UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGE

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In the Matter of)	SEPTEMEN.
Otto Dook Hould Com North America)	DOCKET ORIGINAL
Otto Bock HealthCare North America, Inc.,)	DOCKET SCI. PROTIVAL
a corporation,)	
a corporation,)	
Respondent.)	

NON-PARTY MAYO CLINIC'S MOTION FOR IN CAMERA TREATMENT

Pursuant to Rule 3.45 of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.45(b), non-party Mayo Clinic ("Mayo") respectfully moves this Court for *in* camera treatment of one competitively sensitive, confidential business document (the "Confidential Document"). Mayo produced this document, among others, in response to third-party subpoenas in this matter. The Federal Trade Commission ("FTC") and Otto Bock Health Care North America, Inc. ("Otto Bock") have notified Mayo that they intend to introduce the Confidential Document into evidence at the administrative trial in this matter. *See* Letter from the FTC dated May 22, 2018 (attached as Exhibit A); Letter from Otto Bock dated May 29, 2018 (attached as Exhibit B).

The Confidential Document warrants protection from public disclosure given the sensitive business information it contains and Mayo's contractual obligations to a non-party to keep the document confidential. Thus, Mayo submits this Motion requesting *in camera* treatment of the Confidential Document in its entirety for a period of two years. In support of this motion, Mayo relies on the Declaration of Dr. Kenton Kaufman, attached as Exhibit C. Mayo has met and conferred with the FTC and Otto Bock and they do not object to this motion.

I. The Document for Which Protection is Sought.

Mayo seeks in camera treatment for the following Confidential Document, a copy of which is attached as Exhibit D.

Exhibit No.	Document D Title/Description	Date	Beginning Bates No.	Ending Bates No.	
PX03219 RX-0623	Draft Research Study Manuscript	11/00/2017	MAYO000001_0001	MAYO000001_0024	

II. Legal Standard.

In camera treatment of material is appropriate when its "public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting such treatment." 16 C.F.R. § 3.45(b). The proponent demonstrates serious competitive injury by showing that the documents are secret and that they are material to the business. *In re General Foods Corp.*, 95 F.T.C. 352, 355 (1980); *In re Dura Lube Corp.*, 1999 F.T.C. LEXIS 255, *5 (1999). In this context, courts generally attempt "to protect confidential business information from unnecessary airing." *H.P. Hood & Sons, Inc.*, 58 F.T.C. 1184, 1188 (1961).

In considering both secrecy and materiality, the Court may consider: (1) the extent to which the information is known outside of the business: (2) the extent to which it is known by employees and others involved in the business; (3) the extent of measures taken to guard the secrecy of the information; (4) the value of the information to the business and its competitors; (5) the amount of effort or money expended in developing the information; and (6) the ease or difficulty with which the information could be acquired or duplicated by others. *In re Bristol-Myers Co.*, 90 F.T.C. 455, 456-57 (1977).

III. Mayo's Confidential Document is Secret and Material Such that Disclosure would Result in Serious Injury to Mayo.

In 2014, Mayo and The American Orthotic and Prosthetic Association, Inc. ("AOPA") entered into a Corporate Research Agreement ("Research Agreement") pursuant to which AOPA funded scientific research to be conducted by Dr. Kenton Kaufman and Mayo's Department of Orthopedic Surgery. Dr. Kaufman Decl. ¶¶ 4-5, Ex. 1. The purpose of the scientific research was to compare the effectiveness between microprocessor controlled and non-microprocessor controlled prosthetic knees using a unique activity monitoring device developed at Mayo Clinic. *Id.*

The Research Agreement prohibits Mayo from publishing the results of the scientific research unless Mayo submits the proposed publication or presentation of the scientific research to AOPA prior to publication to allow AOPA the opportunity to identify and seek legal protection for any proprietary or patentable information contained in the publication. Dr. Kaufman Decl. Ex. 1 at § 15.2. The Research Agreement also prohibits Mayo from disclosing AOPA's confidential information. *Id.* at § 13.

