

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NOVEN PHARMACEUTICALS, INC.,

Plaintiff/Counterclaim
Defendant,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant/Counterclaim
Plaintiff.

C.A. No. 18-699-LPS

AMNEAL PHARMACEUTICALS LLC,

Third-Party
Plaintiff,

v.

HISAMITSU PHARMACEUTICAL CO. INC.

Third-Party
Defendant.

THIRD-PARTY COMPLAINT OF AMNEAL PHARMACEUTICALS LLC

1. This is an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the Federal Food, Drug, and Cosmetic Act, and the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*, brought pursuant to Fed. R. Civ. P. 14, based upon an actual controversy between the parties to declare that Amneal Pharmaceuticals LLC (“Amneal”) is free to continue to seek approval of its Abbreviated New Drug Application (“ANDA”) No. 211396, and upon approval by the U.S. Food and Drug Administration (“FDA”), to manufacture, use, market, sell, and offer to sell Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day

and 0.1 mg/day, as described in ANDA No. 211396 (“Amneal ANDA Product”) in the United States.

PARTIES

2. Third-Party Plaintiff Amneal is a limited liability company organized and existing under the laws of the State of Delaware having a principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

3. On information and belief, Third-Party Defendant Hisamitsu Pharmaceutical Co., Inc. (“Hisamitsu”) is a Japanese corporation with a principal place of business at Saga, Tosu, Tashirodiakan-machi, 408, Japan 841-0017.

4. On information and belief, Plaintiff and Counterclaim-Defendant Noven Pharmaceuticals, Inc. (“Noven”) is a wholly-owned subsidiary of Hisamitsu.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of Amneal’s Counterclaims filed May 22, 2018 (D.I. 7) and Third-Party Complaint, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202; 21 U.S.C § 355 (j)(5)(C)(i)(II); and/or 35 U.S.C. § 271(e)(5).

6. This Court has personal jurisdiction over Hisamitsu because Hisamitsu is in the business of manufacturing, marketing, importing into the United States, and selling pharmaceutical products. On information and belief, Hisamitsu, directly or through its affiliates and agents, markets and sells drug products throughout the United States and in this judicial district, and has purposely availed itself of the rights and benefits of Delaware law and this judicial district. Additionally, Hisamitsu has previously availed itself of the rights and benefits of Delaware law and this judicial district by initiating *Noven Pharmaceuticals, Inc., et al. v. Mylan Technologies, Inc., et al.*, C.A. No. 15-0328-LPS (D. Del.), a case in this judicial district

concerning U.S. Patent Nos. 8,231,906 and 6,841,716. By virtue of, *inter alia*, these aforementioned facts, this Court has personal jurisdiction over Hisamitsu.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400, by Noven's choice of forum, and by at least Hisamitsu's choice of forum in *Noven Pharmaceuticals, Inc., et al. v. Mylan Technologies, Inc., et al.*, C.A. No. 15-0328-LPS (D. Del.).

FACTUAL BACKGROUND

8. Amneal filed an ANDA, assigned number 211396, with the FDA seeking approval to engage in the commercial manufacture, use, or sale of the Amneal ANDA Product that is the subject of ANDA No. 211396.

9. Noven filed a Complaint on May 8, 2018, seeking, *inter alia*, a judgment that Amneal infringed one or more claims of U.S. Patent Nos. 9,730,900; 9,724,310; and 9,833,419 (the "Asserted Patents") by filing a paragraph IV certification as to those patents in ANDA No. 211396.

10. On information and belief, Noven caused FDA to list U.S. Patent No. 6,841,716 ("the '716 patent"), in addition to the Asserted Patents, in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") in connection with Minivelle[®]. (The '716 patent is attached hereto as Exhibit 1). By so doing, Noven represented that a claim of patent infringement could reasonably be asserted against any unlicensed manufacture, use, or sale of Minivelle[®].

11. On information and belief, Hisamitsu purports to be the owner of all title, right, and interest in and to the '716 patent by assignment, and therefore to have the full right to sue and recover for the infringement thereof.

