United States District Court
District of Massachusetts

MOMENTA PHARMACEUTICALS, INC., SANDOZ INC., **Plaintiffs,**	)	
v.	)	**Civil Action No. 11-11681-NMG**
AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC. **Defendants.**	)	

MEMORANDUM & ORDER

GORTON, J.

Plaintiffs Momenta Pharmaceuticals, Inc. ("Momenta") and Sandoz Inc. ("Sandoz") (collectively, "the plaintiffs") bring suit against Amphastar Pharmaceuticals, Inc. ("Amphastar"), International Medication Systems, Ltd. ("IMS"), Watson Pharmaceuticals, Inc. ("Watson") and Watson Pharma, Inc. ("Watson Pharma") (collectively, "the defendants") for infringement of U.S. Patent Nos. 7,575,886 ("the '886 patent") and 7,790,466 ("the '466 patent") (Counts I and II, respectively) and for declaratory judgment of infringement of those same patents (Counts III and IV, respectively).

Currently before the Court is the defendants' motion to dismiss the amended complaint or, alternatively, to transfer the

case to the United States District Court for the Central District of California.

I. Background

Plaintiff Momenta is the assignee and owner of two patents, the '886 and '466 patents, related to the manufacture of generic enoxaparin. It is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Plaintiff Sandoz, the entity that markets Momenta's generic product, is a Colorado corporation with its principal place of business in Princeton, New Jersey.

In July, 2010, the plaintiffs began marketing the first generic enoxaparin product in the United States. They filed the instant complaint after the FDA approved Amphastar's application for a generic enoxaparin product and Watson issued a press release on September 19, 2011 announcing that the companies would launch the product in the fourth quarter of 2011 ("the Watson press release").

Amphastar is a privately-held Delaware corporation with its principal place of business in Rancho Cucamonga, California. It develops and manufactures specialty and generic pharmaceutical products and sells them throughout the United States. It has two wholly-owned manufacturing subsidiaries: IMS, also located in California, and Armstrong Pharmaceuticals, Inc. ("Armstrong"), which operates two facilities in Massachusetts. IMS manufactures

sterile injectable pharmaceuticals for sale in the United States and worldwide and has, along with Amphastar, allegedly offered to sell and sold Amphastar's generic enoxaparin product in Massachusetts, either directly or through group purchasing organizations ("GPOs"). Armstrong manufactures inhaled respiratory drugs, unrelated to the instant action, which are distributed across the United States.[1]

Watson, a Nevada corporation with principal places of business in California and New Jersey, is the retail distributor of Amphastar's generic enoxaparin product. In that capacity, it markets, sells and distributes Amphastar's product to pharmacies across the United States via GPOs, wholesalers, warehousing chains, mail order and other entities.

Watson allegedly plans to distribute Amphastar's product to retail pharmacies in Massachusetts through Watson Pharma, one of its 44 subsidiaries. Watson Pharma is a Delaware corporation with its principal place of business in New Jersey. It has a registered agent and conducts business in Massachusetts.

II. Procedural History

Plaintiffs filed their complaint on September 21, 2011 and, shortly thereafter, moved for a temporary restraining order and preliminary injunction to keep the defendants from marketing

[1] Armstrong apparently ceased manufacturing operations in August, 2011 and was selling no products by the end of 2011.

their allegedly infringing product. The Court has allowed the motion and a preliminary injunction is currently in effect. That decision is on appeal to the Federal Circuit, along with two other decisions of this Court denying defendants' motions to stay or dissolve the preliminary injunction.

Plaintiffs filed an amended complaint on October 17, 2011 that added Watson Pharma as an additional defendant. The defendants move to dismiss the amended complaint or to transfer the case to the Central District of California. Plaintiffs have opposed that motion and have also filed a motion for leave to conduct jurisdictional discovery if the Court deems the present record incomplete on the question of jurisdiction.

III. Analysis

Defendants move to dismiss plaintiffs' complaint for lack of personal jurisdiction, improper venue, and failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(2), (3) & (6). In the alternative, defendants request that the Court transfer the case to the Central District of California "for the convenience of parties and witnesses, in the interest of justice." 28 U.S.C. § 1404(a) (2006).

