

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

CONFORMIS, INC.,
Plaintiff,

v.

ZIMMER BIOMET HOLDINGS, INC., and
ZIMMER, INC.,
Defendants.

Civil Action No. 19-1528-RGA

CONFORMIS, INC.,
Plaintiff,

v.

MEDACTA USA, INC., and MEDACTA
INTERNATIONAL SA,
Defendants.

MEMORANDUM ORDER

On October 14, 2020, Conformis filed its Second Amended Complaint (“SAC”), bringing claims of patent infringement against Medacta USA, Inc. (“Medacta USA”) and Medacta International SA (“Medacta International”). (D.I. 85). Defendants move to dismiss Conformis’s claims against Medacta International under Federal Rules of Civil Procedure 12(b)(2), 12(b)(5), and 12(b)(6). (D.I. 107). Conformis also brings a motion for leave to file a sur-reply (D.I. 178), in light of the availability of new evidence relevant to its opposition to Medacta International’s motion to dismiss, which I now GRANT. I have considered the parties’ briefing. (D.I. 108, 118, 122, 178, 179, 186, 187).

Medacta International argues for dismissal on three grounds: (1) insufficient service of process under Rule 12(b)(5), (2) lack of personal jurisdiction under Rule 12(b)(2), and (3) failure to state a claim of direct and contributory infringement under Rule 12(b)(6). I address each of these arguments in turn.

I. Insufficient Service of Process

Medacta International argues Conformis's claims against it should be dismissed under Rule 12(b)(5) for "insufficient service of process" because Conformis did not serve Medacta International with translated copies of all the exhibits attached to the SAC.¹ (D.I. 108 at 5-6). Instead, Conformis served a translated copy of the SAC with an index of web links that direct to non-translated copies of the exhibits, some of which Medacta International claims "materially differ[]"² from the docketed exhibits attached to the SAC. (*Id.*).

Federal Rule of Civil Procedure 4(f)(1) permits service of process on an international defendant through the Hague Convention. Thus, to determine whether service of process was effective here, we must look to the Hague Convention, which sets guidelines for service of judicial documents between signatories, including the United States and Switzerland, where Medacta

¹ The SAC, as docketed, has seven attached exhibits: (1) U.S. Patent No. 8,377,129 ("the '129 Patent"), (2) U.S. Patent No. 8,460,304 ("the '304 Patent"), (3) U.S. Patent No. 9,186,161 ("the '161 Patent"), (4) U.S. Patent No. 9,295,482 ("the '482 Patent"), (5) Medacta International's "Surgical Technique" Guide for the MyKnee product, (6) screenshots from Medacta's website describing the MyShoulder product, and (7) screenshots from Medacta's website describing the Medacta Shoulder System. (D.I. 85-1 Ex. A-C, 85-2 Ex. D-G).

² "Whereas D.I. 85-1 provides the '129 patent with a certificate of correction that modifies claim languages . . . the web link Conformis provided Medacta International displays the original '129 Patent without this certificate of correction," and, "in place of D.I. 85-6 and 85-7, which show printouts of websites in the past, Conformis has merely provided links to the active website that currently exists." (D.I. 108 at 6).

International resides. *Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters*, Nov. 15, 1965, 20 U.S.T. 361, 658 U.N.T.S. 163 (1969).

Under Article 2 of the Convention, each signatory designates a central authority for accepting service, and litigants may serve documents on the central authority, which then forwards them to the recipient. *Id.*, Art. 2. “[T]he Central Authority may require the document to be written in, or translated into, the official language or one of the official languages of the State addressed.” *Id.*, Art. 5. “If the Central Authority considers that the request does not comply with the provisions of the present Convention it shall promptly inform the applicant and specify its objections to the request.” *Id.*, Art. 4.

Medacta International argues Switzerland requires documents to be translated into the local language of the authority addressed in order for service to be “official.” HCCH, *Switzerland – central Authority & practical information*, <https://www.hcch.net/en/states/authorities/details3/?aid=276> (last visited May 25, 2022) (“Switzerland declares that in cases where the addressee does not voluntarily accept a document, it cannot be officially served on him or her in accordance with Article 5(1), unless it is in the language of the authority addressed, *i.e.*, in German, French or Italian . . .”).

