N. Kirkland Pope
kirkpope@pmkm.com

POPE MCGLAMRY
ATTORNEYS AT LAW

3391 Peachtree Road, NE, Suite 300
Atlanta, Georgia 30326

Mailing Address
P.O. Box 19337 (31126-1337)
Atlanta, Georgia 30326

404.523.7706
www.popemcglamry.com

September 27, 2023

VIA ECF FILING
The Honorable Marcia M. Henry
United States District Court for the Eastern District of New York
225 Cadman Plaza East
Brooklyn, New York 11201

Re: ***In Re: Exactech Polyethylene Orthopedic Product Liability Litigation*** **(E.D.N.Y. Case No. 1:22-md-03044-NGG-MMH)**

Dear Magistrate Judge Henry:

Plaintiffs seek an order regarding Defendants' objections to three specific categories of documents: foreign regulatory, other litigation, and Exactech/TPG due diligence materials. After five meet and confers, the Parties are at an impasse, and it is Exactech's position that the requests at issue are not relevant to this litigation. As more fully explained below, the requested information bears directly on the products, claims, and defenses in this MDL, specifically, Exactech's notice and knowledge about the risk the products posed and Defendants' related conduct.

The Parties' conferences focused on Exactech's relevancy objections, and Exactech did not provide specifics in support of its other objections, including the alleged burden of producing the requested materials. The Protective Order (ECF 89) addresses Exactech's attorney-client privilege work-product privilege, privacy and confidentiality objections. The Parties have resolved Exactech's time frame and product definition objections.

In addition to the discovery dispute detailed herein, Plaintiffs now have to contend with Exactech's failure to comply with Your Honor's Order requiring Exactech to produce 123,321 non-privileged documents from the 12 agreed-upon custodians. *See* ECF 399. On September 21, Exactech reported that it had not completed its review of the documents. On September 22, Exactech produced 17,269 documents, a fraction of what it was ordered to produce. Unknown to Plaintiffs is whether Defendants are withholding production for relevance. Exactech did not seek relief from the Court. Exactech's failure to comply in turn impacts the discovery schedule and the pretrial proceedings.

1. Foreign Regulatory Agency Documents (RFPs 4, 5, 12)

Plaintiffs seek documents concerning communications between Exactech and foreign regulatory agencies regarding the orthopedic products at issue in this litigation (RFP #4); interactions between Exactech and foreign regulatory agencies about Exactech's orthopedic products and processes, including inspections, notifications, violations, or corrective and preventative actions (RFP #5); and federal, state, or foreign criminal or regulatory investigations of any Exactech orthopedic product at issue in this litigation (RFP #12). *See* Exhibit 1, Exactech's Objections and Response to Plaintiffs' First RFP. Exactech objects to these requests as irrelevant

because foreign-sold products are subject to different laws, standards, and regulations than Plaintiffs who received their devices in the United States. *Id.* at RFP #4, 5, 12.

Although Exactech is headquartered in Gainesville, Florida, the majority of its hip and knee devices, including the same component parts and devices at issue in the MDL, were sold outside the United States. As in most product liability cases, notice and causation are central issues here. The requested documents are relevant to Exactech's notice and knowledge of safety risks, adverse events, failure rates, safety and efficacy, and the need and timing of any design and marketing changes. The national origin of the requested documents is immaterial because "[r]egardless of the country in which Defendants and their subsidiaries operate, Defendants are obligated to notify regulatory authorities of potential health and safety risks associated with their products." *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, 2:18-MD-2846, 2019 WL 341909, at *2 (S.D. Ohio Jan. 28, 2019) (compelling the production of communications between Defendants and regulatory authorities regarding the products identified in the complaint finding the foreign regulatory documents both relevant and proportional to the MDL). In fact, the "FDA considers an event that occurs in a foreign country reportable under the MDR regulation if it involves a device that has been cleared or approved in the US".[1] Accordingly, Plaintiffs request that the Court overrule Exactech's objections and compel production of these documents.

2. Other Litigations (RFP 2)

Plaintiffs seek discovery from other litigation against Exactech alleging similar claims for personal injury involving Exactech's orthopedic products in this MDL. *See* Ex. 1, RFP #2. Exactech asserts discovery from other cases is irrelevant because facts, claimants, health care providers and other circumstances make *every* prior case dissimilar to this litigation. *Id*. To the extent Exactech claims a different firm represented it in other litigation and makes production unproportional or burdensome is of no consequence as Exactech is the party to the litigation, not the law firm and the requested documents are in Exactech's control.

Sworn testimony, exhibits, expert reports, and document productions from other lawsuits alleging premature failure of the Optetrak knee system and Connexion hip devices –including the polyethylene inserts and liners are relevant and discoverable in this MDL under FRCP 26. For example, plaintiffs are aware of several cases that have litigated the same or similar claims as Plaintiffs allege here—the difference is those claims were brought before Exactech recalled the devices. For example, the *Pandolfo* and *Sacher* cases were filed in 2020 and alleged premature failure of the Optetrak devices and specifically reference defective polyethylene causing similar injuries as alleged by Plaintiffs in the MDL.[2] *Pandolfo v. Exactech, Inc. et al*, Case No. 4:20-cv-00535 (E.D.M.O.) *Sacher v. Exactech*, Case No. 1:20-cv-02562 (S.D.N.Y.) Gary Miller (Optetrak Designer and Executive VP of R&D) was deposed in *Pandolfo*. Gary Miller, Alan Siedel (Engineering and Dev. Manager of Knees), and Laurent Angibaud (VP of Engineering, Advanced

[1] *See* FDA Medical Device Reporting For Manufacturers, § 4.11.13, Nov. 8, 2016, *available at* https://www.fda.gov/files/medical%20devices/published/Medical-Device-Reporting-for-Manufacturers---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.pdf

[2] Notably, the *Pandolfo* and *Sacher* plaintiffs are now parties to this MDL and bring fraud claims against Exactech for its misleading, incomplete discovery responses that led to a settlement before the public disclosure of the Exactech polyethylene recall. *Pandolfo v. Exactech, Inc. et al*, Case No. 1:23-cv-01691 (E.D.N.Y.); *Sacher v. Exactech Inc. et al*, Case No. 1:23-cv-06942 (E.D.N.Y.)

