**PUBLIC**

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

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**DOCKET NO. 9378**

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**In the Matter of**

**OTTO BOCK HEALTHCARE**
**NORTH AMERICA, INC.,**
**a corporation**

**Respondent.**

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# INITIAL DECISION

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**D. Michael Chappell**
**Chief Administrative Law Judge**

**Date: May 6, 2019**

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# I. INTRODUCTION

## A. Summary of the Case

This action, issued by the Federal Trade Commission ("FTC" or "Commission") on December 20, 2017, challenges an acquisition, consummated on September 22, 2017, of FIH Group Holdings, LLC ("Freedom") by Respondent Otto Bock HealthCare North America, Inc. ("Respondent" or "Ottobock"[1]) (the "Acquisition"). Complaint at 1; Joint Stipulations of Law and Fact ¶ 4. In summary, the Complaint alleges that the Acquisition has lessened, and may substantially lessen, competition in the market for the manufacture and sale of microprocessor prosthetic knees ("MPKs") to prosthetic clinics in the United States of America ("United States"), in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45. Complaint ¶¶ 57-58, 64-67.

On February 15, 2018, Respondent filed an Amended Answer and Affirmative Defenses.[2] Respondent denied that the Acquisition has harmed or is likely to harm competition. Answer ¶¶ 57-58, 64-67. Respondent further asserted a number of affirmative defenses, including, among others, that efficiencies or other procompetitive benefits outweigh any alleged procompetitive effects (Third Affirmative Defense); that Freedom was a failing firm at the time of the Acquisition (Sixth Affirmative Defense); and that a planned divestiture by Ottobock of the microprocessor-controlled knee business of Freedom will address any anticompetitive effects in the alleged relevant market (Seventh Affirmative Defense). Amended Answer at 29-30.

On February 13, 2018, Complaint Counsel moved to strike Respondent's Seventh Affirmative Defense ("Motion"). The Motion was referred to the Commission for a ruling,

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[1] The caption of the Complaint issued by the Commission refers to Respondent as "Otto Bock HealthCare North America, Inc." The Complaint, Complaint Counsel's filings, and the transcript, use the name, "Otto Bock" as a shorthand name for Respondent. Respondent's Answer, as well as its internal documents, use the shorthand name "Ottobock." Accordingly, except where quoting sources, this Initial Decision uses the shorthand name "Ottobock."

[2] Respondent's initial answer was filed on January 10, 2018.

pursuant to Commission Rule 3.22(a), which states that motions to strike "shall be directly referred to the Commission and shall be ruled on by the Commission unless the Commission in its discretion refers the motion to the Administrative Law Judge." 16 C.F.R. § 3.22(a). Complaint Counsel argued that a planned divestiture, as averred in Respondent's Seventh Affirmative Defense, is not a valid defense to a consummated transaction "as a matter of law." Motion at 2. Complaint Counsel requested an order that Respondent's Seventh Affirmative Defense be stricken and that Respondent also be precluded from raising any post-Acquisition divestiture as a defense to the allegations in the Complaint. *See* Motion, Proposed Order. Respondent filed an opposition to the Motion on February 23, 2018. Respondent argued that the existence of disputed facts precluded the drastic remedy of striking a defense from a pleading and that the planned divestiture is relevant to whether the Acquisition will substantially lessen competition.

The Commission denied Complaint Counsel's Motion in an opinion and order issued April 18, 2018. *In re Otto Bock HealthCare North America, Inc.*, 2018 WL 2042043 (April 18, 2018). The Commission determined that Respondent's averment of a planned divestiture could not negate liability entirely because of the potential that Complaint Counsel could prove likely anticompetitive effects in the period between September 22, 2017, the date of the Acquisition, and the date of divestiture. Therefore, the Commission reasoned, the averment of a planned divestiture was not properly viewed as an affirmative defense. *Id*. at *2-4. The Commission declined to strike the averment, however, because the averment could "appropriately be viewed as a denial." *Id*. at *2. The Commission explained that while "the averment [redacted] is insufficient in itself to defeat liability[,] . . . [redacted] could potentially be relevant to rebut a showing of likely anticompetitive effects [redacted] *Id.* at *4.

By Order dated April 23, 2018, the Commission granted the parties' Joint Motion to Reschedule the Date for the Hearing to July 10, 2018. The evidentiary hearing in this matter, which began on July 10, 2018, was conducted over 31 days, and was completed on

October 4, 2018. Thereafter, the parties submitted post-trial briefs, proposed findings of fact, and replies to each other's briefs and proposed findings of fact.[3]

Upon full consideration of the entire record, and as more fully explained below, the evidence in this proceeding proves that the Acquisition will significantly increase concentration in the relevant MPK market, which gives rise to a presumption that the Acquisition may substantially lessen competition. In addition, the evidence proves that Ottobock and Freedom are direct competitors in the MPK market, and that such competition has enabled clinic customers to negotiate lower prices and has spurred MPK innovation. This is more than sufficient to meet Complaint Counsel's prima facie burden to show that the Acquisition of Freedom by Ottobock, and the removal of Freedom as an independent competitor, may substantially lessen competition in the MPK market. Furthermore, Respondent's rebuttal arguments and defenses are without merit. The evidence fails to demonstrate that repositioning by competitors in the MPK market will be timely, likely or sufficient to prevent anticompetitive effects; that power buyers or limits on insurance reimbursement will constrain price increases in the MPK market; that Freedom at the time of the Acquisition was a failing (or flailing) company; that Respondent's proposed divestiture of Freedom's MPK-related assets will eliminate any likelihood of anticompetitive effects from the Acquisition; or that the Acquisition is justified by cognizable efficiencies.

Accordingly, the evidence proves that the Acquisition may substantially lessen competition in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act. An appropriate remedial Order is entered herewith.

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[3] Rule 3.51(a) of the Commission's Rules of Practice states that "[t]he Administrative Law Judge shall file an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order . . . ." 16 C.F.R. § 3.51(a). The last reply to proposed findings and conclusions and reply briefs were filed on December 13, 2018. Seventy days from the last filings would have been February 21, 2019. Due to the partial shutdown of the federal government, and pursuant to an order of the Commission, the case was stayed and the deadline for the filing of the Initial Decision was thereby extended. *See* Order Regarding Scheduling, December 28, 2018 (staying case, including Initial Decision deadline, for "the duration of the shutdown and for an additional five business days thereafter"). Absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before March 28, 2019. Based on the voluminous and complex record in this matter, an Order was issued finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of this Initial Decision by April 29, 2019 is in compliance with Commission Rule 3.51(a).

### B. Summary of Evidence Presented

The record in this matter consists of the testimony of a total of 69 witnesses, presented live or by deposition. Over 3,130 exhibits were also admitted into evidence. Individuals referenced in this Initial Decision include current and/or former employees of Ottobock and Freedom, other prosthetic knee manufacturers, and prosthetists and other professionals involved in the selection of MPKs for patients.

This Initial Decision is based on a consideration of the whole record relevant to the issues and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties, and all contentions and arguments therein were thoroughly reviewed and considered. Proposed findings of fact submitted by the parties that were not accepted in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the merits of the case. Similarly, legal contentions and arguments of the parties that are not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit.[4] In addition, all expert opinion evidence submitted in this case has been fully reviewed and considered. Except as expressly relied on or adopted in this Initial Decision, such opinions have been rejected, as either unreliable, unsupported by the facts, or unnecessary to the findings and conclusions herein.

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[4] Ruling upon a decision of the Interstate Commerce Commission, and interpreting language in the Administrative Procedure Act ("APA") that is almost identical to language in Commission Rule 3.51(c)(1), the United States Supreme Court held that "[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are 'material.'" *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. NLRB*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the exceptions were discussed, and stating that "[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency"). Issues of fact or law that do not affect the result in a case are not fairly deemed "material," for purposes of Section 557(c)(3)(A) of the APA, 5 U.S.C. § 557(c)(3)(A), or Rule 3.51(c)(1) of the Commission's Rules of Practice, 16 C.F.R. § 3.51(c)(1), notwithstanding that there may be allegations or evidence presented on such issues. Furthermore, the Commission has held that Administrative Law Judges are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, at *566-67 (Nov. 2, 1983).

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. § 3.51(c)(1); *see In re Chicago Bridge & Iron Co.*, 138 F.T.C. 1024, 2005 FTC LEXIS 215, at **8 n.23 (Jan. 6, 2005), *aff'd, Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 423 n.5 (5th Cir. 2008). Under the Administrative Procedure Act, an Administrative Law Judge ("ALJ") may not issue an order "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by "F."[5]

Pursuant to Commission Rule 3.45(b), several orders were issued in this case granting *in camera* treatment to material, after finding, in accordance with the Rule, that its public disclosure would likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment or that the material constituted "sensitive personal information," as that term is defined in Commission Rule 3.45(b). In addition, when the parties sought to elicit testimony at trial that revealed information that had been granted *in camera* treatment, the hearing went into an *in camera* session. Commission Rule 3.45(a) allows the ALJ "to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the [administrative] law judge or the

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[5] References to the record are abbreviated as follows:

PX – Complaint Counsel's Exhibit
RX – Respondent's Exhibit
JX – Joint Exhibit
Tr. – Transcript of testimony before the Administrative Law Judge
Dep. – Transcript of Deposition
IHT – Transcript of Investigational Hearing
CCB – Complaint Counsel's Post-Trial Brief
CCRB – Complaint Counsel's Post-Trial Reply Brief
CCFF – Complaint Counsel's Proposed Findings of Fact
CCRRFF – Complaint Counsel's Reply to Respondent's Proposed Findings of Fact
RB – Respondent's Post-Trial Brief
RRB – Respondent's Post-Trial Reply Brief
RFF – Respondent's Proposed Findings of Fact
RRCCFF – Respondent's Reply to Complaint Counsel's Proposed Findings of Fact

Commission that public disclosure is required in the interests of facilitating public understanding of their subsequent decisions." *In re Bristol-Myers Co*., 90 F.T.C. 455, 1977 FTC LEXIS 25, at *6 (Nov. 11, 1977). As the Commission later reaffirmed in another leading case on *in camera* treatment, since "in some instances the ALJ or Commission cannot know that a certain piece of information may be critical to the public understanding of agency action until the Initial Decision or the Opinion of the Commission is issued, the Commission and the ALJs retain the power to reassess prior *in camera* rulings at the time of publication of decisions." *In re General Foods Corp*., 95 F.T.C. 352, 1980 FTC LEXIS 99, at *12 n.7 (March 10, 1980). Thus, in instances where a document or trial testimony had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not in fact merit *in camera* treatment, such material is disclosed in the public version of this Initial Decision, pursuant to Commission Rule 3.45(a) (the ALJ "may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding"). Where *in camera* information is used in this Initial Decision, it is indicated in bold font and braces ("**{ }**") in the *in camera* version and is redacted from the public version of the Initial Decision, in accordance with Commission Rule 3.45(e). 16 C.F.R. § 3.45(e).

## II. ANALYSIS

### A. Summary of Background Facts

#### 1. The Parties and the Acquisition

Otto Bock HealthCare North America, Inc. ("Ottobock") is a pioneering prosthetics and orthotics company and is a subsidiary of Otto Bock Healthcare SE & Co. KGaA, which is headquartered in Duderstadt, Germany ("Ottobock Germany"). F. 1. Ottobock Germany opened its first foreign branch, Ottobock, in 1958 in Minneapolis, Minnesota. F. 3. Ottobock is a Minnesota corporation, with its headquarters in Austin, Texas. F. 3. It employs approximately 600 people in the United States. F. 3. Ottobock provides upper and lower-limb prosthetics, orthotics, mobility solutions, and medical-related services to customers in the United States and around the world. F. 4. Ottobock's lower-limb prosthetics include mechanical knees and microprocessor knees ("MPKs").[6] Ottobock currently manufactures the C-Leg 4 MPK and sells it in the United States. F. 5.[7]

Freedom was founded in 2002. F. 7. Freedom is headquartered in Irvine, California and also has facilities in California and Utah. F. 7. Freedom employs approximately 150 people. F. 7. The company began by selling carbon fiber feet and later introduced its first MPK, the Plié, in 2007.[8] F. 8. Today, Freedom manufactures and sells the Plié 3 MPK as well as a range of prosthetic feet and ankles. F. 8. Prior to the Acquisition, Freedom was privately owned and the majority shareholder was Health Evolution Partners ("HEP"). F. 10.

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[6] The differences between mechanical knees and microprocessor knees are discussed in section II.C.2.c.1 *infra*. The terms "microprocessor knees" and "MPKs" are used interchangeably to refer to prosthetic knees that use a microprocessor to regulate the movement and positioning of the knee. F. 102.

[7] Ottobock launched the first version of the C-Leg MPK in 1999, launched the second version approximately three to five years later, and launched the C-Leg 3 approximately five years after the second version. F. 233. The C-Leg 4, launched in 2015, is the current C-Leg model sold by Ottobock in the United States. F. 233. The term "C-Leg," as used in this Initial Decision, refers to the C-Leg 4, unless context otherwise dictates. The microprocessor knees that Ottobock sells in the United States are discussed in more detail in F. 232-254.

[8] Freedom launched the first version of the Plié MPK in 2007, followed by the Plié 2 in 2010. F. 255. The Plié 3, launched in 2014, is the current Plié model sold in the United States. F. 255. The term "Plié," as used in this Initial Decision, refers to the Plié 3, unless context otherwise dictates. The Plié is discussed in more detail in F. 256-270.

On September 22, 2017, Ottobock acquired Freedom for approximately [redacted] million. F. 11. Upon consummation of the Acquisition, Freedom became a wholly owned subsidiary of Ottobock. F. 12. The Acquisition was not reportable under the Hart-Scott-Rodino Act. In September 2017, the FTC began a preliminary investigation into the Acquisition. F. 14. On December 19, 2017, Ottobock and the FTC entered into a Hold Separate Agreement ("Hold Separate Agreement"). F. 15.