Pursuant to the Research Agreement and the substantial monetary funding provided by AOPA, Dr. Kaufman led a multi-year study conducted by a cross-disciplinary team comparing the outcomes and effectiveness of microprocessor controlled and non-microprocessor controlled prosthetic knees in Medicare-aged amputee patients. Dr. Kaufman Decl. ¶ 7.

In November 2017, Dr. Kaufman and his team completed a draft manuscript for publication based on the research study entitled "Functional Assessment and Satisfaction of Transfemoral Amputees with Low Mobility (FASTK2): A Clinical Trial of MPK vs. NMPK Knees." Kaufman Decl. ¶ 8. The manuscript is a draft and is currently being reviewed. *Id.*

Because the manuscript is not in final form, it has not been submitted to AOPA for its review pursuant to the Research Agreement. *Id*.

As set forth in Dr. Kaufman's Declaration, Mayo and those involved in the research study have maintained the confidentiality of the draft manuscript and its findings. Kaufman Decl. ¶ 9. The draft manuscript and its findings are the result of investment of substantial time, scientific expertise, and funds over a multi-year period research study. *Id.* The information contained in the draft manuscript is proprietary and not publicly known. *Id.* Furthermore, Mayo is contractually required to maintain the confidentiality of the manuscript pursuant to the Research Agreement until it has been reviewed by AOPA and a determination regarding intellectual property rights has been made. As a result, Mayo will be harmed significantly if this confidential information is made public as part of this proceeding. Because of the highly confidential and proprietary nature of the information and its materiality to Mayo's business as a research institution, *in camera* treatment is appropriate.

Designating the draft manuscript for *in camera* treatment is also appropriate as a matter of public policy. Mayo recognized in this proceeding that the draft manuscript was responsive to third party subpoenas issued by the FTC and Otto Bock. Mayo advised counsel of the confidentiality of the draft manuscript and designated the document as "Confidential" pursuant to the Protective Order in this case. For this exchange of information to work in future proceedings, protection must exist for research institutions like Mayo to ensure that investment in ongoing and unpublished scientific research is not compromised by disclosure. Kaufman Decl. ¶ 10. Designating draft manuscripts for *in camera* protection appropriately balances the need for disclosure of cutting-edge research with the need for confidentiality of research and protection of intellectual property rights.

Finally, Mayo's status as a third party is relevant to the treatment of its documents. The

FTC has held that "[t]here can be no question that the confidential records of businesses involved

in Commission proceedings should be protected insofar as possible." H.P. Hood & Sons, 58

F.T.C. at 1186. This is especially true in the case of third-parties, which deserve "special

solicitude" in their requests for in camera treatment of their confidential information. See In re

Kaiser Aluminum & Chem. Corp. 103 F.T.C. 500, 500 (1984) ("As a policy matter, extension of

confidential or *in camera* treatment in appropriate cases involving third party bystanders

encourages cooperation with future adjudicative discovery requests." Mayo's third-party status

therefore weighs in favor of granting in camera status to the Confidential Document.

IV. The Court Should Order In Camera Protection for Two Years.

Mayo anticipates that the review process will be completed and the manuscript published

within the next two years. Accordingly, Mayo requests that the Court grant in camera protection

for the Confidential Document for a period of two years.

V. Conclusion.

For the reasons set forth above and in the accompanying Dr. Kaufman Declaration, Mayo

respectfully requests that this Court grant in camera treatment for the Confidential Document in

its entirety for a period of two years.

Dated: June 11, 2018

/s/ Gregory E. Karpenko

Gregory E. Karpenko (#0286473)

FREDRIKSON & BYRON, P.A.

200 South Sixth Street, Suite 4000

Minneapolis, MN 55402-1425

Telephone: 612.492.7000

Facsimile:

612.492.7077

gkarpenko@fredlaw.com

Counsel for Non-Party, Mayo Clinic

64137260.1

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STATEMENT REGARDING MEET AND CONFER

The undersigned certifies that counsel for Non-Party, Mayo Clinic notified counsel for the parties in telephone calls on June 4 and 5, 2018, that Mayo would be seeking *in camera* treatment of the Confidential Document. Both counsel for the Federal Trade Commission and Otto Bock HealthCare North America, Inc. stated that they would not object to Mayo's motion.

