BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: EXACTECH POLYETHYLENE ORTHOPEDIC PRODUCTS LIABILITY LITIGATION	MDL No. _____

MEMORANDUM IN SUPPORT OF MOTION FOR TRANSFER OF ACTIONS TO THE EASTERN DISTRICT OF NEW YORK PURSUANT TO 28 USC §1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS

Pursuant to 28 U.S.C. § 1407 and Judicial Panel on Multi-District Litigation ("JPML") Rule 6.2, Plaintiffs Alexander and Rona Berger, Emanuel Cervelli, Lawrence Daly, Jeffrey and Diane Fassler, Mark Goldman, Michael Head, Michael and Debbie Insdorf and Leslie and Arcangelo Liberatore respectfully move this Judicial Panel on Multi-District Litigation ("Panel") for an Order transferring the currently filed cases marked in the attached Schedule of Actions (collectively the "Actions"), as well as any cases subsequently filed involving similar facts or claims ("tag-along cases"), to the Eastern District of New York before Judge Kiyo A. Matsumoto.

Transfer of these cases at issue is well within the scope of 28 U.S.C. § 1407 as: (i) Each of the actions involves common questions of fact, (ii) consolidation would serve the convenience of the parties and witnesses and (iii) consolidation would promote the just and efficient conduct of the litigation.

I. BACKGROUND

This motion for transfer involves twenty-seven (27) pending cases in eleven (11) district courts asserting similar claims, with seven of the twenty-seven actions pending in the Eastern District of New York.[1] The pending cases allege plaintiffs received either an Optetrak Comprehensive Knee System[2] (hereinafter referred to as "Optetrak Device"), the Truliant Total Knee Replacement System (hereinafter referred to as "Truliant Device"), or the Connexion GXL Acetabular Liner as part of a hip replacement system (hereinafter referred to as "Connexion GXL Device"), all involving the polyethylene components that failed prematurely and all manufactured and sold by a common defendant, Exactech, Inc. (hereinafter referred to as "Exactech") and its affiliated corporations. This motion is also intended to encompass any future case filed involving failure of the Vantage Total Ankle System (hereinafter referred to as "Vantage Device") as that prosthesis was recalled within the same recall period and for the same basis as the Optetrak and Truliant Devices.

Specifically, the polyethylene inserts of the Optetrak, Truliant and Vantage Devices were the subject of a recent recall in which Exactech represented that the polyethylene inserts manufactured as early as 2004 were packaged in out-of-specification vacuum bags that did not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) thereby leading to increased oxidation of the polyethylene and premature wear of the insert.[3] Plaintiffs have required revision surgery to remove the failed tibial insert as well as other components of the Optetrak or

[1] Plaintiffs are aware of an additional Optetrak Device case, *Brickman v. Exactech. Inc.*, that was filed today, June 14, 2022, by the law firm of Pope McGlamry in the Eastern District of Pennsylvania. The case has not yet been assigned to a judge and is not yet docketed. Including the *Brickman* case, there are currently 28 cases pending in 12 different district courts.

[2] Exactech marketed and sold both a partial knee replacement system and total knee replacement system under the "Optetrak" name. In 2010, Exactech introduced the "Optetrak Logic" total knee replacement system. Given that Exactech has represented all polyethylene tibial inserts utilized in an Optetrak knee replacement system dating back to 2004 are subject to the recall, any reference in Plaintiffs' Motion to the "Optetrak Device" is intended to encompass the Optetrak Partial Knee Replacement System, Optetrak Total Knee Replacement System and Optetrak Logic Total Knee Replacement System.

[3] Exactech, Inc., *Urgent Medical Device Correction*, EXACTECH, INC. (Apr. 7, 2022) https://www.exac.com/wp-content/uploads/2022/04/Exactech-DHCP-letter.4.6.2022.pdf.

Truliant Device depending on the extent of damage caused by the premature wear. Similarly, plaintiffs have undergone revision surgery to remove failed Connexion GXL Devices due to premature wear of the polyethylene. Degradation of the polyethylene alone, and potentially in conjunction with any other design issues, results in component loosening, tissue damage, osteolysis, permanent bone loss and other injuries leading to complex revision surgeries and extensive recovery time.

A. Defendants

Exactech was founded in 1985 by orthopedic surgeon Bill Petty, MD, biomedical engineer Gary Miller, PhD, and Betty Petty, MA. Exactech Inc. was publicly traded until 2018 and is headquartered in Gainesville, Florida. The company was sold to private equity in 2018, through complex transactions which they describe as a merger with Osteon Holdings, its new corporate parent, which is owned or otherwise closely affiliated with the private equity firm TPG Capital. Exactech USA, Inc. is a subsidiary of Exactech, Inc. and is also headquartered in Gainesville, Florida.[4] As a result it ceased to be publicly traded on the stock market.