12. By listing the '716 patent in the Orange Book, Noven created a reasonable apprehension that it and/or Hisamitsu would file a patent infringement action against applicants seeking regulatory approval for Estradiol Transdermal System based on the '716 patent, including Amneal, for the manufacture of a generic version of Minivelle[®].

13. Amneal submitted to FDA, and is continuing to seek FDA approval of, ANDA No. 211396 directed to Estradiol Transdermal System, USP, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day and 0.1 mg/day.

14. Amneal submitted to the FDA a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '716 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Amneal ANDA Product that is the subject of ANDA No. 211396.

15. Pursuant to subsection 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and § 315.95 of Title 21 of the U.S. Code of Federal Regulations, on March 26, 2018, Amneal provided notice to Noven and Hisamitsu of the Paragraph IV Certification with respect to the '716 patent ("Notice Letter").

16. As part of the Notice Letter, Amneal provided Noven and Hisamitsu with an offer of confidential access to ANDA No. 211396.

17. Noven and/or Hisamitsu could have, but did not, bring an action for patent infringement against Amneal based on the '716 patent during the 45-day statutory period under 21 U.S.C. § 355(j)(5)(B)(iii) following receipt of the Notice Letter.

18. Since Noven brought a patent infringement action against Amneal before the expiration of 45 days after Noven received notice of the Paragraph IV Certification from Amneal

for the Asserted Patents, pursuant to 21 U.S.C. § 355U)(5)(B)(iii), Amneal expects to receive approval from FDA to engage in the commercial manufacture, use, or sale of the Amneal ANDA Product no earlier than the expiration of the thirty-month stay, thus allowing it to manufacture and market the Amneal ANDA Product in the United States.

19. On information and belief, Mylan Technologies Inc. (“MTI”) is the holder of ANDA No. 206685 for Estradiol Transdermal System, USP, "Twice-Weekly" 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day and 0.1 mg/day (“Mylan's ANDA Products”), which contains, *inter alia*, Paragraph IV Certifications as to the '906 and '716 patents.

20. On information and belief, August 18, 2014 is the date on which MTI submitted to FDA a substantially complete ANDA for Mylan's ANDA Products.

21. Pursuant to subsection 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and § 315.95 of Title 21 of the U.S. Code of Federal Regulations, and on information and belief, Noven and Hisamitsu received from MTI a notice of the Paragraph IV Certifications with respect to the '906 and '716 patents (“Mylan's Notice Letter”) on or around March 12, 2015.

22. On April 23, 2015, Noven and Hisamitsu sued MTI, Mylan Pharmaceuticals Co., Inc., and Mylan Inc. in the U.S. District Court for the District of Delaware, alleging infringement of the '906 and '716 patents. Complaint, *Noven Pharms., Inc. v. Mylan Techs. Inc.*, C.A. No. 15-328- LPS (D. Del. Apr. 23, 2015).

23. On information and belief, Noven and Hisamitsu brought the action against MTI, Mylan Pharmaceuticals Co., Inc., and Mylan Inc. in the U.S. District Court for the District of Delaware, alleging infringement of the '906 and '716 patents within 45 days after receipt of Mylan's Notice Letter, thereby preserving Noven and Hisamitsu's right to a 30-month stay under

21 U.S.C. § 355(j)(5)(B)(iii).

24. On April 24, 2015, Noven and Hisamitsu sued MTI, Mylan Pharmaceuticals Co., Inc., and Mylan Inc. in the U.S. District Court for the Northern District of West Virginia, alleging infringement of the '906 and '716 patents. Complaint, *Noven Pharms., Inc. v. Mylan Techs. Inc.*, No. 1:15-69-IMK (N.D. W. Va. Apr. 24, 2015).

25. On information and belief, Noven and Hisamitsu brought the action against MTI, Mylan Pharmaceuticals Co., Inc., and Mylan Inc. in the U.S. District Court for the Northern District of West Virginia, alleging infringement of the '906 and '716 patents within 45 days after receipt of Mylan's Notice Letter, thereby preserving Noven and Hisamitsu's right to a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

26. On May 5, 2015, Mylan N.V. issued a press release stating that "Mylan believes that it is the first company, or among the first companies, to have filed a substantially complete ANDA containing a paragraph IV certification for this product and expects to be eligible for 180 days of marketing exclusivity upon receiving final FDA approval." Press Release, Mylan N.V. Mylan Confirms First-to-File Patent Challenge Relating to Minivelle[®] (May 5, 2015).