### 2. Prosthetic knees

Above-the-knee (or transfemoral) amputees typically receive a prosthetic leg that consists of (1) either a suspension or a liner, (2) a socket, which is a rigid or semi-rigid negative of the residual limb, (3) a knee, (4) a pylon connecting the knee to a foot, and (5) a foot shell with a covering. F. 68, 71. Regarding prosthetic knees, according to Respondent's website:

> In general, there are two kinds of prosthetic knees: non-microprocessor (or "mechanical") and microprocessor. F. 95.
>
> Mechanical knees all use a mechanical hinge to replace your knee joint. How quickly or easily the hinge swings is often controlled by friction, some type of hydraulic system or a locking mechanism. F. 96.
>
> Microprocessors, on the other hand, provide a more sophisticated method of control to a prosthetic knee. These more complex knee joints are designed to help you walk with a much more stable and efficient gait that more closely resembles a natural walking pattern. F. 331.

### 3. Process that determines whether a patient receives an MPK or a mechanical knee

The process for fitting a transfemoral patient with a prosthetic knee is detailed in section III.B.1 of the Findings of Fact and summarized below. Several categories of healthcare professionals play a role.

A surgeon, who performs the amputation, or a physiatrist[9] provides a patient with a prescription to receive a prosthesis and a referral to a prosthetist. F. 75, 135. The prescription for a prosthesis generally includes identifying information, such as the patient's name, date of

[9] A physiatrist is a medical professional who specializes in rehabilitation. F. 74.

birth, height, and weight, time since amputation or last surgery, and the specific goals of and justification for the device. F. 137. The level of detail in a prescription varies from relatively vague, i.e., "transfemoral or above-knee amputee, fit with prosthesis," to more detailed specifications, such as a particular type of knee, depending on the physician's level of knowledge. F. 138-39. Sometimes the prescription will note the patient's K-Level, discussed below. F. 140.

A prosthetist designs and fits prostheses for lower-limb amputees. F. 76. Prosthetic clinics typically employ one or more prosthetists to make and fit prostheses and manage patient care. F. 77. These clinics provide comprehensive patient care for amputees, including the fitting of the prosthesis. F. 77. Prosthetic clinics can operate as independent entities, through large networks of clinics, or be affiliated with a hospital. F. 78. There are approximately 3,400 prosthetic clinics in the United States. F. 78.

A patient arriving at a prosthetic facility with a prescription for a new prosthesis will be evaluated by a prosthetist first to determine the patient's K-Level, based on validated tests. F. 157. K-Levels are designations developed by the Centers for Medicare and Medicaid Services ("CMS") to assess an amputee's current and potential mobility. F. 84. The K-Level definitions are used throughout the orthotic and prosthetics industry in the United States to classify amputees into five ascending mobility levels, K-Level 0 to K-Level 4. F. 85.

The K-Levels, as described by CMS, are:

- K-Level 0 ("K-0") Nonambulatory: "Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility." F. 86.

- K-Level 1 ("K-1") Household Ambulator: "Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence." F. 87.

- K-Level 2 ("K-2") Limited Community Ambulator: "Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces." F. 88.

- K-Level 3 ("K-3") Unlimited Community Ambulator: "Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion." F. 89.

- K-Level 4 ("K-4") Very Active: "Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete." F. 90.

Medicare and most third-party payers ("payers") will only provide reimbursement for MPKs for K-3 or K-4 patients. F. 163. Medicare regulations, which are also followed by most private insurers, do not allow for reimbursement to clinics for fitting MPKs on K-0, K-1, or K-2 patients. F. 162. Therefore, as a practical matter, only amputees identified as a K-3 or K-4 ambulator are considered candidates for an MPK by their healthcare professionals.

After establishing a patient's K-Level, healthcare professionals consider various factors to determine whether an MPK is medically appropriate for that particular K-3/K-4 patient. These factors include: (1) a patient's age, overall health, and fitness; (2) the activities in which the patient engages or desires to engage; (3) the degree to which the patient stumbles, falls, or experiences other negative consequences when wearing a mechanical knee; and (4) the patient's comfort with an MPK. F. 169-186.

Next, the clinic will evaluate whether the patient has insurance that is likely to cover the cost of an MPK. MPKs are significantly more expensive than mechanical knees. F. 394-399.[10] In order to receive insurance reimbursement for an MPK, the prosthetist or clinic submits various categories of information on the patient's behalf to payers, including Medicare, private insurance, Medicaid, the United States Department of Veterans Affairs, the United States Department of Defense, and workers' compensation programs. F. 106-107, 168. To receive reimbursement, payers often require clinics to obtain prior authorization or predetermination of coverage based on a medical provider's written clinical assessment of the patient. F. 113.

[10] One calculation shows the Medicare reimbursement rate for MPKs ranges from approximately $26,000 to $35,000, while the Medicare reimbursement rate for non-MPKs ranges from approximately $5,000 to $8,000. F. 404.

*See also* F. 191. Some clinics seek predetermination from insurance plans before fitting a prosthetic, even if prior authorization is not required. F. 113.

If the prosthetist determines that a patient is a K-3 or K-4 ambulator, and would benefit from an MPK, in order to obtain insurance reimbursement for an MPK, the prosthetist must demonstrate "medical necessity." F. 187. "Medical necessity" in this context is not a health determination. Instead, it refers to eligibility for a particular device using criteria established by the payer. F. 190. To demonstrate medical necessity, insurers require clinics to provide evidence showing that a patient will experience significant health, safety, or quality of life benefits by wearing an MPK rather than a mechanical knee. F. 189, 192-195, 205-206. Clinics provide physicians' notes, narrative justifications of medical necessity from the prosthetist, and/or completed intake forms to demonstrate that the patient has unmet needs with their current prosthesis that can be fulfilled by an MPK, but not by a less expensive alternative, such as a mechanical knee. F. 189, 191, 204, 210. *See also* F. 193-202, 207-209, 210. The most important unmet need that could be argued to justify medical necessity of an MPK is a need for more safety, which typically requires documentation that a patient has experienced frequent falls with a mechanical knee. F. 195. If a clinic cannot document medical necessity, an insurer will deny coverage for an MPK and approve coverage only for a mechanical knee. F. 213, 217.

Even when a patient is eligible for an MPK, there are circumstances when a clinic may determine that an MPK is not medically appropriate for an individual, given the patient's specific health or lifestyle characteristics. F. 150. Mechanical knees may be preferable to MPKs for patients engaging in certain sports and activities, such as cycling, weightlifting, and CrossFit, because mechanical knees are lighter, more durable, cheaper, and easier to replace if they break. F. 220. Some mechanical knees are waterproof, or even salt-waterproof, making them preferable for fishermen or others who engage in water activities. F. 222-223. Hunters may prefer mechanical knees for their ability to handle wet or cold environments and to avoid the need to recharge the microprocessor knee. F. 224. Because MPKs need to be charged, patients with cognitive deficits or who do not have access to chargers may be better suited for mechanical knees. F. 226, 228. In addition, patients who have started out on a mechanical knee and are used to using a mechanical knee may prefer not to change to an MPK. F. 231.

### 4. Process through which MPKs are purchased

If the patient's medical team determines that an MPK is the most appropriate option for the patient and it appears that the clinic will be reimbursed for the cost of the MPK, the clinic will purchase an MPK for that patient. F. 314, 368. Clinics then seek reimbursement for the prosthetic knee from the payer. F. 106, 114. Payers reimburse clinics for the provision of prosthetic devices based on the L-Code system created by CMS. F. 115. L-Codes describe certain features or functions of components of a prosthetic device. F. 439. Each component of a prosthetic device will have one or more L-Codes for various functional aspects of the device. F. 117. CMS establishes an allowed reimbursement amount for each L-Code. F. 119. Other public and private insurance payers derive reimbursement amounts for the same devices from the amounts set by CMS with respect to each particular L-Code. F. 115. Private insurance payers generally reimburse at amounts below the CMS allowed reimbursement. F. 125. Payers do not reimburse clinics at different rates for different manufacturers' MPKs. F. 120. Rather, L-Code reimbursement rates are tied to the claimed functionality of the device for which a clinic is seeking reimbursement. F. 117, 320-321.

Clinics bill payers for the prosthetic devices they deliver to patients by identifying applicable L-Codes and then adding up the allowed reimbursement corresponding to each identified L-Code for the prosthetic device. F. 115-118. Prosthetic components generally have a base L-Code associated with them, and could have additional codes, depending on functionality. F. 117, 439. *See, e.g.*, F. 442. Manufacturers recommend certain L-Codes for their prosthetic components based on the manufacturers' claims about the functionality of their respective prosthetic devices. F. 234, 258, 282, 302, 308.

The allowed CMS L-Code reimbursement sets a ceiling on the clinic's ability to recover compensation for its services. F 115, 119-121. Clinics incur costs that are not separately reimbursable through L-Codes, including the cost of marketing, administrative costs, costs associated with the work performed by a clinic's certified prosthetists, costs associated with the technical staff building the leg, overhead costs, human resources, payroll, facility costs, and other operational costs. F. 122. The L-Code reimbursement is intended to compensate the clinic for

the entire patient-care episode, including the time spent by the prosthetist in seeing the patient, and any overhead associated with the patient's visit. F. 322-324.

Typically, clinics do not stock prosthetic knees, but, instead, purchase each knee when needed for a particular patient. F. 313. Although MPK manufacturers publish list prices, customers typically pay a negotiated MPK sales price that is below the manufacturer's list price. F. 317. MPK manufacturers charge different sales prices to different clinic customers. F. 316. Clinics generally negotiate MPK prices with MPK manufacturers on an annual basis during contract renewal negotiations. F. 315. The overall volume of MPKs that a clinic customer purchases during the term of the contract affects the discounts the clinic receives from MPK suppliers. F. 318. Clinics receive the same reimbursement amount for each L-Code, regardless of the cost to the clinic of the device purchased. F. 121, 320-321. Thus, the lower the price of an MPK, the higher the clinic's margin. F. 324-326.

With this background in mind, the analysis turns to whether the Acquisition violates Section 5 of the FTC Act and Section 7 of the Clayton Act.

### B. Applicable Legal Standards

#### 1. In general

The parties' burdens of proof are governed by Commission Rule 3.43(a), Section 556(d) of the APA, and case law. Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d). The APA, "which is applicable to administrative adjudicatory proceedings unless otherwise provided by statute, establishes '. . . the traditional preponderance-of-the evidence standard.'" *In re Rambus, Inc.*, 2006 FTC LEXIS 101, at *45 (Aug. 20, 2006) (quoting *Steadman v. SEC*, 450 U.S. 91, 95-102 (1981)), *rev'd on other grounds*, 522 F.3d 456 (D.C. Cir. 2008).

Section 11 of the Clayton Act vests jurisdiction in the FTC to determine the legality of a corporate acquisition under Section 7. 15 U.S.C. § 21(b); *In re R.R. Donnelley & Sons Co.*, 1995

FTC LEXIS 450, at *11 (July 21, 1995). Corporations are included within the definition of "persons" that are subject to jurisdiction under the Clayton Act, 15 U.S.C. § 12(a), and the FTC Act, 15 U.S.C. § 44. Respondent is a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44. F. 3. Respondent manufactures microprocessor knees and sells them to consumers throughout the United States. F. 4-5. Respondent's challenged activities relating to the sale of MPKs are in or affect commerce in the United States, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44. Joint Stipulations of Law and Fact ¶ 1. Thus, the Commission has jurisdiction over Respondent and the subject matter of this proceeding, pursuant to Section 5 of the FTC Act, and Sections 7 and 11 of the Clayton Act, 15 U.S.C. § 18, 21(b).

### 2. Merger law

#### a. Statutory framework

Section 7 of the Clayton Act prohibits mergers or acquisitions "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or . . . activity affecting commerce in any section of the country." 15 U.S.C. § 18. The allegation that an acquisition is a Section 5 violation, as well as a Section 7 violation, "does not require an independent analysis . . . ." *In re Chicago Bridge*, 2005 FTC LEXIS 215, at **8 n.23. *Accord FTC v. PPG Indus., Inc.*, 798 F.2d 1500, 1501 n.2 (D.C. Cir. 1986) (stating that Section 5 of the FTC Act "may be assumed to be merely repetitive of [Section] 7 of the Clayton Act").

"Congress used the words '*may be* substantially to lessen competition' to indicate that its concern was with probabilities, not certainties." *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962); *accord FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 35 (D.D.C. 2009). "Congress enacted Section 7 to curtail anticompetitive harm in its incipiency." *In re Polypore Int'l Inc.*, 150 F.T.C. 586, 2010 WL 9549988 at *8 (Nov. 5, 2010), *aff'd*, 686 F.3d 1208 (11th Cir. 2012). Thus, it is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive effects, or even that such effects are highly probable, *FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989), "but only that the loss of competition is a 'sufficiently probable and imminent' result of the merger or acquisition." *CCC Holdings*, 605 F. Supp. 2d at 35 (quoting *United States v. Marine Bancorp.*, 418 U.S. 602, 623 n.22 (1974)); *accord In re ProMedica Health Sys., Inc.*, 2012 FTC LEXIS 293, at *33-34 (June 25, 2012).

*See FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1218 (11th Cir. 1991) ("[T]o satisfy section 7, the government must show a reasonable probability that the proposed transaction would substantially lessen competition in the future."). "Of course the word 'may' [in Section 7] should not be taken literally, for if it were, every acquisition would be unlawful. But the statute requires a prediction, and doubts are to be resolved against the transaction." *Elders Grain*, 868 F.2d at 906.

**b. Burden shifting framework**

"Courts have traditionally analyzed Section 7 claims under a burden-shifting framework. *See, e.g.*, *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 715 (D.C. Cir. 2001); *United States v. Baker Hughes Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990)." *Polypore*, 2010 WL 9549988, at *9. Under this framework, for its prima facie case, a plaintiff may establish a presumption of liability by defining a relevant product and geographic market, and showing that the transaction will lead to undue concentration in the relevant market. *Id.* (citing *Baker Hughes*, 908 F.2d at 982-83).