B. The Devices

i. Optetrak Tibial Insert

Close to three decades ago, the Optetrak Device was developed by Exactech working with the Hospital for Special Surgery (HSS) located in New York, New York. "[U]nder the close direction of Albert Burstein, PhD, the Optetrak design team, in cooperation with engineers at Hospital for Special Surgery and an extensive team of clinical evaluators, developed a knee design based closely on the clinically successful Total Condylar, Insall/Burstein (I/B) and Insall/Burstein

[4] Exactech, Inc., *Exactech Announces Completion of Merger with TPG Capital* (February 14, 2018) https://www.exac.com/exactech-announces-completion-of-merger-with-tpg-capital/#:~:text=The%20total%20transaction%20is%20valued,be%20listed%20on%20the%20Nasdaq.

II® (I/B II) knees."[5] As a result, thousands of Optetrak Devices were implanted in patients by surgeons at HSS, and many of those patients reside in the Eastern District of New York. The design of the device changed over the years and changes to the polyethylene components changed over the years. The Hospital for Special Surgery was not involved in the manufacturing and packaging of the device, nor were they involved in the specification changes to the polyethylene manufacturing process that were enacted since the early device design.[6]

Exactech obtained 510(k) clearance from the Food and Drug Administration ("FDA") for various Optetrak total knee system devices and components beginning in 1994 including under the names: Optetrak and Optetrak Logic. The Optetrak Total Knee System is classified as a knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. It features a mix of polyethylene and metal-based components and is comprised of the following parts: a patellar cap, femoral cap, tibial insert and tibial tray. The tibial insert is made of ultra-high molecular weight polyethylene (UHMWPE).[7] The tibial insert is implanted between the femoral cap and tibial tray to act as a new cushion or cartilage for the replaced joint.

On August 30, 2021, the FDA noted a recall of many of the Optetrak Tibial Inserts, however, it was not posted on the FDA website until October 4, 2021. The FDA noted the expansion of the recall in February of 2022.[8]

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[5] Exactech, Inc., *Optetrak: a comprehensive knee system*, EXACTECH, INC. 1, 2 (2010) https://www.exac.com/wp-content/uploads/2020/04/712-01-21_RevD_Optetrak_Main_Brochure.pdf.

[6] HSS surgeons and scientists have published medical literature warning of polyethylene degradation concerns years before the belated recall. *See, e.g.*, Alexandra Stavrakis et al, *Less Midterm Damage and Oxidation Are Seen in Retrieved Highly Crosslinked Ultrahigh-Molecular-Weight Polyethylene Tibial Inserts than in Direct Compression Molded Polyethylene Inserts*, 14 HSS J. 159 (2018); Cynthia A. Kahlenberg et al, *Early Failure of a Modern Moderately Cross-Linked Polyethylene Acetabular Liner*, 6 Arthroplasty Today 224 (2020).

[7] Exactech Optetrak Total Knee System Size 0/1 Delta Line Extension, 510(k) No. K011976, 21 C.F.R. § 888.5360 (July 16, 2001) https://www.accessdata.fda.gov/cdrh_docs/pdf/k011976.pdf.

[8] *See* Exactech, Inc., *Class 2 Device Recall OPTETRAK Comprehensive Knee System*, EXACTECH, INC. (Oct. 4, 2021) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266.

Notably, in a publication from 2018 entitled "Less Midterm Damage and Oxidation Are Seen in Retrieved Highly Crosslinked Ultrahigh-Molecular-Weight Polyethylene Tibial Inserts than in Direct Compression Molded Polyethylene Inserts," authored by surgeons, engineers and scientists at the Hospital for Special Surgery, the authors concluded that the compression molded polyethylene "CompPE" used in the Exactech inserts "had greater overall oxidation when compared to XLPE in both loaded and unloaded surface and subsurface regions…Our findings suggest that compPE may be more susceptible to oxidative degradation, and the accompanying alterations in mechanical properties may explain the greater damage seen in the compPE group than in the XLPE group."[9]

ii. Truliant Tibial Insert

In 2017, Exactech obtained clearance from the FDA to market and sell the Truliant Tibial Insert stating "[p]roposed Truliant tibial inserts represent modifications to One Logic tibial inserts cleared per 510(k) K152170 and rebranded as Truliant per 510(k) K170240. The proposed Truliant inserts are identical to cited predicate inserts except for dimensional modifications representing new additions to the product scope."[10] Thus, Exactech was able to expand its line of knee replacement devices. On August 30, 2021, the FDA noted a recall of many if not all of the Truliant Tibial Inserts, however per the posting, it was not posted on the FDA website until October 4, 2021.[11]

iii. Vantage Tibial Insert

[9] Stavrakis, *supra* note 6.
[10] Exactech Truliant Line Extensions, 510(k) No. K171045, 21 C.F.R. § 888.3560 (Apr. 28, 2017) https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171045.pdf.
[11] Exactech, Inc., *Class 2 Device Recall OPTETRAK Comprehensive Knee System*, *supra* note 8.

