

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ABRAXIS BIOSCIENCE, LLC and  
CELGENE CORPORATION,

Plaintiffs,

v.

HBT LABS, INC.,

Defendant.

Civil Action No. 18-2019-RGA

MEMORANDUM ORDER

Currently pending before the Court is Defendant's Motion to Dismiss and to Transfer. (D.I. 7). The parties have fully briefed the issues (D.I. 8, 23, 27) and filed supplemental authority. (D.I. 34, 35). I have fully considered the parties' filings.

**I. BACKGROUND**

Plaintiffs Abraxis Bioscience, LLC and Celgene Corporation brought suit against Defendant HBT Labs on December 19, 2018 alleging infringement of twelve patents under 35 U.S.C. § 271(e). (D.I. 1). The patents-in-suit<sup>1</sup> relate to various methods of use for Plaintiffs' Abraxane® drug product. Defendant has filed a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") for approval of a generic of Plaintiffs' Abraxane® product. (D.I. 8 at 2; D.I. 23 at 3). Plaintiffs initiated suit after receiving written notice of Defendant's Paragraph IV certification pursuant to 21 U.S.C. § 355(b)(2)(A). (D.I. 6 ¶ 27). The notice

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<sup>1</sup> The patents-in-suit include United States Patent Nos. 7,758,891 ("the '891 patent"), 7,820,788 ("the '788 patent"), 7,923,536 ("the '536 patent"), 8,034,375 ("the '375 patent"), 8,138,229 ("the '229 patent"), 8,268,348 ("the '348 patent"), 8,314,156 ("the '156 patent"), 8,853,260 ("the '260 patent"), 9,101,543 ("the '543 patent"), 9,393,318 ("the '318 patent"), 9,511,046 ("the '046 patent"), and 9,597,409 ("the '409 patent").

informed Plaintiffs that Defendant seeks approval to market its proposed generic of Abraxane and alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Defendant's NDA. (*Id.*).

After Plaintiffs filed suit, Defendant filed this motion seeking to (1) dismiss Plaintiff Celgene Corporation for lack of standing, (2) transfer the case to the Central District of California, and (3) dismiss Counts I, IV, VI, VII, and IX-XII of the Complaint for failure to state a claim. (D.I. 7; D.I. 8).

## **II. DISCUSSION**

### **A. Standing**

Plaintiff Celgene Corporation does not oppose Defendant's motion to dismiss Celgene from the case. (D.I. 23 at 3). As that portion of the motion is unopposed, I will dismiss Celgene as a Plaintiff.

### **B. Motion to Transfer under 28 U.S.C. § 1404(a)**

Defendant also requests that I transfer this case to the United States District Court for the Central District of California under 28 U.S.C. § 1404(a). (D.I. 8 at 6). Section 1404(a) provides, "For the convenience of the parties and witnesses, in the interests of justice, a district court may transfer any civil action to any other district or division where it might have been brought." It requires a two-step analysis. First, I must determine whether this case could have been brought in the Central District of California. Second, I must determine whether the Defendant has shown that the balance of the parties' convenience is strongly in favor of transfer to the Central District of California.

Both Plaintiff Abraxis and Defendant are Delaware entities. (D.I. 23 at 5). The parties agree that Defendant's principal place of business is in the Central District of California, but

dispute whether Plaintiff Abraxis' principal place of business is in the Central District of California or the District of New Jersey. (D.I. 8 at 7; D.I. 23 at 5). As it is undisputed that Defendant's principal place of business is located in the Central District, Plaintiff could have brought this action in the Central District. Thus, the only issue under § 1404(a) is whether I should exercise my discretion to transfer the case to California.

It is the Defendant's burden "to establish that a balancing of proper interests weigh[s] in favor of the transfer." *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir. 1970). "[U]nless the balance of convenience of the parties is *strongly* in favor of [the] defendant, the plaintiff's choice of forum should prevail." *Id.* (internal quotation marks and citation omitted). The Third Circuit has set forth a non-exhaustive list of private and public interest factors to be weighed by a court in considering transfer. *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879–80 (3d Cir. 1995). The private interests have included: (1) plaintiff's forum preference as manifested in the original choice; (2) the defendant's preference; (3) whether the claim arose elsewhere; (4) the convenience of the parties as indicated by their relative physical and financial condition; (5) the convenience of the witnesses—but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and (6) the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum). *Id.* at 879. The public interests have included: (7) the enforceability of the judgment; (8) practical considerations that could make the trial easy, expeditious, or inexpensive; (9) the relative administrative difficulty in the two fora resulting from court congestion; (10) the local interest in deciding local controversies at home; (11) the public policies of the fora; and (12) the familiarity of the trial judge with the applicable state law in diversity cases. *Id.* at 879–80.