The plaintiff can bolster a prima facie case based on a market concentration presumption by adducing evidence showing that anticompetitive unilateral or coordinated effects are likely. *Polypore*, 2010 WL 9549988, at *9 (citing *Heinz*, 246 F.3d at 717). In this regard, ordinary course of business documents of the merging parties "are often highly probative of both industry conditions and the likely competitive effects of a merger." *Polypore*, 2010 WL 9549988, at *9. *See Chicago Bridge*, 2005 FTC LEXIS 215, at **43-44 (noting that qualitative evidence on pre-acquisition competition may support conclusions based on market structure and can provide an independent basis for a prima facie case under Section 7). "Evidence that sheds light on the strategic objectives of the merging parties is also probative of likely competitive effects." *Polypore*, 2010 WL 9549988, at *9 (citing *FTC v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1047 (D.C. Cir. 2008) (Tatel, J., concurring); 4A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 964, at 18-19 (3d ed. 2009); 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines § 2.2.1) (hereinafter "Merger Guidelines § __")).

If the plaintiff establishes a prima facie case, the burden shifts to the defendant to show that "traditional economic theories of the competitive effects of market concentration are not an accurate indicator of the merger's probable effect on competition in these markets or that the

procompetitive effects of the merger are likely to outweigh any potential anticompetitive effects." *CCC Holdings*, 605 F. Supp. 2d at 46. *See also FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 347 (3d Cir. 2016) (stating that in order to rebut the prima facie case, defendants "must show either that the combination would not have anticompetitive effects or that the anticompetitive effects of the merger will be offset by extraordinary efficiencies resulting from the merger"). Although the courts have not defined a precise standard that must be met to rebut a prima facie case, the courts advise that "[t]he more compelling the prima facie case, the more evidence the defendant must present to rebut [the presumption] successfully." *Baker Hughes*, 908 F.2d at 991; *Heinz*, 246 F.3d at 725; *Polypore*, 2010 WL 9549988, at *9.

The defendant "can rely on a variety of types of evidence to meet its burden on rebuttal, including evidence that casts doubt on the significance or accuracy of the plaintiff's market share and concentration evidence, factors that indicate that collusion is improbable, and evidence of likely efficiencies." *Polypore*, 2010 WL 9549988, at *9 (citing *Baker Hughes*, 908 F.2d at 985). "If the defendant successfully rebuts the presumption [of illegality], the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Baker Hughes*, 908 F.2d at 983; *Heinz*, 246 F.3d at 715; *Polypore*, 2010 WL 9549988, at *9.

Although mindful of the traditional burden-shifting framework, courts recognize that, in practice, evidence is often considered all at once and the burdens are often analyzed together. *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 424-25 (5th Cir. 2008) (citing *Univ. Health*, 938 F.2d at 1218-19). "The Ninth and Eleventh Circuits interpret *Baker Hughes*' burden-shifting language as describing a flexible framework rather than an air-tight rule." *Chicago Bridge*, 534 F.3d at 424. As a practical matter, the distinction between the burden of production and the ultimate burden of persuasion can be elusive. *See Baker Hughes*, 908 F.2d at 991. This more flexible approach accommodates the practical difficulties in separating the burden to persuade and the burden to produce, and "allows the Commission to preserve the *prima facie* presumption if the respondent . . . fails to satisfy the burden of production in light of contrary evidence in the *prima facie* case." *Chicago Bridge*, 534 F.3d at 425. *See also United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1111 (N. D. Cal. 2004) (noting that the Supreme Court and appellate

courts acknowledge the need to adopt a flexible approach in determining whether anticompetitive effects are likely to result from a merger, and that the Merger Guidelines view statistical and non-statistical factors as an integrated whole, avoiding the burden shifting presumptions of the case law).

### C. Relevant Market

The first step in evaluating whether an acquisition may substantially lessen competition in any "line of commerce" in any "section of the country" is to determine the "line of commerce" and the "section of the country"; in other words, to determine the relevant product market and the relevant geographic market. *Oracle*, 331 F. Supp. 2d at 1110. Complaint Counsel bears "the burden of proving a relevant market within which anticompetitive effects are likely as a result of the acquisition." *In re R.R. Donnelley & Sons*, 1995 FTC LEXIS 450, at *38.

#### 1. Geographic market

The relevant geographic market alleged in the Complaint is the United States. Complaint ¶ 31. Respondent does not dispute the relevant geographic market. Hearing Tr. 91; RRCCFF 829-31. *See also* RX1049 (Argue Expert Report at 0020-21 ¶¶ 34, 36) (Respondent's economic expert witness, Dr. David A. Argue, agreeing that the United States is the relevant geographic market). Accordingly, the relevant geographic market in this case is the United States.

#### 2. Product market

The relevant product market alleged in the Complaint is the sale of MPKs to prosthetic clinics in the United States. Complaint ¶ 17. Respondent argues, as further explained below, that Complaint Counsel has not proven its relevant product market principally because the market should include all prosthetic knees (both mechanical and microprocessor) that are clinically appropriate for K-3 and K-4 patients. RB at 35-50. As found below, the relevant product market in this case is the sale of MPKs to prosthetic clinics in the United States.

##### a. Legal standards

A relevant product market consists of "products that have reasonable interchangeability for the purposes for which they are produced – price, use and qualities considered." *United*

*States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325; *see du Pont*, 351 U.S. at 395. Further, "within [a] broad market, well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes." *Brown Shoe*, 370 U.S. at 325 (citing *United States v. E. I. du Pont de Nemours & Co.*, 353 U.S. 586, 593-95 (1957)). "The boundaries of such a submarket may be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Id*. Courts routinely rely on these *Brown Shoe* factors to define the relevant product market. *See, e.g., FTC v. Staples*, 970 F. Supp. 1066, 1075-80 (D.D.C. 1997); *FTC v. Cardinal Health*, 12 F. Supp. 2d 34, 46-48 (D.D.C. 1998); *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 159-64 (D.D.C. 2000).

Market definition must "take into account the realities of competition." *FTC v. Whole Foods Mkt.*, 548 F.3d 1028, 1039 (D.C. Cir. 2008). Ordinary course of business documents reveal the contours of competition from the perspective of the parties, who may be presumed to "have accurate perceptions of economic realities." *Whole Foods*, 548 F.3d at 1045 (concurring op.) (quoting *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 218 n.4 (D.C. Cir. 1986)). Thus, in determining the relevant product market, courts pay "close attention to the defendants' ordinary course of business documents." *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 52 (D.D.C. 2011).

Finally, in addition to practical indicia and ordinary course of business documents, courts rely on testimony from experts in the field of economics. *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017); *FTC v. Sysco Corp*., 113 F. Supp. 3d 1, 27 (D.D.C. 2015). Expert testimony is used to analyze the approach set forth in the Merger Guidelines, which instruct that a relevant market may be defined by asking whether a hypothetical monopolist of the proposed market could impose a small but significant and nontransitory increase in price ("SSNIP") without losing sufficient sales to render the price increase unprofitable. Merger Guidelines § 4.1.1; *see also Whole Foods*, 548 F.3d at 1038. "Under the [hypothetical monopolist test], [a] market is any grouping of sales whose sellers, if unified by a hypothetical

cartel or merger, could profitably raise prices significantly above the competitive level." *United States v. Am. Express Co.*, 838 F.3d 179, 198-99 (2d Cir. 2016) (internal quotations omitted). "If a small price increase would drive consumers to an alternative product, then that product must be reasonably substitutable for those in the proposed market and must therefore be part of the market, properly defined." *Whole Foods*, 548 F.3d at 1038 (citing Merger Guidelines).

These approaches for defining the relevant product market are addressed in turn below.

**b. Interchangeability and cross-elasticity of demand**

"Interchangeability of use and cross-elasticity of demand look to the availability of products that are similar in character or use to the product in question and the degree to which buyers are willing to substitute those similar products for the product." *Swedish Match*, 131 F. Supp. 2d at 157 (citing *du Pont*, 351 U.S. at 393). As stated by the Court of Appeals in *ProMedica Health Sys. v. FTC*, 749 F.3d 559 (6th Cir. 2014):

> The first principle of market definition is substitutability: a relevant product market must "identify a set of products that are reasonably interchangeable[.]" Horizontal Merger Guidelines § 4.1. Chevrolets and Fords might be interchangeable in this sense, but Chevrolets and Lamborghinis are probably not. *See* 2B Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, Antitrust Law ¶ 533e at 259 (3d ed. 2007). "The general question is whether two products can be used for the same purpose, and if so, whether and to what extent purchasers are willing to substitute one for the other." *F.T.C. v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 119 (D.D.C. 2004) (quotations omitted).

*Id.* at 565.

In this case, the purchasers of prosthetic knees are the prosthetic clinics who purchase prosthetic knees on an individual basis for each particular patient. F. 313-314. Prosthetists have an ethical and reputational obligation to fit each patient with a prosthetic knee that best meets the patient's medical needs. F. 447. As discussed below in relation to the "peculiar characteristics" of MPKs, the evidence shows that prosthetic clinics view MPKs as superior to mechanical knees for K-3 and K-4 patients unless there are patient-specific reasons that a mechanical knee is more appropriate for an individual patient. F. 365-368. Further, clinic customers believe that MPKs provide more safety and stability than mechanical knees, leading to fewer stumbles and falls; that

MPKs allow patients to more easily traverse everyday environmental barriers, such as curbs, steps, and slopes, as well as walk in crowded areas; and that MPK users demonstrate a much better gait, and are better able to walk with variable cadence, compared with users of mechanical knees. F. 365-367. For example, Keith Senn, president of the Kentucky and Indiana operations of the Center for Orthotics & Prosthetic Care ("COPC") testified that it is "rare" for any of COPC's K-3 or K-4 patients to be fit with a mechanical knee instead of a microprocessor knee because the "MPK is the best available knee that's available to those patients, so we want to provide . . . what those patients deserve and what works best." F. 368.

"An element for consideration as to cross-elasticity of demand between products is the responsiveness of the sales of one product to price changes of the other." *du Pont*, 351 U.S. at 400. "If an increase in the price for product A causes a substantial number of customers to switch to product B, the products compete in the same market." *Sysco*, 113 F. Supp. 3d at 25; *see du Pont*, 351 U.S. at 400. A key legal and economic issue in this case is whether an increase in the price of MPKs would cause a substantial number of clinics to switch to mechanical knees. *See du Pont*, 351 U.S. at 400; *Sysco*, 113 F. Supp. 3d at 25; Merger Guidelines § 4.

Respondent argues that, for purposes of determining interchangeability between MPKs and mechanical knees, it is margin, and not price, that is the relevant economic metric to prosthetists. RB at 44-45. Respondent asserts that the evidence shows MPKs are more expensive for prosthetists to fit and maintain than mechanical knees, due to the number of follow-up visits and documentation associated with reducing the risk of RAC audits[11] for MPKs. RB at 44-45.[12] Respondent further asserts that clinics sometimes earn higher margins on mechanical knees and that, as a result, they are willing to substitute non-MPKs for MPKs on the basis of margin. RB at 44-45. Relying on a "Model of Clinic Profitability" developed by its economic expert witness, Dr. David Argue, Respondent asserts that clinics can earn little to no

[11] Medicare and other payers conduct audits known as recovery audit contractor audits, referred to as "RAC audits." F. 128. During a RAC audit, the payer reviews a patient file from a prosthetic clinic that is associated with a prior reimbursement claim. If the audit determines that the patient's file does not contain sufficient documentary justification for the claim, the payer recoups the payment from the prosthetic clinic. F. 129.

[12] The evidence does show that clinics incur costs associated with MPKs that are not separately reimbursable through L-Codes, including costs associated with the work performed by a clinic's certified prosthetists and administrative costs, and that this affects the margins clinics earn. F. 322-323.

margin on MPKs that they fit on patients with private insurance, but almost always earn some margin on mechanical knees, and that the closeness in margin between MPKs and mechanical knees encourages prosthetists to consider switching to non-MPKs for certain patients. RB at 44-45. Respondent does not, however, point to evidence estimating the average margin from an MPK compared to the average margin from a mechanical knee. *See* RB at 44-45; RFF 433-35. Furthermore, Respondent does not cite to any evidence of prosthetists' considering switching, or actually switching, patients from MPKs to mechanical knees on the basis of the margin that the clinic would earn. RB at 44-45. Moreover, the evidence in this case is contrary to this proposition. The record shows that prosthetists have an ethical obligation to fit each patient with a prosthetic knee that best meets the patient's medical needs, F. 447, and that as long as clinics can fit an MPK on a patient who has a prescription and insurance coverage, without losing money, they will. F. 448-453.

Prosthetists testified that the choice between fitting a patient with an MPK or a mechanical knee (if insurance coverage were available for both products) is a clinical decision and is not based on the relative prices a clinic pays for MPKs and mechanical knees. For instance, Michael Fillauer, who used to be a practicing prosthetist, testified as follows:

> Q. When you were a clinician, did you decide whether to fit your patients in mechanical or microprocessor knees based on – was that a clinical decision, or a price decision?
>
> A. I would like to say that it was mostly a clinical decision. Obviously, funding is a factor. If you can't get the device paid for, you can't fit it. But the goal was always for it to be a clinical decision. F. 448.

In addition, Keith Watson of Fourroux Prosthetics testified as follows:

> Q. If the price of these microprocessor knees increased fifteen hundred dollars, would Fourroux clinicians stop fitting patients with these microprocessor knees?
>
> A. When I listed all the reasons that a clinician might go through and – with a K-3 or K-4 ambulator to develop a plan of care, none of those factors are financial. Clinicians are clinical. They make clinical decisions based on clinical data. So based on the way [you have] asked that question, I would have to say that it's not relevant to the clinical evaluation and clinical recommendations of a clinician. F. 448.

Many prosthetists and clinic owners testified they would not switch patients to mechanical knees even if prices of MPKs were increased by 5 to 10%. F. 449-453. For example, Jeffrey Brandt, the chief executive officer ("CEO") of Ability Prosthetics and Orthotics, testified that his clinic would not move its patients to mechanical knees if the cost of all of the MPKs the clinic currently purchased were to increase by 5%. F. 450. Mr. Brandt explained, "Because clinically we make decisions at Ability about the patient, and so a 5% increase would not have me moving my patients to a non-MPK when they, in fact, needed the safety of an MPK." F. 450. Similarly, Keith Senn, the President of Kentucky and Indiana Operations at the Center for Orthotic and Prosthetic Care, testified that it "would be a disservice to the patients and poor patient care" to threaten to shift COPC's MPK volume to mechanical knees because MPKs are "a much better knee, and if a patient is [an] eligible candidate for one, that is the knee they would prefer and deserve." F. 449.