A. Personal Jurisdiction

1. Legal Standard

On a motion to dismiss for lack of personal jurisdiction, a plaintiff must make a prima facie showing that a defendant is

subject to personal jurisdiction.[2] Silent Drive, Inc. v. Strong Indus., Inc., 326 F.3d 1194, 1201 (Fed. Cir. 2003). The Court must accept as true the uncontroverted allegations in a plaintiff's complaint and resolve any factual conflicts in the affidavits in plaintiff's favor. Elecs. for Imaging, Inv. v. Coyle, 340 F.3d 1344, 1349 (Fed. Cir. 2003). It also considers uncontradicted facts offered by a defendant. Newman v. European Aeronautic Defence & Space Co. Eads N.V., 700 F. Supp. 2d 156, 159 (D. Mass. 2010). If the Court concludes that the existing record is insufficient to support personal jurisdiction, jurisdictional discovery is appropriate if "a party demonstrates that it can supplement its jurisdictional allegations through discovery." Trintec Indus., Inc. v. Pedre Promotional Prods., Inc., 395 F.3d 1275, 1283 (Fed. Cir. 2005) (internal quotation omitted).

Personal jurisdiction over an out-of-state defendant exists where jurisdiction is 1) statutorily authorized and 2) consistent with the Due Process Clause of the United States Constitution. Avocent Huntsville Corp. v. Aten Intern. Co., Ltd., 552 F.3d 1324, 1329 (Fed. Cir. 2008). Because the Massachusetts long-arm statute, M.G.L. c. 223A, § 3, reaches to the full extent that the

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[2] Federal Circuit law governs the issue of personal jurisdiction in a patent infringement case. Deprenyl Animal Health, Inc. v. Univ. of Toronto Innovations Found., 297 F.3d 1343, 1348 (Fed. Cir. 2002).

Constitution allows, the Court may proceed directly to the constitutional analysis. See Tatro v. Manor Care, Inc., 416 Mass. 763, 771 (1994).

Due Process requires that the defendant have "minimum contacts" with the forum state such that the "maintenance of the suit does not offend traditional notions of fair play and substantial justice." Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945). Under that standard, a defendant's conduct and connection with the forum State must be such that he should reasonably anticipate being haled into court there. World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980).

Minimum contacts may be established in two ways. Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc., 148 F.3d 1355, 1359 (Fed. Cir. 1998). First, the Court may exercise general jurisdiction where the defendant has "continuous and systematic contacts" with the forum state, even where those contacts are unrelated to the cause of action. Id. Second, the Court may exercise specific jurisdiction where the defendant has purposefully directed its activities at residents of the forum and the cause of action "arises out of or relates" to those activities. Id. If minimum contacts are established, the Court must assess whether exercising jurisdiction is reasonable and fair. Id.

2. Application

Plaintiffs, in their complaint, state that the Court has personal jurisdiction over the defendants because defendants:

> (a) knowingly transact a large volume of business in Massachusetts, (b) on information and belief, have engaged in, and made meaningful preparations to engage in, infringing conduct in Massachusetts, and (c) have caused, and are causing, injury in Massachusetts by reason of their conduct within and outside of the Commonwealth.

Plaintiffs also state that each of the defendants is in the business of manufacturing pharmaceutical products to sell in the United States, including Massachusetts, and worldwide. Attached as an exhibit to the complaint is the Watson press release, which states that 1) Amphastar is preparing to launch a generic enoxaparin product, 2) pursuant to the terms of defendant's exclusive distribution agreement, Amphastar will supply its generic product to Watson which will, in turn, market, sell and distribute the product to the United States retail pharmacy channel and 3) Amphastar will receive 50-55% of Watson's gross profits and will market, sell and distribute the product to all other channels. Plaintiffs allege that the defendants infringe the '886 and '466 patents insofar as Amphastar and IMS manufacture generic enoxaparin for commercial sale using Momenta's patented methods and the defendants offer the infringing product for sale in the United States.

Defendants respond that Watson is not subject to this

Court's jurisdiction because it has no registered agent or office in Massachusetts and does not transact any business here. Plaintiffs reply that Watson is subject to general jurisdiction in this district because, through Watson Pharma, it conducts regular business sales in this state.

Watson is the third largest seller of generic drugs in the country with net revenue in 2010 of $3.6 billion. In the United States, it markets its generic products to various drug wholesalers, mail order, government and national retail drug and food store chains. It sells approximately 160 different generic pharmaceutical products and approximately 30 brand-name pharmaceutical products in the United States and abroad. Watson distributes those products through its many subsidiaries, including Watson Pharma. The generic prescription products are primarily sold under the "Watson Laboratories" and "Watson Pharma" labels and the brand products are generally sold under the "Watson Pharma" label.

Watson Pharma was poised to sell Amphastar's generic enoxaparin product prior to entry of the preliminary injunction. The parties agree that Watson Pharma has a registered agent and conducts business in Massachusetts and is thus subject to this Court's jurisdiction.