## 1. Plaintiff's Forum Preference

This factor weighs against transfer. Plaintiff's choice to file this case in the District of Delaware was motivated by legitimate and rational reasons including the place of incorporation of both parties and Delaware's proximity to Plaintiff's corporate headquarters in New Jersey.<sup>2</sup> Defendant asserts that I should not give weight to Plaintiff's choice to file in Delaware because Plaintiff initially also filed the same suit in the District of New Jersey. (D.I. 8 at 8). I disagree. Plaintiff's motivations for originally filing in New Jersey also motivated filing this suit here in Delaware, specifically the proximity of Plaintiff's headquarters in New Jersey. (D.I. 23 at 5). Additionally, I will not discount Plaintiff's choice of forum based on a lack of physical ties to Delaware. Plaintiff incorporated in Delaware and chose to avail itself of that venue; physical ties are more appropriately considered under later factors. Moreover, *Shutte* recognizes that the plaintiff's choice of forum should be the "paramount consideration" in the § 1404(a) analysis. *Shutte*, 431 F.2d at 25. Plaintiff's forum preference and the reasons for that choice weigh against transfer.

## 2. Defendant's Forum Preference

This factor favors transfer. Defendant has legitimate and rational reasons for wanting to litigate the case in the Central District of California, specifically the proximity to its own corporate headquarters. (D.I. 8 at 9). Plaintiff argues that I should discount Defendant's preference because Defendant has chosen to incorporate in Delaware, thereby opening itself to the possibility of

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<sup>2</sup> The parties dispute whether Abraxis is headquartered in Los Angeles, CA or Summit, New Jersey. While Plaintiff's original complaint states that Plaintiff Abraxis' principal place of business was in Los Angeles, California (D.I. 1), Plaintiff filed an amended complaint correcting that statement (D.I. 6). Plaintiff has represented that the error was a result of the use of a form complaint and has provided documentation supporting its correction. (D.I. 23 at 4, 7-8). Based on the documents submitted with the parties' briefs, the facts indicate that Plaintiff Abraxis, both now and at the time this suit was filed, has its corporate headquarters in Summit, New Jersey, and not Los Angeles, California. (D.I. 25-1 at 2, 5, 7-8, 12, 77, 80, 88).

litigation against it in this District. (D.I. 23 at 12). However, incorporation is more properly considered with other factors, and therefore I will not discount Defendant's preference. Thus, Defendant's preference weighs in favor of transfer.

### **3. Whether the Claim Arose Elsewhere**

Plaintiff is suing under 35 U.S.C. § 271(e) based on Defendant's notice of its filing an NDA for an Abraxane® generic drug product. Plaintiff is correct that if the Defendant's application were granted, infringing acts would likely occur nationwide, including in the District of Delaware. (D.I. 23 at 7). However, as Defendant represents, the majority of the infringing acts, including manufacture, would occur in California. (D.I. 8 at 9-10). Therefore, this factor weighs in favor of transfer, albeit only slightly.

### **4. The Convenience of the Parties as Indicated by their Relative Physical and Financial Condition**

"[A]bsent some showing of a unique or unexpected burden, a company should not be successful in arguing that litigation in its state of incorporation is inconvenient." *ADE Corp. v. KLA-Tencor Corp.*, 138 F. Supp. 2d 565, 573 (D. Del. 2001). Here, both parties are Delaware entities. Thus, Defendant must demonstrate some unique or unexpected burden in having to litigate this case in the District for this factor to weigh in favor of transfer.

Defendant asserts that it would be more convenient to litigate in the Central District of California because of the ease in producing witnesses and documents that are already located there. (D.I. 8 at 11). It appears that litigating in the District of Delaware is more convenient to Plaintiff as its corporate headquarters are located in New Jersey.