27. The '716 patent remains listed in the Orange Book for Minivelle[®] and, as a result, Amneal is suffering an actual injury. A declaratory judgment of non-infringement is the only way to redress this injury.

28. Because neither Noven nor Hisamitsu asserted the '716 patent against Amneal within 45 days following receipt of the Notice Letter, Amneal faces a restraint on its ability to commercially market the Amneal ANDA Product and further faces the risk that Noven and/or Hisamitsu will sue Amneal asserting infringement of the '716 patent.

29. In view of the foregoing, an actual case and controversy exists between Amneal on the one hand, and Noven and Hisamitsu on the other, with respect to the '716 patent that is within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201 and, in addition, such patent may be the basis for first-to-file exclusivity and a regulatory obstacle to final approval of Amneal's ANDA No. 211396.

Declaratory Judgment of Noninfringement of U.S. Patent No. 6,841,716

30. Amneal incorporates by reference and realleges each of the allegations set forth in paragraphs 1-29 of this Third-Party Complaint as though fully set forth herein.

31. A present, genuine, and justiciable controversy exists between Amneal on the one hand, and Noven and Hisamitsu on the other, regarding, *inter alia*, whether the manufacture, use, sale, offer for sale, or importation of the Amneal ANDA Product would infringe the '716 patent.

32. Neither the filing of ANDA No. 211396 nor the manufacture, use, sale, offer for sale, or importation of the Amneal ANDA Product would infringe directly and/or indirectly any valid or enforceable claim of the '716 patent, either literally or under the doctrine of equivalents.

33. A declaration that neither the filing of ANDA No. 21136, nor the manufacture, use, sale, offer for sale, or importation of the Amneal ANDA Product would infringe any valid or enforceable claim of the '716 patent, is appropriate and warranted.

PRAYER FOR RELIEF

WHEREFORE, Amneal respectfully requests that the Court enter judgment in its favor and grant the following relief:

a. Declaring that Amneal has not infringed any valid and enforceable claim of the '716 patent;

b. Declaring that the Amneal ANDA Product and the submission of ANDA No.

211396 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Product prior to the expiration of the '716 patent does not and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '716 patent;

c. Declaring that Noven, Hisamitsu, and their respective agents, representatives, attorneys, and those persons in active concert or participation with them who receive notice therefor be preliminarily and permanently enjoined from initiating infringement litigation against, or threatening Amneal or any parties associated therewith (including Amneal's customers) or charging any of them either orally or in writing with infringement, or inducement of infringement, or contributory infringement of the '716 patent;

d. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Amneal its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

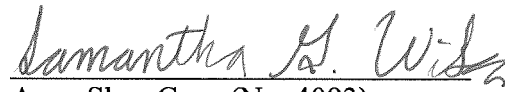
e. Awarding Amneal such other and further relief as the Court deems just and proper.

Dated: June 1, 2018

YOUNG CONAWAY STARGATT &
TAYLOR, LLP

Of Counsel:

MADDOX EDWARDS, PLLC
Steven Maddox
Jeremy Edwards
Matthew Ruedy
Kaveh Saba
1900 K Street NW, Suite 725
Washington, D.C. 20006
(202) 830-0707
smaddox@meiplaw.com
jedwards@meiplaw.com
mrueidy@meiplaw.com
ksaba@meiplaw.com



Anne Shea Gaza (No. 4093)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
swilson@ycst.com

*Attorneys for
Third-Party Plaintiff
Amneal Pharmaceuticals LLC*

CERTIFICATE OF SERVICE

I, Samantha G. Wilson, Esquire, hereby certify that on June 1, 2018, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered participants.

I further certify that on June 1, 2018, I caused the foregoing document to be served by e-mail on the following counsel of record:

John G. Day
Andrew C. Mayo
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
jday@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs

Dated: June 1, 2018

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Samantha G. Wilson

Anne Shea Gaza (No. 4093)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
swilson@ycst.com

Attorneys for Defendant/Counterclaim Plaintiff