The Court concludes that plaintiffs have made a prima facie showing that Watson is subject to general jurisdiction in this

district. Watson sells an enormous quantity of drugs nationwide and into Massachusetts, which is indisputably a significant part of the retail pharmacy market in the United States. Given Watson's demonstrated distribution channel into Massachusetts through Watson Pharma, the Court finds that it maintains "continuous and systematic" contacts in this state.

With respect to defendants Amphastar and IMS, Defendants claim that neither general nor specific jurisdiction exists because those entities do not engage in any activity, purposeful or otherwise, in Massachusetts. According to defendants, any infringement of Momenta's process patent would have occurred, if at all, in California where defendants manufacture and test Amphastar's generic enoxaparin product. According to defendants, plaintiffs are merely speculating that they will suffer injuries in the future in Massachusetts because of defendants' activities elsewhere. Furthermore, defendants assert, plaintiffs' jurisdictional arguments improperly rely on the Massachusetts contacts of Amphastar's subsidiary, Armstrong, a separate corporate entity which does not produce any product related to this case.

The Court declines to address the parties' arguments with respect to general jurisdiction because it is satisfied that it may exercise specific jurisdiction over both Amphastar and IMS. The Federal Circuit uses a tripartite analysis to determine

whether specific jurisdiction is appropriate: 1) whether the defendant purposefully directed its activities at residents of the forum, 2) whether the claim arises out of or relates to those activities and 3) whether assertion of personal jurisdiction is reasonable and fair. 3D Systs., Inc. v. Aarotech Labs., Inc., 160 F.3d 1373, 1378 (Fed. Cir. 1998).

First, the record demonstrates that Amphastar and IMS have purposefully directed activities at residents of Massachusetts. Prior to the Court's entry of the temporary restraining order, Amphastar and IMS had 1) submitted a bid on an annual $34 million contract with a GPO whose members include 350 Massachusetts healthcare providers and 2) engaged in active talks and preparations to make a bid on a contract with a GPO whose members include at least 20 Massachusetts healthcare providers, three of which are the largest healthcare providers in the state.

In so doing, Amphastar and IMS offered their allegedly infringing product for sale into Massachusetts and fully expected it to be sold here. Simply because those offers were made to GPO "middlemen" does not mean that Amphastar and IMS did not purposefully avail themselves of this forum. Healthcare providers generally do not buy drugs directly from manufacturers but rather through contracts negotiated by GPOs. Thus, Amphastar and IMS exploited the typical industry medium by which manufacturers can reach the Massachusetts pharmaceutical market

and thereby availed themselves of the privilege of doing business in Massachusetts. J. McIntyre Machinery, Ltd. v. Nicastro, 131 S. Ct. 2780, 2790 (2011) (noting that a finding of purposeful availment depends in each case on the "defendant's conduct and the economic realities of the market the defendant seeks to serve"); Eli Lilly & Co. v. Sicor Pharms., Inc., No. 06-cv-238, 2007 WL 1245882, at *6 (S.D. Ind. 2007) (finding purposeful availment where defendant pharmaceutical company made sales into forum through out-of-state and independent GPOs).

Second, plaintiffs' claims of patent infringement arise out of or relate to defendants' offers to sell in the United States, including into Massachusetts, which plaintiffs allege violate 35 U.S.C. § 271(g).[3] See HollyAnne Corp. v. TFT, Inc., 199 F.3d 1304, 1308 (Fed. Cir. 1999) (noting that an activity gives rise to a cause of action where it is a basis for the action). Plaintiffs have demonstrated that defendants' actions in Massachusetts will generate commercial interest in the allegedly infringing product in this forum to plaintiff's detriment. See 3D Sys., 160 F.3d at 1379 (noting that the primary purpose of

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[3] Section 271(g) provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

prohibiting "offers to sell" is to prevent "generating interest in a potential infringing product to the commercial detriment of the rightful patentee").

Third, exercising jurisdiction over all defendants is reasonable and fair. When determining if jurisdiction is reasonable, the court considers: 1) the burden on the defendant, 2) the forum state's interest in adjudicating the dispute, 3) the plaintiff's interest in obtaining convenient and effective relief, 4) the judicial system's interest in obtaining the most efficient resolution of the controversy and 5) the common interests of the states in furthering substantive social policies. Ma. Inst. of Tech. v. Micron Tech., Inc., 508 F. Supp. 2d 112, 116 (D. Mass. 2007). "[T]he burden of proof is on the defendant, which must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable...." Avocent Huntsville, 552 F.3d at 1332.

Defendants argue that they would suffer undue hardship if forced to litigate the action in Massachusetts because IMS and Amphastar, along with key witnesses and evidence, are located in California. They further contend that 1) because defendants have had no contact with Massachusetts, it has no interest in adjudicating the dispute but 2) plaintiffs would not be inconvenienced litigating in California where the alleged infringing activity occurred.