Defendant also asserts that the financial strain of litigating in this District will be high because it has no sales revenue and has only forty-seven full time employees. (*Id.*). However,

while this is a burden, it is not a “unique or unexpected burden.” Numerous companies incorporate in Delaware while having their headquarters located elsewhere. That litigation may occur before the company has begun to generate sales revenue is not a unique or unexpected burden. However, Plaintiff is larger in size and has significantly more revenue than Defendant. (*Id.* at 11)

Thus, on balance, this factor weighs in favor of transfer, albeit slightly.

#### **5. The Convenience of the Witnesses**

This factor should be weighed “only to the extent that the witnesses may actually be unavailable for trial in one of the fora.” *Jumara*, 55 F.3d at 879. Defendant contends that there are numerous witnesses, including named inventors, who would be unavailable in this District but subject to subpoena power in the Central District. (D.I. 8 at 12). Defendant argues that even for those witnesses outside the subpoena power of either district, travel to the Central District would be more convenient. (*Id.*). However, Plaintiff represents that at least one named inventor would not be subject to the subpoena power of either district and lives in Massachusetts rather than California. (D.I. 23 at 9-10). Moreover, Plaintiff represents that there are other named inventors who would be willing to testify in Delaware, (*id.* at 10), and therefore those witnesses’ unavailability is not at issue under this factor.

Because it appears that (1) there are potential witnesses who will be unavailable regardless of the forum, (2) it is not more convenient for all third party witnesses to travel to California, and (3) there are witnesses who are willing to travel to testify in Delaware should the trial occur, I find this factor to be neutral, especially in light of the fact that the inventor’s testimony is almost always irrelevant to the issues that need to be decided in a bench trial of this sort.

## **6. The Location of Books and Records**

This factor is only relevant “to the extent that the files could not be produced in the alternative forum.” *Jumara*, 55 F.3d at 879. Defendant has made no representation that there are files or other documentary evidence that would not be able to be produced in this District. Defendant argues that this factor weighs in favor of transfer because both parties have their headquarters in the Central District. (D.I. 8 at 12-13). However, Plaintiff’s headquarters and documentary evidence are located in New Jersey. (D.I. 23 at 11). Therefore, as there is no evidence that there are files or documents that could not be produced in the District of Delaware and there is no District where all relevant files and documentary evidence are located, this factor is neutral.

## **7. The Enforceability of the Judgment**

This factor is neutral as judgments from either this District or the Central District of California would be equally enforceable.

## **8. Practical Considerations**

This factor assesses “practical considerations that could make the trial easy, expeditious, or inexpensive.” *Jumara*, 55 F.3d at 879. Defendant argues that trial in the Central District of California will be easier, quicker, and cheaper for the parties. (D.I. 8 at 13). However, Plaintiff disagrees and argues that transfer will merely shift costs from Defendant to Plaintiff because Plaintiff is located in New Jersey, and not the Central District. (D.I. 23 at 11). Moreover, because the dockets are similarly congested, the case will likely not be expedited by transferring the case to the Central District. Therefore, I find this factor to be neutral.

## **9. Relative Administrative Difficulty Due to Court Congestion**

This factor is neutral, as both districts have congested dockets.

### **10. Local Interest in Deciding Local Controversies at Home**

This factor is neutral. “Patent issues do not give rise to a local controversy or implicate local interests.” *TriStata Tech., Inc. v. Emulgen Labs., Inc.*, 537 F. Supp. 2d 635, 643 (D. Del. 2008).

### **11. Public Policies of the Fora**

“The public policy of Delaware encourages the use by Delaware corporations of Delaware as a forum for the resolution of business disputes.” *Wacoh Co. v. Kionix Inc.*, 845 F. Supp. 2d 597, 604 (D. Del. 2012). All parties are organized under the laws of Delaware. Defendant argues that because both companies are located in California, there is an interest in having the case litigated there. (D.I. 8 at 19). However, the parties are not both located in California. Therefore, this factor weighs slightly against transfer.

### **12. Familiarity of the Trial Judges with the Applicable State Law in Diversity Cases**

This factor is neutral as it is inapplicable to a patent case where only federal law is at issue.