The evidence shows that although mechanical knees designed for K-3/K-4 patients and MPKs designed for K-3/K-4 patients can be used for the same purpose – as a prosthetic knee for a K-3/K-4 patient – clinics (the purchasers in this case) are not willing to substitute an MPK for a mechanical knee based on an increase in the price of MPKs.

#### c. *Brown Shoe* practical indicia

In addition to interchangeability of use and cross-elasticity of demand, *Brown Shoe* sets forth additional "practical indicia" as guides for defining the appropriate market. Because the Supreme Court "described [the *Brown Shoe*] factors as 'practical indicia' rather than requirements, subsequent cases have found that submarkets can exist even if only some of these factors are present." *Staples*, 970 F. Supp. at 1075 (citations omitted).[13] The *Brown Shoe* indicia in this case point to a distinct relevant product market consisting only of MPKs.

##### i. Product's peculiar characteristics

The use of a microprocessor in an MPK allows the MPK to function, operate, and perform in a way that is different from how a mechanical knee functions, operates, and performs.

[13] *Brown Shoe* factors that are not dispositive in this case are unique production facilities, distinct customers, and specialized vendors.

F. 330. The microprocessor in an MPK controls a user's walking pattern using a series of sensors. F. 103-104, 332. The microprocessor uses sensors to assess what is happening with the knee and makes changes in the function of the knee as a result. F. 103-104, 332, 359-360. The microprocessor reads sensors located throughout the device to help position the knee during a user's gait cycle. F. 103, 332. These adjustments can predict a user's activities and the walking terrain with each step. F. 332.

By contrast, mechanical knees use other mechanisms to control how quickly or easily the hinge swings. F. 96. Mechanical knees are divided into subcategories based on their design and function. F. 98. Mechanical knees that use friction to provide resistance are known as "friction-brake" or "constant friction" mechanical knees. F. 99. A friction-brake or constant friction knee provides a uniform resistance level in both the swing and stance phases of the gait cycle. F. 99. Mechanical knees that use air to regulate the cylinder of the knee are known as "pneumatic" knees. F. 100. The air pressure in the cylinder of a pneumatic mechanical knee regulates the swing of the leg during the swing phase and stabilizes the knee in the stance phase of a user's gait. F. 100. Mechanical knees that use liquids to regulate the cylinder of the knee are known as "hydraulic" or "fluid controlled" knees. F. 101. Similar to the function of the air in a pneumatic knee, the pressure from the liquids in the cylinder of an hydraulic knee regulates the swing and stance phases of a user's gait. F. 101.

Ordinary course of business documents from Ottobock promote the benefits of MPKs over mechanical knees. On its website, Ottobock distinguishes MPKs from mechanical knees as follows: "Microprocessors, on the other hand, provide a more sophisticated method of control to a prosthetic knee. These more complex knee joints are designed to help you walk with a much more stable and efficient gait that more closely resembles a natural walking pattern." F. 331. Ottobock posted to its website a summary of a publication, including the conclusion of the study that, "'. . . there was sufficient evidence to suggest that the C-Leg provided increased efficacy in safety, energy efficiency, and cost effectiveness when compared with other [non-MPKs] for transfemoral amputees.'" F. 338. A presentation sent by Ottobock's executive medical director, Andreas Kannenberg, to a certified prosthetist highlighted several benefits of Ottobock's C-Leg 4 and Compact, compared to mechanical knees, as supported by clinical evidence, including, "improved safety – less stumbles and falls (up to 80%!), improved balance and confidence,"

"improved and faster slope negotiation," "improved and faster negotiation of uneven terrain and obstacles," "improved stair descent," "reduced cognitive demand to walk and improved multi-tasking," and "potential to increase overall mobility/K-Level." F. 339.

Testimony from Ottobock executives further demonstrates that MPKs provide important clinical benefits for patients that mechanical knees do not offer. Dr. Kannenberg testified that the C-Leg, due to its microprocessor, provides greater mobility than a mechanical knee because "the microprocessor control allows a knee to do more activities without the threat of collapsing and causing a fall." F. 336. Additionally, "the resistances that are produced in the knee [are] much more flexible and adaptable to many more activities that you encounter in your daily life than a mechanical control. So when you – when you adjust the mechanical and – mechanical knee, it is usually quite nice for level walking, but as soon as you have to negotiate uneven terrain, slopes and stairs, you're in trouble." F. 336. Scott Schneider, Ottobock's vice president of government, medical affairs, and future development, testified that there is more safety in stance control with a microprocessor knee than with a mechanical knee. "Microprocessors are proven to have stumble recovery, making them very, very safe. . . . [M]icroprocessors [also] allow for more cadence variance, so walking fast or slow, so the computer can adjust to those speed differences. Microprocessors can enable people to have more comfort because [a microprocessor knee has] additional features and benefits [so] that [the user does] not have to overcompensate with their muscular structure." F. 333.

Similarly, ordinary course of business documents from Freedom promote the benefits of MPKs over mechanical knees. Freedom's website includes Plié 3 materials, designed to assist customers with insurance reimbursement, that claim benefits of MPKs over mechanical knees. F. 353. The materials include a "Microprocessor Knee Literature Review," collecting and summarizing clinical research articles and stating that "research has been able to show that the [MPK] user feels more stable on stairs, inclines, and uneven terrain, while reducing the cognitive demand required for walking" and that "the user experiences less stumbles and falls while expressing a higher level of satisfaction and stability with MPKs." F. 353. A 2015 Freedom presentation titled, "Microprocessor Controlled Knees" includes slides titled, "What makes MPC

Knees[14] different?" The listed benefits of MPKs include: increases stability and confidence; reduces cognitive burden because of stumble recovery feature; studies have shown that MPC knees can elevate some user's functional abilities (K-Level) compared to conventional knees; and studies have also shown 88.4% improvement in gait agility, compared to non-MPKs. F. 352. An August 2016 internal Freedom memorandum highlighted the "[k]ey differences between mechanical knee[s] and microprocessor knee[s,]" including improved stability, a smoother and more natural gait, expenditure of less energy, and the ability to walk with variable cadences for MPK users. F. 351. Freedom's CEO at the time of the Acquisition, David Smith, distinguished a mechanical knee from an MPK as follows: "One is rudimentary and one is sophisticated. One doesn't allow mobility and ambulation and one does. One restricts activity or limits your activity, or you want it limited for safety reasons because the patient is incapable. The other one allows it and facilitates it." F. 344. These differences are because "one of them has different componentry and different functionality than the other one." F. 344.

Össur and Endolite, other manufacturers of MPKs, similarly highlight the benefits of microprocessor knees compared to mechanical knees. F. 354-357. Manufacturers of mechanical knees also explain that MPKs have characteristics not found in mechanical knees. F. 358 (College Park) ("[A] microprocessor knee offers infinite adjustment and it thinks for you, whereas, you know, a hydraulic knee is manually set."); F. 360 (WillowWood) ("Microprocessor knees provide additional features and benefits and function that mechanical knees could not."). F. 361 (ST&G) (MPKs provide "stability, safety, and better resistance and adjustments for the patient during gait cycle.").

Prosthetic clinics, the purchasers or customers in this case, believe that MPKs provide important clinical benefits for patients that mechanical knees do not offer. Prosthetists believe that MPKs provide more safety and stability than mechanical knees, leading to fewer stumbles and falls. F. 365-368. As explained by Tracy Ell, owner and chief prosthetist of Mid-Missouri Orthotics and Prosthetics, the inherent stability of microprocessor knees is "far superior" to mechanical knees, and the benefits of MPKs include reducing falls, allowing more variation in walking speed, improving gait patterns and efficiency, and decreasing the wear and tear on a

[14] The term "MPC knee" is used at times in Freedom documents to refer to a microprocessor-controlled knee and means the same thing as an MPK. F. 256 n.57.

patient's body. F. 365. Keith Senn of COPC believes that a "big benefit" of MPKs is "stumble recovery, so there's less falls." F. 365. According to Michael Oros, president and CEO of Scheck & Siress Prosthetics, MPKs provide greater safety to amputees because they are more responsive to sudden movements than mechanical knees because of the microprocessor in the knee. F. 365. Prosthetists believe that MPKs allow patients to more easily traverse everyday environmental barriers, such as curbs, steps, and slopes, as well as walk in crowded areas. F. 365. Mark Ford, president and managing partner of Prosthetic and Orthotic Associates, has found that an MPK "can accommodate variable cadence, it can accommodate different types of terrain, it can accommodate ramps, steps, much more [quickly] and more responsively than a mechanical knee." F. 366. Prosthetists believe that MPK users demonstrate a much better gait and are better able to walk with variable cadence, compared with users of mechanical knees. F. 367. Keith Senn of COPC explained that MPK users "are able to have a much better gait, which means to walk better, as well as amputees go, to be able to improve their gait." F. 367. Michael Oros of Scheck & Siress Prosthetics has found that MPKs respond to variable cadence much faster than mechanical knees, make adjustments more rapidly than mechanical knees, provide a higher level of stability than mechanical knees, and provide benefits walking down slopes relative to mechanical knees. F. 367.

Furthermore, insurers, including Medicare and private payers, view MPKs as having distinct functions from mechanical knees. Under the L-Code system, created by CMS, each L-Code describes the function of each prosthetic device component and establishes an allowed reimbursement amount for each L-Code. F. 115-117, 438-439. Microprocessor knees and mechanical knees qualify for different sets of L-Codes, such that the aggregate reimbursement amounts from Medicare are significantly different for the two classes of products. F. 440. L-Code 5856 covers "endoskeletal knee-shin system, microprocessor control feature, [and] swing and stance phase[.]" F. 442. L-Code 5856 is used for the C-Leg 4 MPK, Plié 3 MPK, Rheo 3 MPK and Orion MPK, but is not used for any mechanical knees. F. 443-444. Mechanical knees do not qualify for reimbursement under L-Code 5856. F. 444-445.

Peer-reviewed research articles have found increased safety and performance of MPKs compared to mechanical knees. F. 369. For example, a 2017 report by the RAND Corporation titled, *Economic Value of Advanced Transfemoral Prosthetics* reviewed existing clinical research

and utilized a simulation model "to assess the differential clinical outcomes and costs of microprocessor-controlled knees compared with [non-MPKs]." F. 381. The RAND Report concluded: "In summary, the existing published literature shows that among transfemoral amputees, MPKs are superior to [non-]MPKs in improving parameters of physical function, such as walking speed, gait symmetry, and obstacle assessments. Those improvements lead to fewer falls and lower incidences of osteoarthritis in the intact limb." F. 387. Other clinical research has found that, as compared to mechanical knee users, microprocessor knee users have significant improvements in gait and balance, have increased ability to walk on difficult terrain, experienced fewer falls, engaged in more physical activity, and experienced overall improvement in quality of life. F. 390-393.

Respondent argues that, because most MPK studies were based on the C-Leg, the clinical research does not show that the Plié offers superior functionality and performance over mechanical knees. RB at 38-39. Although most clinical research has been based on the C-Leg, the clinical studies have been used widely throughout the industry, including by Freedom, to promote the benefits of MPKs over mechanical knees. F. 204, 338, 343, 353; *see also* F. 356. Furthermore, the FAST K2 study, which was conducted by the Mayo Clinic, but has not yet been published, [redacted] *See also* F. 378-380. Clinical studies based on the C-Leg are used throughout

the industry to promote the benefits of MPKs generally over mechanical knees and the FAST K2 study specifically tested the Plié 3. Therefore, Respondent's argument that clinical studies supporting the conclusion that MPKs have peculiar characteristics as compared to mechanical knees apply only to the C-Leg, and do not apply to the Plié 3, is not persuasive.

Respondent also argues that the Plié 3 functions differently from other MPKs because the microprocessor in the Plié 3 does not provide full control throughout the swing and stance phases. RB at 37-39. The evidence at trial establishes that the microprocessor in the Plié 3 switches the knee between a fixed stance phase resistance and a fixed swing phase resistance, but does not vary the resistance throughout the gait cycle. F. 264. The microprocessor in the Plié 3 is always on and will control the knee when there is some kind of abnormality that the sensors pick up. F. 265. If there is movement when the user is transitioning in a specific way from stance to swing, the microprocessor will put the knee into a safe stance mode thereby making real-time adjustments that help reduce falls in patients. F. 265. The evidence at trial also establishes that Freedom markets the Plié as a swing and stance MPK (F. 257), that Freedom recommends that customers seek reimbursement for the Plié as a swing and stance MPK under L-Code 5856 (F. 258), and that the Plié is reimbursed as a swing and stance MPK under L-Code 5856 (F. 259). In addition, the evidence establishes that other manufacturers and prosthetists consider the Plié to be an MPK. F. 267-269. Based on the foregoing, Respondent has failed to demonstrate that the asserted functional differences of the Plié are so significant that the "peculiar characteristics" distinguishing MPKs from mechanical knees do not apply to the Plié 3.

For the above reasons, the "peculiar characteristics" factor points to a distinct relevant product market consisting only of MPKs.

#### ii. Industry recognition of the submarket as a separate economic entity

Ottobock, Freedom, other MPK manufacturers, and mechanical knee manufacturers all view the market for MPKs as a distinct market from mechanical knees. "The 'industry or public recognition of the submarket as a separate economic' unit matters because we assume that economic actors usually have accurate perceptions of economic realities." *Rothery Storage*, 792 F.2d at 218-19 n.4.