In March 2016, Exactech sought clearance to market and sell the Vantage Total Ankle System.[12] Like the tibial insert sold with the Optetrak and Truliant Devices, the insert is made of UHMWPE.[13] The Vantage Device is comprised of a tibial plate, a tibial insert, a locking component, and a component. The tibial insert fits between the tibial component and the talar component to act as a new cushion or cartilage for the replaced ankle joint.

iv. Connexion GXL Enhanced UHMWPE Acetabular Liner

In 2005 Exactech began to market its AcuMatch A-Series "Connexion GXL Enhanced UHMWPE Acetabular Liner."[14] To purportedly "enhance" the standard UHMWPE, Exactech exposed the GXL liner to two treatments of gamma radiation at 25kGy for each treatment. This two-step process and levels of gamma radiation is different from and lower than radiation doses and methods traditionally used by other orthopedic device manufacturers. Departing from the industry standard of making "highly cross-linked" polyethylene, this manufacturing process instead chose to only "moderately cross- link" the polyethylene, and Exactech marketed these liners as creating a "robust arthroplasty respecting the need for lower wear, sufficient fracture toughness and oxidation to provide a lifelong implant for patients."[15]

C. Recall of the Optetrak, Truliant and Vantage Tibial Inserts

On August 30, 2021, Exactech first issued a partial recall of all Optetrak All-polyethylene tibial components.[16] In issuing the August 2021 recall, Exactech stated "inserts were packaged in

[12] Exactech Vantage Total Ankle System, 510(k) No. K152217, 21 C.F.R. § 888.3110 (Mar. 10, 2016) https://www.accessdata.fda.gov/cdrh_docs/pdf15/K152217.pdf.
[13] *Id.*
[14] Exactech AcuMatch A-Series Enhance Polyethylene Acetabular Liner, 510(k) No. K051556 (Aug. 2005) https://www.accessdata.fda.gov/cdrh_docs/pdf5/K051556.pdf.
[15] Exactech, Inc. *Assessing the Long-Term Clinical Performance of Connexion GXL Polyethylene Acetabular Liners in Total Hip Arthroplasty*, EXACTECH, INC. (2017) https://content.exac.com/wp-content/uploads/sites/3/2018/09/046H_GXL_White_Paper_Web.pdf.
[16] The components subject to the recall included: the OPTETRAK All-polyethylene CC Tibial Components; OPTETRAK All-polyethylene CR Tibial Components; OPTETRAK All-polyethylene CR Tibial Sloped Components; OPTERAK All-polyethylene PS Tibial Components; OPTETRAK HI-FLEX PS Polyethylene Tibial Components; OPTETRAK Logic All-polyethylene CR Tibial Components; OPTETRAK Logic All-polyethylene

vacuum bags that lacked an additional oxygen barrier layer."[17] According to the FDA website, "Exactech began notification to distributors and sales representatives on about 08/30/2021 via letter titled "URGENT MEDICAL DEVICE RECALL." Actions being taken by Exactech included removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months. Phase 1 includes immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags. Phase 2 includes, between 05/31/2022 to 08/31/2022, returning all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags."[18] Despite initial communications with distributors and sales representatives, Exactech did not issue any communications to surgeons who had implanted Optetrak, Truliant or Vantage Devices with a recalled polyethylene component or to patients who had received one of these devices until months later in February 2022.

On February 7, 2022, Defendants issued an "Urgent Medical Device Correction" in which it informed health care professionals that:

> After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as "non-conforming") vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both**

CRC Tibial Components; OPTETRAK Logic All-polyethylene PSC Tibial Components; OPTETRAK Logic Modular PS Tibial Components; OPTETRAK Logic RBK PS Tibial Components; TRULIANT CR Tibial Inserts; TRULIANT CRC Tibial Inserts; TRULIANT PS Tibial Inserts; and TRULIANT PSC Tibial Inserts.

