David L. Hecht (Bar No. 028802008)
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 506-3905
Facsimile: (212) 506-3950
dhecht@steptoe.com

Of Counsel:
John L. Abramic
STEPTOE & JOHNSON LLP
115 South LaSalle Street, Suite 3100
Chicago, IL 60603
TEL: (312) 577 1264
FAX: (312) 577 1370
jabramic@steptoe.com

Cassandra Adams
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 378-7615
Facsimile: (212) 378-3950
cadams@steptoe.com

Attorneys for Plaintiffs Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PURDUE PHARMACEUTICAL PRODUCTS L.P.; PURDUE PHARMA L.P.; and PURDUE PHARMA TECHNOLOGIES INC., Plaintiffs, v. LANNETT HOLDINGS, INC. and LANNETT COMPANY, INC., Defendants.	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

Defendants Lannett Holdings, Inc. and Lannett Company, Inc. ("Lannett" and "Defendants," collectively), 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. Purdue Pharma L.P. and/or its affiliates own, lease and maintain several facilities in the State of New Jersey.

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, Defendant Lannett Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 103 Foulk Road, Suite 202, Wilmington, Delaware 19803.

5. On information and belief, Defendant Lannett Company, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 13200 Townsend Road, Philadelphia, Pennsylvania 19154.

6. On information and belief, Lannett Holdings, Inc. is a wholly owned subsidiary of Lannett Company, Inc.

7. On information and belief, Lannett manufactures and/or distributes generic drugs for sale and use throughout the United States, including in this Judicial District. On information

and belief, Lannett also prepares and/or aids in the preparation and submission of ANDAs to the United States Food and Drug Administration ("FDA").

Nature of Action and Jurisdiction

8. 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 Lannett to the FDA for approval to market oral 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.

9. Upon information and belief, Lannett has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Lannett has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Upon information and belief, Lannett has committed, aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in New Jersey. Upon information and belief, Lannett has customers in the State of New Jersey and substantial contacts with the State of New Jersey.

10. Upon information and belief, Lannett Company, Inc. contracts with at least eleven authorized distributors in New Jersey for business purposes and for the promotion of its generic pharmaceuticals to potential purchasers. In addition, Lannett Company, Inc. holds a manufacturer license in New Jersey (Registration No. 5004020) and files income tax returns in Pennsylvania, New Jersey and California. Further, upon information and belief, Lannett

Company, Inc. has previously consented to personal jurisdiction in this Court including removing a civil action against it from New Jersey state court to this Court (*see, e.g.*, Civil Action No. 05-4202), and purposefully availed itself of the benefits of this forum by filing counterclaims in that action and seeking injunctive relief in the form of a temporary restraining order and preliminary injunction.

11. Upon information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. operate as an integrated business.

12. Upon information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. share common officers and directors and are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in New Jersey.

13. Upon information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. together formulate, develop, market, and sell active pharmaceutical ingredients ("APIs"), solid dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations that they distribute in New Jersey and throughout the United States.

14. Upon information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. together routinely file, and/or aid, abet, contribute to, and/or participate in the filing of, ANDAs to seek FDA approval to market their products in the United States, including in New Jersey.

15. On information and belief, Lannett Company, Inc., acting either alone or in concert with Lannett Holdings, Inc., either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes pharmaceutical products in New Jersey.

16. Upon information and belief, Lannett Company, Inc. directs, authorizes, cooperates, participates, and/or assists Lannett Holdings, Inc. with the marketing, selling, and/or distributing pharmaceutical products in New Jersey. Upon information and belief, the acts of Lannett Holdings, Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Lannett Company, Inc.

17. Upon information and belief, this Judicial District is a likely destination of products that will be manufactured and sold as a result of FDA approval of Lannett's ANDA No. 207108, which is the subject of this lawsuit.

18. Upon information and belief, Lannett Holdings, Inc. and Lannett Company, Inc. have committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Purdue Pharma L.P., which conducts business in New Jersey.