Surgical Technologies) were deposed in *Sacher*. In 2017, the *Adkins* case alleged Exactech's now recalled hip liner prematurely wore and failed. *Adkins et al. v. Exactech, Inc.*, Case No. 5:17-cv-00955 (WDOK). Gary Miller and Bennie Gladdish (Dir. of Engineering 2003-2017) were deposed in *Adkins*. Notably, Exactech phased out its UHMWPE polyethylene liner a year after this case was filed. *Shorter v. Exactech, Inc. et al.*, Case No. 2:18-cv-00480 (EDPA) and *Ferm et al v. Exactech, Inc.*, Case No. 2:18-cv-0001 (NDGA) are cases alleging premature failures of the Optetrak knee system. Several cases filed by Cory Watson P.C. in 2017 alleged failures of the Optetrak knee system: *McFadden v. Exactech, Inc. et al.*, Case No. 2:17-cv-00427 (NDAL); *Durr v. Exactech, Inc.*, Case No. 2:17-cv-00766 (NDAL); *Barnes v. Exactech Inc. et al*, 2:17-cv-01052 (NDAL). Exactech was represented by Bowman & Brooke LLP in all cases except *Ferm*.

Exactech vehemently objects to producing documents from the *qui tam* on the grounds that it is a False Claims Act case, not a product liability or personal injury case. But the *qui tam* centers around whistleblowers' allegations that a component of Exactech's Optetrak knee, the Finned Tibial Tray, had a known design defect that Exactech failed to report to the FDA. Without knowledge of the design defect, there is no submission of a false claim to the government. Many of the documents on file in the *qui tam* speak to Exactech's notice and knowledge of potential and actual risks with its Optetrak knee devices that are not limited to the Finned Tibia Tray component. The *qui tam* contains discovery reflecting Exactech's conduct with respect to premature failures of the Optetrak knee, including responses to surgeon's concerns, placement of blame on surgical technique, downplaying of complaints as outliers, and failure to report revisions to the FDA. *See also* Exhibit 2, Memorandum of Opinion. The company's failure to report revisions to the FDA is strikingly similar to the allegations here and reflect Exactech's approach to disregard safety and regulatory compliance, namely adverse event reporting. Additionally there are materials titled "Knee Sales Problem", "Meeting Regarding Optetrak Tibial Loosening", reports called "Optetrak-PS/Optetrak Total Knee Investigation" and product development timelines that on their face, and as quoted in the publicly available depositions are relevant to the claims and defenses in this MDL. Furthermore, there are departments and functional roles within Exactech that are implicated in both litigations. Plaintiffs have shown (and can further show if requested) Exactech's objections to produce documents from prior and ongoing litigation and are due to be overruled.

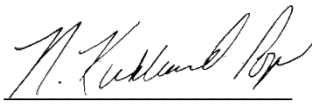
3. Due Diligence Documents Relating to Exactech/TPG Merger (RFPs 29, 32; ROG 16)

Exactech refuses to provide due diligence documents related to the Exactech/TPG merger claiming they are irrelevant. *See* Ex. 1 at RFP # 29, 32; Exhibit 3, Exactech Obj. and Answers to Interrogatories at No. 16. However, the due diligence documents contain discoverable information related to Exactech's contingent liabilities and known manufacturing and design concerns and defects. This includes information shared with TPG regarding premature polyethylene degradation that is relevant to defect, notice, concealment, and Exactech's recall issued four years after the acquisition. Further, in granting TPG's Motion to Stay Discovery Your Honor ruled "there would be no prejudice to Plaintiffs, who will receive discovery from the Exactech Defendants," which weighed in favor of granting the stay of discovery. *See* May 30, 2023 text order. Further, TPG represented (and Exactech's counsel did not object) that Plaintiffs would receive "due diligence documents related to the merger" and other materials from Exactech. *See* Exhibit 4, TPG's Motion to Stay Discovery Tr., May 19, 2023, at 10. Plaintiffs request that the Court overrule Exactech's objections and compel production of all TPG/Exactech due diligence documents responsive to RFPs 29 and 32 and fully answer Interrogatory # 16.

Certification Under Rule 37(a)(1)

As set forth herein, the Parties have made good faith efforts pursuant to Local Civil Rule 26.4 and Fed. R. Civ. P. 37(a)(1), to resolve the dispute, including discussion by contemporaneous means (e.g., telephone, video conference, letter).

Respectfully submitted,



N. Kirkland Pope, Esq.
POPE MCGLAMRY, P.C.
3391 Peachtree Road, NE, Suite 300
Atlanta, GA 30326
404-523-7706
kirkpope@pmkm.com

/s/ Ellen Relkin
Ellen Relkin, Esq.
WEITZ & LUXENBERG, P.C.
700 Broadway
New York, New York 10003
212-558-5500
erelkin@weitzlux.com

Plaintiffs' Co-Lead Counsel

CC: All counsel of Record via ECF