IN THE UNITED STATES DISTRICT COURT
FOR DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN TECHNOLOGIES INC.,	)	
MYLAN PHARMACEUTICALS INC.,	)	
and MYLAN INC.	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Endo Pharmaceuticals Inc. ("Endo"), for its Complaint against defendants Mylan Technologies Inc. ("MTI"), Mylan Pharmaceuticals Inc. ("MPI"), and Mylan Inc.("Mylan Inc.") (collectively, "Mylan" or "Mylan Defendants"), alleges 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, including its LIDODERM® Patch.

2. Upon information and belief, MTI is a West Virginia corporation, having its principal place of business at 110 Lake Street, Saint Albans, Vermont 05478.

3. Upon information and belief, MTI is primarily responsible for the development and manufacture of Mylan Inc.'s transdermal patch technologies.

4. Upon information and belief, MPI is a West Virginia corporation, having its principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505. MPI is registered to do business in the State of Delaware.

5. Upon information and belief, MPI is primarily responsible for the marketing, distribution, and sales of Mylan Inc.'s products.

6. Upon information and belief, Mylan Inc. is a Pennsylvania corporation, having its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

7. Upon information and belief, MTI and MPI are wholly-owned subsidiaries of Mylan Inc.

JURISDICTION AND VENUE

8. This is an action arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and 28 U.S.C. §§ 2201 and 2202. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

9. Upon information and belief, Mylan Inc. conducts its North American operations, in part through MTI and MPI. Together, MTI, MPI, and Mylan Inc. collaborate in the research, development, manufacture, marketing, distribution and/or the sale of many pharmaceutical products manufactured and sold pursuant to approved abbreviated new drug applications, such as Mylan's Fentanyl transdermal patch system, within the United States generally and the State of Delaware specifically.

10. This Court has personal jurisdiction over each of the Mylan 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 Plaintiff, a Delaware corporation.

11. In addition, this Court has personal jurisdiction over each of the Mylan Defendants by virtue of their systematic and continuous contacts with the State of Delaware.

12. On information and belief, the Mylan Defendants plan to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, their aforementioned business of preparing generic pharmaceuticals, such as Mylan's Fentanyl transdermal patch system, for distribution in the State of Delaware.

13. Based on the facts and causes alleged herein, and for additional reasons to be developed through discovery, this Court has personal jurisdiction over the Mylan Defendants.

THE DRUG APPROVAL PROCESS

14. 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).

15. 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").

16. 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 so-called "Paragraph IV Certification."

17. 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.

18. 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

19. On April 21, 1998, the PTO duly and legally issued U.S. Patent No. 5,741,510 (the '510 patent), entitled "Adhesive Patch For Applying Analgesic Medication To The Skin" to LecTec Corporation ("LecTec") as assignee. A true and correct copy of the '510 patent is attached as Exhibit A.

20. On March 19, 1999, the United States Food and Drug Administration (the "FDA") approved a New Drug Application, 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").

21. Approximately 500,000 cases of herpes zoster (a.k.a. "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.

22. 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.

23. 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.

24. Teikoku Pharma USA, Inc. ("TPU"), is a wholly-owned subsidiary of Teikoku Seiyaku of Japan, and is currently the owner of and entity responsible for the LIDODERM® Patch NDA.

25. Endo is the exclusive distributor of the LIDODERM® Patch in the United States and sells the product under the authority of Teikoku's NDA.

26. Endo has the exclusive rights under the '510 patent to market and sell the LIDODERM® Patch in the United States.

27. Information regarding the '510 patent has been submitted to the FDA for listing in the Orange Book with respect to the LIDODERM® Patch.

28. Pursuant to 21 C.F.R. § 314.53(e), the FDA has listed the '510 patent in the Orange Book with respect to the LIDODERM® Patch.

29. Upon information and belief, prior to January 28, 2011, the Mylan 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.

30. On January 28, 2011, Endo received a letter purporting to notify Endo that Mylan had submitted ANDA No. 20-2346, naming MTI as the ANDA applicant and seeking approval to manufacture, use, or sell generic lidocaine patches 5% (the "Mylan Letter"). The notice identified a "Mylan" executive who, on information and belief is an officer of Mylan, Inc., as the contact person for obtaining confidential access to the ANDA and as the person authorized to accept service of process for the applicant.

31. The Mylan Letter claimed that Mylan's ANDA included a Paragraph IV Certification that it was Mylan's opinion that 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 '510 patent, and that the '510 patent is invalid.

32. Mylan asserted incorrectly in the Mylan Letter that the Patent and Trademark Office ("PTO") records indicate that the '510 patent was assigned to Endo.