19. Upon information and belief, Lannett has maintained continuous and systematic contacts with the State of New Jersey, and plans to continue to maintain its systematic and continuous contacts with the State of New Jersey, including but not limited to, its aforementioned business of marketing and selling pharmaceuticals in the State of New Jersey. This Court has personal jurisdiction over Lannett.

Venue

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

FACTUAL BACKGROUND

21. 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.

22. 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.

23. Purdue Pharmaceutical Products L.P. is the owner and holder of approved New Drug Application ("NDA") No. 19-891, which covers the manufacture and sale of Dilaudid® (hydromorphone hydrochloride) oral solution ("Dilaudid®"), which is sold throughout the United States.

24. 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®.

25. Upon information and belief, Lannett submitted ANDA No. 207108 to the FDA under § 505(j)(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 a generic hydromorphone hydrochloride oral solution product containing 5 mg/5mL hydromorphone hydrochloride ("the Lannett Products") before the expiration of the '960 Patent.

26. Upon information and belief, Lannett's ANDA No. 207108 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 not infringed and/or is invalid.

27. Lannett sent to Purdue Pharmaceutical Products L.P. a letter ("the Lannett Paragraph IV Notice Letter") signed by a representative of Lannett, purporting to be notice in

compliance with 21 U.S.C. § 355(j)(2)(B) of Lannett's filing of ANDA No. 207108, and stating that said ANDA contains a Paragraph IV Certification regarding the '960 Patent.

28. The Lannett Paragraph IV Notice Letter states Lannett's intention to seek approval to market the Lannett Products prior to the expiration of the '960 Patent. On information and belief, Lannett markets and/or sells other products containing hydromorphone hydrochloride in the United States, including this Judicial District.

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

29. The allegations of the preceding paragraphs 1-28 are repeated, realleged, and incorporated herein by reference.

30. Under 35 U.S.C. § 271(e)(2)(A), Lannett's submission to the FDA of ANDA No. 207108 to obtain approval for the commercial manufacture, importation, use, and/or sale throughout the United States, including New Jersey, of the Lannett Products, before the expiration of the '960 Patent constitutes infringement of the '960 Patent.

31. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Lannett 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, Lannett 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 Lannett 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.

32. The acts of infringement by Lannett set forth above will cause Plaintiffs 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 Lannett has infringed the '960 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207108 to the FDA to obtain approval for the commercial manufacture, importation, use, offer for sale, and/or sale of the Lannett Products, and that the commercial manufacture, importation, use, offer for sale, and/or sale of the Lannett 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 Lannett's ANDA No. 207108, 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., Lannett, 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.

Dated: August 6, 2015

Respectfully submitted,

s/David L. Hecht
David L. Hecht (Bar No. 028802008)
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 506-3905
Facsimile: (212) 506-3950
dhecht@steptoe.com

Of Counsel:
John L. Abramic
STEPTOE & JOHNSON LLP
115 South LaSalle Street, Suite 3100
Chicago, IL 60603
Telephone: (312) 577 1264
Facsimile: (312) 577 1370
jabramic@steptoe.com

Cassandra A. Adams
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 378-7615
Facsimile: (212) 378-3950
cadams@steptoe.com

Attorneys for Plaintiffs Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiffs, Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies Inc., by their undersigned counsel, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy in this case is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceedings.

Dated: August 6, 2015

Respectfully submitted,

s/David L. Hecht
David L. Hecht (Bar No. 028802008)
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 506-3905
Facsimile: (212) 506-3950
dhecht@steptoe.com

Of Counsel:
John L. Abramic
STEPTOE & JOHNSON LLP
115 South LaSalle Street, Suite 3100
Chicago, IL 60603
Telephone: (312) 577 1264
Facsimile: (312) 577 1370
jabramic@steptoe.com

Cassandra A. Adams
STEPTOE & JOHNSON LLP
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 378-7615
Facsimile: (212) 378-3950
cadams@steptoe.com

Attorneys for Plaintiffs Purdue Pharmaceutical Products L.P., Purdue Pharma L.P., and Purdue Pharma Technologies Inc.