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VIA ECF

Hon. Lewis J. Liman, U.S.D.J.
United States District Court
Southern District of New York
Daniel Patrick Moynihan
United States Courthouse, Courtroom 15C
500 Pearl Street
New York, New York 10007-1312

Re: Rouviere, et al. v. DePuy Orthopaedics, Inc., et al.
Docket No. 1:18-cv-04814-LJL-SDA

Dear Judge Liman:

On behalf of Defendant Howmedica Osteonics Corp. ("HOC"), and further to the Court's December 5, 2022 Order (ECF No. 350) denying without prejudice Plaintiffs' motion to seal certain motion-related exhibits and permitting the parties to submit a revised motion, please accept this letter brief and accompanying Declaration in support of HOC's revised motion to seal the documents that were the subject of Plaintiffs' original motion to seal. For the reasons set forth below, sealing of the documents at issue is necessary, and the scope of the requested sealing is appropriate.[1]

HOC has communicated with Plaintiffs' counsel and confirmed that Plaintiffs do not oppose this Motion.

RELEVANT BACKGROUND

In this action, Plaintiffs assert medical device products liability claims arising out of implantation of the MDM (modular dual mobility) hip system, a hip replacement prosthetic device designed, manufactured and sold by HOC. The MDM system has been on the market since 2011

[1] Additionally, the undersigned determined that one of HOC's confidential design documents, ECF 346-26, a three-page engineering analysis memorandum taken from HOC's Design File, was inadvertently filed publicly by Plaintiffs, but instead should have been included with Plaintiffs' motion to seal. Counsel for HOC notified the Court Clerk, and the document has been temporarily sealed. HOC requests that this document be permanently sealed along with the other confidential HOC documents annexed to Plaintiffs' original motion to seal.

and, importantly, remains on the market today. *See* Declaration of Christopher Heffernan ("Heffernan Decl.") at ¶3. In May 2022 counsel for the parties agreed that some of the exhibits that Plaintiffs planned to file in connection with their opposition to HOC's summary judgment motion were HOC's confidential documents that had been produced subject to Protective Order, and, accordingly, would be filed under seal. These confidential exhibits included:

(1) Design File. Plaintiffs sought to file under seal large portions of HOC's Design File for the MDM system. As explained in the accompanying Declaration of Christopher Heffernan, HOC's Chief Engineer in the Engineering Standards Department and one of the senior engineers that designed and developed the MDM system, the Project File/Design Master Records ("Design File") provides a step-by-step history of the process of design and development of the MDM system and its components from its conception onwards. The Design File contains the entire design history for the device, specifically including the original concepts, preliminary plans, product development and engineering specifications, modifications to the design or manufacturing, the decisions and selections for the materials to be used, risk analyses and mitigation, testing, project evaluations, marketing and sales strategies, customer information and finalization of the design and manufacturing process. The Design File also reflects HOC's research and project development organization, provides the manner in which HOC's internal divisions and teams collaborate, as well as the sequential outline for HOC's design, development and manufacturing of the product at issue. *See* Heffernan Decl, ¶5.

(2) 510k File. Plaintiffs sought to file under seal the entirety of HOC's internal regulatory file ("510k File") for the MDM system. The 510k File is HOC's internal regulatory file documenting HOC's confidential submissions to the FDA in connection with regulatory clearance of the product. The 510k file includes confidential design and engineering drawings, detailed confidential information regarding materials, test protocols and reports, draft labeling, and documents evidencing communications with the FDA reviewer(s) regarding design and engineering, testing, and related confidential and proprietary information and documents. The 510k File also includes HOC's internal communications, memos and other documents not submitted to the FDA, but which involve and discuss the design, development and manufacturing processes from a regulatory perspective. The confidential information contained in HOC's 510k File largely overlaps with the confidential information in the Design File. *See* Heffernan Decl, ¶6.

(3) Manufacturing records. Plaintiffs sought to file under seal the manufacturing records for the MDM system components. These records include detailed descriptions and instructions in connection with the manufacturing processes for the components at issue. This includes records documenting the actual manufacture of the lots of the specific components implanted into Plaintiff, as well as related design drawings, detailed procedures of the various steps in the manufacturing

process and machines/methods used in that process.[2] Many of these records overlap with the Design File. *See* Heffernan Decl, ¶7.