Dated: June 11, 2018

/s/ Gregory E. Karpenko

Gregory E. Karpenko (#0286473) FREDRIKSON & BYRON, P.A.

200 South Sixth Street, Suite 4000 Minneapolis, MN 55402-1425

Telephone: 612.492.7000 Facsimile: 612.492.7077 gkarpenko@fredlaw.com

Counsel for Non-Party, Mayo Clinic

CERTIFICATE OF SERVICE

I, Cindy Thomas, declare under penalty of perjury under the laws of the State of Minnesota that the following is true and correct. On June 11, 2018, I caused to be served the following documents on the parties listed below by the manner listed:

- Non-Party Mayo Clinic's Motion for In Camera Treatment with Exhibits A-D (Public Version and Non-Public Version)
- [Proposed] Order

The Office of the Secretary (via E-Filing)

Donald S. Clark
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, N.W., Room H-172
Washington, D.C. 20580

The Office of the Administrative Law Judge (via email (public version only))

D. Michael Chappell Chief Administrative Law Judge Federal Trade Commission 600 Pennsylvania Avenue, N.W., Room H-106 Washington, D.C. 20580 aolj@ftc.gov

Federal Trade Commission (via E-Filing)

Steven C. Lavender Federal Trade Commission Washington, D.C. 20580

Counsel for Otto Bock HealthCare North America, Inc. (via E-Filing)

William Shotzbarger Duane Morris LLP 30 South 17th Street Philadelphia, PA 19103-4196

/s/ Cindy Thomas
Cindy Thomas

EXHIBIT A



UNITED STATES OF AMERICA Federal Trade Commission WASHINGTON, D.C. 20580

May 22, 2018

VIA EMAIL

Mayo Clinic c/o Joseph M. Colaiano, Esq. 200 First Street SW Rochester, MN 55905

RE: <u>In the Matter of Otto Bock HealthCare North America, Inc.</u>, Federal Trade Commission Dkt. No. 9378

Dear Mr. Colaiano,

By this letter we are providing formal notice, pursuant to Rule 3.45(b) of the Commission's Rules of Practice, 16 C.F.R. § 3.45(b), that Complaint Counsel intend to offer the documents and testimony referenced in the enclosed Attachment A into evidence in the administrative trial in the above-captioned matter. The administrative trial is scheduled to begin on July 10, 2018. All exhibits admitted into evidence become part of the public record unless in camera status is granted by Administrative Law Judge D. Michael Chappell.

For documents or testimony which include sensitive or confidential information that you do not want on the public record, you must file a motion seeking in camera status or other confidentiality protections pursuant to 16 C.F.R §§ 3.45, 4.10(g). Judge Chappell may order that materials, whether admitted or rejected as evidence, be placed in camera only after finding that their public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting in camera treatment.

Motions for in camera treatment for evidence to be introduced at trial must meet the strict standards set forth in 16 C.F.R. § 3.45 and explained in In re 1-800 Contacts, Inc., 2017 FTC LEXIS 55 (April 4, 2017); In re Jerk, LLC, 2015 FTC LEXIS 39 (Feb. 23, 2015); and In re Basic Research, Inc., 2006 FTC LEXIS 14 (Jan. 25, 2006). Motions also must be supported by a declaration or affidavit by a person qualified to explain the confidential nature of the documents. In re 1-800 Contacts, Inc., 2017 FTC LEXIS 55 (April 4, 2017); In re North Texas Specialty Physicians, 2004 FTC LEXIS 66 (April 23, 2004). You must also provide one copy of the documents for which in camera treatment is sought to the Administrative Law Judge.

Please be aware that under the current Scheduling Order dated April 26, 2018, the deadline for filing motions seeking in camera status is June 11, 2018.

If you have any questions, please feel free to contact me at (202) 326-3563.