Ottobock analyzes MPKs as a distinct market from mechanical knees in its ordinary course of business documents. In numerous documents, Ottobock estimates its market share only in relation to other MPKs: Freedom's Plié, Össur's Rheo, and Endolite's Orion. F. 411-416. Ottobock tracks sales of its own MPKs separately from sales of Ottobock's mechanical knees. F. 417. In its analysis of competition, Ottobock compares the C-Leg 4 only to the Plié 3, the Orion 2, and the Rheo 3 MPKs. F. 418-421. For example, in materials drafted for Ottobock's sales force in February 2015 in preparation for the launch of the C-Leg 4, Ottobock compared the C-Leg 4 only to the Plié 3, Orion 2, and Rheo 3. F. 419. According to Scott Schneider, Ottobock's vice president of government, medical affairs, and future development, the launch preparation materials referred only to those competitors because they are the "primary competitors" for the C-Leg 4 in the United States. F. 419.

Freedom also analyzes MPKs as a distinct market from mechanical knees in its ordinary course of business documents, examining the market shares for the Plié only in relation to shares of other MPKs (C-Leg, Rheo, and Orion), and views the Plié as competing in that market. F. 422-426. For instance, Freedom's Plié 3 Selling Guide includes a "benefits matrix," which compares the functionality, adaptability, safety, versatility, and other factors of the Plié to other MPKs. F. 425.

Other MPK manufacturers also view MPKs as a distinct market. F. 427-430. From the perspective of Össur's executive vice president of research and development, Kim Peter Vivianne De Roy, MPKs and mechanical knees "don't really compete for the same population." F. 427. Mr. De Roy described the patient population for MPKs as "people with access to certain funds," and believes that if patients "have access to a microprocessor knee, they'll buy a microprocessor knee." F. 427. In Mr. De Roy's view, patients who do not have access to an MPK will buy a mechanical knee. F. 427. Endolite's executive chairman, Stephen Blatchford, testified that Endolite "only look[s] at other MPKs" and not at mechanical knees when analyzing competition for the Orion 3 because "the price point is completely different" and "customers don't tend to think of [the two types of knees] in the same way." F. 430.

Similarly, mechanical knee manufacturers also view MPKs as competing in a different market. For example, William Carver, the president and chief operating officer of College Park, a mechanical knee manufacturer, does not believe that its hydraulic mechanical knee in development will compete for patients who qualify for reimbursement of an MPK. F. 432. He elaborated that "if you were evaluating a microprocessor knee and felt that you could get payment for it, a prosthetist wouldn't order one of our hydraulic knees to compare in that category." F. 432. Michael Fillauer, of Fillauer Companies, believes that its mechanical knees do not compete with microprocessor knees. F. 436. Instead, the company "always, from a marketing and sales standpoint, felt like we would compete with mechanical knees against other mechanical knees." F. 436.

For the above reasons, the "industry recognition" factor points to a distinct relevant product market consisting only of MPKs.

**iii. Distinct prices and sensitivity to price changes**

Prosthetic clinics pay significantly more for microprocessor knees than for mechanical knees. F. 394. A microprocessor knee costs on average anywhere from four to eleven times more than a mechanical knee. F. 395. For example Hanger, the largest network of orthotic and prosthetic clinics in the United States, pays between [redacted] for MPKs and between [redacted] for mechanical knees. F. 395. *See also* F. 395 (Sprinkle Prosthetics pays on average [redacted] for an MPK and [redacted] on average for a mechanical knee; COPC pays between [redacted] for an MPK and between [redacted] [redacted] for a mechanical knee; North Bay clinic's average price for an MPK is around [redacted] while mechanical knees range from [redacted] Empire pays [redacted] on average for MPKs and between [redacted] for mechanical knees). Dr. Fiona Scott Morton, Complaint Counsel's expert witness, estimated that the average sales price of an MPK in 2017 was [redacted] and that the average sales price of a mechanical knee from manufacturers that sell both MPKs and mechanical knees was approximately [redacted] F. 398. Furthermore, prosthetic clinics are reimbursed by payers at much higher rates for MPKs than for mechanical knees. *See, e.g.*, F. 401 (prosthetic clinic POA is reimbursed "[f]our to five times" higher for fitting an MPK over a mechanical knee); F. 402 (United Healthcare reimburses, on average,

typically thousands of dollars more for an MPK than a mechanical knee); F. 403 (prosthetic manufacturers agree that the reimbursement by both private payers and Medicare is substantially greater for MPKs than it is for mechanical knees). Dr. David Argue, Respondent's expert witness, estimated that the Medicare reimbursement rate for MPKs ranged from approximately $26,000 to $35,000, while the Medicare reimbursement amount for non-MPKs was $5,000 to $8,000. F. 404. Respondent's argument that the relevant economic metric that prosthetists examine is margin, not price, discussed above, is immaterial and does not undermine the evidence of the stark differences in both price and reimbursement of MPKs as compared to mechanical knees ("distinct pricing"), all of which supports a finding that MPKs are in a different product market than mechanical knees. *See Brown Shoe,* 370 U.S. at 325 (noting that "distinct prices" may be considered in assessing the boundaries of a market).

In evaluating the "distinct pricing" and the "sensitivity to price changes" factors, evidence of the development of "pricing and business strategy with [a particular] market and those competitors in mind" is also "strong evidence" of the relevant product market. *H&R Block*, 833 F. Supp. 2d at 51, 53. *See*, *e.g.*, *Swedish Match*, 131 F. Supp. 2d at 165 (holding that the product market for loose leaf tobacco did not include moist snuff where, among other factors, "loose leaf pricing is determined upon the basis of competition with other loose leaf products, not moist snuff"); *Aetna*, 240 F. Supp. 3d at 24-25 (noting that evidence that Aetna does not assess the price of Medicare Advantage plans when it sets the price of MedSupp plans indicates that the two types of plans are not in the same relevant product market); *FTC v. Coca Cola Co.*, 641 F. Supp. 1128, 1132-33 (D.D.C. 1986) (stating that evidence that concentrate companies "make pricing and marketing decisions based primarily on comparisons with rival carbonated soft drink products, with little if any concern about possible competition from other beverages" shows that carbonated soft drinks is a relevant product market). In the instant case, as summarized below, the evidence proves that Ottobock and Freedom, as well as other MPK manufacturers, "make pricing and marketing decisions based primarily on comparisons with rival [MPKs], with little if any concern about possible competition" from mechanical knees. *Coca Cola*, 641 F. Supp. at 1133.

In setting the price of its C-Leg 4, Ottobock looked at the prices and reimbursement rates of only three other products, all of which are MPKs – Freedom's Plié 3, Össur's Rheo 3, and

Endolite's Orion. F. 405. Similarly, when setting the price of the Plié 3, Freedom looks at the pricing of other MPKs and does not look to pricing of mechanical knees. F. 406. As explained by Freedom's CEO at the time of the Acquisition, David Smith, Freedom's Plié 3 and mechanical knees are "completely different products [at] completely different price points." F. 344. Össur and Endolite also do not look at the prices of mechanical knees when setting the prices of their MPKs. F. 407-408. Össur does not consider the prices of MPKs when setting the prices for its K-3 mechanical knees because Össur believes MPKs "play in a different segment." F. 431.

Furthermore, various clinics reported that prices of MPKs do not respond to price changes of mechanical knees and that clinics are unable to use prices of mechanical knees when negotiating with manufacturers for the price of MPKs. F. 409-410.

For the above reasons, the "distinct prices" and "sensitivity to price changes" factors point to a distinct relevant product market consisting only of MPKs.

**d. Economic evidence**

In addition to the *Brown Shoe* practical indicia, courts and the Commission rely on the approach set forth in the Merger Guidelines to define the relevant product market – the hypothetical monopolist test. *See, e.g.*, *Staples*, 190 F. Supp. 3d at 121-22; *Sysco*, 113 F. Supp. 3d at 33-34; *ProMedica*, 2012 FTC LEXIS 293, at *40-41 (citations omitted); *Polypore*, 2010 WL 9549988 at *11, *15. That test asks whether a hypothetical monopolist of a particular group of substitute products could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP"), typically five percent, on at least one of the products in the candidate market, including at least one product sold by one of the merging firms. Merger Guidelines §§ 4.1.1-4.1.3. "If enough consumers are able to substitute away from the hypothetical monopolist's product to another product and thereby make a price increase unprofitable, then the relevant market cannot include only the monopolist's product and must also include the substitute goods. On the other hand, if the hypothetical monopolist could profitably raise price by a small amount, even with the loss of some customers, then economists consider the monopolist's product to constitute the relevant market." *Sysco*, 113 F. Supp. 3d at 33.

Complaint Counsel's economic expert witness, Dr. Fiona Scott Morton, conducted a critical loss analysis to test whether a hypothetical monopolist of Ottobock's MPKs and Freedom's Plié could profitably impose a SSNIP on either Freedom's Plié or one of Ottobock's MPKs. F. 457. *See* Merger Guidelines § 4.1.3 ("Critical loss analysis asks whether imposing at least a SSNIP on one or more products in a candidate market would raise or lower the hypothetical monopolist's profits.").

To perform the critical loss test, Dr. Scott Morton used as inputs estimates of margins and diversion[15] from Freedom's Plié to Ottobock's MPKs derived from Freedom's and Ottobock's internal documents. F. 458. Dr. Scott Morton calculated the diversion rates at which a 10% SSNIP would be unprofitable and found that because those rates were less than the [redacted] diversion rate projected by Ottobock of sales of the Plié that would be converted to the C-Leg, should the Plié be discontinued (F. 465), imposing a SSNIP on one of the merged firm's MPKs would be profitable. F. 466, 470. From this, she concluded that a candidate market consisting of only Ottobock's MPKs and Freedom's Plié 3 constituted a relevant product market. F. 466, 470.

Dr. Scott Morton next opined that if a hypothetical monopolist could profitably raise the price on the Plié or an Ottobock MPK if it owned only those products, then it would be profitable for a hypothetical monopolist to impose a SSNIP in the wider market of MPKs manufactured by Össur, Endolite, Nabtesco, and DAW as well. F. 471. Thus, she concluded that if the narrow candidate market of Ottobock's MPKs and Freedom's Plié 3 is a relevant antitrust market, then "a wider market consisting of all microprocessor knees sold in the United States is also a relevant market." F. 471.

Respondent argues that Dr. Scott Morton's critical loss analysis should be rejected. RRB at 30-33. In support of this argument, Respondent asserts that the documents upon which she relied to derive the margin and diversion rate inputs to her critical loss analysis are unreliable. RRB at 31. This criticism is unavailing. The margin rate Dr. Scott Morton used is comparable to the rate used by Respondent's expert, Dr. Argue. F. 460. The diversion rate

[15] In the context of the critical loss analysis, the margin indicates how profitable a product is and diversion is the percentage of departing customers that go to a particular place. F. 460-461. In the example of diversion from Plié to C-Leg, if one were to raise the price of a Plié and 100 customers leave and 50 of those customers then buy a C-Leg, the diversion from Plié to C-Leg is 50%. F. 461.

Dr. Scott Morton used was derived from Ottobock's own diversion estimates, which were part of an August 2017 Ottobock due diligence summary prepared by the head of corporate strategy and mergers and acquisitions at Ottobock in connection with the purchase of Freedom by Ottobock. F. 458. As Dr. Scott Morton testified, she relied on the document because, as "a board level document," it could be expected "that the people providing the information [for] this document took some pains to make sure it was correct and accurate." F. 459.

Respondent next criticizes Dr. Scott Morton's methodology for concluding first that the Ottobock MPKs and the Plié constitute their own relevant product market and then adding in additional MPKs in the candidate market to conclude that all MPKs sold in the United States is a relevant market. RRB at 32. Dr. Scott Morton's application of the hypothetical monopolist test adhered to the Merger Guidelines. Under the Merger Guidelines, it is appropriate to apply the hypothetical monopolist test first on a candidate market comprised of at least one product of each merging firm. Merger Guidelines §§ 4.1.1-4.1.3. The test "is iterative, meaning it should be repeated with ever-larger candidates until it identifies a [relevant market]," but once a candidate set of products passes the test, the analysis can stop. *FTC v. Advocate Health Care Network*, 841 F.3d 460, 468 (7th Cir. 2016) (internal citation omitted). If enough customers would switch to products outside the candidate market in the face of a SSNIP to render the price increase unprofitable, then the candidate market is too narrow. Merger Guidelines §§ 4.1.1-4.1.3. In that case, additional products should be added to the candidate market until a hypothetical monopolist could profitably impose a SSNIP – at which point, a relevant antitrust product market has been defined. *Id.* Here, no more products need be added to Dr. Scott Morton's candidate market because her analysis shows that a hypothetical monopolist could profitably impose a SSNIP on clinics if it owned only Freedom's Plié and Ottobock's MPKs.[16] F. 471.

Respondent, through its economic expert witness, Dr. David Argue, asserts that the hypothetical monopolist test actually supports a relevant product market broader than MPKs that also includes what Respondent refers to as "sophisticated non-MPKs." *See* RB at 46-50. It is

[16] This methodology does not unfairly bias the presumption of likely anticompetitive effects that are drawn from market shares and market concentration in this case because, as discussed in detail in II.D.1 *infra*, in reaching her conclusions regarding market shares and concentration levels, Dr. Scott Morton analyzed two broader relevant markets: (1) the sale of all MPKs to United States clinics (F. 478); and (2) a market containing only Ottobock's C-Leg, Freedom's Plié, Össur's Rheo, Endolite's Orion, each of DAW's MPKs, and Nabtesco's Allux (F. 482).

not necessary to analyze Dr. Argue's application of the hypothetical monopolist test because, as analyzed in section II.D.1 *infra*, even the broader relevant market advanced by Respondent is highly concentrated, and the increase in the Herfindahl-Hirschmann Index ("HHI") level in that proposed market is high enough to create a presumption of anticompetitive effects.

Dr. Scott Morton's conclusion that a hypothetical monopolist controlling all MPKs would be able to profitably impose a SSNIP on clinics for either Freedom's Plié or one of Ottobock's MPKs is consistent with the evidence in this case that the choice between fitting a patient with an MPK or a mechanical knee (if insurance coverage were available for both products) is a clinical decision and is not based on the relative prices a clinic pays for MPKs and mechanical knees. *See* section II.C.2.b. If a hypothetical monopolist tried to impose a SSNIP on one of Respondent's MPKs, it would be profitable to do so, because clinics would not switch to mechanical knees to defeat it. *See* section II.C.2.b. Based on the evidence in this case, mechanical knees are properly excluded from the relevant product market.

