

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC,)
)
<i>Plaintiff,</i>)
)
v.)
)
AMNEAL PHARMACEUTICALS LLC, AMNEAL)
PHARMACEUTICALS OF NEW YORK, LLC, and)
AMNEAL EU, LIMITED,)
)
<i>Defendants.</i>)
)

Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC (“Fresenius” or “Plaintiff”) brings this action for patent infringement against Defendants Amneal Pharmaceuticals LLC (“Amneal Pharma”), Amneal Pharmaceuticals of New York, LLC (“Amneal NY”), and Amneal EU, Limited (“Amneal EU”) (collectively, “Amneal” or “Defendants”).

1. This is an action by Fresenius against Defendants for infringement of United States Patent No. 8,476,010 (“the ’010 patent”). This action arises out of Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell a generic version of Diprivan[®], an innovative intravenously administered sedative and anesthetic, prior to the expiration of the ’010 patent.

THE PARTIES

Plaintiff

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius was formerly known as APP Pharmaceuticals, LLC.

Defendants

3. Upon information and belief, Defendant Amneal Pharma is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, NJ 08807.

4. Upon information and belief, Defendant Amneal NY 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, 3rd Floor, Bridgewater, NJ 08807. Upon information and belief, Amneal NY is a wholly owned subsidiary of Amneal Pharma. Upon information and belief, Amneal NY is the U.S. agent for Amneal EU.

5. Upon information and belief, Defendant Amneal EU is a company organized and existing under the laws of Ireland, having a place of business at Cahir Road, Cashel, Co. Tipperary, Ireland E25 XD51. Upon information and belief, Amneal EU is an indirect wholly owned subsidiary of Amneal Pharma.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

6. This action for patent infringement arises under 35 U.S.C. § 271.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction

8. Upon information and belief, this Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of New Jersey.

9. Upon information and belief, this Court also has personal jurisdiction over Defendants because, *inter alia*, they have committed, or aided, abetted, contributed to, or

participated in the commission of, tortious conduct, which will lead to foreseeable harm and injury to Fresenius in the State of New Jersey, and by doing so, Defendants have purposefully directed their activities at the residents of this forum.

10. Upon information and belief, this Court has personal jurisdiction over Defendant Amneal Pharma because it has its principal place of business in New Jersey.

11. Upon information and belief, this Court has personal jurisdiction over Defendant Amneal NY because it has its principal place of business in New Jersey.

12. Upon information and belief, this Court has personal jurisdiction over Defendant Amneal EU because its U.S. agent, Amneal NY, has its principal place of business in New Jersey.

13. Upon information and belief, Defendants have previously availed themselves of this Judicial District by not contesting personal jurisdiction in at least the following actions: *Cubist Pharms. LLC v. Amneal Pharms. LLC et al.*, Civil Action No. 3:19-cv-15439 (D.N.J. filed July 16, 2019); and *TherapeuticsMD, Inc. v. Amneal Pharms., Inc. et al.*, Civil Action No. 3:20-cv-05256-FLW-TJB (D.N.J. filed Apr. 29, 2020).

14. Upon information and belief, Defendants have engaged in continuous and systematic contacts with the State of New Jersey and/or purposefully have availed themselves of this forum by, *inter alia*, individually and/or in concert, making, marketing, shipping, using, offering to sell or selling Defendants' pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

15. Upon information and belief, Defendants have engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and have purposefully availed themselves of the benefits and protections of the laws of the State of New Jersey, rendering them at home in the State of New Jersey.

16. Upon information and belief, Defendants operate as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this Judicial District.

17. Upon information and belief, Defendants, individually and/or in concert, have committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which sells Diprivan[®] for use throughout the United States, including the State of New Jersey.

18. Upon information and belief, Defendants have applied for FDA approval to market and sell a generic version of Diprivan[®] throughout the United States, including the State of New Jersey.

19. Defendants' submission of their ANDA to FDA evinces their intent to subject themselves to the jurisdiction of the courts where the drug that is the subject of the ANDA will be sold, including in the State of New Jersey.

20. Defendants sent a letter, dated June 28, 2023 (the "Notice Letter"), to Fresenius stating that Defendants had filed ANDA No. 217525 seeking FDA approval to market generic Diprivan[®] products ("Defendants' generic Diprivan[®] products") prior to the expiration of the '010 patent. The Notice Letter was sent from the State of New Jersey by Bryan Sommese, Esq., Senior Patent Litigation Counsel IP, for Amneal Pharma in Bridgewater, New Jersey, on behalf of Amneal NY and Amneal EU.

21. Upon information and belief, Defendants acted in concert to prepare and submit ANDA No. 217525.

22. Upon information and belief, Defendants, individually and/or in concert, will market, sell and offer for sale Defendants' generic Diprivan[®] products in the State of New Jersey following FDA approval of those products.

23. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of Defendants' generic Diprivan[®] products in the State of New Jersey, Fresenius will lose sales of Diprivan[®] and be injured in the State of New Jersey.

24. This Court's exercise of jurisdiction over Defendants is fair and reasonable. Defendants are not burdened by litigating this suit in the State of New Jersey. The State of New Jersey has an interest in providing a forum to resolve Hatch-Waxman litigation, including in this case, because this case involves products that will be sold in the State of New Jersey by New Jersey-based companies and injury to Fresenius in the State of New Jersey. This Court's exercise of jurisdiction serves the interests of the judicial system in efficient resolution of Hatch-Waxman litigation.

25. Upon information and belief, this Court has personal jurisdiction over Defendants for the reasons stated herein, including, *inter alia*, Defendants' activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendants at home in the forum. Personal jurisdiction is proper at least under *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

26. In the alternative, Defendant Amneal EU is subject to personal jurisdiction in this forum under Federal Rule of Civil Procedure 4(k)(2).

Venue

27. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

28. Upon information and belief, Defendants have a regular and established place of

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