Defendants' arguments do not raise compelling reasons for the Court to decline to exercise jurisdiction over them. As to the first factor, defendants all sell their products on a nationwide, even international, basis and each is an established, profitable corporation that has directed activity into Massachusetts, as discussed above. Defendants will suffer only minimal hardship in litigating this case in Massachusetts. As to the second factor, Momenta is headquartered in Massachusetts and eight of the ten inventors of the patent-in-suit reside here. A state indisputably has an interest in protecting the intellectual property of its citizens. Foster-Miller, Inc. v. Babcock & Wilcox Canada, 975 F. Supp. 30, 38 (D. Mass. 1997).

With respect to the third factor, Massachusetts appears to be the most convenient forum in which plaintiffs can litigate their claims because it is where they have chosen to proceed and where Momenta conducts its business. Micron Tech., 508 F. Supp. 2d at 124. As to the fourth factor, considerations of judicial efficiency counsel in favor of exercising jurisdiction in Massachusetts, where proceedings have begun and other litigation involving the same patents is currently pending. The fifth factor is neutral because this case is controlled by federal law and the jurisprudence of the Federal Circuit and implicates no social or policy issues unique to Massachusetts or California. In sum, the reasonableness factors support the conclusion that

maintaining the instant suit in Massachusetts would comport with due process.

B. Venue and motion to transfer

In a suit for patent infringement, venue is proper

> 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 (2006). A corporate defendant resides in "any judicial district in which it is subject to personal jurisdiction at the time the action is commenced." 28 U.S.C. § 1391(c).

Because the Court, as determined above, has personal jurisdiction over the defendants, venue in this district is proper. Nevertheless, defendants ask that, even if the Court deems venue to be proper, the case be transferred to the Central District of California pursuant to 28 U.S.C. § 1404(a). Section § 1404(a) states:

> For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.

While the decision to transfer a case under § 1404 lies solely within the discretion of the trial court, there is a presumption in favor of the plaintiff's choice of forum and the defendant must bear the burden of proving that a transfer is warranted. Holmes Grp., Inc. v. Hamilton Beach/Proctor Silex, Inc., 249 F. Supp.2d 12, 15 (D. Mass. 2002). Factors to be considered in determining whether transfer is warranted include

1) the plaintiff's choice of forum, 2) the relative convenience of the parties, 3) the convenience of the witnesses and location of documents, 4) any connection between the forum and the issues, 5) the law to be applied and 6) the state or public interests at stake. Id. at 17.

Defendants arguments in favor of transfer largely echo their arguments for reasonableness, summarized above. They add that the bulk of discovery in this case will necessarily take place in California, where all preparations and tests for Amphastar's submissions to the FDA were conducted and that key Amphastar personnel, who both prepared the submissions and performed the underlying research, are in California. Plaintiffs respond that many witnesses are situated in Massachusetts and a substantial amount of discovery will take place in this forum. Nearly all of the pertinent patent documents, eight of the ten inventors of the patents-in-suit and the law firm that prosecuted the patents are in Massachusetts.

Given the relative balance of documents and witnesses, defendants' arguments simply are not compelling enough to overcome the presumption in favor of plaintiffs' choice of forum. It would be more convenient for defendants to litigate the dispute in California but less convenient for plaintiffs. "Transfer of venue is inappropriate ... where its effect merely shifts the inconvenience from one party to another." Holmes

Grp., 249 F. Supp. 2d at 18.

C. Fed. R. Civ. P. 12(b)(6)

Defendants contend that plaintiffs have failed to state a claim upon which relief can be granted, Fed. R. Civ. P. 12(b)(6), because plaintiffs' claims are barred by the safe harbor provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1). That argument was also raised in defendants' opposition to the plaintiffs' motion for a preliminary injunction. For the same reasons stated in the Court's Memorandum and Order issued on October 28, 2011, the Court concludes that the safe harbor provision does not absolve defendants' allegedly infringing activity. See Momenta Pharms., Inc. v. Amphastar Pharms., Inc., Civ. No. 11-11681, 2011 WL 5114475, at *9-10 (Oct. 28, 2011).

ORDER

In accordance with the foregoing,

1) defendants' Motion to Dismiss the Amended Complaint or Transfer (Docket No. 100) is **DENIED**, and

2) plaintiffs' Conditional Motion for Leave to Conduct Jurisdictional Discovery if the Court Finds the Present Record Insufficient (Docket No. 67) is **DENIED** as moot.

So ordered.

/s/ Nathaniel M. Gorton

Nathaniel M. Gorton
United States District Judge

Dated January 19, 2012