[17] *See* Exactech, Inc., *Class 2 Device Recall OPTETRAK Comprehensive Knee* System, EXACTECH, INC. (Oct. 4, 2021) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=189266.

[18] *Id.*

accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.[19]

The "Urgent Medical Device Correction" went on to further state that Exactech was expanding the recall to include all polyethylene inserts packed in non-conforming bags regardless of label or shelf life.[20] In the months thereafter, some surgeons began notifying patients of the recall and the need to return to their offices for a physical and radiological evaluation. It is expected that additional surgeons and hospitals, after they complete the process of identifying which patients received the recalled devices, will notify their patients.

As of April 2022, Exactech estimated there are approximately 143,484 inserts implanted in patients in the United States that were distributed in non-conforming packaging.[21] Over 120,000 of the recalled tibial inserts were implanted as part of an Optetrak Device (knee) as compared with the 1,561 Vantage Devices (ankle) with a polyethylene liner.[22] Thus, it is anticipated the vast majority of cases will involve a failed knee replacement device.

D. Recall of the Connexion GXL Acetabular Liner

On or about June 28, 2021, in a communication directed to "Surgeons, Hospitals, Health care professionals" and posted on its website, Exactech "[d]uring the past ~24 months, Exactech has observed that in a small percentage of patients (.118%) who are between 3-6 years from index

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[19] *See* Exactech Inc., *Urgent Medical Device Correction*, EXACTECH, INC (February 7, 2022) https://gwick42bmpq1joaxl1a0cctp-wpengine.netdna-ssl.com/wp-content/uploads/Exactech-DHCP-letter.02.07.2022.pdf.

[20] *Id.* The components subject to the February 2022 recall was expanded to include: OPTETRAK®: All-polyethylene CR Tibial Components, All-polyethylene PS Tibial Components, CR Tibial Inserts, CR Slope Tibial Inserts, PS Tibial Inserts, HI-FLEX® PS Tibial Inserts; OPTETRACK Logic®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts, CC Tibial Inserts; and TRULIANT®: CR Tibial Inserts, CR Slope Tibial Inserts, CRC Tibial Inserts, PS Tibial Inserts, PSC Tibial Inserts.

[21] *Id.* Of note, Exactech's original "Dear Doctor" letter issued on February 7, 2022, states that approximately 147,732 inserts were implanted in patients in the United States as opposed to 143,484. The 147,732 figure is consistent with a tally of Exactech's breakdown of each component subject to the recall. *See* Exactech Inc., *Urgent Medical Device Correction, supra* note 19.

[22] *See* Exactech Inc., *Urgent Medical Device Correction, supra* note 19.

total hip arthroplasty, the Connexion GXL liner exhibits early linear and volumetric wear" which has led to proximal femoral and acetabular osteolysis in some patients.[23] Exactech recommended patients who had received a Connexion GXL Liner less than six years ago undergo x-rays and that for "patients with edge loading components, early asymmetric polyethylene wear, and early signs of lysis, the surgeon should consider revising the Connexion GXL liner to Exactech's latest generation HXLPE, Vitamin E liner, if possible." [24]

In this communication, Exactech failed to advise physicians it was in the process of initiating a recall of the Connexion GXL liner. In fact, on July 22, 2021, the FDA posted a Class 2 Device Recall citing that Exactech had initiated the recall on June 29, 2021.[25] The notice explained the "Manufacturer Reason for Recall Risk of edge-loading and premature prosthesis wear is possible in a specific subset of patients with certain implant configurations and surgical implant positioning" and that the recall implicated 89,050 liners in circulation within the United States.[26]

E. The Premature Failures of the Polyethylene in the Knee, Ankle and Hip Devices Are Inextricably Related

There are five (5) cases pending in four (4) different federal district courts involving the Connexion GXL Device. The recall notice issued by Exactech on June 28, 2021, stated "the Connexion GXL liner exhibits early linear and volumetric wear." Akin to the failure of the polyethylene inserts in the Optetrak, Truliant and Vantage Devices, wear has led to the femoral and acetabular osteolysis and the need for revision surgery.[27] While Exactech's recall notice of

[23] Exactech Inc., *Urgent Dear Healthcare Professional Communication*, EXACTECH, INC (June 28, 2022) https://www.exac.com/wp-content/uploads/2021/06/DHCP-Letter_Final-_for-Website_GXL.pdf.
[24] *Id*.
[25] Exactech, Inc., *Class 2 Device Recall Exactech Connexion*, 510(k) No. K051556 (July 22, 2021) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=188085.
[26] *Id.*
[27] Exactech Inc., *Urgent Dear Healthcare Professional Communication, supra* note 23.