#### 3. Conclusion

For all the reasons set forth above, the relevant market is the sale of MPKs to prosthetic clinics in the United States. Accordingly, the analysis now turns to the likely anticompetitive effects of the Acquisition in this market.

### D. Reasonable Likelihood of Anticompetitive Effects

#### 1. Market shares and concentration

After determining the relevant market, the next step of the analysis is to "consider the likely effects of the proposed acquisition on competition within that market." *Swedish Match*, 131 F. Supp. 2d at 166. "[T]he government must show that the merger would produce 'a firm controlling an undue percentage share of the relevant market, and [would] result[] in a significant increase in the concentration of firms in that market." *Heinz*, 246 F.3d at 715 (citing *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 363 (1963)). "Such a showing establishes a 'presumption' that the merger will substantially lessen competition." *Heinz*, 246 F.3d at 715 (citing *Baker Hughes*, 908 F.2d at 982).

"Market concentration . . . is often measured by the Herfindahl-Hirschmann Index (HHI)." *Heinz*, 246 F.3d at 716; *Swedish Match*, 131 F. Supp. 2d at 166 n.11. As the court explained in *Swedish Match*:

> The HHI calculates market power [by] summing the squares of the individual market shares of all the firms in the market. The HHI takes into account the relative size and distribution of the firms in a market, increasing both as the number of firms in the market decreases and as the disparity in size among those firms increases.

131 F. Supp. 2d at 166 n.11.

Complaint Counsel's economic expert witness, Dr. Fiona Scott Morton, calculated market shares and concentration using sales data provided by the six providers of microprocessor knees in the United States – Ottobock, Freedom, Össur, Endolite, Nabtesco, and DAW. F. 472. Dr. Scott Morton performed four analyses to calculate market shares. She calculated market shares based on a market consisting of all MPKs sold in the United States ("all MPK market").[17] F. 478. In addition, she calculated market shares for a narrower market that excluded lower-end MPKs and higher-end MPKs ("narrower MPK market").[18] F. 478, 482. For each of these markets, although she concluded that it was more appropriate to calculate market shares by revenue (as opposed to units sold) (F. 474-476), Dr. Scott Morton calculated market shares both ways - based on revenue and based on unit sales. F. 479-480, 483-484. The results of her calculations are set forth below:

- In a market of all MPKs, using revenues in the United States market in 2017, market shares and concentration are as follows: Ottobock [redacted] Freedom [redacted] Össur [redacted] Endolite [redacted] DAW [redacted] and Nabtesco [redacted] The Acquisition would increase the HHI by 1,522 points, to 6,767 points. F. 479.

- In a market of all MPKs, using units sold in the United States market in 2017, market shares and concentration are as follows: Ottobock [redacted] Freedom [redacted] Össur [redacted] Endolite [redacted] DAW

[17] Dr. Scott Morton's "all MPK market" includes sales in the United States of all Ottobock MPKs, Freedom's Plié, Endolite's Orion, all Össur MPKs, all DAW MPKs, and all Nabtesco MPKs. F. 478.

[18] Dr. Scott Morton's narrower market excluded Ottobock's lower-end Kenevo and Compact MPKs, Ottobock's higher-end Genium and X3 MPKs, and Össur's XC and Power Knee. F. 482.

[redacted] and Nabtesco [redacted] The Acquisition would increase the HHI by 1,799 points, to 6,813 points. F. 480.

- In a narrower MPK market, using revenues in the United States market in 2017, market shares and concentration are as follows: Ottobock [redacted] Freedom [redacted] Össur [redacted] Endolite [redacted] DAW [redacted] and Nabtesco [redacted] The Acquisition would increase the HHI by 1,949 points, to 6,240 points. F. 483.

- In a narrower MPK market, using units sold in the United States market in 2017, market shares and concentration are as follows: Ottobock [redacted] Freedom [redacted] Össur [redacted] Endolite [redacted] DAW [redacted] and Nabtesco [redacted] The Acquisition would increase the HHI by 2,062 points, to 6,542 points. F. 484.

The market shares calculated by Dr. Scott Morton are consistent with Respondent's market share estimates in its ordinary course of business documents. F. 411-416, 423. *E.g.*, F. 415 (In conducting due diligence on Freedom, Ottobock estimated market shares on August 29, 2017 and estimated that, in 2016, based on United States sales, its C-Leg had a [redacted] market share and Freedom's Plié had a [redacted] market share.).

Respondent argues that Dr. Scott Morton erroneously included lower-end MPKs and higher-end MPKs[19] in her market share calculations and that by using revenue data instead of unit sales data to calculate market shares, she biased her market share calculations in favor of higher concentration. RB at 53-54. This criticism is unfounded. As summarized above, Dr. Scott Morton calculated four alternative scenarios. Even in her narrower market, using unit sales data, the statistics in this case far exceed the thresholds for presumptive illegality provided in the Merger Guidelines. *See* Merger Guidelines § 5.3.

The Merger Guidelines consider markets with an HHI above 2500 to be "highly concentrated," and state that "[m]ergers resulting in highly concentrated markets that involve an increase in the HHI of more than 200 points will be presumed to be likely to enhance market

[19] Respondent argues that lower-end MPKs that are designed for K-2 patients (Ottobock's Compact and Kenevo) should not be included in the relevant market because they do not compete against knees designed for K-3/K-4 patients and that higher-end MPKs (Ottobock's X3 and Genium and Össur's Rheo XC and Power Knee) should not be included in the relevant market because they are significantly more expensive than other MPKs and Medicare and private payers typically do not reimburse clinics for these MPKs. RB at 53-54. Respondent further argues that because Ottobock has comparatively high sales in these segments and because the higher-end MPKs are significantly more expensive, Dr. Scott Morton's market share analysis is erroneous. RB at 53.

power." Merger Guidelines § 5.3; *Heinz*, 246 F.3d at 715 (citing *Baker Hughes*, 908 F.2d at 982) (noting that a significant increase in market concentration "establishes a 'presumption' that the merger will substantially lessen competition"). Dr. Scott Morton's calculations show that, regardless of whether market shares are calculated in units sold or dollar revenue, and regardless of whether the market analyzed is all MPKs or the narrower market excluding low-end and high-end MPKs, the Acquisition would increase the HHI by at least 1500 points, to a level of at least 6000 points. These HHI levels are high enough to create a presumption of anticompetitive effects. *See, e.g., Heinz*, 246 F.3d at 716 (holding that a merger that would have increased the HHI by 510 points from 4775 created presumption of anticompetitive effects by a "wide margin"); *Swedish Match,* 131 F. Supp. 2d at 166-67 (60% market share and 4733 HHI established presumption).

Furthermore, the market share analysis conducted by Respondent's economic expert witness, Dr. David Argue, also shows that the Acquisition would result in a highly concentrated market under the Merger Guidelines. Dr. Argue opined that the relevant product market is prosthetic knees for K-3 and K-4 mobility levels (including non-MPKs and excluding certain high-end MPKs sold as part of a microprocessor-controlled integrated leg system[20]) and calculated the shares of participants in that proposed market based on units of production. F. 486. Under Dr. Argue's proposed market, post-Acquisition, Ottobock and Freedom would have a combined market share of over 50% and the Acquisition would increase the HHI by 599 points to 4359 points. F. 486. Thus, even using Respondent's expert witness' market and market share calculations, the post-Acquisition HHI level in this case of 4359 points is well above 2500 points, which demonstrates a highly concentrated market, and the increase in the HHI of at least 599 points is much greater than an increase of 200 points, which is high enough to create a presumption of anticompetitive effects. *See H&R Block*, 833 F. Supp. 2d at 72.

Accordingly, based on the foregoing, Complaint Counsel has established a presumption that the effect of the Acquisition may be to substantially lessen competition. In the instant case, Complaint Counsel further relies on additional evidence to support its prima facie burden of proving a reasonable probability of anticompetitive effects, as analyzed below.

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[20] An integrated leg system combines a microprocessor-controlled knee with a microprocessor-controlled ankle. F. 310.

### 2. Unilateral effects theory

A plaintiff can bolster a prima facie case based on a market concentration presumption by adducing evidence showing that anticompetitive unilateral or coordinated effects are likely. *Polypore*, 2010 WL 9549988, at *9 (citing *Heinz*, 246 F.3d at 717). In the instant case, Complaint Counsel relies on the theory of unilateral effects. *See* CCB at 59-63.

The Merger Guidelines distinguish between unilateral effects in markets for homogenous products and unilateral effects in markets with differentiated products. *ProMedica*, 749 F.3d at 568-69; *see* Merger Guidelines § 6.1. "Homogeneous products are indistinguishable from each other – oil, corn, coal – whereas differentiated products are similar enough to compete in a relevant market, but different enough that some customers prefer one product over another." *ProMedica*, 749 F.3d at 569. Complaint Counsel relies at least in part on the differentiated products theory set forth in section 6.1 of the Merger Guidelines. CCB at 61-62; PX06001A (Scott Morton Expert Report at 118-19 ¶ 155). Respondent also takes the position that MPKs are differentiated products. RB at 2, 26; Argue, Tr. 6285.

"A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above the pre-merger level." Merger Guidelines § 6.1. The Merger Guidelines explain: "Some of the sales lost due to the price rise will merely be diverted to the product of the merger partner and, depending on relative margins, capturing such sales loss through merger may make the price increase profitable even though it would not have been profitable prior to the merger." *Id*.

"Mergers that eliminate head-to-head competition between close competitors often result in a lessening of competition." *Aetna*, 240 F. Supp. 3d at 43 (quoting *FTC v. Staples, Inc.*, 190 F. Supp. 3d. 100, 131 (D.D.C. 2016)). *See also Sysco*, 113 F. Supp. 3d at 61 (same) (collecting cases); *Swedish Match*, 131 F. Supp. 2d at 169 ("[A] unilateral price increase . . . is likely after the acquisition because it will eliminate one of Swedish Match's primary direct competitors."); Merger Guidelines § 6 ("The elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition."). To establish a reasonable likelihood of unilateral effects, it is not necessary for the merging products to be each

other's closest competitor. *ProMedica*, 749 F.3d at 569; *see also H&R Block*, 833 F. Supp. 2d at 83 (holding that the fact that another product "may be the closest competitor" to a merging product "does not necessarily prevent a finding" that unilateral effects are likely (citing Areeda & Hovenkamp, ¶ 914, 77-80 (explaining that the merging parties need not be the closest rivals for there to be unilateral anticompetitive effects) and Commentary on the Horizontal Merger Guidelines (2006) at 28 ("A merger may produce significant unilateral effects even though a non-merging product is the 'closest' substitute for every merging product . . .")).

"The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects. Unilateral price effects are greater, the more the buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice." Merger Guidelines § 6.1. "For a merger to raise concerns about unilateral effects, however, not every consumer in the relevant market must regard the products of the merging firms as her top two choices." *ProMedica*, 749 F.3d at 569. It is sufficient that "a significant fraction of the customers purchasing that product view products formerly sold by the other merging firm as their next-best choice," and the "significant fraction . . . need not approach a majority." *ProMedica*, 749 F.3d at 569 (quoting Merger Guidelines § 6.1 at 20-21).

In addition, "[a] merger between two competing sellers prevents buyers from playing those sellers off against each other in negotiations. This alone can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it, and less favorable to the buyer, than the merging firms would have offered separately absent the merger." Merger Guidelines § 6.2. Furthermore, "[a]dverse unilateral price effects can arise when the merger gives the merged entity an incentive to raise the price of a product previously sold by one merging firm and thereby divert sales to products previously sold by the other merging firm, boosting the profits on the latter products." Merger Guidelines § 6.1.

### 3. Direct competition between C-Leg and Plié

Complaint Counsel asserts that, prior to the Acquisition, Ottobock and Freedom competed vigorously "head-to-head" for MPK sales, which benefitted clinics and their patients through lower prices and higher-quality products and services. CCB at 63-74. Respondent contends that the evidence fails to prove that Ottobock and Freedom are close competitors, due

to asserted differences between the C-Leg 4 and the Plié 3 in functionality, quality, and price. RB at 57-70.

**a. Clinic preferences**

The facts, detailed in section III.D.2.b of the Findings of Fact and summarized below, support the conclusion that, for a significant fraction of clinic customers, C-Leg 4 and Plié 3 are the top two MPK choices. For Hanger, the largest United States clinic (F. 42), the C-Leg 4 is the most widely used MPK, followed by the Plié 3. F. 500-501, 503. In 2017, approximately [redacted] of the MPKs fitted by Hanger were Ottobock's C-Leg, followed by [redacted] Pliés. F. 499. According to Vinit Asar, CEO of Hanger, these two MPKs are "pretty equivalent" in terms of functionality and patient satisfaction. F. 504. Another clinic, Center for Orthotic and Prosthetic Care ("COPC") purchased [redacted] of its MPKs from Ottobock or Freedom in 2017, with the majority from Freedom and only [redacted] from Ottobock. F. 508. For most uses, COPC prosthetists like and are satisfied with both knees, but prefer the functionalities of the Freedom MPK, particularly for K-3 amputees. F. 509-510, 512. Mid-Missouri Orthotics and Prosthetics ("Mid-Missouri O&P") also generally purchases its MPKs from Ottobock and Freedom, because both manufacturers "have clearly defined themselves as providing and servicing a better product" for patients and present "similar componentry." F. 537-538. C-Legs and Pliés are also the two preferred MPKs for Prosthetic and Orthotic Associates' ("POA") clinicians, although POA has bought few Pliés in recent years. F. 542, 545.

