

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

VIFOR (INTERNATIONAL) AG and
AMERICAN REGENT, INC.,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

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Civil Action No. 25-211

MEMORANDUM OPINION AND ORDER

Plaintiffs Vifor (International) AG and American Regent, Inc. (collectively, “Vifor”) brought this Hatch-Waxman litigation against defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”). On February 20, 2025, Vifor filed its complaint in this district, alleging that Apotex has infringed certain patents by virtue of Apotex’s submission of an Abbreviated New Drug Application (“ANDA”). Apotex has moved to transfer this litigation to the District Court for the District of New Jersey. Dkt. No. 19. The motion is denied.

I. Background

Apotex has applied for approval of ANDA No. 219993 (“Apotex’s ANDA”). Following notice of Apotex’s ANDA filing, Vifor initiated this litigation. Vifor has alleged that venue is proper in this district for the following reasons: First, venue is proper with regard to Apotex Inc. because Apotex Inc. regularly does or solicits business in Delaware, has conducted business throughout the United States and specifically in Delaware, and plans to sell its ANDA product in Delaware. Dkt. No. 1 at ¶ 9. Second, venue is proper for Apotex Inc. because it has previously availed itself of the protections of Delaware law by pursuing counterclaims in previous litigation.

Id. at ¶ 10. Vifor makes similar allegations regarding Apotex Corp. *Id.* at ¶¶ 11–12. Third, Vifor alleges that Apotex’s ANDA product will be marketed, distributed, offered for sale, sold, prescribed, administered, and used in Delaware, and that Apotex will derive substantial revenue from such use and consumption in Delaware. *Id.* at ¶¶ 13–14. Finally, Vifor alleges that Apotex Corp. is incorporated in Delaware while Apotex Inc. is a foreign company not residing in any judicial district within the United States and therefore may be sued in any district. *Id.* at ¶ 16.

Apotex has moved to transfer this litigation to the District of New Jersey. Apotex explains that Vifor has initiated five previous lawsuits seeking to block defendants from launching generic formulations of ferric carboxymaltose, which will compete with Vifor’s Injectafer® product. Dkt. No. 19-1 at 1. Those five lawsuits were filed in the District of New Jersey. *Id.* Apotex further explains that this lawsuit is the only lawsuit brought by Vifor and involving generic formulations of ferric carboxymaltose that has been filed in the District of Delaware. *Id.* Therefore, it seeks to have this lawsuit transferred so that it can proceed with the related cases in a court that is familiar with the facts and issues common to this set of lawsuits. *Id.*

II. Legal Standard

Under 28 U.S.C. § 1404(a), a district court may, for the convenience of the parties and witnesses, “transfer any civil action to any other district or division where it might have been brought” if doing so would be “in the interest of justice.” The Third Circuit has explained that “[t]he burden of establishing the need for transfer . . . rests with the movant” and that “the plaintiff’s choice of venue should not be lightly disturbed.” *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995).

In evaluating a motion to transfer, the court must first determine “whether the case could have been brought in the district to which the movant wishes to transfer.” *Cisco Sys., Inc. v. Ramot*

at Tel Aviv Univ., Ltd., No. 21-1365, 2022 WL 16921988, at *3 (D. Del. Nov. 14, 2022) (citing *Jumara*, 55 F.3d at 878). In actions alleging patent infringement, the action “may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.” 28 U.S.C. § 1400(b). If venue would have been proper in that district, the court must then evaluate whether the public and private interest factors set forth in *Jumara* favor transfer. *Cisco*, 2022 WL at 16921988, *3–4. The defendant must show that “the balance of convenience of the parties is *strongly* in favor” of transfer to prevail on its motion. *Paycom Software, Inc. v. Travelers Cas. & Sur. Co. of Am.*, No. 21-01403, 2022 WL 1063845, at *2 (D. Del. Apr. 8, 2022) (quoting *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir. 1970)) (emphasis in *Paycom*).

III. Discussion

The first issue to resolve is whether this lawsuit could have been filed in the United States District Court for the District of New Jersey. Apotex argues that Vifor could have filed this litigation in the District of New Jersey because Apotex has consented to personal jurisdiction and venue in the District of New Jersey in numerous recent actions and has filed counterclaims in those actions. Dkt. No. 19-1 at 7. Apotex further represents that it will consent to venue and personal jurisdiction in the District of New Jersey for this case. *Id.*

Vifor disagrees that this litigation could have been filed in the District of New Jersey. First, Vifor argues that whether venue would have been proper in the District of New Jersey is assessed as of the date that the complaint was filed. Dkt. No. 26 at 4–5. Therefore, Vifor argues that Apotex’s representation that it would consent to this lawsuit proceeding in the District of New Jersey is irrelevant. *Id.* I agree with Vifor.

Section 1404(a) states that an action may be transferred to any district “where it might have been brought.” The Supreme Court has held that “where it might have been brought,” as used in section 1404, does not mean “where it may now be rebrought, with defendants’ consent.” *Hoffman v. Blaski*, 363 U.S. 335, 342–43 (1960). As explained in *Hoffman*, “venue, like jurisdiction over the person, may be waived . . . [b]ut the power of a District Court under § 1404(a) to transfer an action to another district is made to depend not upon the wish or waiver of the defendant but, rather, upon whether the transferee district was one in which the action ‘might have been brought’ by the plaintiff.” *Id.* at 343–44. Therefore, Apotex’s representation that it now—i.e., after the filing of the complaint—will consent to venue in the District of New Jersey is insufficient to establish that this action could have been brought in the District of New Jersey. *See Roku, Inc. v. AlmondNet, Inc.*, No. CV 21-1035, 2021 WL 5299247, at *4 (D. Del. Nov. 15, 2021) (“Defendants’ argument that they [would] now consent to jurisdiction in the Western District of Texas does not confer jurisdiction at the time Roku filed the present action.”).