the Connexion GXL liner does not cite to packaging failures, the mode of packaging for the Connexion GXL liners has not been publicly disclosed. Whether Exactech used the same deficient liners used with their knee inserts, or instead, a more protective liner with the secondary barrier layer containing ethylene vinyl alcohol (EVOH), case discovery will certainly overlap. If better packaging was used for the hip acetabular liners, then logically the design, packaging and manufacturing witnesses would be questioned why they chose to use the enhanced packaging for acetabular liners and not the tibial inserts for the knees/ ankles. If the same deficient packaging was used, then the issue is entirely cross-cutting even though Exactech remained silent in its minimal statements about the earlier hip liner recall.

Moreover, while Exactech is exclusively attributing the failure of the knee and ankle inserts to the "non-conforming packaging," certain experts believe that the magnitude of the failure goes beyond packaging and relates as well to the design changes made in the polyethylene manufacturing process including the omission of Vitamin E, the degree of cross-linking, and the manner and amount of radiation used in the sterilization processing that are distinct from methods used by competitor devices which do not have this premature polyethylene failure. Since Exactech attributes the failure of their ankle and knee implants to the same root cause, it is apparent that an MDL should encompass both of those products. The hip liner polyethylene recall overlaps in time period and in the same damage endpoints: oxidation of UMHWPE cross-linked polyethylene causing inflammatory responses, polyethylene debris, cracking, and loosening of the device, all requiring revision surgery. Thus, these products share a multitude of factual and expert discovery and proofs. Plaintiffs will seek discovery regarding Exactech's manufacturing and packaging processes to ascertain if and why the polyethylene components for knee and ankle replacements were packaged differently than acetabular liners and how those processes impact oxidation and

premature wear. Additionally, the polyethylene utilized in the Connexion GXL liner and the Optetrak, Truliant and Vantage Devices all involve moderately cross-linked polyethene as opposed to highly cross-linked polyethylene[28] which is often regarded as the industry standard for polyethylene components in orthopedic devices. Furthermore, Exactech adopted molding processes for manufacture of the polyethylene components utilized in both its knee and hip replacement systems.[29] Thus, there is overlap in the materials, technology, and machinery utilized to manufacture these components and the Plaintiffs will certainly be seeking discovery to ascertain the nuances and how each process may have contributed to the resulting failures.

Despite different joint replacement products being at issue, there are certainly common questions of fact and consolidation of all the recalled components for pretrial proceedings pursuant to 28 U.S.C. § 1407 is appropriate. In the past, the Panel has consolidated different products in a single Multi-District Litigation if the underlying factual and legal allegations are sufficiently similar. *See In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig*., 597 F. Supp. 2d 1377, 1378 (J.P.M.L. 2009); *In re Pella Corp. Architect & Designer Series Windows Mktg.*, 996 F. Supp 2d 1380, 1381 (J.P.M.L. 2014). Moreover, as is often customary, the transferee judge could implement a discovery track for Optetrak, Truliant and Vantage Devices and a separate discovery track for cases involving the Connexion GXL liner. *See In re Stryker Rejuvenate*, 949 F. Supp. 2d 1378, 1379 (J.P.M.L. 2013) (noting that while there was enough commonality in the actions to permit a single MDL proceeding, the transferee judge could establish separate tracks for the Rejuvenate and the ABG II modular-neck stems); *In re Darvocet, Darvon and Propoxyphene*

[28] *Id.*; Exactech, Inc., *Optetrak: a comprehensive knee system*, *supra* note 5.
[29] Gary Miller, *Optimizing Polyethylene Materials to the Application When it Comes to Manufacturing Methods, Hips Are Not Knees*, EXACTECH, INC. (Mar. 14, 2017) https://www.exac.com/optimizing-polyethylene-materials-to-the-application/ ("Optimizing Polyethylene Materials to the Application: When it Comes to Manufacturing Methods, Hips are Not Knees.").

Prods. Liab. Litig. 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011). Accordingly, Plaintiffs certainly believe transfer of cases involving failure of the Optetrak, Truliant and Vantage and Connexion GXL Devices is warranted under 28 U.S.C. § 1407.

II. ARGUMENT

Transfer to the Eastern District of New York for consolidation and coordination of pretrial proceedings is appropriate and necessary as the Actions involve common questions of fact, the centralization of these Actions will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. 28 U.S.C. § 1407.