Clinic witnesses were not uniform in preferring C-Legs and Pliés as the top two MPK choices. [redacted] percent of MPK purchases by Scheck & Siress ("S&S") are approximately [redacted] between Ottobock and Össur. F. 525. Most of S&S' Ottobock MPK purchases are C-Legs. F. 525. The remaining [redacted] of S&S' MPK purchases are of the Plié, the Orion, and the Allux. F. 525. The vast majority of MPKs purchased by Scott Sabolich Prosthetic & Research ("SSPR") are C-Legs, followed by the Össur Rheo 3; and SSPR considers the Rheo 3 to be the closest substitute for a C-Leg 4. F. 531-532. However, the totality of the evidence supports the conclusion that, for a significant fraction of clinic customers, C-Leg and Plié are the top two MPK choices. *See also* F. 491 (For United Healthcare, the most common microprocessor knee pre-authorization requests are for the Ottobock C-Leg 4 and the

Freedom Plié 3. United Healthcare would not include Össur in the category of most common MPKs submitted to United Healthcare for pre-authorization.).

In addition, clinics have experienced Ottobock and Freedom directly competing for their MPK purchases, and this competition has enabled clinics to negotiate lower pricing. Clinics generally negotiate MPK prices with MPK manufacturers on an annual basis during contract renewal negotiations. F. 315. A clinic has greater bargaining leverage in negotiations with an MPK supplier if it can credibly threaten to switch some portion of its purchases to another MPK. F. 495. Clinic customers will use a competitor's MPK prices to negotiate for lower prices. F. 496. Moreover, customers use the presence of Freedom to negotiate lower prices from Ottobock. F. 497. For example, Tracy Ell, the owner and chief prosthetist at Mid-Missouri O&P, testified that, in competing for Mid-Missouri O&P's business, Ottobock and Freedom have both offered discounts and Ottobock has matched Freedom's MPK prices to Mid-Missouri O&P. F. 538. Similarly, because POA clinicians are comfortable with either the C-Leg or Plié option, POA has been able, in negotiations with Ottobock, to rely on the option of purchasing Pliés "to get better pricing on the C-Leg 4." F. 547-548. Ottobock also competes with Freedom for sales of MPKs to Jonesboro Prosthetic & Orthotic Laboratory ("Jonesboro O&P"), including on price, and, as a result of this competition, Jonesboro O&P has been able to obtain "relatively competitive pricing structures from both manufacturers." F. 552. *See also* F. 507, 513-514, 521 (Increased purchases of Plié 3 by COPC resulted in COPC's obtaining a greater discount from Ottobock.); F. 557 (The price paid by Ability Prosthetics & Orthotics for the C-Leg has gone down significantly in the past six or seven years, in part due to competition from the Plié.).

Clinic customers have also observed Freedom and Ottobock competing over the years on the basis of product innovation in MPK features, including water resistance features and processor speeds. F. 505-507, 540-541, 550, 552, 555, 557. As Mr. Ell of Mid-Missouri O&P explained, "Generally, if you have a design of a component and their competitor exceeds the design by some characteristic, then it's only common nature to evolve your product, as in the C-Leg 1 through 4 and the Plié 1, 2 and 3." F. 541. Rob Yates of Jonesboro O&P has observed that "over time the [C-Leg and Plié] products have become better," "more reliable [and] more feature-rich." F. 555.

As noted above, Respondent argues that Ottobock and Freedom are not close competitors in the MPK market, based on asserted functional, quality, and price differences between the C-Leg and the Plié. RB at 58-65. Respondent refers to Össur as Ottobock's "closest competitor" and refers to Endolite, Nabtesco, and DAW as "Freedom's closest competitors." RB at 65; *see also* RFF IV.B.5 (asserting that Ottobock's C-Leg competes most closely with Össur's Rheo with respect to functionality, quality, and reliability). However, as set forth above, it is not necessary for the merging products to be each other's closest competitor in order for the merger to present a reasonable likelihood of unilateral effects. *ProMedica*, 749 F.3d at 569; *H&R Block*, 833 F. Supp. 2d at 83. Furthermore, Respondent's argument ignores testimony from clinic customers that, in their view, C-Leg 4 and Plié 3 present "similar componentry," F. 538, are based on "similar platforms," F. 543, and that, for most patients, C-Leg and Plié are "functionally similar." F. 554.

The evidence demonstrates that, regardless of the asserted differences between the C-Leg 4 and the Plié 3, from the perspective and experience of a significant fraction of clinic customers, both knees are acceptable, C-Legs and Pliés are their top two choices, and Freedom's presence as a competitor has enabled clinics to increase their bargaining leverage and negotiate lower prices. This evidence weighs in favor of concluding that there is direct competition between Ottobock's C-Leg and Freedom's Plié for purposes of determining whether Ottobock's acquisition of Freedom presents a reasonable likelihood of unilateral effects.[21]

**b. Competitive responses between Ottobock and Freedom**

In addition, as detailed in section III.D.2.c-f of the Findings of Fact and summarized below, there is a substantial history of Ottobock and Freedom responding competitively to each

[21] Respondent asserts that the primary reason clinicians select the Plié is because it is less expensive and yields a higher margin for the clinics. RRCCFF 1148; *see also* RB at 59-60 n.2 (arguing that "Freedom's overly aggressive [L-Code 5856 recommendation] . . . most likely explains its popularity among price-sensitive customers . . ."). The evidence supports the conclusion that the lower price of the Plié can motivate clinics to increase purchases of the Plié in order to receive a higher margin. *E.g.*, F. 515, 518. As Keith Senn of COPC testified, where "two knees are essentially clinically the same, [and] are good for a patient and one is substantially cheaper than the other one," it is beneficial for the clinic's business to take the cost savings." F. 511. However, the evidence fails to support a conclusion that prosthetists are willing to, or do, sacrifice patient care in the pursuit of higher margin. F. 447 (Prosthetists have an ethical and reputational obligation to fit a patient with a prosthetic knee that best meets the patient's medical needs.); F. 536 (At SSPR, if what the patient wants is the clinic's least profitable component, the clinic will consider whether the component is "really the best thing for the patient or is there an alternative, effective alternative device" for the patient that the clinic could "bill out reasonabl[y]."). Moreover, as discussed in subsection 3.c below, higher margins help clinics invest in facilities and support patient care.

other in the MPK market. This further supports a conclusion that Ottobock and Freedom directly compete, for purposes of determining whether Ottobock's acquisition of Freedom presents a reasonable likelihood of unilateral effects.

#### i. Freedom's launch of the Plié 3

Freedom designed the Plié 3 to target the C-Leg, referring to it in development as "a C-Leg killer." F. 561. When Freedom launched the Plié 3 in 2014, Freedom highlighted improvements over the prior generation Plié 2, such as better reliability, improved software, and "submersibility," meaning the ability to "be safely submer[g]ed in fresh shallow water for up to 30 minutes at a time." F. 560, 562. Freedom particularly emphasized Plié 3's water resistance, which was a feature that the Ottobock C-Leg 3, on the market at that time, did not have. F. 564. In addition, Freedom adopted a "penetration pricing" strategy for the Plié 3, pricing it lower than Ottobock's then current version of the C-Leg, the C-Leg 3 (F. 233). F. 570.

The launch of the Plié 3 in 2014 increased Freedom's MPK sales and share of the MPK market in the United States and worldwide. F. 571. The Plié 3's water resistance feature proved particularly attractive to clinic customers. F. 565.

Ottobock's MPK sales and market share decreased after the launch of the Plié 3, which Ottobock attributed to the launch of Freedom's Plié 3. F. 573. In August 2015, Ottobock determined that its C-Leg 3 sales decreased in part because of Freedom's "effective and aggressive promotion and selling" of the Plié 3. F. 578. In addition, the Plié 3 had better water resistance than the C-Leg 3. F. 578.

Ottobock monitored Freedom's marketing claims for the Plié 3 because it saw Freedom "as one of [Ottobock's] two most viable competitors." F. 574. After the launch of the Plié 3 and Ottobock's resulting loss of market share, Ottobock provided marketing materials to its sales force in order to assist the sales force in responding to Freedom's marketing claims for the Plié 3. F. 575. These materials were essentially "arguments to convince customers to not walk away from the C-Leg" and "to continue to buy C-Legs . . . instead of Pliés." F. 579. These included the argument that the Plié 3 is "basically a mechanical knee with a microprocessor switch" that does not control resistance through the entire gait cycle, and is not properly eligible for

reimbursement as a microprocessor-controlled swing and stance knee under L-Code 5856. F. 575.

Ottobock also used promotions and discounts to sell the C-Leg 3 in the wake of the Plié 3 launch. In the first quarter of 2015, Ottobock sold 44 C-Leg 3 MPKs, based on a promotion, to customers that had not purchased any MPK from Ottobock in 2014. F. 576. Twenty-one of those sales included a $2,500 discount. F. 576. Ottobock executives viewed these results as a positive development, referring to the increased sales as "momentum." F. 576. After COPC increased its Plié purchases in 2015, Ottobock responded with "increasingly more aggressive pricing," meaning greater discounts for COPC. F. 513-514, 521.

**ii. Ottobock's launch of the C-Leg 4**

Ottobock launched the C-Leg 4 in July 2015. F. 581. Ottobock's launch materials, prepared for the sales force, contained a comparison between the features of the C-Leg 4 and the Plié 3. F. 582. The materials asserted that the C-Leg 4 had a greater knee flexion angle than the Plié 3, had a greater battery capacity than the Plié 3, and had Bluetooth compatibility and a protective cover, which were not features possessed by the Plié 3. F. 582. Ottobock added a water resistance feature to the C-Leg 4, in response to the launch of the Plié 3. F. 586.

Ottobock predicted that the C-Leg 4 was "going to blow the Plié out of the water." F. 588. Ottobock's sales and marketing goal was to regain market share from competitors "especially from Plié" in the United States. F. 590. According to Ottobock's Scott Schneider, Ottobock highlighted the Plié because it recognized that Freedom had done "a very effective job" promoting and selling the Plié 3, and causing a decline in sales of the C-Leg 3. F. 591.

Freedom's sales of the Plié 3 in the United States significantly declined after the launch of the C-Leg 4 in the United States. This occurred after a period in which Plié 3 sales had been increasing. F. 592; *see also* F. 593 (Freedom's Plié 3 sales took a "big hit" following the C-Leg 4 launch). Freedom recognized that, in adding the ability to walk backwards and water resistance to the features of the C-Leg 4, Ottobock had addressed two "major shortcomings" of the C-Leg 3 and removed two advantages of the Plié 3 that had helped Freedom increase market share. F. 589, 594.

Freedom concluded that Ottobock's launch of the C-Leg 4 was largely responsible for the decline in Plié sales. F. 595-596, 598-600. For example, in March 2016, Ned Brown, a member of Freedom's board of directors, wrote to Thomas Chung, vice president of Health Evolution Partners Fund ("HEP"),[22] and others at HEP, that Ottobock's "new C[-L]eg launch" correlated "exactly" with a decline in Freedom's Plié sales to Hanger, explaining: "We didn't respond fast enough to their competitive attack, and we are seeing a broadening competitive impact across our knee business into 2016." F. 598. *See also* F. 595 (Report prepared for Freedom's board of directors stating that "[t]he new Otto Bock C-Leg 4 is adversely impacting Plié sales"); F. 600 (Freedom's lender, Madison Capital Funding, attributing [redacted] decline in Plié 3 unit sales from September 2015 to April 2016 to Ottobock's release of the C-Leg 4, referring to it as a "direct competitive product to Freedom's Plié 3").

**iii. Freedom's response to the launch of the C-Leg 4**

Freedom took action to respond to the launch of the C-Leg 4 in an attempt to regain Plié 3 sales. After the launch of the C-Leg 4, Freedom's marketing team brainstormed various ideas as to "how to best combat the launch of the C-Leg 4." F. 601. Freedom marketing and clinical teams created presentations comparing the features of the Plié 3 to the C-Leg 4 to make sure the sales team understood how to compete against the C-Leg 4. F. 604-605. For example, in 2015, Freedom published on its website a "Plié 3 Microprocessor Knee Fact Sheet" comparing the features of the Plié 3 directly to features of the C-Leg 4. F. 607. The Plié 3 fact sheet markets the Plié 3 as having comparable features to the C-Leg 4, such as real-time swing and stance control, proven stumble recovery and weatherproofing with an IP67 rating,[23] and as having features which Freedom claims the C-Leg 4 does not possess, including customized stumble recovery, full submersibility, the ability to make manual adjustments, and remote access. F. 608-609. The Plié 3 fact sheet also responds to an Ottobock marketing claim that the C-Leg is

[22] Prior to the Acquisition, HEP, a private equity firm, was the majority shareholder of Freedom. F. 10.

[23] In an IP (ingress protection) rating, the first number stands for dustproof protection. Six is the highest rating of dustproof protection. The second number stands for waterproofness. The standard for reaching a seven is that the knee must be waterproof if submersed in one meter of freshwater for half an hour. (Kannenberg (Ottobock) Tr. 1986-87).

PDAC[24] verified, compared to the Plié 3, which is not, by asserting that "PDAC is not required for reimbursement." F. 610.

Freedom also developed promotions to try to regain sales, which had been adversely impacted by the launch of the C-Leg 4. F. 603. In the summer of 2015, Freedom began running a promotion it called the "ideal combo," which bundled a discounted Kinterra (hydraulic ankle and foot), or a free graphite foot, with the purchase of a Plié 3. F. 612, 614-615, 618, 622. In addition, Freedom lowered the price of the Plié 3 in response to the launch of the C-Leg 4. F. 633.

Ottobock took notice of Freedom's promotions and discounts, and attributed these actions to competitive pressure from the C-Leg 4. F. 631, 634-638. As Cali Solario, senior prosthetics marketing manager of Ottobock testified, "Freedom seemed to be dropping their pricing most aggressively post C-Leg 4 launch, and they were the ones that were the most active in dropping price and having some sort of additional element to their promotion, whether that be a free foot or an additional discount on their higher-end feet." F. 611. In September 2015, Ms. Solario provided advice for the sales team for countering Freedom's "Buy a Plié 3 and 50% off a Kinterra" promotion. F. 632. Setting out a comparison chart of likely customer margins, Ms. Solario wrote, "You'll see that even with a hefty 50% discount on Kinterra, C-Leg 4 combined with Triton Smart Ankle or Triton Harmony still offers a better margin for your customer!" F. 632. A November 2015 Ottobock marketing plan assessed that "[p]ressure from C-Leg 4 has driven lower [Plié 3] prices and bundle[d] promotions with feet (50% off Kinterra) consistently seeing prices as low as [redacted] F. 635.

