IN THE UNITED STATES DISTRICT COURT
FOR DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC., TEIKOKU PHARMA USA, INC. and TEIKOKU SEIYAKU CO., LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC. and WATSON PHARMA, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo"), Teikoku Pharma USA, Inc. ("Teikoku Pharma"), and Teikoku Seiyaku Co., Ltd. ("Teikoku Seiyaku") (collectively, "Teikoku"), for their Complaint against defendants Watson Laboratories, Inc. ("Watson Labs"), Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") and Watson Pharma, Inc. ("Watson Pharma") (collectively, "Watson") allege as follows:

PARTIES

1. Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceutical company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain. Endo markets and distributes Lidoderm®, an innovative lidocaine-containing pain patch for the treatment of post-herpetic neuralgia.

2. Teikoku Seiyaku is a Japanese corporation, having its principal place of business at 567 Sanbonmatsu, Higashikagawa, Kagawa 769-2695, Japan. Teikoku Seiyaku is a

specialty pharmaceutical company that develops and makes enhanced pharmaceutical products based on its transdermal drug delivery technologies. Teikoku Seiyaku's drug delivery technologies include the technology used in the Lidoderm® patch.

3. Teikoku Pharma is a California corporation, having its principal place of business at 1718 Ringwood Avenue, San Jose, California. Teikoku Pharma is a wholly-owned subsidiary of Teikoku Seiyaku.

4. Watson Pharmaceuticals is a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, CA 92880 and its commercial headquarters at 360 Mount Kemble Avenue, Morristown, New Jersey.

5. Watson Labs is a Nevada corporation, having its principal place of business at 311 Bonnie Circle, Corona, California.

6. Watson Pharma is a Delaware corporation, having its principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey.

7. Watson Labs and Watson Pharma are wholly-owned subsidiaries of Watson Pharmaceuticals.

NATURE OF ACTION

8. This is an action for infringement of United States Patent No. 5,827,529 ("the '529 patent") arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

10. Watson is in the business of making and selling generic drug products. Watson organizes its operations not by corporation, but by division, such that the Generic Division of Watson is responsible for developing and submitting Abbreviated New Drug Applications ("ANDAs") in reliance upon contributions from Watson Pharmaceuticals, Watson Laboratories and Watson Pharma. Each Watson entity acts as the agent of the other.

11. Watson Laboratories has transacted business, including contracting with, and/or purchasing goods and services with companies located in Delaware, sells products in Delaware, and has an agent, Watson Pharma, which also engages in commercial activity in Delaware. As the Court decided in *Cephalon, Inc. v. Watson Pharmaceuticals, et al*, 629 F. Supp. 2d 338 (D. Del. 2009), Watson Laboratories is subject to general personal jurisdiction in Delaware.

12. Watson Pharmaceuticals conducts business in Delaware on its own behalf and/or through its agents, Watson Pharma and Watson Laboratories, and is subject to personal jurisdiction in Delaware.

13. Watson Pharma is a Delaware corporation and, therefore, is subject to personal jurisdiction in Delaware.

FACTUAL BACKGROUND

14. On October 27, 1998, the United States Patent and Trademark Office ("PTO") duly and legally issued the '529 patent, entitled "External Preparation for Application to the Skin Containing Lidocaine" to Teikoku Seiyaku Kabushiki Kaisha, also known as Teikoku Seiyaku Co., Ltd., as assignee. A true and correct copy of the '529 patent is attached hereto as Exhibit A.

15. On March 19, 1999, the United States Food and Drug Administration (the "FDA") approved Hind Health Care, Inc.'s ("Hind") New Drug Application ("NDA") under § 505(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)) for Lidoderm®, an adhesive patch product that contains lidocaine in the amount of 5%, for the relief of pain associated with post-herpetic neuralgia ("PHN"). Teikoku Pharma assumed from Hind full ownership of and responsibility for the Lidoderm® NDA effective on June 1, 1999.

16. Approximately 500,000 cases of herpes zoster, commonly known as shingles, occur in the United States each year. Patients suffering from herpes zoster typically have a painful rash that is usually isolated to a specific region of the skin on one side of the body. In the majority of patients, the pain abates and the rash resolves in approximately 2-3 weeks.

17. The most common complication of herpes zoster is PHN, which is a disorder characterized by pain along the cutaneous nerve region of a previous herpes zoster flare-up that persists for more than 30 days after the lesions have resolved. Approximately 20% of patients with herpes zoster will experience this complication.

18. PHN pain is often chronic and lifelong. The pain can be excruciating for the patient and result in debilitating effects on the lives of those suffering from the condition. As a result of their chronic pain, patients may suffer from anxiety and depression, and experience social isolation. Lidoderm® is a unique, first-line therapy approved by the FDA for treatment of PHN pain.

19. Following the issuance of the '529 patent, Teikoku submitted information regarding the '529 patent to the FDA for listing in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (referred to as the "Orange Book"), with respect to

Lidoderm®. Pursuant to 21 C.F.R. § 314.53(e), the FDA thereafter listed the '529 patent in the Orange Book with respect to Lidoderm®.

20. Endo is the exclusive licensee of the '529 patent in the relevant field of use, and has the exclusive right to market and sell Lidoderm® in the United States.

21. Upon information and belief, prior to January 14, 2010, Watson Laboratories submitted to the FDA paperwork purporting to constitute an ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a lidocaine patch 5%, as a generic version of Lidoderm®.

22. On or about January 14, 2010, Watson Laboratories sent Teikoku a notice stating that it had submitted ANDA No. 200675 seeking approval to manufacture, use, or sell generic lidocaine patches 5% prior to the expiration of the '529 patent (the "Watson Notice").

23. The Watson Notice was signed by the Director, Regulatory Affairs of Watson Laboratories, Inc. and upon information and belief, ANDA No. 200675 was created on behalf of Watson Pharmaceuticals and Watson Pharma, which intend to market and distribute a Lidoderm® generic under ANDA No. 200675.

24. The Watson Notice advised Teikoku that Watson's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that it was Watson's opinion that the proposed manufacture, importation, use, sale, or offer for sale of the generic lidocaine 5% patch described in its ANDA would not infringe any claim of the '529 patent, and that the '529 patent is invalid.

INFRINGEMENT OF THE '529 PATENT

25. Plaintiffs incorporate each of the preceding paragraphs 1 to 24 as if fully set forth herein.

26. Watson's submission of an ANDA to the FDA, including its allegations under § 505(j)(2)(A)(vii)(IV), constitutes infringement of the '529 patent under 35 U.S.C. § 271(e)(2)(A).

27. Watson's commercial manufacture, offer for sale or sale of its proposed generic lidocaine 5% patch would infringe the '529 patent.

28. Watson was aware of the existence of the '529 patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '529 patent constitutes infringement of the patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Watson has infringed the '529 patent;

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Watson's ANDA No. 200675 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration date of the '529 patent, including any extensions;

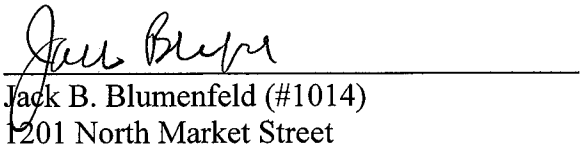
C. A preliminary and permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Watson, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from infringement of the '529 patent for the full term thereof, including any extensions;

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

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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February 19, 2010