### **13. Conclusion**

The *Jumara* factors can thus be summarized as follows: seven are neutral, three weigh in favor of transfer in varying degrees, and two weigh against transfer in varying degrees. Considering the factors in totality and treating Plaintiff’s choice of this forum as a paramount consideration, I find that Defendant has not demonstrated that the *Jumara* factors weigh in favor of transfer. Thus, I will deny Defendant’s motion to transfer.

### C. Motion to Dismiss for Failure to State a Claim

Defendant requests that I dismiss Counts I, IV, VI, VII, and IX-XII because those counts assert patents that solely encompass indications for which Defendant has not sought FDA approval. (D.I. 8 at 14).

When reviewing a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must accept the complaint's factual allegations as true. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007). Rule 8(a) requires “a short and plain statement of the claim showing that the pleader is entitled to relief.” *Id.* at 555. The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a “formulaic recitation” of the claim elements. *Id.* (“Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).”). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content “allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (“Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief.” (internal quotation marks omitted)).

Plaintiff alleges infringement under 35 U.S.C. § 271(e)(2). Section 271(e)(2) provides,

It shall be an act of infringement to submit [] an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Defendant has filed such an NDA and provided a Paragraph IV certification to Plaintiff as required by the Act. 21 U.S.C. § 355(b)(2). Under this statute, the submission of the application is the infringing act.

Defendant argues that Plaintiff's claims in Counts I, IV, VI, VII, and IX-XII should be dismissed for failure to state a claim because Defendant, in addition to the Paragraph IV certification, also submitted a Section viii statement that the method of use patents encompassed by the challenged counts do not claim the use for which Defendant is seeking approval. (D.I. 8 at 14); 21 U.S.C. § 355(j)(2)(A)(viii). Plaintiff argues that (1) Defendant's NDA is not integral to the Complaint and therefore is not properly considered at this stage, and (2) that under § 271(e), Defendant's submission and maintenance of Paragraph IV certifications is dispositive as to whether Plaintiff has properly stated a claim. (D.I. 23 at 13-14).

I agree with Plaintiff. Plaintiff states a plausible claim for patent infringement under § 271(e)(2) by alleging that Defendant 1) made a Paragraph IV filing and 2) provided the required notice to Plaintiff. The documents that Defendant relies upon, specifically the NDA, are outside the pleadings. Here, Plaintiff's Complaint does not rely upon the NDA, but the notice letter it received. Therefore, the NDA is "not integral to or explicitly relied upon in the complaint" and it would be improper to consider it for the purposes of this motion. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *see also Par Pharm. v. Hospira, Inc.*, 2018 WL 3343238, at \*2 (D. Del. May 11, 2018) ("[G]eneral reference to an [NDA] fall short of explicit reliance, precluding consideration of the [NDA] in a ruling on a motion to dismiss.").

Moreover, the notice letter, as explicitly relied upon in the complaint, does not justify dismissal of the challenged counts. Defendant's reliance on *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012) is misplaced. There, the applicant submitted *only* Section

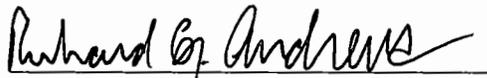
viii statements for the patents-in-suit, rather than submitting Paragraph IV certifications. *AstraZeneca*, 669 F.3d at 1374. As the Federal Circuit noted in *AstraZeneca*, “The Act specifies that filing an [NDA] containing a Paragraph IV certification constitutes an act of infringement.” *Id.* Defendant, here, notified Plaintiff that it submitted Paragraph IV certifications for *all* of the patents-in-suit. (D.I. 10-1 at 3). Moreover, while the notice letter does state that “HBT’s NDA seeks approval for the treatment of breast cancer as the only indication and use on the product’s proposed labeling,” it makes no mention of a Section viii statement for any of the patents.

Plaintiff have adequately pled a claim for infringement under § 271(e)(2) in Counts I, IV, VI, VII, and IX-XII. Thus, I deny Defendant’s motion to dismiss those counts.

### III. CONCLUSION

For the foregoing reasons, IT IS HEREBY ORDERED that Defendant’s Motion (D.I. 7) is GRANTED as to Plaintiff Celgene, DENIED as to transfer, and DENIED as to Counts I, IV, VI, VII, and IX-XII.

Entered this 24 day of May, 2019.

  
United States District Judge