective date of any FDA approval for Watson to make, use, sell, offer for sale, market, distribute, or import Watson's ANDA Product described in ANDA No. 200147 be no earlier than the date on which the '705 and '211 patent expire or any later expiration of exclusivity to which Noven is or becomes entitled;

E. An Order permanently enjoining Watson, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities, and all other persons acting in concert, participation or privity with it, their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing Watson's ANDA Product and from infringing, contributorily infringing, or inducing others to infringe the '705 and '211 patents until after the expiration of the '705 and '211 patents;

F. An Order that damages or other monetary relief, including prejudgment interest, be awarded to Noven if Watson engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Watson's ANDA Product, or in inducing or contributing to such conduct by others, prior to the expiration of the '705 and '211 patents;

G. Reasonable attorneys fees, filing fees, and reasonable costs of suit incurred by Noven in this action; and

H. Such further and other relief as this Court may deem just and proper.

Dated: October 13, 2011

Respectfully submitted,

s/ Donald A. Robinson
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LOCAL CIVIL RULE 11.2 CERTIFICATION

The undersigned hereby certifies that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 13, 2011

By: s/ Donald A. Robinson
Donald A. Robinson