IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACURA PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
PAR PHARMACEUTICAL, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Acura Pharmaceuticals, Inc. ("Acura") files this Complaint for patent infringement against Par Pharmaceutical, Inc. ("Par") under 35 U.S.C. § 271(e)(2). This patent action concerns the pharmaceutical drug product Oxecta®. Plaintiff, Acura, hereby states as follows:

JURISDICTION AND PARTIES

1. Plaintiff Acura is a New York corporation that has its corporate offices and principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois 60067. Acura is engaged in the business of research, development, and manufacture of pharmaceutical products in the United States. Acura is the current owner of United States Patent No. 7,510,726 ("the '726 patent").

2. On information and belief, Par is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. On information and belief, Par is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

3. On information and belief, Par does business in the State of Delaware. On information and belief, Par is registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DM-0007883) and "Pharmacy-Wholesale" (License No. A4-0001326) pursuant to DEL. CODE ANN. tit. 24 § 2540 (West 2012).

4. The Court has personal jurisdiction over Par because, on information and belief, it is incorporated in Delaware and purposely avails itself of the privilege of doing business in Delaware.

5. In addition, personal jurisdiction over Par is proper because, on information and belief, of its regular marketing and sales activities in Delaware, including the substantial, continuous, and systematic distribution and sales of generic drug products to residents of Delaware. It purposefully avails itself of the privilege of selling generic products in Delaware and can therefore reasonably expect to be subject to jurisdiction in Courts in Delaware.

6. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '726 Patent Under 35 U.S.C. § 271(e)(2))

7. Acura realleges and incorporates by reference paragraphs 1-6.

8. The '726 patent, entitled "Methods and Compositions for Deterring Abuse of Opioid Containing Dosage Forms," was duly and legally issued to Acura by the United States Patent and Trademark Office ("USPTO") on March 31, 2009. The patent claims, *inter alia*, abuse deterrent dosage forms of oxycodone. The '726 patent expires on March 16, 2025. This expiration date results from a terminal disclaimer corresponding to the expiration date of U.S.

Patent No. 7,201,920, granted by the PTO pursuant to 35 U.S.C. § 253. A true and correct copy of the '726 patent is attached as Exhibit A. A true and correct copy of the terminal disclaimer is attached as Exhibit B. Since its date of issue, Acura has been, and continues to be, the owner of the '726 patent.

9. On June 17, 2011, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 20-2080 for the use of Oxecta® for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. The Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") lists the '726 patent for NDA No. 20-2080.

10. On information and belief, Par filed or caused to be filed with the FDA ANDA No. 20-4108 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of oxycodone hydrochloride tablets, 5 mg and 7.5 mg ("Par's Oxycodone HCl Tablets"), in the United States before the expiration of the '726 patent.

11. On information and belief, ANDA No. 20-4108 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), alleging that the claims of the '726 patent are either invalid or will not be infringed by Par's Oxycodone HCl Tablets.

12. Par sent or caused to be sent to Acura a letter ("Par's Notice Letter") dated September 20, 2012, notifying Acura that Par filed ANDA No. 20-4108 and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Par's Notice Letter alleges that the claims 8–14 of the '726 patent would not be infringed by Par's Oxycodone HCl Tablets and at least claims 1–7 and 15 –20 are invalid as anticipated by, or rendered obvious over, prior art

references that were either previously considered by the USPTO, or cumulative to prior art previously considered by the USPTO.

13. Under 35 U.S.C. § 271(e)(2)(A), Par's submissions of ANDA No. 20-4108 to the FDA to obtain approval for the commercial manufacture, use, or sale of Par's Oxycodone HCl Tablets in the United States before the expiration date of the '726 patent constitutes an act of infringement. If ANDA No. 20-4108 is approved by the FDA, Par's commercial manufacture, use, sale, or offer to sell in, or importation into the United States of its Oxycodone HCl Tablets would infringe, either literally or under the doctrine of equivalents, one or more claims of the '726 patent under 35 U.S.C. § 271.

14. On information and belief, Par has knowledge of the '726 patent and has filed ANDA No. 20-4108 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Oxycodone HCl Tablets in the United States. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Oxycodone HCl Tablets in accordance with the indications sought by Par, and will therefore infringe, either literally or under the doctrine of equivalents, one or more claims of the '726 patent under 35 U.S.C. § 271(b).

15. Acura will be substantially and irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Acura has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '726 Patent Under 35 U.S.C. § 271(a) and/or (b))

16. Acura realleges and incorporates by reference paragraphs 1-15.

17. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a) and (b), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

18. On information and belief, Par filed or caused to be filed with the FDA ANDA No. 20-4108 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Par's Oxycodone HCl Tablets in the United States before the expiration of the '726 patent.

19. On information and belief, if the FDA approves ANDA No. 20-4108, Par and/or its agents plan to begin marketing, selling, and offering to sell Oxycodone HCl Tablets in the United States immediately or soon after receiving FDA approval for the indication(s) sought in ANDA No. 20-4108. Such conduct will constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '726 patent under 35 U.S.C. § 271(a) and/or (b).

20. On information and belief, Par has knowledge of the '726 patent and has filed ANDA No. 20-4108 seeking authorization to commercially manufacture, use, offer for sale, and sell Par's Oxycodone HCl Tablets in the United States. On information and belief, Par knows and intends that physicians, health care providers, and/or patients will use Par's Oxycodone HCl Tablets in accordance with the indications sought by Par, and will therefore infringe, either literally or under the doctrine of equivalents, one or more claims of the '726 patent under 35 U.S.C. § 271(b).

21. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Acura and Par as to liability for the infringement of

the '726 patent. Par's actions have created in Acura a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Acura respectfully requests that this Court enter judgment in its favor as follows:

a) declare that United States Patent No. 7,510,726 is valid and enforceable;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Par infringed the '726 patent by submitting ANDA No. 20-4108 to the FDA to obtain approval to commercially manufacture, use, offer for sale, or sell in, or import into the United States Par's Oxycodone HCl Tablets prior to the expiration of said patent;

c) declare that Par's commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Par's Oxycodone HCl Tablets prior to the expiration of the '726 patent would constitute infringement of said patent under 35 U.S.C. § 271(a) and/or (b) as set forth above and in violation of Acura's patent rights;

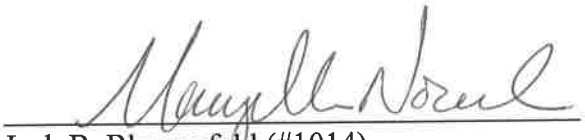
d) order that the effective date of any FDA approval of Par's Oxycodone HCl Tablets shall be no earlier than the expiration date of the '726 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Par, and all persons acting in concert with Par, from seeking, obtaining, or maintaining approval of ANDA No. 20-4108 until the expiration of the '726 patent;

f) enjoin Par, and all persons acting in concert with Par, from commercially manufacturing, using, offering for sale, or selling Par's Oxycodone HCl Tablets within the United States, or importing Par's Oxycodone HCl Tablets into the United States, until the expiration of the '726 patent, in accordance with 35 U.S.C. § 271(e)(4)(B); and

g) grant Acura such further and additional relief that this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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