Transfer is not premature as there are a significant number of Exactech cases involving failed polyethylene components already pending in multiple federal district courts; at least twenty-seven cases on file in at least eleven different federal district courts and it is anticipated that many more will be filed given the numerosity of the numbers of recalled devices that have been implanted in hundreds of thousands of patients. Given the geographic variety of these cases, the lack of advanced discovery in any filed case (with only one case filed in 2021), and the anticipated number of future filings, these cases are ripe for consolidation before one transferee judge. Transfer pursuant to 28 U.S.C. § 1407 will lead to a just and expeditious resolution of these actions to the benefit of all parties.

A. The Exactech Cases Involve Common Questions of Fact

The pending cases allege that the plaintiffs have received knee and hip replacement devices all of which encompass a failed polyethylene component manufactured and sold by common defendants, Exactech, Inc. and Exactech U.S., Inc. Federal civil actions are eligible for transfer pursuant to 28 U.S.C. § 1407 if they involve "common questions of fact" subject to discovery. *See* 28 U.S.C. § 1407(a); *In re Kugel Mesh Hernia Patch Prods. Liab. Litig*., 493 F. Supp. 2d 1371,

1372-73 (J.P.M.L. 2007). The statute, however, does not require complete identification of common questions of fact to justify transfer. *In re Zyprexa Prods, Liab. Litig.*, 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004). Almost all personal injury cases involve individualized factual issues, such as questions of causation that are case-specific. However, the existence of such differences has not been an impediment to centralization in the past and does not negate the common factual issues. *See In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F. Supp. 3d 1402, 1404 (J.P.M.L. 2014); *In* re *Wright Medical Technology, Inc., Conserve Hip Implant Prods. Liab. Litig*., 844 F. Supp. 2d 1371, 1372 (J.P.M.L. 2012).

The Panel has regularly ordered transfer for coordinated or consolidated proceedings in instances involving the implantation of alleged defective joint replacement devices that were manufactured and distributed by a common defendant. Prior MDL's involving defective joint replacements include: *In Re: Inter-Op Hip Prosthesis Liability Litigation,* MDL No. 140*; In Re: Zimmer Durom Hip Cup Products Liability Litigation,* MDL No. 2158, *In Re: DePuy Orthopedics, Inc., ASR Hip Implant,* MDL No. 2197*; In Re: DePuy Orthopedics, Inc. Pinnacle Hip Implant Products Liability Litigation,* MDL No. 2244*; In Re: Wright Medical Technology Inc., Conserve Hip Implant Products Liability Litigation,* MDL No. 2329*; In Re: Biomet M2A Magnum Hip Implant Products Liability Litigation,* MDL No. 2391*; In Re: Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation,* MDL No. 2441; *In Re: Stryker LFIT V40 Femoral Head Products Liability Litigation,* MDL No. 2768; *In re: Zimmer M/L Taper Hip Prosthesis or M/L Taper Hip Prosthesis with Kinectiv Technology and VerSys Femoral Head Products Liability Litigation,* MDL No. 2859; *In Re: Zimmer Nexgen Knee Implant Products Liability Litigation,* MDL No. 2272; and *In Re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*, MDL No. 2775. Notably in the Biomet MDL referenced above, the

litigation involved two different models of metal-on-metal hip components, one branded the M2A and the other branded the Magnum. They were both metal-on-metal designs but had certain distinctions. The same is true for the Stryker Rejuvenate MDL that involved two different recalled modular hips – the Rejuvenate and the ABG II, which had different designs and lengths, but shared the fact that they were both modular necks and stems.

Similarly, the cases presented here share a common core of operative facts. All plaintiffs allege that an Optetrak, Truliant or Connexion GXL Device failed due to premature degradation of polyethylene, and the components at issue were surgically removed or are scheduled to be removed in the coming weeks. The cases involve a shared mechanism of failure as well as similar injuries to each plaintiff, including but not limited to the need for revision surgery, component loosening, tissue damage, osteolysis, and bone loss.

Among the common factual issues are the causal relationship between the design, manufacture and packaging of the polyethylene inserts, failure to warn of premature wear and degradation, and failure to recall the inserts sooner. Each Plaintiff alleges Exactech knew or should have known of the defective nature of the polyethylene insert and yet failed to properly warn doctors and patients and failed to timely remove the products from the market when it knew of the dangers associated with these products. Cases that share core issues of fact concerning design, manufacture, testing and marketing of a product are appropriate for consolidation. *See In re Cook Medical, Inc., Pelvic Repair System Prods. Liab. Litig.*, 949 F. Supp. 2d 1373, 1375 (J.P.M.L. 2013); *In re Cook Medical, Inc., IVC Filters Marketing, Sales Pracs. and Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1380 (J.P.M.L. 2014); *In re Power Morcellator Prods. Liab. Litig.*, 140 F. Supp. 3d 1351, 1353 (J.P.M.L. 2015).