Sincerely,

Stevent Lavender
Counsel Supporting the Complaint

Attachment A

Exhibit No.	Doscription	Date	BegBates	EndBates
PX03219	Mayo Clinic Document: Functional Assessment and Satisfaction in Transfernoral Amputees with Low Mobility	11/00/2017	MAY0000001_0001	MAYO000001_0024
PX03220	Mayo Clinic Presentation: Functional Assessment and Satisfaction in Transfemoral K2 Amputees (FASTK2)	1/30/2018	MAYO000002_0001	MAYO000002_0006
PX03221	Mayo Clinic Presentation: How do we define K2.5 or K3- (Hanger Education Fair).	2/1/2018	MAYO000003_0001	MAYO000003_0002
PX03222	Mayo Clinic Document: Presentations; Microprocessor - Controlled Knees	00/00/2016	MAYQ000004_0001	MAY0000004_0001
PX05008	Investigational Hearing Transcript of Kenton Kaufman, Ph.D. (Mayo Clinic)	12/6/2017	FTC-PROD-005252	FTC-PROD-005267
PX05160	Deposition Transcript of Kenton Kaufman, Ph.D. (Mayo Clinic)	4/8/2018	PX05160-001	PX05160-087

EXHIBIT B

NEW YORK LONDON SINGAPORE PHILADELPHIA CHICAGO WASHINGTON, DC SAN FRANCISCO SILICON VALLEY SAN DIEGO LOS ANGELES TAIWAN BOSTON HOUSTON AUSTIN HANOI HO CHI MINH CITY

Duane Morris*

FIRM and AFFILIATE OFFICES

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MY ANMAR
OMAN
AGCC REPRESENTATIVE OFFICE
OF DUMPE MORRIS

ALLIANCES IN MEXICO AND SRI LANKA

May 29, 2018

VIA EMAIL AND FEDEX

Mayo Clinic c/o Gregory Karpenko Fredrikson & Byron, PA 200 South Sixth Street, Suite 4000 Minneapolis, MN 55402 gkarpenko@fredlaw.com

Re: In the Matter of Otto Bock Health Care North America, Inc., Federal Trade Commission Dkt, No. 9378

Dear Mr. Karpenko:

By this letter, we are providing formal notice, pursuant to Rule 3.45(b) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.45(b), that Respondent Counsel intend to offer the documents and testimony referenced in the enclosed Attachment A into evidence in the administrative trial in the above-captioned matter. The administrative trial is scheduled to begin on July 10, 2018. All exhibits admitted into evidence become part of the public record unless in camera status is granted by Administrative Law Judge D. Michael Chappell.

For documents or testimony which include sensitive or confidential information that you do not want on the public record, you must file a motion seeking in camera status or other confidentiality protections pursuant to 16 C.F.R §§ 3.45, 4.10(g). Judge Chappell may order that materials, whether admitted or rejected as evidence, be placed *in camera* only after finding that their public disclosure will likely result in a clearly defined, serious injury to the person, partnership, or corporation requesting *in camera* treatment.

Motions for *in camera* treatment for evidence to be introduced at trial must meet the strict standards set forth in 16 C.F.R. § 3.45 and explained in *In re 1-800 Contacts, Inc.*, 2017 FTC LEXIS 55 (April 4, 2017); *In re Jerk, LLC*, 2015 FTC LEXIS 39 (Feb. 23, 2015); and *In re Basic Research, Inc.*, 2006 FTC LEXIS 14 (Jan. 25, 2006). Motions also must be supported by a

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<u>Duane</u> Morris

May 29, 2018 Page 2

declaration or affidavit by a person qualified to explain the confidential nature of the documents. *In re 1-800 Contacts, Inc.*, 2017 FTC LEXIS 55 (April 4, 2017); *In re North Texas Specialty Physicians*, 2004 FTC LEXIS 66 (April 23, 2004). You must also provide one copy of the documents for which in camera treatment is sought to the Administrative Law Judge.

Please be aware that under the current Scheduling Order dated April 26, 2018, the deadline for filing motions seeking *in camera* status is June 11, 2018.

If you have any questions, please feel free to contact me at 215-979-1997.