(4) The report of HOC's engineering expert, Jorge Ochoa, Ph.D. This expert report contains detailed discussion of the design of the MDM system, including discussion of and quotations from various confidential design documents and photocopies of some of those design documents. In the report, Dr. Ochoa discusses in detail the design of the MDM system, design verification, testing, risk analysis and manufacturing processes.

Notably, because of sensitivity of the above information and potential for competitive harm, none of the above documents were produced to co-defendant, DePuy, a medical device company and competitor of HOC, in this case.

ARGUMENT

This Court has "considerable discretion in determining whether good cause exists to overcome the presumption of open access to documents." *Geller v. Branic Int'l Realty Co*., 212 F.3d 734, 738 (2d Cir. 2000). In its December 5, 2022 Orders, the Court granted leave for the parties to file a revised motion explaining why "sealing (1) is necessary 'to preserve higher values,' and (2) 'is narrowly tailored to serve that interest.'" *See* ECF No. 351, fn. 3, citing *Metcalf v. TransPerfect Translations Int'l, Inc*., 2022 WL 2116686 at *1 (quoting *Lugosch v. Pyramid Co. of Onondaga*, 435 F3d 110, 120 (2d Cir. 2006)).

It is well recognized in the Second Circuit that preventing competitive harm is a countervailing interest, i.e., a higher value, that can override the presumed public right of access to judicial documents. *See, e.g., United States v. Amodeo*, 71 F.3d 1044, 1051 (2d Cir. 1995) ("Commercial competitors seeking an advantage over rivals need not be indulged in the name of monitoring the courts…"); *Rowe v. Google LLC*, 2022 WL 4467628 at *2 (S.D.N.Y. Sept. 26, 2022) ("Preventing competitive harm is a countervailing interest that can override the public right of access.")

This Court has permitted sealing sensitive documents related to the design, manufacture, and marketing of products, including medical devices, where such disclosure could be harmful to the company. In *In re Zimmer M/L Taper Hip Prosthesis*, 2021 WL 4706199 (S.D.N.Y. 2021), this Court recognized the potential for competitive harm and permitted sealing of documents regarding Zimmer's research and development of its hip device, testing methods and results, device design and potential future design, internal risk analysis, engineering analyses, and marketing/sales data. *See id*. at *2-5. *See also Hypnotic Hats, Ltd. v. Wintermantel Enterprises, LLC*, 335 F. Supp. 3d 566, 600 (S.D.N.Y. 2018) (All of these documents "fall[ ] into categories

[2] As an example, STRROUV00486-500 is the material and processing specification for the X3 polyethylene material used to make the MDM insert component. As another example, STRROUV00295-309 is the detailed procedure to set up and operate one of the machines used in the manufacture of the MDM insert component.

commonly sealed[:] those containing trade secrets, confidential research and development information, marketing plans, revenue information, pricing information, and the like.") (citation omitted); *GoSMiLE, Inc. v. Dr. Johnathan Levine, D.M.D. P.C.,* 769 F. Supp. 2d 630, 649-50 (S.D.N.Y. 2011) (granting motion to seal "highly proprietary material concerning the defendants' marketing strategies, product development, costs and budgeting.")

In the instant case, public disclosure of the documents sought to be sealed would cause significant competitive harm to HOC. In his attached Declaration, Mr. Heffernan details how public disclosure of the documents at issue would allow competitors access to HOC's design, development, research and marketing strategies with regards to HOC's current and future product lines and applications. *See* Heffernan Decl., ¶13. Competitors could readily use the material specifications, design plans, testing information and manufacturing processes of HOC's products to enhance their own products and/or undercut HOC's share of the joint replacement industry. *Id.* at ¶12. Competitors could copy HOC's confidential records and processes and market their own products with the very same attributes, characteristics and properties that distinguish HOC's products from other products on the market. *Id.* It is for these very reasons that, although the documents sought to be sealed were shared with Plaintiffs in discovery, none were shared with HOC's co-defendant, DePuy, nor were DePuy's similar categories of documents shared with HOC.

HOC's request for sealing of the confidential exhibits is narrowly and appropriately tailored to serve the above interest of preventing competitive harm to HOC. The parties did not agree to seal *all* exhibits to Plaintiffs' summary judgment opposition, only those from HOC's Design File, 510k File and manufacturing records, for the reasons discussed above, as well as the expert report specifically discussing those records in detail and quoting from them.

