IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMACEUTICAL PRODUCTS L.P., PURDUE PHARMA L.P., and PURDUE PHARMA TECHNOLOGIES INC.	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
HIKMA (MAPLE) LTD. and WEST-WARD PHARMACEUTICALS CORP.	)	
Defendants.	)	

COMPLAINT

Plaintiffs, Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies, Inc. ("Purdue" and "Plaintiffs," collectively), file this Complaint against Defendants Hikma (Maple) Ltd. ("Hikma") and West-Ward Pharmaceuticals Corp. ("West-Ward") (collectively, "Defendants"), 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, Hikma is a company organized and existing under the laws of Great Britain.

5. Upon information and belief, West-Ward is incorporated in Delaware, with a principal place of business in New Jersey.

Nature of Action and Jurisdiction

6. 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 an Abbreviated New Drug Application ("ANDA") submitted by Hikma to the United States Food and Drug Administration ("FDA") for approval to market injectable hydromorphone HCl 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.

7. Upon information and belief, Defendants are in the business of marketing and selling pharmaceutical products. Upon information and belief, West-Ward acts as a distributor of pharmaceutical products for entities affiliated with Hikma Pharmaceuticals PLC. Upon information and belief, Hikma Pharmaceuticals PLC, a British company, is the parent corporation of Defendants.

8. West-Ward's website states the following: "West-Ward Pharmaceuticals is one of the top 20 generic prescription medication providers in the US, providing pharmaceuticals to a growing number of chain stores, wholesalers, distributors, health systems and government agencies. We are the US agent and subsidiary of Hikma PLC." West-Ward's website indicates that West-Ward has a representative for the state of Delaware.

9. Upon information and belief, in or around October 2010, Defendants acquired the U.S. generic injectables business of Baxter International Inc., which included a

portfolio of 41 products in over 150 dosage strengths and forms. Upon information and belief, Defendants also acquired a manufacturing facility in Cherry Hill, New Jersey. Upon information and belief, Hikma and West-Ward are parties to an Asset Purchase Agreement with Baxter.

10. Upon information and belief, Defendants have purposefully availed themselves of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Defendants regularly conduct business in Delaware and in this Judicial District. Upon information and belief, Defendants have maintained continuous and systematic contacts with the State of Delaware. Upon information and belief, Defendants have an intent and purpose to, and do, market and sell pharmaceutical products to retailers, hospitals, nursing homes, governmental agencies, wholesalers, and/or pharmacies throughout the United States, including in the state of Delaware and in this Judicial District. Upon information and belief, Defendants manufacture pharmaceutical products in the United States that Defendants market, and intend to market, in the United States, including in the state of Delaware and in this Judicial District. Upon information and belief, Defendants intend to market the products that are the subject of this lawsuit throughout the United States, including in the state of Delaware and in this Judicial District.

11. This Court has personal jurisdiction over Defendants.

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

Factual Background

13. 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.

14. 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.

15. Purdue Pharmaceutical Products 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.

16. 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®.

17. Upon information and belief, Hikma submitted ANDA No. 202159 to the FDA under § 505(j) 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 hydromorphone HCl 2 mg/mL injectable products ("the Hikma Products") before the expiration of the '960 Patent.

18. Upon information and belief, Hikma's ANDA No. 202159 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that the '960 Patent, which is listed in the Orange Book as covering Purdue's Dilaudid® products, is invalid, unenforceable or not infringed.

19. On or after June 28, 2011, Purdue received a letter ("the Hikma Paragraph IV Notice Letter"), signed by a representative of Hikma, purporting to be notice in

compliance with 21 U.S.C. § 355(b)(3) of Hikma's filing of ANDA No. 202159, and that said ANDA contains a Paragraph IV Certification regarding the '960 Patent.

20. The Hikma Paragraph IV Notice Letter states Hikma's intention to seek approval to market the Hikma Products prior to the expiration of the '960 Patent.

21. Upon information and belief, West-Ward assisted Hikma in activities related to Hikma's ANDA application No. 202159. Upon information and belief, Defendants intend to manufacture the Hikma Products in the United States and market the Hikma Products throughout the Unites States, including in the state of Delaware.

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

22. The allegations of the preceding paragraphs 1-21 are repeated, realleged, and incorporated herein by reference.

23. Under 35 U.S.C. § 271(e)(2)(A), Hikma's submission to the FDA of ANDA No. 202159 to obtain approval for the commercial manufacture, importation, use, and/or sale throughout the United States, of the Hikma Products, before the expiration of the '960 Patent constitutes infringement of the '960 Patent.

24. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Hikma 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, Defendants have been aware of the existence of the '960 Patent and have no reasonable basis for believing that the manufacture, use, offer for sale, sale, and/or importation of the Hikma 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.

25. There is a substantial and continuing justiciable controversy between Plaintiffs and Defendants as to the infringement of the '960 Patent. The acts of infringement 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 Hikma has infringed the '960 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202159 to the FDA to obtain approval for the commercial manufacture, importation, use, offer for sale, and/or sale of the Hikma Products, and that the commercial manufacture, importation, use, offer for sale, and/or sale of the Hikma 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 Hikma's ANDA No. 202159, under § 505(j) of the Federal Food, Drug and Cosmetic Act, 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., Defendants, their 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 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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