33. In fact, the PTO records then and now accurately reflect that the '510 patent is owned by LecTec.

COUNT I

34. Plaintiff incorporates each of the preceding paragraphs 1 to 33 as if fully set forth herein.

35. Pursuant to 21 U.S.C. § 355(b)(3)(C)(1) and 21 C.F.R. 314.95(a), an ANDA filer making a Paragraph IV Certification must give notice of the certification to the patent owner or the patent owner's designee.

36. The purpose of this requirement is to insure that the patent holder has adequate time to evaluate whether to bring suit within the 45 day window provided by the Act.

37. The FDA regulation pertaining to Paragraph IV notice requirements, 21 C.F.R. § 314.95(a), states that "[t[he name and address of the patent owner or its representative may be obtained from the United States Patent and Trademark Office." 21 C.F.R. § 314.95(a).

38. The '510 patent is owned by LecTec, and the Mylan Letter is not addressed to LecTec. Upon information and belief, Mylan has not served LecTec with the Mylan Letter, and Mylan has not made an offer of confidential access to LecTec under the terms required by law.

39. Mylan's failure to prepare and provide a valid Paragraph IV Notice renders the Mylan ANDA incomplete and of no force and effect.

40. An actual and substantial justiciable controversy exists between Endo and Mylan as to whether Mylan's purported Paragraph IV Notice is null, void, and without legal effect, and as a consequence, whether Mylan properly triggered the ANDA litigation process by failing to serve a Paragraph IV Notice relating to the '510 Patent on LecTec.

41. Mylan's failure to serve a Paragraph IV Notice on LecTec has created an actual controversy and cloud of uncertainty surrounding the rights of Endo and others under the statutory and regulatory scheme carefully constructed by Congress. That controversy includes, without limitation, whether Endo is obligated to file suit for infringement under 35 U.S.C. § 271(e) within 45 days of receiving the Mylan Letter in order to preserve its statutory rights to a thirty-month stay of approval of Mylan's ANDA

42. The controversy as to the validity and effectiveness of Mylan's Paragraph IV Notice will cause Endo, as well as Mylan's generic competitors, to suffer substantial prejudice unless the controversy and corresponding cloud of uncertainty is resolved by the Court.

43. Accordingly, Endo is entitled to a declaration as follows: (1) that Mylan's Paragraph IV Notice is null, void and without legal effect; (2) that the Mylan Letter did not commence the 45-day period for filing a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii); and (3) that Mylan is not entitled to obtain FDA approval of its ANDA prior to expiration of the '510 patent.

COUNT II

44. Plaintiff incorporates each of the preceding paragraphs 1 to 43 as if fully set forth herein and pleads in the alternative as follows.

45. Endo is an exclusive licensee with the right to sue for infringement under the '510 patent.

46. The patent holder, LecTec, has not had an adequate opportunity to investigate the merits of the infringement claim against Mylan because, upon information and belief, Mylan failed to serve a Paragraph IV Notice on LecTec and failed to offer confidential access to the ANDA to LecTec under the terms required by law.

47. Mylan asserts in the Mylan Letter that its ANDA product does not infringe the '510 patent because, *inter alia*, "[t]he MVTR [moisture vapor transmission rate] of Mylan's product is typically 14 g/m/24 hr." Mylan provided insufficient information from which to determine what Mylan means by the word "typically" or the range of MVTR values for patches likely to be manufactured by Mylan under the ANDA.

48. Both the patent owner, LecTec, and Endo are entitled to an adequate opportunity to determine the accuracy of this and other representations in the Mylan Letter, and to further investigate the physical and functional characteristics of Mylan's ANDA products and the components thereof.

49. Mylan's submission 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 prior to expiration of the '510 patent constitutes infringement of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

50. If the Court determines now or at a future date that Mylan has complied with its obligations under the Hatch Waxman Act to provide valid notice of a Paragraph IV Certification, Endo pleads in the alternative that Mylan has infringed the '510 patent by

submitting an ANDA on the LIDODERM® Patch containing a Paragraph IV certification with respect to that patent.

PRAYER FOR RELIEF

WHEREFORE, Endo respectfully requests the following relief:

A. A declaration that Mylan's Paragraph IV Notice is null, void and without legal effect;

B. A declaration that the Paragraph IV Notice served by Mylan did not commence the 45-day period for filing a patent infringement action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii);

C. A declaration that Mylan is not entitled to obtain FDA approval of its ANDA prior to expiration of the '510 patent;

D. An injunction enjoining the manufacture, distribution, and sale of products made under the Mylan ANDA prior to expiration of the '510 patent;

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Julia Heaney

Jack B. Blumenfeld (#1014)
Julia Heaney (#3052)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jheaney@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Martin J. Black
Robert D. Rhoad
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
(215) 994-4000

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