Plaintiffs have also asserted the same legal theories of liability, including negligence, negligent manufacturing, breach of express and implied warranties, strict liability and defective design. Plaintiffs raise common questions of fact to support their theories of liability including: the propensity of these polyethylene inserts to rapidly oxidize and then deteriorate, how the packaging of the polyethylene inserts was developed, what were the manufacturing and packaging processes implemented by Exactech, when Exactech first learned of the harmful effects caused by these devices; whether, and for how long, Exactech concealed this knowledge from surgeons and physicians and continued to promote sales of these devices; whether the polyethylene insert was defectively designed in additional to being defectively manufactured; whether Exactech failed to provide adequate warnings concerning these devices; whether Exactech engaged in fraudulent and negligent marketing practices regarding these devices; and the nature and extent of damages suffered by Plaintiffs as a result of these devices.

Moreover, intertwined with these facts, is the timing of the corporate changes. The formerly publicly traded Exactech was purchased by private equity, Osteon Holdings Inc. and TPG Capital, during a period when the problems with the products were being observed by surgeons and there were early literature reports of concern. Discovery will likely be fruitful as to what role the merger had with disclosure or suppression of these significant safety problems.

Accordingly, the Interested Parties respectfully request the Panel order coordinated or consolidated proceedings for cases involving failure of the polyethylene components of the Exactech Optetrak, Truliant, Vantage and GXL Connexion Devices.

B. Consolidation of these Cases Would Serve the Convenience of the Parties and Witnesses

Pretrial coordination of the Optetrak, Truliant, Vantage and Connexion GXL Device cases will serve the convenience of the parties and witnesses. When cases involve common issues of

fact, consolidation will serve the convenience of the parties and witnesses by preventing the duplication of discovery as well as inconsistent or repetitive pretrial rulings. *In re Meridia Prods. Liab. Litig.*, 217 F. Supp. 2d 1377 (J.P.M.L. 2002). It will also conserve the resources of the parties and the judiciary. *Id.* at 1378.

Plaintiffs' common theories of product defect run throughout each action and will reduce duplicative discovery and motion practice relating to those common theories. Consolidation will reduce the number of discovery requests and the costs associated with multiple productions in numerous district courts. Specifically, depositions of key witnesses can be coordinated. Additionally, Exactech can produce documents to one central location as opposed to producing documents to each individual plaintiff. If transfer is denied in this litigation, these cases will proceed on independent tracks, requiring duplicative discovery, and repeated depositions of the same corporate personnel. Both Plaintiffs and Defendants would benefit from centralization, and the economies of scale that it would bring.

Furthermore, to be discussed in greater detail below, the Eastern District of New York, Brooklyn Division would be the most convenient venue for the parties and witnesses as the Optetrak Device was likely implanted in more New York area residents than anywhere else given the extensive use of these devices by HSS, an internationally preeminent hospital that is devoted to orthopedic care and performs many thousands of arthroplasties a year. Brooklyn is a very convenient venue for key witnesses, including those of Exactech and many of the Plaintiff's and Plaintiff's treating physicians who live and practice in the area. Therefore, consolidation of the Optetrak, Truliant, Connexion GXL and Vantage Device cases will serve the convenience of the parties and witnesses, with the Eastern District of New York being the most convenient and efficient venue.

C. Transfer to The Eastern District of New York Promotes the Just and Efficient Conduct of the Litigation.

Lastly, consolidation of the litigations regarding these recalled Exactech polyethylene components cases would promote the just and efficient conduct of the litigation. In the matters presently pending, discovery is in its earliest stages or has not yet commenced. Thus, since the parties have not yet endeavored into extensive discovery, pretrial coordination would prevent the production of duplicative discovery in at least twenty-seven different actions and avoid repetitive disputes over the same issues in multiple federal district courts. The Movants maintain that centralization will create for greater efficiency, alleviate the potential for inconsistent rulings and preserve the resources of the judiciary.

As to what is an appropriate transferee forum, the Panel must balance a number of factors, including: the experience, skill and caseloads of the available judges; the number of cases pending in the jurisdiction; the convenience of the parties; the location of the witnesses and evidence; and the minimization of cost and inconvenience to the parties. *See In re Lipitor (No. II)*, 997 F. Supp. 2d at 1357; *In re Preferential Drugs Prods. Pricing Antitrust Litig.*, 429 F. Supp. 1027, 1029 (J.P.M.L. 1977); *In re Tri-State Crematory Litig.*, 206 F. Supp. 1376, 1378 (J.P.M.L. 2002).

