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. _____
TWI PHARMACEUTICALS, INC. and TEH SENG PHARMACEUTICAL MFG. CO., LTD.,	)	
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 TWi Pharmaceuticals, Inc. and Teh Seng Pharmaceutical Mfg. Co., Ltd. (collectively "Defendants"), 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.

4. Upon information and belief, TWi Pharmaceuticals, Inc. ("TWi") is a corporation organized under the laws of Taiwan, with its principal place of business at 4F, No. 41, Lane 221, Kang Chien Rd., Nei Hu Dist., Taipei 114, Taiwan.

5. Upon information and belief, TWi is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of generic prescription pharmaceutical products.

6. Upon information and belief, Teh Seng Pharmaceutical Mfg. Co., Ltd. ("Teh Seng") is a company organized under the laws of Taiwan, with its principal place of business in Tainan, Taiwan.

7. Upon information and belief, Teh Seng is engaged in the development and manufacture of patch products, including hydrogel patches.

NATURE OF ACTION

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*.

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), and 28 U.S.C. §§ 2201 and 2202. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

10. Upon information and belief, TWi and Teh Seng intend to collaborate to manufacture, distribute and sell generic lidocaine 5% in Delaware should ANDA No. 20-3128 be approved by FDA.

11. Upon information and belief, TWi currently manufactures and exports drug products into the United States for sale in Delaware. Those products include generic divalproex sodium, which TWi manufactures and ships to the United States where it is distributed by Anchen Pharmaceuticals, Inc. and sold in Delaware.

12. Upon information and belief, TWi is continuously conducting clinical bioavailability and/or bioequivalence studies for ANDA registration in the United States. According to its website, TWi's goal is to develop technology and manufacturing capability in Taiwan and China into products suitable for registration in the United States in order to reach the common goal of expanding Taiwan's pharmaceutical industry.

13. By letter dated June 28, 2012, TWi has consented to personal jurisdiction and venue in this Court for this matter.

14. Upon information and belief, Teh Seng currently manufactures and exports drug products into the United States for sale in Delaware.

15. Accordingly, this Court also has personal jurisdiction over Teh Seng virtue of its systematic and continuous contacts with the State of Delaware.

16. On information and belief, the Defendants plan to continue to maintain continuous and systematic contacts with the State of Delaware, including but not limited to, their aforementioned business of manufacturing and distributing pharmaceuticals.

17. Moreover, this Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, they are collaborating in preparation to infringe certain

patents described herein, which will lead to foreseeable harm and injury to Endo, a Delaware corporation.

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

THE DRUG APPROVAL PROCESS

19. 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).

20. 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 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").

21. 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."

22. 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.

23. 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

Endo's LIDODERM® Patch

24. 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").

25. 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.

26. 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.

27. 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.

28. 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.

29. Endo has the exclusive rights to market and sell the LIDODERM® Patch in the United States.

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

THE ROLF PATENTS

31. On April 21, 1998, the United States Patent and Trademark Office ("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. The '510 patent expires on March 30, 2014.

32. On August 1, 2000, the PTO duly and legally issued U.S. Patent No. 6,096,334 (the "'334 patent"), entitled "Adhesive Patch For Applying Medication To The Skin And Method" to LecTec as assignee. A true and correct copy of the '334 patent is attached as Exhibit B. The '334 patent expires on March 30, 2014.

33. The '510 patent and the '334 patent are known collectively as "the Rolf patents."

34. In or about November 2009, Endo obtained an exclusive license under the Rolf patents to make and sell prescription pain medicines and treatments that contain 5% lidocaine, in a patch dosage form. Recently, Endo acquired from LecTec full title to each of the Rolf patents, and accordingly, Endo is now the owner and assignee of the Rolf patents.

35. In or about October 2010, Endo granted Teikoku a sublicense under the '510 patent to make and sell prescription pain medicines and treatments that contain 5% lidocaine, in a patch dosage form, including the LIDODERM® Patch.

36. Promptly thereafter, Teikoku submitted to the FDA information regarding the '510 patent for listing it in the Orange Book with respect to the LIDODERM® Patch. 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.

37. The LIDODERM® Patch is covered by one or more claims of the Rolf Patents.

THE '529 PATENT

38. On October 27, 1998, the PTO duly and legally issued U.S. Patent No. 5,827,529 (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 C. The '529 Patent expires on October 27, 2015.

39. Endo is the exclusive licensee of the '529 patent in the relevant field of use.

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

41. 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.

42. The LIDODERM® Patch is covered by one or more claims of the '529 patent.

TWI'S ANDA FILING

43. Upon information and belief, before May 24, 2012, TWi submitted to the FDA 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.

44. On May 25, 2012, Endo and Teikoku received letters purporting to notify Endo and Teikoku that TWi had submitted ANDA No. 20-3128, naming TWi as the ANDA applicant and seeking approval to manufacture, use, or sell generic lidocaine patches 5% ("the Generic Lidocaine Patches") before the expiration of the '510 and '529 patents (the "TWi Letter").

45. The TWi Letter claimed that TWi's ANDA included a Paragraph IV Certification that it was TWi's opinion that the proposed manufacture, importation, use, sale, or offer for sale of the Generic Lidocaine Patches described in its ANDA would not infringe any claim of the '510 or '529 patents, and that the '510 and '529 patents are invalid.

46. TWi's ANDA indicates that the Generic Lidocaine Patches described in its ANDA will be manufactured by Teh Seng.

47. Upon information and belief, TWi and Teh Seng have collaborated in the formulation and manufacture of the Generic Lidocaine Patches.

48. Upon information and belief, Teh Seng collaborated with TWi in producing the TWi ANDA, including creating documents that are included in ANDA No. 20-3128.