Additionally, it is important to note that instead of attaching only the handful of HOC's confidential documents actually referred to in their opposition papers, Plaintiffs attached HOC's confidential files in their entirety or in very large portions, amounting to more than 2,000 pages of confidential documents. This is significant for two reasons. First, by the very nature of these documents, redaction or selective public disclosure is not possible or practical and would not avoid the harm to HOC; the documents would need to be redacted in their entirety or very nearly so. *See Amodeo*, 71 F. 3d 1044, 1053 (2d Cir. 1995) (finding redaction not to be a viable option since redactions would include "virtually the entire text"); *NCUA v. Deutsche Bank Nat'l Trust Co*., 2022 WL 1515159 (S.D.N.Y. May 13, 2022) (so-ordering request to seal documents in their entirety because the documents are so voluminous as to make redactions impracticable); *Hypnotic Hats, Ltd.*, 335 F. Supp. 3d 566, 600 (S.D.N.Y. 2018) (maintaining entire exhibit under seal because it could not "be practicably redacted").

Second, the Court presumably did not review, and certainly could not reasonably have been expected to review, the entire confidential HOC files attached by Plaintiffs to their opposition, particularly when only a handful of documents were actually referenced in Plaintiffs' papers. Thus, the vast majority of confidential documents attached to Plaintiffs' opposition papers were unnecessary to adjudication of the motion, a factor which weighs in favor of sealing. *See Mirlis*

v. Greer, 952 F. 3d 51, 59 (2d Cir. 2020) (noting that the weight to be accorded to the presumption of access to a judicial document is "governed by the role of the material at issue in the exercise of Article III judicial power and the resultant value of such information to those monitoring the federal courts"), citing *Amodeo*, 71 F. 3d at 1049. *See also Avocent Redmond Corp. v. Raritan Ams. Inc*., 2012 WL 3114855, *15 (S.D.N.Y. 2012) (concluding that the weight given to public access is less because of the confidential information "does not go to the heart of the judicial process. The information is at the margins of this Court's rulings and has not required the Court to redact any portion of its Memorandum and Order.")

Indeed, even those confidential documents actually referenced were not relied on by the Court in its decision. All of the confidential documents at issue were presented by Plaintiffs on the issue of equitable estoppel. However, the Court decided that issue as a matter of law without regard to the documents. On that issue, the Court found that equitable estoppel based on alleged misrepresentations only applies to misrepresentations specifically directed to Plaintiffs, not those made to the community at large, the latter of which Plaintiffs argued was shown by the documents. Thus, the referenced documents were not at the heart of the Court's ruling.[3]

CONCLUSION

For the reasons set forth above, sealing of the records annexed to Plaintiffs' original motion to seal is necessary to preserve higher values and is narrowly tailored under the circumstances. Additionally, ECF 346-26, a three-page engineering analysis memorandum taken from HOC's Design File, was inadvertently filed publicly by Plaintiffs and should also be sealed. HOC respectfully requests that the Court enter an Order sealing HOC's confidential documents filed in connection with Plaintiffs' opposition to HOC's summary judgment motion.

Respectfully submitted,

s/Paul E. Asfendis
Paul E. Asfendis

ORDER: The request to seal certain motion-related exhibits is GRANTED IN PART AND DENIED IN PART. Defendant may seal the design file, the 510k file, and the manufacturing records in full. "Such documents fall into categories commonly sealed[:] those containing trade secrets, confidential research and development information, marketing plans, revenue information, pricing information, and the like." *Hypnotic Hats, Ltd. v. Wintermantel Enterprises, LLC*, 335 F. Supp. 3d 566, 600 (S.D.N.Y. 2018) (cleaned up). This is also true of the report of expert Jorge Ochoa, except for the Table of Contents and Sections 1, 1.1, 1.2, and 4 of that report. It is not clear what competitive harm public disclosure of these sections of the report would cause. Thus, Defendant is directed to file the expert report with everything redacted but the Table of Contents and Sections 1, 1.1, 1.2, and 4.

Date: 12/20/2022

SO ORDERED.

LEWIS J. LIMAN
United States District Judge