

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

PURDUE PHARMACEUTICAL)
PRODUCTS L.P., PURDUE PHARMA L.P.,)
and PURDUE PHARMA TECHNOLOGIES)
INC.)

Plaintiffs,

v.

HOSPIRA, INC.,

Defendant.

Civil Action No.:

COMPLAINT

Plaintiffs, Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies, Inc. (“Purdue” and “Plaintiffs,” collectively), file this Complaint against Defendant Hospira, Inc. (“Hospira” and “Defendant”), and allege as follows:

The Parties

1. Purdue Pharmaceutical Products L.P. is a Delaware limited partnership having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

2. Purdue Pharma L.P. is a Delaware limited partnership having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

3. Purdue Pharma Technologies Inc. is a Delaware corporation having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431.

4. Upon information and belief, Hospira, Inc. (“Hospira”) is a Delaware corporation with a principal place of business in Lake Forest, Illinois, and conducts business in this Judicial District.

Nature of Action and Jurisdiction

5. This cause of action arises under the Patent laws of the United States, Title 35, United States Code, and more particularly under 35 U.S.C. §§ 271 et seq. This action relates to a New Drug Application (“NDA”) submitted by Hospira to the United States Food and Drug Administration (“FDA”) for approval to market injectable hydromorphone hydrochloride products. This Court has jurisdiction over the subject matter of this patent infringement action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201-02 and 35 U.S.C. § 271.

6. Hospira has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Hospira is an Illinois citizen. Upon information and belief, Hospira is in the business of marketing pharmaceutical products and employs residents of the state of Illinois. Upon information and belief, Hospira conducts business and has offices throughout the United States and abroad. Upon information and belief, Hospira markets and sells pharmaceutical products throughout the United States, including in the state of Illinois and in this Judicial District. Upon information and belief, Hospira has previously consented to personal jurisdiction in this Judicial District. Hospira has purposefully availed itself of the benefits of this Court, including by filing an unrelated patent infringement action in this Court, and has affirmatively sought relief from this Court.

7. Upon information and belief, Hospira regularly conducts business in Illinois and in this Judicial District. Upon information and belief, Hospira is registered to do business in Illinois and has a registered agent in this Judicial District. Upon information and belief, Hospira has maintained continuous and systematic contacts with the State of Illinois, and plans to continue to maintain its systematic and continuous contacts with the State of Illinois, including but not limited to, its aforementioned business of marketing and selling pharmaceuticals in the State of Illinois. This Court has personal jurisdiction over Hospira.

Venue

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b) in that Hospira is a corporation residing in this Judicial District and has a regular and established place of business in this Judicial District.

FACTUAL BACKGROUND

9. United States Patent No. 6,589,960 (“the ‘960 Patent”), entitled “Hydromorphone And Hydrocodone Compositions And Methods For Their Synthesis,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on July 8, 2003. A true and correct copy of the ‘960 Patent is attached hereto as Exhibit A.

10. Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies, Inc. are joint owners, by assignment, of the entire right, title, and interest in the ‘960 Patent, including the right to sue for infringement of the ‘960 Patent.

11. Purdue Pharma L.P. is the owner and holder of approved New Drug Application (“NDA”) No. 19-034, which covers the manufacture and sale of Dilaudid®

(hydromorphone hydrochloride) for injection (“Dilaudid®”), which is sold throughout the United States.

12. The ‘960 Patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) as covering Dilaudid®.

13. Upon information and belief, Hospira submitted NDA No. 200403 to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act to obtain approval to engage in the commercial manufacture, importation, use, offer for sale, and/or sale of injectable hydromorphone hydrochloride products containing 1, 2, and 4 mg/mL hydromorphone hydrochloride (“the Hospira Products”) before the expiration of the ‘960 Patent.

14. Upon information and belief, Hospira’s NDA No. 200403 contains a certification under 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV Certification”) alleging that the ‘960 Patent, which is listed in the Orange Book as covering Purdue’s Dilaudid® products, is not infringed, is invalid, and/or is unenforceable.

15. Some time after August 27, 2010, certain of the Plaintiffs received a letter dated August 27, 2010 (“the Hospira Paragraph IV Notice Letter”), and signed by a representative of Hospira, purporting to be notice in compliance with 21 U.S.C. § 355(b)(3) of Hospira’s filing of NDA No. 200403, and that said NDA contains a Paragraph IV Certification regarding the ‘960 Patent. A copy of the Hospira Paragraph IV Notice Letter, absent enclosure unilaterally stamped confidential by Defendant, is attached hereto as Exhibit B.

16. The Hospira Paragraph IV Notice Letter states Hospira’s intention to seek approval to market the Hospira Products prior to the expiration of the ‘960 Patent.

COUNT I: Infringement of the '960 Patent Under 35 U.S.C. § 271

17. The allegations of the preceding paragraphs 1-16 are repeated, realleged, and incorporated herein by reference.

18. Under 35 U.S.C. § 271(e)(2)(A), Hospira's submission to the FDA of NDA No. 200403 to obtain approval for the commercial manufacture, importation, use, and/or sale throughout the United States, including Illinois, of the Hospira Products, before the expiration of the '960 Patent constitutes infringement of the '960 Patent.

19. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Hospira Products prior to patent expiration will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '960 Patent. Upon information and belief, Hospira has been aware of the existence of the '960 Patent and has no reasonable basis for believing that the manufacture, use, offer for sale, sale, and/or importation of the Hospira Products will not infringe, contribute to the infringement of, and/or induce the infringement of the '960 Patent, thus rendering the case "exceptional" as that term is used in 35 U.S.C. § 285.

20. The acts of infringement by Hospira set forth above will cause Purdue irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

PRAYER FOR RELIEF

Plaintiffs respectfully pray for the following relief:

A. Adjudging that Defendant Hospira has infringed the '960 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting NDA No. 200403 to the FDA to obtain approval for

the commercial manufacture, importation, use, offer for sale, and/or sale of the Hospira Products, and that the commercial manufacture, importation, use, offer for sale, and/or sale of the Hospira Products would infringe, contribute to the infringement of, and/or induce the infringement of the '960 Patent;

B. Adjudging that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Hospira's NDA No. 200403, under § 505(b) of the Federal Food, Drug and Cosmetic Act, to be a date not earlier than the date of expiration of the '960 Patent plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendant Hospira, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of any drug product that infringes the '960 Patent;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

E. Awarding Plaintiffs costs and expenses; and

F. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Date: October 8, 2010

Respectfully submitted,

/s/ John L. Abramic

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