Vifor acknowledges that venue in the District of New Jersey would be proper as to Apotex Inc. because it is a foreign company, so venue is proper in any United States district court. Dkt. No. 26 at 5. But Vifor disputes that venue would be proper as to Apotex Corp. Vifor cites 28 U.S.C. § 1400(b), which provides that “[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.” Vifor explains that “resides” refers to the state of incorporation, and that “regular and established place of business” refers to

the corporation's headquarters.¹ Dkt. No. 26 at 6. Based on that understanding, Vifor argues that this lawsuit could be brought only in Delaware where Apotex Corp. is incorporated or in Florida where Apotex Corp. is headquartered. *Id.* at 6.

Apotex admits that Apotex Corp. is neither headquartered nor incorporated in New Jersey. Dkt. No. 30 at 2. But it argues that in previous litigation, Vifor alleged that Apotex Corp. regularly and continuously transacts business in New Jersey. *Id.* It also argues that Vifor previously alleged that Apotex Corp. has a permanent and continuous presence in New Jersey because it is registered with the state as a drug wholesaler, sells its products in New Jersey, employs a salesforce in New Jersey, and will sell the ANDA product at issue in New Jersey. *Id.* at 3.

Although not cited by either party, a recent Federal Circuit decision conclusively resolves where venue is proper for cases in which the allegedly infringing act is the submission of an ANDA: “For Hatch-Waxman cases, . . . venue is proper ‘where an ANDA-filer submits its ANDA to the FDA,’ not ‘wherever future distribution of the generic is contemplated.’” *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1120 (Fed. Cir. 2021) (citing *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1378–79, 1384 (Fed. Cir. 2020)). Apotex does not argue that it submitted its ANDA to the FDA from New Jersey. Accordingly, there has been no act of infringement in New Jersey. For that reason, venue is not proper in New Jersey under the second prong of section 1400(b). *See id.*; *see also id.* at 1120 (for venue to be proper, the plaintiff must show “both the defendants’ acts of infringement in the district and their regular and established place of business there”).

¹ As explained below, I conclude that Vifor’s interpretation of the phrase “regular and established place of business” as restricted to the place where the defendant is headquartered to be too narrow.

Venue is also not proper in New Jersey because Apotex has not shown that Apotex Corp. has a regular and established place of business there. The Federal Circuit has provided guidance regarding the meaning of “regular and established place of business.” To show that a defendant has a regular and established place of business, there are three requirements: “(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant.” *In re Cray Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017); *Celgene*, 17 F.4th at 1122. With regard to the third requirement, the court has identified relevant factors to consider:

(1) whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place; (2) whether the defendant conditioned employment on an employee’s continued residence in the district or the storing of materials at a place in the district so that they can be distributed or sold from that place; (3) a defendant’s representations about that place, including advertisements; and (4) the nature and activity of the alleged place of business of the defendant in the district in comparison with that of other places of business of the defendant in other venues.

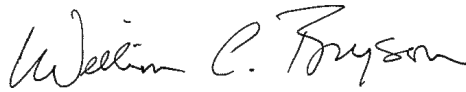
Id. (citations and quotation marks omitted); *see also Cray*, 871 F.3d at 1364. Vifor argues that Apotex Corp. has its regular and established place of business in Florida, where Apotex Corp. is headquartered. Dkt. No. 26 at 6. Under the guidance set forth by the Federal Circuit, however, Vifor’s reading of “regular and established place of business” as limited the location of the headquarters is too narrow. Although the location of the headquarters is likely to be a regular and established place of business, it is not necessarily the only place that meets that requirement as interpreted by the Federal Circuit in *Cray* and subsequent decisions. *See, e.g., In re Google LLC*, 949 F.3d 1338, 1345 (Fed. Cir. 2020) (“We conclude that a ‘regular and established place of business’ requires the regular, physical presence of an employee or other agent of the defendant conducting the defendant’s business at the alleged ‘place of business.’”); *Andra Grp., LP v. Victoria’s Secret Stores, L.L.C.*, 6 F.4th 1283, 1290 (Fed. Cir. 2021) (applying *Cray* and *Google*).

Nevertheless, the burden to prove that transfer is appropriate rests with Apotex, and Apotex has not shown that Apotex Corp. maintains a regular and established place of business in New Jersey even under the broader reading of the phrase as spelled out by *Celgene*. Instead, Apotex merely cites allegations made in separate litigation by Vifor regarding Apotex Corp.'s place of business, but Apotex has identified no evidence to support such a conclusion. Apotex has not shown that the second requirement of prong two in section 1400(b) is met. It has therefore failed to meet its burden to establish that transfer is permissible. *See Jumara*, 55 F.3d at 879 (“The burden of establishing the need for transfer still rests with the movant.”).

Because this case could not have been brought in the District of New Jersey, the motion to transfer is denied. *See* 28 U.S.C. § 1404(a).

IT IS SO ORDERED.

SIGNED this 22nd day of August, 2025.

A handwritten signature in black ink, reading "William C. Bryson". The signature is fluid and cursive, with the first name "William" and last name "Bryson" clearly legible.

WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE