IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., and THE P.F. LABORATORIES, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACURA PHARMACEUTICALS, INC., EGALET CORPORATION, and EGALET US, INC.,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. (collectively "Plaintiffs"), by their attorneys, demand a trial by jury on all issues so triable and for their complaint against Acura Pharmaceuticals, Inc., Egalet Corporation, and Egalet US, Inc. (collectively "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

THE PARTIES: PLAINTIFFS

2. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an owner of United States Patent No. 9,308,171 identified in paragraph 15 below.

3. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of United States Patent No. 9,308,171 identified in paragraph 15 below.

4. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is an owner of United States Patent No. 9,308,171 identified in paragraph 15 below.

5. Plaintiffs Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are associated companies.

THE PARTIES: DEFENDANTS

6. Upon information and belief, Defendant Acura Pharmaceuticals, Inc. ("Acura") is a corporation organized and existing under the laws of the state of New York, having a principal place of business at 616 N. North Court, Suite 120, Palatine, Illinois 60067.

7. Upon information and belief, Defendant Egalet Corporation ("Egalet Corp.") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 460 East Swedesford Road, Suite 1050, Wayne, Pennsylvania 19087.

8. Upon information and belief, Defendant Egalet US, Inc. ("Egalet US") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 460 East Swedesford Road, Suite 1050, Wayne, Pennsylvania 19087. Upon information and belief, Egalet US is a wholly owned subsidiary of Egalet Corp. As used herein, Egalet Corp. and Egalet US are referred to collectively as "Egalet."

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).

10. On information and belief, jurisdiction and venue for this action are proper in the District of Delaware.

11. This Court has personal jurisdiction over Acura because, *inter alia*, Acura has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. On information and belief, Acura does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives or plans to derive substantial revenue from things used or consumed in this State and this Judicial District. On information and belief, Acura engages in research, development, and commercialization of pharmaceutical products within and directed to the United States and this Judicial District specifically. On information and belief, Acura has entered into agreements with several Delaware corporations, including Egalet, Impax Laboratories, Inc., Pfizer, Inc. and Par Pharmaceutical Companies, Inc.

12. This Court also has personal jurisdiction over Acura because this action arises out of Acura's purposefully directed activities toward the residents of Delaware. Specifically, this action arises out of Acura's actions in connection with the accused Oxaydo® oxycodone hydrochloride immediate-release tablets. On information and belief, Oxaydo® was launched on September 9, 2015 for commercial distribution in the United States and in this Judicial District. On information and belief, Acura is actively using, promoting, selling, offering for sale, commercializing and/or manufacturing Oxaydo® in this State and this Judicial District. On information and belief, Oxaydo® is, among other things, marketed, sold, and distributed in

Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which have substantial effect in Delaware. Upon information and belief, Acura knows and intends that Oxaydo® has been and will continue to be distributed and sold in the United States, including in Delaware. For example, on information and belief, Acura has entered into an agreement with Egalet, which is organized and existing under the laws of this State, regarding the accused Oxaydo® product as described in paragraphs 16-19 below. As described in paragraph 16 below, Acura previously co-developed and promoted Oxecta® oxycodone hydrochloride immediate-release tablets (which, on information and belief, is the same product as Oxaydo®) with Delaware corporations King Pharmaceuticals, Inc. and Pfizer, Inc. On information and belief, Acura partnered with Pfizer, Inc. to market, promote, distribute or sell Oxecta® in the United States, including in Delaware. Acura also has filed suit for patent infringement previously in this District, including four lawsuits regarding its Oxecta® product described in paragraph 16 below: *Acura Pharmaceuticals Inc. v. Impax Laboratories Inc.*, C.A. No. 12-1371-RGA; *Acura Pharmaceuticals Inc. v. Par Pharmaceutical Inc.*, C.A. No. 12-1372-RGA; *Acura Pharmaceuticals Inc. v. Sandoz Inc.*, C.A. No. 12-1373-RGA; and *Acura Pharmaceuticals Inc. v. Watson Laboratories Inc. – Florida et al.*, C.A. No. 12-01374-RGA. Acura has purposefully directed its actions with respect to the accused Oxaydo® product and the former Oxecta® product at the state of Delaware, the consequences of which are suffered and will be suffered by Purdue in Delaware. Acura knew or should have known that its actions with regard to Oxaydo®, which will constitute and/or will result in patent infringement of U.S. Patent No. 9,308,171, would cause injury to Delaware residents in Delaware. Accordingly, Acura should have reasonably anticipated that its actions would cause injury in Delaware and that it would be liable for suit in Delaware to redress that injury.

13. This Court has personal jurisdiction over Egalet because, *inter alia*, Egalet has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. On information and belief, Egalet is organized and existing under the laws of this State. On information and belief, Egalet does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives or plans to derive substantial revenue from things used or consumed in this State and this Judicial District. On information and belief, Egalet engages in the development, manufacture, and sale of pharmaceutical products within and directed to the United States and this Judicial District specifically. This Court also has personal jurisdiction over Egalet because this action arises out of Egalet's purposefully directed activities toward the residents of Delaware. On information and belief, Egalet is using, selling, offering for sale, commercializing and/or manufacturing Oxaydo® in this State and this Judicial District. On information and belief, Oxaydo® has been and will continue to be, among other things, marketed, sold, and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which will have substantial effect in Delaware. Upon information and belief, Egalet knows and intends that Oxaydo® has been and will continue to be distributed and sold in the United States, including in Delaware. Egalet is purposefully directing its actions with respect to the accused Oxaydo® product at the state of Delaware, the consequences of which are suffered and will be suffered by Purdue in Delaware. Egalet knew or should have known that its actions with regard to Oxaydo®, which will constitute patent infringement of U.S. Patent No. 9,308,171, would cause injury to Delaware residents in Delaware. Accordingly, Egalet should have reasonably anticipated that its actions would cause injury in Delaware and that it would be liable for suit in Delaware to redress that injury.

14. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT-IN-SUIT

15. Plaintiffs are the lawful owners of all right, title, and interest in United States Patent No. 9,308,171 entitled "PHARMACEUTICAL COMPOSITION CONTAINING GELLING AGENT" ("the '171 patent"), including the right to sue and to recover for infringement thereof. A copy of the '171 patent is attached hereto as Exhibit A, which was duly and legally issued on April 12, 2016, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

BACKGROUND

16. On information and belief, Acura co-developed the drug Oxaydo® (formerly known as Oxecta®) with King Pharmaceuticals, Inc. (later acquired by Pfizer, Inc.). The FDA approved NDA No. 20280 for Oxecta® on June 17, 2011. The labelling name change from Oxecta® to Oxaydo® was approved by the FDA on January 26, 2015. On information and belief, Oxaydo® currently is approved by the FDA.

17. Oxaydo® is approved for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. A copy of the package insert for Oxaydo®, including approved prescribing information, is attached as Exhibit B. On information and belief, Oxaydo® infringes one or more claims of the '171 patent.

18. On information and belief, Egalet and Acura entered into a collaboration and license agreement in January 2015 under which Defendants have and will continue to commercialize Oxaydo®. Under the agreement, on information and belief, Acura has transferred the Oxaydo® NDA to Egalet as well as granted an exclusive license under Acura's intellectual

property rights for Egalet to develop and commercialize Oxaydo®. Further, on information and belief, Acura and Egalet have formed a joint steering committee to coordinate commercialization strategies. Attached as Exhibits C and D are excerpts from SEC filings from Acura and Egalet, respectively, which include descriptions of the agreement and relationship between Acura and Egalet, and statements regarding the Defendants' preparations for the launch of Oxaydo®. (*See, e.g.*, Ex. C at 2; Ex. D at 3, 10.)

19. On information and belief, Defendants launched Oxaydo® for commercial sale in the United States on September 9, 2015.

20. Defendants have specifically identified Purdue Pharma in SEC filings as a competitor with respect to opioid abuse deterrent technologies and products. (*See* Ex. C at 6; Ex. D at 7.)

21. On information and belief, at least as of the date of receiving notice of this lawsuit, Defendants have had knowledge of the existence of the '171 patent. On information and belief, despite knowledge of '171 patent, Defendants will continue to commercialize Oxaydo® as described herein.

22. By virtue of Defendants' activities in connection with Oxaydo®, a real and substantial controversy exists between Plaintiffs and Defendants as to the present and/or future infringement of one or more claims of the '171 patent.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,308,171

23. Plaintiffs incorporate by reference the allegations contained in paragraphs 1 to 22 above.

24. On information and belief, Oxaydo® is covered by one or more claims of the '171 patent.

25. On information and belief, Defendants presently engage in activities that would infringe one or more claims of the ‘171 patent.

26. On information and belief, Defendants’ manufacture, use, sale, and/or offer for sale of Oxaydo® infringes, contributes to the infringement of, and/or induces the infringement of one or more claims of the ‘171 patent. Claim 1 of the ‘171 patent claims, *inter alia*, an immediate release oral dosage form comprising oxycodone hydrochloride, polyethylene oxide, a disintegrant, sodium lauryl sulfate and magnesium stearate. The approved prescribing information for Oxaydo® states: “OXAYDO (oxycodone HCl, USP) tablets are an immediate-release opioid analgesic intended for oral administration only,” “contain[] oxycodone HCl, USP as the active analgesic ingredient” and “also contain colloidal silicon dioxide NF; crospovidone NF; magnesium stearate NF; microcrystalline cellulose NF; polyethylene oxide NF; and sodium lauryl sulfate NF.” (*See* Ex. B, Oxaydo® Approved Prescribing Information, at 10). On information and belief, the Oxaydo® tablets infringe one or more claims of the ‘171 patent such that any person or entity that manufactures, uses, sells, and/or offers for sale Oxaydo® is liable for direct infringement.

27. On information and belief, at least as of the date of notice of the present lawsuit, Defendants are aware of the existence of the ‘171 patent, and have no reasonable basis for believing that Oxaydo® will not infringe the ‘171 patent or that the ‘171 patent is invalid, thus rendering the case exceptional under 35 U.S.C. § 285. On information and belief, Defendants’ acts with respect to Oxaydo® are willful, deliberate, and with reckless disregard of the ’171 patent.

28. The acts of infringement by Defendants set forth above have caused and will continue to cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

29. As a result of the acts of infringement by Defendants, Plaintiffs also have suffered and will continue to suffer substantial damages in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment:

A. That Defendants' present and future activity constitutes infringement of the '171 patent, and that the commercial sale, offer for sale, use, manufacture and/or import of Oxaydo® infringes, induces infringement of, and/or contributes to the infringement of the '171 patent;

B. Preliminarily and permanently enjoining Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, joint ventures, 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 Oxaydo® and any other drug product that infringes the '171 patent prior to the expiration of the '171 patent plus any additional periods of exclusivity;

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

D. Awarding damages adequate to compensate Plaintiffs for the Defendants' acts of patent infringement, including enhanced damages, up to and including treble damages, together with interest and costs as fixed by the Court; and

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

JURY DEMAND

Plaintiffs respectfully request a jury trial on all issues so triable.

Respectfully submitted,

/s/ *Jeffrey T. Castellano*

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Dated: April 12, 2016