It is not clear from the Swiss Guidelines, however, whether this translation requirement applies to all exhibits accompanying the main document, here, the SAC, which was translated into Italian. Regardless, the Central Authority for the Ticino canton of Switzerland did not object to Conformis’s request for service, as it was required to do under Article 4 of the Hague Convention if it found the service did not comply with the provisions of the Convention, and indeed served the

summons, the SAC, and an index of the exhibits³ on Medacta International. (D.I. 108 at 4; D.I. 112-3). Because the Central Authority completed service on Medacta International without objection, I find that Conformis’s service on Medacta International properly complied with the requirements of the Hague Convention, and, as a result, satisfied the requirements of Federal Rule of Civil Procedure 4.

For these reasons, Medacta International’s motion to dismiss for insufficient service of process under Rule 12(b)(5) is DENIED.

II. Lack of Personal Jurisdiction

Medacta International argues the claims against it should be dismissed under Federal Rule of Civil Procedure 12(b)(2), because “Conformis cannot demonstrate that Medacta International has purposely directed any conduct at Delaware or the United States that gives rise to the asserted infringement claims.” (D.I. 108 at 10). I disagree.

I find that this Court’s exercise of specific personal jurisdiction over Medacta International is proper under Federal Rule of Civil Procedure 4(k)(2). For a court to exercise personal jurisdiction over a defendant under Rule 4(k)(2), the following requirements must be met: “the plaintiff’s claim must arise under federal law, the defendant must not be subject to jurisdiction in

³ I am not persuaded by Medacta International’s argument that service of process was ineffective due to the use of a web-linked index rather than attachments, the lack of translated exhibits, or the fact that the linked exhibits differed slightly from the exhibits docketed with the SAC. Conformis informed Medacta International that copies of the exhibits were available “upon request to Conformis.” (D.I. 112-3 at 42, 76). Moreover, all the exhibits are either publicly available U.S. patents or informational/promotional material prepared, in English, by Medacta International and its related companies. (D.I. 85-1 Ex. A-C, 85-2 Ex. D-G). In this case, Medacta International cannot seriously argue that it lacked actual notice of the nature of the suit against it. *See Burda Media, Inc. v. Viertel*, 417 F.3d 292, 301 (2d Cir. 2005) (citing a district court for the proposition that “the Hague Convention should be read together with Rule 4, which stresses actual notice, rather than strict formalism.”) (cleaned up).

any state’s court of general jurisdiction, and exercise of jurisdiction must comport with due process.” *Touchcom, Inc. v. Bereskin & Parr*, 574 F.3d 1403, 1412 (Fed. Cir. 2009).⁴

Here, the first two requirements are easily met. Conformis’s claim is for patent infringement, and therefore arises under federal law, and Medacta International has not identified any state in the United States in which it can be sued. *Id.* at 1415 (“if the defendant contends that he cannot be sued in the forum state and refuses to identify any other where suit is possible, then the federal court is entitled to use Rule 4(k)(2)”) (cleaned up). Therefore, the only remaining question is whether this Court’s exercise of jurisdiction over Medacta International comports with due process. I find that it does, based on the actions Medacta International has taken to conduct business directly with United States customers.

To determine whether due process permits the exercise of personal jurisdiction under Rule 4(k)(2), “we must consider whether (1) defendant has purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to the defendant’s activities with the forum, and (3) assertion of personal jurisdiction is reasonable and fair.” *Id.* at 1416 (cleaned up). “Rule 4(k)(2) contemplates a defendant’s contacts with the entire United States, as opposed to the state in which the district court sits.” *Id.* (cleaned up).

Here, there is ample evidence⁵ that Medacta International purposefully directed its activities toward residents of the United States by directly collaborating with surgeons in the

⁴ A district court should apply Federal Circuit law to determine whether it may exercise personal jurisdiction over out-of-state defendants in patent infringement cases. *Hildebrand v. Steck Mfg. Company, Inc.*, 279 F.3d 1351, 1354 (Fed. Cir. 2002).

⁵ Medacta International contends, “Conformis cannot demonstrate that Medacta International has purposely directed any conduct at Delaware or the United States that gives rise to the asserted infringement claims.” (D.I. 108 at 10). This is a factual challenge to jurisdiction. “In addressing a factual challenge to jurisdiction, the court may consider evidence outside the

United States to custom-design the accused products. These activities are integrally related to Conformis's infringement claims.