Judge Kiyo A. Matsumoto of the Eastern District of New York in Brooklyn is already presiding over four (4) Optetrak Device cases and three (3) other Exactech cases are in Central Islip.[30] Judge Matsumoto presided over a pharmaceutical MDL that concluded a decade ago, so she has MDL experience but has not had a recent MDL litigation. *See In re Pamidronate Prods. Liab. Litig.*, 657 F. Supp. 2d 1368, 1369 (J.P.M.L. 2009). Moreover, her many years as an

[30] As demonstrated on the Schedule of Actions, *Alberti v. Exactech, Inc.*, a Connexion GXL acetabular liner case is also pending before Judge Eric Komitee in Central Islip, *Fassler v. Exactech, Inc.*, an Optetrak case is pending before Judge Gary R. Brown in Central Islip, and *Cuneo v. Exactech, Inc.*, an Optetrak case is pending before Judge Joanna Seybert in Central Islip.

assistant United States Attorney and her eighteen years on the Federal bench, including her time as a United States Magistrate Judge, make her imminently qualified.

As of May 2022, there are only five (5) MDLs pending in the Eastern District of New York, four of which are antitrust cases. The only open products liability MDL, *In Re: Propecia (Finasteride) Products Liability Litigation*, has one open case pending and is thus for all practical purposes, closed.[31] While the Panel may also consider the Southern District of New York, there are sixteen (16) MDLs pending in the Southern District.[32] Although HSS is located in Manhattan, the MDL caseload is significantly less in Brooklyn and Brooklyn is just as convenient for the parties. Per Google Maps, the Brooklyn courthouse in Cadman Plaza is located ten miles from or twenty minutes away from LaGuardia Airport, and just five miles and a sixteen-minute subway ride from Penn Station where trains from the entire Northeast Corridor including Boston, Philadelphia and Washington DC travel. Similarly, it is 7.3 miles from the Hospital for Special Surgery to Cadman Plaza, Brooklyn. Further, there is an abundance of hotel options walking distance from the courthouse.

While there are two (2) cases pending in the District of New Jersey, and numerous experienced jurists there who have handled MDLs and complex pharmaceutical and medical device cases, that District has many large MDLs and has one of the busiest dockets in the federal court system.

While no cases have yet been filed in the Northern District of Florida, the federal district where Exactech is headquartered, Movants would strongly urge the Panel to avoid any transfer to this district as there are well more than 100,000 cases pending in the *In Re: 3M Combat Arms*

[31] *MDL Statistics Report – Distribution of Pending MDL Dockets by District*, U.S. JUDICIAL PANEL ON MULTIDISTRICT LITIGATION (May 16, 2022) https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-May-16-2022.pdf.
[32] *Id.*

Earplug Products Liability Litigation, 366 F. Supp. 3d. 1368, 1369 (J.P.M.L. 2019). Indeed, the 2021 statistics of the Administrative Office of the U.S. Courts note that "personal injury/product liability filings surged 150 percent (up 138,436 cases) as cases involving other personal injury/product liability rose by 136,905 filings (up 210 percent).[33] Most were MDL cases filed in the Northern District of Florida that addressed 3M Combat Arms earplugs."[34]

Thus, given Judge Matsumoto's notable qualifications, the ubiquitous implantation of Exactech Devices in New York areas residents, the convenience of the parties and witnesses, and that only a single products liability MDL is pending with one open case, the Eastern District of New York would best promote just and efficient conduct of the Exactech Litigation.

III. CONCLUSION

Transfer and consolidation for pre-trial proceedings of all pending and subsequently filed Optetrak, Truliant, Vantage and Connexion GXL Device cases will promote the just and efficient conduct of these actions by allowing national coordination of discovery and other pretrial efforts, will prevent duplicative and potentially conflicting pre-trial rulings, will reduce the costs of litigation, and allow cases to proceed more efficiently to trial.

For all of the foregoing reasons, Plaintiffs respectfully request that the Panel issue an order transferring all actions listed in the attached Schedule of Actions, as well as all subsequently filed related actions, for coordinated and consolidated pretrial proceedings to the Eastern District of New York.

Dated: June 14, 2022

Respectfully Submitted,

/s/ Ellen Relkin

Ellen Relkin (ER-9536)

[33] Administrative Office of the United States Courts, *Federal Judicial Caseload Statistics 2021*, ADMIN. OFF. OF THE U.S. CTS. (2021) https://www.uscourts.gov/statistics-reports/federal-judicial-caseload-statistics-2021.
[34] *Id.*

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