49. This action is being commenced before the expiration of forty-five days from the date Endo and Teikoku received the TWi Letter.

COUNT I
INFRINGEMENT OF THE '529 PATENT

50. Plaintiffs incorporate each of the preceding paragraphs 1 to 49 as if fully set forth herein.

51. TWi is seeking FDA approval to engage in the commercial manufacture, use, or sale of the Generic Lidocaine Patches before the expiration of the '529 patent. If granted

approval, TWi intends to launch the Generic Lidocaine Patches before expiration of the '529 patent.

52. TWi's submission of an ANDA seeking to obtain FDA approval to engage in the commercial manufacture, use, or sale of Generic Lidocaine Patches before expiration of the '529 patent constitutes infringement of the '529 patent under 35 U.S.C. § 271(e)(2)(A).

53. Defendants' commercial manufacture, offer for sale, or sale of the Generic Lidocaine Patches would infringe the '529 patent under 35 U.S.C. § 271(a)-(c).

54. Any launch by TWi of the Generic Lidocaine Patches before expiration of the '529 patent would cause Endo and Teikoku to suffer immediate and irreparable harm.

55. Upon information and belief, Teh Seng was aware that it was manufacturing the Generic Lidocaine Patches for submission in TWi's ANDA that references the '529 patent.

56. TWi 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.

COUNT II
INFRINGEMENT OF THE '510 PATENT

57. Plaintiffs incorporate each of the preceding paragraphs 1 to 56 as if fully set forth herein.

58. TWi is seeking FDA approval to engage in the commercial manufacture, use, or sale of the Generic Lidocaine Patches before the expiration of the '510 patent. If granted approval, TWi intends to launch the Generic Lidocaine Patches before expiration of the '510 patent.

59. TWi's submission of an ANDA seeking to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Generic Lidocaine Patches before expiration of the '510 patent constitutes infringement of one or more claims of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

60. Defendants' commercial manufacture, offer for sale, or sale of the Generic Lidocaine Patches would infringe the '510 patent under 35 U.S.C. § 271(a)-(c).

61. Any launch by TWi of the Generic Lidocaine Patches before expiration of the '510 Patent would cause Endo to suffer immediate and irreparable harm.

62. Upon information and belief, Teh Seng was aware that it was manufacturing the Generic Lidocaine Patches for submission in TWi's ANDA that references the '510 patent.

63. TWi was aware of the existence of the '510 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 '510 patent constitutes infringement of the patent.

COUNT III
INFRINGEMENT OF THE '334 PATENT

64. Plaintiff incorporates each of the preceding paragraphs 1 to 63 as if fully set forth herein.

65. TWi is seeking FDA approval to engage in the commercial manufacture, use, or sale of the Generic Lidocaine Patches before the expiration of the '334 patent. If granted approval, TWi intends to launch the Generic Lidocaine Patches before expiration of the '334 patent.

66. TWi's submission of an ANDA seeking to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Generic Lidocaine Patches

before expiration of the ’334 patent constitutes infringement of one or more claims of the ’334 patent under 35 U.S.C. § 271(e)(2)(A).

67. Defendants’ commercial manufacture, offer for sale, or sale of the Generic Lidocaine Patches would infringe the ’334 patent under 35 U.S.C. § 271(a)-(c).

68. Any launch by TWi of the Generic Lidocaine Patches before expiration of the ’334 Patent would cause Endo to suffer immediate and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed and that Defendants’ making, using, selling, offering to sell, marketing, distributing, or importing the Generic Lidocaine Patches described in ANDA No. 20-3128 will constitute infringement, contributory infringement, and active inducement of infringement of the ’529 patent.

B. A judgment that Defendants have infringed, and that Defendants’ making, using, selling, offering to sell, marketing, distributing, or importing the Generic Lidocaine Patches described in ANDA No. 20-3128 will constitute infringement, contributory infringement, and active inducement of infringement of the ’510 patent.

C. A judgment that Defendants have infringed, and that Defendants’ making, using, selling, offering to sell, marketing, distributing, or importing the Generic Lidocaine Patches described in ANDA No. 20-3128 will constitute infringement, contributory infringement, and active inducement of infringement of the ’334 patent.

D. A declaration that Defendants’ commercial manufacture, distribution, use, and sale of the Generic Lidocaine Patches would infringe the ’529 patent;

E. A declaration that Defendants' commercial manufacture, distribution, use, and sale of the Generic Lidocaine Patches would infringe the '510 patent;

F. A declaration that Defendants' commercial manufacture, distribution, use, and sale of the Generic Lidocaine Patches would infringe the '334 patent;

G. An order that TWi is not entitled to obtain FDA approval of its ANDA No. 20-3128 before expiration of the '529, '510, and '334 patents, including any extensions;

H. An injunction enjoining TWi and Teh Seng, and both companies' officers, agents, servants, employees, and those persons in active concert or participation with any of them from making, using, selling, offering to sell, marketing, distributing, or importing products made under the TWi ANDA No. 20-3128 before expiration of the '529, '510, and '334 patents, including any extensions;

I. An order that damages or other monetary relief, including prejudgment interest, be awarded to Endo if TWi or Teh Seng engage in the commercial manufacture, use, sale, offer to sell, marketing, distribution or importation of TWi's ANDA Product, or in inducing or contributing to such conduct by others, before the expiration of the '510 and '334 patents.

J. An order that damages or other monetary relief, including prejudgment interest, be awarded to Endo and Teikoku if TWi or Teh Seng engage in the commercial manufacture, use, sale, offer to sell, marketing, distribution or importation of TWi's ANDA Product, or in inducing or contributing to such conduct by others, before the expiration of the '529 patent.

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

L. Costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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