IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC., TEIKOKU PHARMA USA, INC., and TEIKOKU SEIYAKU CO., LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
NOVEN PHARMACEUTICALS, INC. and NOVEN THERAPEUTICS, LLC,	)	
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 Noven Pharmaceuticals, Inc. and Noven Therapeutics, LLC (collectively "Noven") 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, among other things, to treat and manage pain. Endo markets and distributes Lidoderm®, an innovative lidocaine-containing patch for the relief of pain associated with 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. Teikoku Pharma imports the Lidoderm® patch into the United States.

4. Upon information and belief, Noven Pharmaceuticals, Inc. ("Noven Pharmaceuticals") is a Delaware corporation, having its principal place of business at 11960 SW 144th Street, Miami, Florida 33186.

5. Upon information and belief, Noven Pharmaceuticals is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven Pharmaceuticals' business and operations are focused in three principal areas — transdermal drug delivery and related manufacturing, the Novogyne Pharmaceuticals joint venture with Novartis Pharmaceuticals, and Noven Therapeutics, LLC.

6. Upon information and belief, Noven Therapeutics, LLC ("Noven Therapeutics") is a Delaware limited liability company, having its principal place of business at Empire State Building, 350 Fifth Avenue, 37th Floor, New York, NY 10118.

7. Upon information and belief, Noven Therapeutics is primarily responsible for the marketing, distribution, and sales of Noven Pharmaceuticals' products.

8. Upon information and belief, Noven Therapeutics is a wholly-owned subsidiary of Noven Pharmaceuticals.

NATURE OF ACTION

9. 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

10. 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).

11. Upon information and belief, Noven Pharmaceuticals conducts its North American operations, in part, through Noven Therapeutics. Together, Noven Therapeutics and Noven Pharmaceuticals (collectively the "Noven Defendants") collaborate in the research, development, manufacture, marketing, distribution and/or the sale of many pharmaceutical products, such as Daytrana®, within the United States generally and the State of Delaware specifically.

12. This Court has personal jurisdiction over each of the Noven Defendants by virtue of the fact that, *inter alia*, they have committed — or aided, abetted, contributed to, or participated in the commission of — tortious conduct that has led to foreseeable harm and injury to Endo, a Delaware corporation.

13. In addition, this Court has personal jurisdiction over each of the Noven Defendants by virtue of their continuous and systematic contacts with the State of Delaware. Noven Pharmaceuticals is a Delaware Corporation. Noven Therapeutics is a Delaware limited liability company. Upon information and belief, the Noven Defendants have purposefully availed themselves of the benefits of doing business in Delaware by, among other things, manufacturing products that are distributed and sold here.

14. On information and belief, the Noven Defendants plan to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, their business of preparing pharmaceutical products for distribution in this State.

15. Based on the facts and causes alleged herein, this Court has personal jurisdiction over both of the Noven Defendants.

THE DRUG APPROVAL PROCESS

16. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to FDA, and FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

17. On the other hand, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "listed drug" or "branded drug").

18. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange

Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

19. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owners of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

20. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

21. 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 as Exhibit A.

22. 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 the LIDODERM® Patch, an adhesive patch product that contains lidocaine in the amount of 5%, for the relief of pain associated with post-herpetic neuralgia ("PHN").

23. Teikoku Pharma is a wholly-owned subsidiary of Teikoku Seiyaku, and is currently the owner of and the entity responsible for the LIDODERM® Patch NDA. Teikoku Pharma assumed from Hind full ownership of and responsibility for the LIDODERM® Patch NDA effective on June 1, 1999.

24. 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.

25. The most common complication of herpes zoster, however, is PHN. This disorder is 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.

26. PHN pain can be chronic and lifelong. Such chronic pain is often excruciating for the patient and typically results in debilitating effects on the lives of these individuals. As a result of their chronic pain, it is not uncommon for these patients to have

anxiety, depression and experience social isolation. The LIDODERM® Patch is a unique, first-line therapy approved by the FDA for treatment of PHN pain.

27. Endo is the exclusive licensee of the '529 patent in the relevant filed of use, and has the exclusive right to market and sell the LIDODERM® Patch in the United States.

28. Information regarding the '529 patent has been submitted to the FDA for listing in the Orange Book with respect to the LIDODERM® Patch.

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

30. Upon information and belief, prior to May 15, 2012, the Noven Defendants submitted or cooperated in the submission to the FDA of paperwork purporting to constitute an Abbreviated New Drug Application ("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 the LIDODERM® Patch.

31. On May 16, 2012, Endo and Teikoku received letters purporting to notify Endo and Teikoku that Noven had submitted ANDA No. 20-3265, naming Noven Pharmaceuticals as the ANDA applicant and seeking approval to manufacture, use, or sell generic lidocaine patches 5% prior to the expiration of the '529 patent (the "Noven Letter").

32. The Noven Letter claimed that Noven Pharmaceutical's ANDA included a Paragraph IV Certification stating that, in Noven's opinion, the proposed manufacture, importation, use, sale, or offer for sale of the generic lidocaine patch 5% described in its ANDA would not infringe any claim of the '529 patent, and that the '529 patent is invalid.

33. Endo and Teikoku's counsel met and conferred with the Noven Defendant's counsel regarding Noven's "Offer of Confidential Access" to information regarding Noven's ANDA submission. The Noven Defendants, however, insisted on imposing unnecessary and burdensome restrictions on access to such information — restrictions beyond what would apply were a protective order entered for the purpose of protecting trade secrets and other confidential business information as required by 21 U.S.C. § 355(j)(5)(C)(i)(III). Thus, to date, Noven has blocked Endo and Teikoku from access to Noven's ANDA submission.

34. Plaintiffs are not aware of any other means of obtaining information regarding Noven's generic lidocaine patches 5% within the 45-day statutory period. In absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Noven's generic lidocaine patches 5% fall within the scope of one or more claims of '529 patent.

CLAIM FOR INFRINGEMENT OF THE '529 PATENT

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

36. The Noven Defendants' submission, through Noven Pharmaceuticals, of an ANDA seeking to obtain FDA approval to engage in the commercial manufacture, use, or sale of its generic copy of the LIDODERM® Patch before expiration of the '529 patent constitutes infringement of the '529 patent under 35 U.S.C. § 271(e)(2)(A).

37. The Noven Defendants were aware of the existence of the '529 patent as demonstrated by its reference to that patent in its ANDA, and were further aware that the filing of its Paragraph IV Certification with respect to the '529 patent constitutes patent infringement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the Noven Defendants have infringed the '529 patent.

B. An order that the Noven Defendants are not entitled to obtain FDA approval of its ANDA No. 20-3265 prior to expiration of the '529 patent, including any extensions;

C. An injunction enjoining each of the Noven Defendants, and each defendant's officers, agents, servants, employees, and those persons in active concert or participation with any of them from the manufacture, distribution, and sale of products made under the Noven ANDA No. 20-3265 before expiration of the '529 patent, 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.

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