The process by which Medacta's MyKnee product, one of the accused products, is designed for a U.S. patient is as follows. First, the U.S. patient's surgeon uploads scans of the patient's knee to a portal operated by Medacta International. (D.I. 180-1 Ex. 20 at 66:14-67:14). From there, Medacta International engineers in Switzerland "generate sort of a default plan based upon the surgeon's default preferences." (*Id.*). The surgeon in the United States then has the opportunity to review and propose changes to the plan, before the plan is validated and production of the custom implant begins in Switzerland by Medacta International engineers. (*Id.*). The design process is overseen entirely by engineers from Medacta International; nobody from Medacta USA is "actually involved in designing the MyKnee product from the images." (*Id.* at 74:3-75:4). The accused MyShoulder product is designed according to the same process, where the surgeon in the U.S. "indicates the patient for anatomic or reverse shoulder replacement, sends them – refers them out for a CT scan, scan is executed per the parameters, uploaded to the cloud, off it goes to Switzerland, they work their magic, and then a default plan is produced by the surgeon preferences." (*Id.* at 83:2-12).

This collaborative process by which Medacta International works directly with U.S. customers to custom-design the accused products is precisely the sort of purposeful activity

pleadings and is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." *Creative Compounds, LLC v. Starmark Lab 'ys*, 651 F.3d 1303, 1315 (Fed. Cir. 2011) (citing *Lawrence v. Dunbar*, 919 F.2d 1525, 1529 (11th Cir. 1990)); *Gould Elec. Inc. v. U.S.*, 220 F.3d 169, 176 (3d Cir. 2000).

directed toward the United States that fairly and reasonably subjects a defendant to jurisdiction in the United States.

For these reasons, Medacta International's motion to dismiss for lack of personal jurisdiction is DENIED.

III. Failure to State a Claim

Medacta International argues Conformis has failed to state a claim against it for direct and contributory infringement.⁶ (D.I. 108 at 18-19). In its answering brief, Conformis concedes to dismissal of its contributory infringement claim. (D.I. 118 at 17 n.11). Therefore, Conformis's claim of contributory infringement is DISMISSED.

35 U.S.C. § 271(a) creates a cause of action for direct infringement against “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent” Conformis argues it has adequately pled direct infringement by alleging, “Medacta International is presently making, using, offering for sale, and/or selling [the accused products],” and, “Medacta International's direct infringement has included, but is not limited to, selling its products directly to Medacta USA for further dissemination to United States customers.” (D.I. 118 at 17-18 (citing D.I. 85 ¶¶ 36, 50, 70, 90)). The only other portion of the SAC Conformis cites in support of its direct infringement claim is paragraph B of its Prayer for Relief, where it asks the Court for declaratory judgment “that Medacta International's importing, making, using, offering to sell

⁶ Conformis also brings a claim of induced infringement against Medacta International. Medacta International does not argue for the dismissal of that claim.

and/or selling at least MyShoulder products in the United States are and would be acts of infringement of one or more claims of [the Asserted Patents].” (*Id.* at 19 (citing D.I. 85 at 33 ¶ B)).

These bare, conclusory allegations are no more than a “formulaic recitation of the elements of a cause of action” and are therefore inadequate to survive a motion to dismiss. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Nowhere does Conformis specifically allege infringing activity by Medacta International taking place in the United States, as required by § 271(a). Conformis asks that I read between the lines of its allegations regarding Medacta International’s sales to Medacta USA to find an implicit allegation of importation, because, it argues, these allegations “strongly imply that Medacta International imports the accused products.” (D.I. 118 at 19). I decline to do so. While the standard for evaluating a plaintiff’s allegations on a motion to dismiss requires accepting all of plaintiff’s factual allegations as true and viewing them in the light most favorable to the plaintiff, it does not require a court to reach beyond what is actually alleged. Because Conformis has failed to specifically allege any infringing activity by Medacta International occurring in the United States, Conformis’s claim of direct infringement by Medacta International is DISMISSED without prejudice.⁷

IT IS SO ORDERED.

Entered this 3rd day of June, 2022.

/s/ Richard G. Andrews
United States District Judge

⁷ Conformis asks for leave to amend its complaint “to clarify its direct infringement allegations.” (D.I. 118 at 20). If Conformis wants to file an amended complaint, it has two weeks from the date of this Memorandum to file a motion for leave to do so.