

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

CONFORMIS, INC.,

Plaintiff,

v.

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

Defendants.

C. A. No. 19-1528-RGA (CONSOL.)

CONFORMIS, INC.,

Plaintiff,

v.

MEDACTA USA, INC. and MEDACTA
INTERNATIONAL SA,

Defendants.

C. A. No. 19-1618-RGA

JURY TRIAL DEMANDED

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

For its Second Amended Complaint against Medacta USA, Inc. (“Medacta USA”) and Medacta International SA (“Medacta International”) (collectively “Medacta” or “Defendants”), Plaintiff Conformis, Inc. (“Conformis” or “Plaintiff”), by its attorneys, alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action.
2. Conformis brings this action to seek damages and other relief arising from the infringement by Medacta of (i) U.S. Patent No. 8,377,129 (“the ’129 Patent,” attached hereto as Exhibit A), entitled “Joint Arthroplasty Devices and Surgical Tools,” (ii) U.S. Patent No. 8,460,304 (“the ’304 Patent,” attached hereto as Exhibit B), entitled “Joint Arthroplasty Devices and Surgical Tools,” (iii) U.S. Patent No. 9,186,161 (“the ’161 Patent,” attached hereto as Exhibit C), entitled “Surgical Tools for Arthroplasty,” and (iv) U.S. Patent No. 9,295,482 (“the ’482 Patent,” attached hereto as Exhibit D), entitled “Patient Selectable Joint Arthroplasty Devices and Surgical Tools” (collectively, “the Patents-In-Suit”).

PARTIES

3. Plaintiff Conformis, Inc. is a Delaware corporation with its worldwide headquarters at 600 Technology Park Drive, Billerica, Massachusetts 01821.

4. Conformis is the assignee and owner of the Patents-In-Suit.

5. Upon information and belief, Defendant Medacta International SA is organized and existing under the laws of Switzerland and has its principal place of business at Strada Regina, Castel Pietro, Switzerland.

6. Upon information and belief, Defendant Medacta USA, Inc. is a Delaware corporation with its principal place of business at 6640 Carothers Parkway, Franklin, Tennessee 37067. Medacta USA is a wholly owned subsidiary of Medacta International.

JURISDICTION AND VENUE

7. Conformis' patent infringement claims arise under the Patent Laws of the United States, Title 35, of the United States Code and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* Accordingly, this Court has subject matter jurisdiction over such claims pursuant to 28 U.S.C. §§ 1331 (federal question), 1338 (action arising under an Act of Congress relating to patents), 2201 (creation of remedy), and 2202 (further relief).

8. This Court has personal jurisdiction over Medacta USA, at least because Medacta USA is at home in the State of Delaware, where it is incorporated and has a registered agent for service of process. In addition, upon information and belief, Medacta USA regularly does or solicits business in the State of Delaware and has committed one or more acts of patent infringement complained of herein in the District of Delaware.

9. This Court has personal jurisdiction over Medacta International, because, directly and through Medacta USA, it has committed acts in the District giving rise to this action for patent infringement and/or has established minimum contacts with Delaware such that the

exercise of jurisdiction would not offend traditional notions of fair play and substantial justice. Medacta International manufactures and sells the infringing MyKnee and MyShoulder patient-specific instruments and systems to Medacta USA. Thus, Medacta International has placed, and continues to place infringing products into the stream of commerce, via its established distribution channel through Medacta USA, with the knowledge, intent, and/or understanding that such products are sold in the State of Delaware and elsewhere in the United States. Medacta International also has induced and continues to induce infringement in the State of Delaware and elsewhere in the United States, including by providing surgical technique guides, bearing the Medacta International name, associated with the infringing products and made available to United States customers. Moreover, Medacta International has received and continues to receive revenue from U.S. sales.

10. The Court has personal jurisdiction over Medacta International for the additional reason that it utilizes Medacta USA, its wholly owned subsidiary, as its agent for conducting business in the United States.

11. On the Medacta International website, Medacta International publicly identifies Medacta USA's principal place of business in the United States as the location of its "representative." Medacta International's publicly available Annual Reports further describe their Executive Management, based in Medacta International's Swiss headquarters, as being "responsible for" regional Directors, who oversee and manage each of the Medacta's internationally based "branches." Medacta International also issues press releases on behalf of Medacta USA. For example, Medacta International's CEO announced the opening of Medacta USA's offices in a press release issued by Medacta International, describing them as "Medacta's US headquarters." On information and belief, Medacta International executive and/or

management teams also have responsibilities with respect to Medacta USA. Medacta International also appoints senior employees at Medacta USA, including the director of Medacta USA's spine division.

12. In addition, although Medacta International is responsible for the design and development of the infringing products and submitted 510(k) premarketing submissions to the U.S. Food and Drug Administration, it is Medacta USA's Senior Director of Quality and Regulatory who is listed as the applicant's "correspondent." Consistent with Medacta International's use of Medacta USA as its agent, Medacta International's website explains that "We received the first FDA product clearance and implanted the first prosthesis in the USA."

13. Further, Medacta International is involved in the management of Medacta USA, including approving operating budgeting, planning initiatives, acquisitions, significant capital expenditures and major U.S. based litigation decisions like settlement or budgets. On information and belief, Medacta International also dictates to Medacta USA the amount of revenue it receives from it.

14. Venue in this Court is proper under the provisions of 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400. Medacta USA is incorporated in Delaware and thus resides in this State. In addition, Medacta International is subject to suit in this Court pursuant to 28 U.S.C. 1391(c)(3).

FACTUAL BACKGROUND

A. Background

15. Conformis is the world's leading designer, developer, and manufacturer of patient-specific instrument systems required to best fit implants into a specific patient's body. Conformis also designs and manufactures patient-specific knee and hip replacement implant systems. Founded by doctors affiliated with Stanford and Harvard Medical Schools, Conformis

began with a revolutionary idea: make the implant and tools fit the patient rather than forcing the patient to fit the implant and tools.

16. For decades before Conformis' innovation, surgeons have been implanting medical devices using (and many are still using) standard instrument systems that have not been designed with reference to the anatomy of individual patients. As a result of this imprecise approach, after surgery, patients commonly suffer loss of movement and function, instability, and lingering pain.

17. Conformis recognized that the conventional process of joint repair was backwards: rather than fitting the patient to the tools, the tools should be designed and developed specifically for the patient, as this produces a better-seated implant.

18. Conformis therefore set out to develop patient-specific instrument systems, which precisely place an implant, reduce surgical time and trauma, and create a reproducible surgical technique. Conformis' patient-specific instrument systems eliminate many of the traditional instruments associated with conventional surgery while concurrently simplifying and improving surgical technique.

B. Conformis' Patents

19. Conformis has made significant investments in the research, development, and testing of patient-specific instrument systems for knee and hip replacement surgery.

20. To protect those investments, Conformis applied for and obtained a number of patents, including the Patents-In-Suit.

21. Patent authorities worldwide have recognized that Conformis' patient-specific instrument systems are worthy of patent protection, and have granted Conformis over 200 patents on its technologies. These patents, and Conformis' many additional pending patent

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