Very truly yours,

/s/ William Shotzbarger

William Shotzbarger

WS

Enclosures cc: Jose

Joseph M. Colaiano Sean S. Zabaneh Sean P. McConnell Sarah O'Laughlin Kulik

Attachment A

Exhibit No.	Description Description	Date	BegBates	EndBates
	Investigational Hearing Transcript of Kenton Kauffman, M.D. (Mayo Clinic)	12/6/2017	FTC-MAYO- 000013	FTC-MAYO- 000048
	Deposition Transcript of Kenton Kauffman, M.D.	4/6/2018		
RX-0623 (MAYO000 001_0001)	Functional Assessment and Satisfaction of Transfemoral Amputees with Low Mobility (FASTK2): A Clinical Trial of MPK vs. NMPK Knees (Kenton R. Kaufman, Kathie A. Bemhardt, Kevin Symms)	11/01/2017	MAYO00001	MAYO000001
RX-0802 (MAYO000 002_0001)	PowerPoint Slides: Functional Assessment and Satisfaction in Transfemoral K2 Amputees (FASTK2): A Comparative Effectiveness Study of MPK vs. NMPK Knees	02/26/2018	MAYO000002	MAYO000002
RX-0803 (MAYO000 003_0001)	PowerPoint Slides: Hanger Clinic - How Do We Define K2.5 or K3?	02/26/2018	MAYO000003	MAYO000003
RX-0133 (MAYO000 004_0001)	Kenton R. Kaufman, PhD PE - Presentations: Microprocessor-Controlled Knees - 2016 to Present	02/02/2016	MAYO000004	MAYO000004
RX-0667 (FTC- MAYO- 000005)	Email chain from Terrí J. Mossyge to William Cooke, cc: Joseph M. Colaiano, Stefani M. Iverson re: Dr. Kaufman	11/20/2017	FTC-MAYO- 000005	FTC-MAYO- 000006

EXHIBIT C

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	
Otto Bock HealthCare North America, Inc.,) DOCKET NO. 9378
a corporation,)
Respondent.))

DECLARATION OF DR. KENTON KAUFMAN IN SUPPORT OF NON-PARTY MAYO CLINIC'S MOTION FOR IN CAMERA TREATMENT

I, Dr. Kenton Kaufman, hereby declare as follows:

- I am an employee of Mayo Clinic ("Mayo"), where I serve as the W. Hall Wendel Jr. Musculoskeletal Research Professor, Professor of Biomedical Engineering, and Director of the Motion Analysis Laboratory. I make this declaration in support of Non-Party Mayo Clinic's Motion for In Camera Treatment (the "Motion"). I have personal knowledge of the matters stated herein and, if called upon to do so, could competently testify about them.
- 2. I have reviewed and am familiar with the documents Mayo produced in the above-captioned matter in response to subpoenas served by the Federal Trade Commission and Otto Bock HealthCare North America, Inc. I provided a certification of authenticity as to the produced documents, including the document that is the subject of the Motion. Given my position with Mayo and my role as the lead author for the draft manuscript that is the subject of this motion, I am familiar with the information contained in the document at issue, its significance to Mayo Clinic, and Mayo's confidentiality obligations with respect to that document. Based on my personal knowledge, I submit that the disclosure of the draft manuscript to the public and potential competitors of Mayo would cause serious injury to Mayo.

3. The FTC and Otto Bock have informed Mayo that they intend to offer a draft manuscript that I co-authored at the administrative hearing in this matter. As described in the Motion, Mayo seeks in camera protection of this draft manuscript for a period of two years.

	Document Title/Description	Date	Beginning Bates No.	Ending Bates No.
PX03219 RX-0623	Draft Research Study Manuscript	11/00/2017	MAYO000001_0001	MAYO000001_0024

- 4. In 2014, Mayo and The American Orthotic and Prosthetic Association, Inc. ("AOPA") entered into a Corporate Research Agreement ("Research Agreement") pursuant to which AOPA funded scientific research to be conducted by my team and Mayo's Department of Orthopedic Surgery. The purpose of the scientific research was to compare the effectiveness between microprocessor controlled and non-microprocessor controlled prosthetic knees using a unique activity monitoring device developed at Mayo Clinic.
- 5. A true and correct copy of the Research Agreement is attached as Exhibit 1. The Research Agreement has been redacted to remove the monetary amounts paid by AOPA to Mayo for the research study.
- 6. The Research Agreement prohibits Mayo from publishing the results of the scientific research unless Mayo submits the proposed publication or presentation of the scientific research to AOPA prior to publication to allow AOPA the opportunity to identify and seek legal protection for any proprietary or patentable information contained in the publication. Ex. 1 at § 15.2. The Research Agreement also prohibits Mayo from disclosing AOPA's confidential information. *Id.* at § 13.
- 7. Pursuant to the Research Agreement and the substantial monetary funding provided by AOPA, I led a multi-year study conducted by a cross-disciplinary team comparing

the outcomes and effectiveness of microprocessor controlled and non-microprocessor controlled prosthetic knees in Medicare-aged amputee patients.

- 8. In November 2017, my team and I completed a draft manuscript for publication based on the research study entitled "Functional Assessment and Satisfaction of Transfemoral Amputees with Low Mobility (FASTK2): A Clinical Trial of MPK vs. NMPK Knees." The manuscript is a draft and is currently being reviewed. Because the manuscript is not in final form, it has not yet been submitted to AOPA for its review pursuant to the Research Agreement.
- 9. Mayo and those involved in the research study have maintained the confidentiality of the draft manuscript and its findings. Mayo and those involved in the research study keep it confidential because the draft manuscript and its findings are the result of investment of substantial time, scientific expertise, and funds over a multi-year period research study. The information contained in the draft manuscript is proprietary and not publicly known. Furthermore, Mayo is contractually required to maintain the confidentiality of the manuscript pursuant to the Research Agreement until it has been reviewed by AOPA and a determination regarding intellectual property rights has been made. As a result, Mayo will be harmed significantly if this confidential information is made public as part of this proceeding. Because of the highly confidential and proprietary nature of the information and its materiality to Mayo's business as a research institution, in camera treatment is appropriate.
- 10. Mayo advised counsel of the confidentiality of the draft manuscript and designated the document as "Confidential" pursuant to the Protective Order in this case. For this exchange of information to work in future proceedings, protection must exist for research institutions like Mayo to ensure that investment in ongoing and unpublished scientific research is not compromised by disclosure.

I declare under penalty of perjury that the foregoing is true and correct. Executed June 8, 2018, at Rochester, Minnesota.

Kenton Kaufman, Ph.D

64143455.1

EXHIBIT D

Hearing Exhibit Nos. PX03219/RX-0623

MARKED CONFIDENTIAL REDACTION IN THEIR ENTIRETY REQUESTED

Notice of Electronic Service

I hereby certify that on June 11, 2018, I filed an electronic copy of the foregoing Non-Party Mayo Clinic's Motion for In Camera Treatment, with:

D. Michael Chappell Chief Administrative Law Judge 600 Pennsylvania Ave., NW Suite 110 Washington, DC, 20580

Donald Clark 600 Pennsylvania Ave., NW Suite 172 Washington, DC, 20580

I hereby certify that on June 11, 2018, I served via E-Service an electronic copy of the foregoing Non-Party Mayo Clinic's Motion for In Camera Treatment, upon:

Steven Lavender Attorney Federal Trade Commission slavender@ftc.gov Complaint

William Cooke Attorney Federal Trade Commission wcooke@ftc.gov Complaint

Yan Gao Attorney Federal Trade Commission ygao@ftc.gov Complaint

Lynda Lao Attorney Federal Trade Commission llao1@ftc.gov Complaint

Stephen Mohr Attorney Federal Trade Commission smohr@ftc.gov Complaint

Michael Moiseyev Attorney Federal Trade Commission mmoiseyev@ftc.gov Complaint

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Kelly Eckel Duane Morris LLP KDEckel@duanemorris.com Respondent

Theresa A. Langschultz Duane Morris LLP TLangschultz@duanemorris.com Respondent

> Gregory Karpenko Attorney