According to Ms. Solario, Freedom's price discounting and promotions "definitely" impacted Ottobock's sales. F. 637.

[24] A prosthetic manufacturer may submit a prosthetic device to the Medicare Pricing Data Analysis and Coding (PDAC) organization for review and confirmation of its L-Code recommendations ("PDAC verification"). F. 610 n.60. PDAC verification is only directly applicable to reimbursement under Medicare and is not required for prosthetic devices, including MPKs. F. 610 n.60.

#### c. Benefits of competition to clinics and patients

As noted above in section II.D.3.a, competition between the C-Leg and the Plié has contributed to improved technology. As Vinit Asar of Hanger testified, "every time a new generation [MPK] from one manufacturer comes out, the other manufacturer is working on something to leapfrog it. . . . [T]hat's the general nature of medical devices . . . ." F. 505. *See also* F. 541. The continued evolution of technology in MPKs benefits clinics and their patients. F. 507, 540, 550-551.

Furthermore, as set forth in section II.D.3.a above, competition between Ottobock and Freedom has also enabled clinics to negotiate lower prices. *See* F. 507, 513, 521, 540, 548, 552, 557. For example, after COPC increased Plié purchases, Ottobock responded with greater discounts on the C-Leg. F. 513, 521. One customer's price for the Ottobock C-Leg 3 decreased from [redacted] after the launch of the Plié 3. F. 577.

Lower prices benefit clinics and their patients. Because the clinic receives the same reimbursement regardless of which brand of MPK it purchased and regardless of how much it paid for an MPK, lower prices increase clinics' margins. F. 120-121, 324-326. Expanded margins have allowed Hanger to reinvest in its business, for example, by investing in an electronic medical records system. F. 507. Higher price discounts benefit COPC by supporting hiring, facilities, and various programs that support patient care, such as compliance. F. 523. Competition between Ottobock and Freedom has benefitted Jonesboro O&P by enabling Jonesboro O&P to obtain "relatively competitive pricing structures from both manufacturers," and to use the increased margins for investing in facilities and technology, hiring staff, and providing patient support services that are not reimbursable, such as peer counseling. F. 552. POA uses its profits on the cost of MPKs to invest in training, new technology systems, and office expansion. F. 549.

### 4. Conclusion

The evidence proves that the Acquisition will significantly increase concentration in the MPK market, which gives rise to a presumption that the Acquisition may substantially lessen competition. In addition, the evidence proves that, for a significant fraction of clinic customers,

C-Leg and Plié are the two top choices for MPKs; that Ottobock and Freedom are direct competitors in the MPK market; and that such competition has helped clinic customers negotiate lower prices and has spurred MPK innovation. This is more than sufficient to meet Complaint Counsel's prima facie burden of proving that the acquisition of Freedom by Ottobock, and the removal of Freedom as an independent competitor, may substantially lessen competition in the MPK market. Accordingly, the analysis now turns to Respondent's rebuttal evidence.[25]

### E. Rebuttal and Defenses

As noted in section II.B.2.b above, a defendant may rebut a prima facie showing of likely anticompetitive effects with evidence that anticompetitive effects are not likely to result from the merger, or that procompetitive benefits, such as efficiencies, outweigh any likely anticompetitive effects. *See, e.g.*, *Baker Hughes*, 908 F.2d at 985; *Polypore*, 2010 WL 9549988, at *9. In the instant case, Respondent has failed to rebut Complaint Counsel's prima facie case, as explained below.

#### 1. Expansion

In a unilateral effects case involving differentiated products, the Merger Guidelines recognize that, "[i]n some cases, non-merging firms may be able to reposition their products to offer close substitutes for the products offered by the merging firms." Merger Guidelines § 6.1. "Repositioning is . . . evaluated much like entry, with consideration given to timeliness, likelihood, and sufficiency. . . . The Agencies consider whether repositioning would be

[25] Complaint Counsel makes a number of additional arguments in support of a conclusion that the Acquisition is likely to have anticompetitive effects, including that the Acquisition will lessen competition between Ottobock and Freedom as to future products currently in development, such as the Freedom Quattro MPK, F. 9, and the Ottobock C-Leg 5 MPK, F. 6. (CCB at 74-80); that part of Respondent's objective in acquiring Freedom was to eliminate or reduce competition from the Plié 3 and the Quattro post-Acquisition (CCB at 80-87); that after the Acquisition, Ottobock made plans to raise the price of and/or reposition the Plié 3, and to reposition the future Quattro MPK to compete with MPKs other than the C-Leg (CCB at 87-90); and that, after the Acquisition, Ottobock harmed competition by changing Freedom personnel, canceling certain planned upgrades to the Plié 3, delaying the launch of the Quattro, and competing less aggressively with respect to sales of the C-Leg 4 and Plié 3 (CCB at 92-94). Because the prima facie proof of market structure and direct competition between Ottobock and Freedom is sufficient to raise an inference of likely anticompetitive effects and to shift the burden to Respondent for rebuttal, it is not necessary, at this prima facie stage of analysis, to determine whether additional evidence strengthens the inference of likely anticompetitive effects. *See Baker Hughes*, 908 F.2d at 983 ("If the defendant successfully rebuts the presumption, the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.").

sufficient to deter or counteract what otherwise would be significant anticompetitive unilateral effects from a differentiated products merger." *Id.*

"The ability and willingness of current competitors to expand their foothold in the market and/or reposition greatly reduces the anticompetitive effects of a merger, and is essentially equivalent to new entry." *CCC Holdings*, 605 F. Supp. 2d at 57. "[L]ikely entry or expansion by other competitors can counteract anticompetitive effects that would otherwise be expected." *H&R Block*, 833 F. Supp. 2d at 73 (citing *Heinz*, 246 F.3d at 717 n.13 ("Barriers to entry are important in evaluating whether market concentration statistics accurately reflect the pre- and likely post-merger competitive picture."); *Baker Hughes*, 908 F.2d at 987 ("In the absence of significant barriers, a company probably cannot maintain supracompetitive pricing for any length of time."). "Determining whether there is ease of entry hinges upon an analysis of barriers to new firms entering the market or existing firms expanding into new regions of the market." *H&R Block*, 833 F. Supp. 2d at 73 (citing *CCC Holdings*, 605 F. Supp. 2d at 47 (quoting *Cardinal Health*, 12 F. Supp. 2d at 55)).

Because Complaint Counsel has established its prima facie case, Respondent must produce evidence "sufficient to demonstrate the ability" of other competitors "to fill the competitive void that will result if [Respondent is] permitted to acquire" Freedom. *Swedish Match*, 131 F. Supp. 2d at 169. It is not sufficient to show that expansion would replace "some of the competition" lost to the Acquisition. *Id.* at 170. Instead, existing competitors must be "poised to expand in a way that is 'timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract' any potential anticompetitive effects resulting from the merger." *H&R Block*, 833 F. Supp. 2d at 74. As noted above, repositioning by existing competitors is evaluated similarly to entry under the Merger Guidelines, which state that "in a differentiated product industry, entry may be insufficient because the products offered by entrants are not close enough substitutes to the products offered by the merged firm to render a price increase by the merged firm unprofitable." Merger Guidelines § 9.3. "Entry may also be insufficient due to constraints that limit entrants' competitive effectiveness, such as limitations on the capabilities of the firms best placed to enter or reputational barriers to rapid expansion by new entrants." *Id.*

Respondent asserts that existing manufacturers of MPKs can expand and compete for market share in the marketplace and that this expansion will counteract any anticipated anticompetitive effects. RB at 65-70. Respondent does not assert that new firms are likely to enter the relevant market. *Id*. Thus, the analysis focuses on the likelihood of repositioning or expansion by existing competitors.

Respondent asserts that Össur and Endolite are "willing, able, and incentivized to expand and compete for market share" and that Nabtesco/Proteor "has taken the necessary steps to timely, likely, and sufficiently compete for market share." RB at 68-70.[26] As shown below, the evidence fails to justify the conclusion that any of these competitors are poised to expand in a way that is timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract any potential anticompetitive effects resulting from the Acquisition.

With respect to Össur, the manufacturer of the Rheo 3 MPK, Respondent asserts that Össur has a large and robust research and development group and budget, has the ability to significantly increase its MPK supply to the United States, and is currently [redacted] RB at 68. Respondent relies on testimony from Kim Peter Viviane De Roy, executive vice president of research and development at Össur (F. 29), that if demand for Össur's Rheo Knee were to increase in the United States, Össur "would be able to" expand to produce an additional [redacted] Rheos, but that this would require "more than some investment," and "a year [would be] a tight time frame" for any such expansion. F. 655. Respondent does not point to any evidence of a plan for Össur to expand, or to any specific evidence indicating the likelihood of an Össur expansion, *see* RB at 68; RFF 789-807, which casts doubt on the timeliness and likelihood of an Össur expansion.

Furthermore, even if Össur has the ability and willingness to expand, the evidence fails to support the conclusion that such expansion would fill the competitive void left by Freedom because clinicians view the Rheo 3 as functionally different from C-Leg 4 and the Plié 3. For example, COPC is not presently willing to move volume to Rheo because COPC "practitioners

[26] Respondent does not assert that DAW is expanding. RB at 68-70; *see also* RFF 927-40. DAW does not manufacture its own MPKs, but is a distributor of MPKs manufactured by a company named Teh Lin, located in Taipei, Taiwan. F. 305. DAW has minimal MPK sales in the United States (less than [redacted]) and its MPKs sales have decreased each year since 2015. F. 479-480, 483-484, 676.

do not like the Rheo knee" and believe that "the functions or the capability of that knee" "do not compare to the Freedom and Ottobock knees at this time." F. 650. *See also* F. 649 (COPC prosthetists find the Rheo to be heavier and not as good at stumble recovery, which are disadvantages compared to the Plié and the C-Leg.). Mid-Missouri O&P has not purchased any MPKs from Össur, based on its clinicians' experience with the demonstration models and personal preferences. F. 651. According to Tracy Ell of Mid-Missouri O&P, Össur's MPK is "not as inherently safe throughout all its usage." F. 651. To Mark Ford of POA, while Össur's Rheo MPK is used by "a lot of practices," and provides competition for the C-Leg, "for many clinicians," the Rheo MPK is "viewed as a different product than the C-Leg or the Plié knee because of the platform, the functional platform that it's built on." F. 653. *See also* F. 652 (POA has found that the Rheo MPK is larger than is preferred by POA's prosthetists and that the Rheo's software works differently than what is preferred by POA's prosthetists.).

With respect to Endolite, the manufacturer of the Orion 3 MPK (F. 286), Respondent asserts that Endolite supplies a complete line of lower-limb prosthetic devices and has had significant sales growth in MPKs in 2017 and 2018. RB at 68-69. Respondent further asserts that Endolite plans to significantly grow its business by 2025, has capacity to supply an additional [redacted] MPKs per month to the United States, and has [redacted] RB at 68-69. The greater weight of the evidence is contrary to a conclusion that Endolite is capable of replacing lost competition, as shown below.

As an initial matter, Endolite is a small competitor in the United States MPK market. Despite the fact that Endolite has been selling MPKs in the United States for 20 years, Endolite has no more than a [redacted] share of the United States MPK market. F. 479-480, 656. Endolite sells significantly fewer MPKs each year than Freedom. In 2016, Endolite sold [redacted] MPKs in the United States, while Freedom sold [redacted] MPKs. F. 657. In 2017, Endolite sold [redacted] MPKs in the United States, while Freedom sold [redacted] MPKs. F. 657. While Stephen Blatchford, executive chairman of Blatchford, testified that Endolite has a strategic plan to significantly grow the business by 2025, he did not specifically attribute the planned growth to growth in sales of MPKs in the United States. F. 664. Further, Endolite has [redacted]

[redacted] F. 665. This casts doubt on the timeliness and likelihood of an Endolite expansion.

Furthermore, even if Endolite has the ability and willingness to expand, Endolite faces barriers arising from negative customer perception of the Endolite MPK. Endolite's chairman explained that Endolite has "suffered" from having a reputation of "having a product that isn't very reliable, British engineering at its worst." F. 659. *See also* F. 660 (Stephen Blatchford testifying that Endolite has "suffered from a legacy of launching our first microprocessor-controlled swing and stance knee . . . but reliability was atrocious, so it has taken us awhile to overcome that, and prosthetists do seem to have quite long memories."). "[R]eputation can be a barrier to entry and expansion." *Chicago Bridge*, 2005 FTC LEXIS 215, at **75, n.209 (citing *Cardinal Health*, 12 F. Supp. 2d at 57; *Swedish Match*, 131 F. Supp. 2d at 170-71).

Although Endolite has seen sales growth since the launch of the Orion 3 in September 2016, some prosthetic clinics are reluctant to purchase Endolite's Orion MPK. COPC has no plans to move volume to the Orion at this time because, to COPC, "the two primary knees that we use [C-Leg and Plié] are better than their knee [Orion], and so there's no reason today to try to move patients to their knee." F. 661. Because Endolite is a "smaller company," that doesn't have as much support staff, as large a sales force, and far fewer clinicians, it is more challenging for POA to get support from Endolite in a timely manner and with the level of support that POA gets from Ottobock, Freedom, and Össur. F. 662. Hanger makes fewer MPK purchases from Endolite than from Ottobock and Freedom in part due to Endolite's lack of presence in the United States. F. 663. Hanger sees Endolite sales representatives less frequently and has found that Endolite offers less support in the United States for its products. F. 663.

With respect to Nabtesco, Respondent asserts only that Nabtesco released the full-launch version of the Allux MPK in June 2017, that Proteor entered into an exclusive distribution agreement to sell Nabtesco's products in the United States in 2018, and that Proteor has quickly realized sales of the Allux. RB at 69-70. Respondent does not claim that Nabtesco's sales will increase sufficiently to replace Freedom's sales. RB at 69-70. Instead, Respondent asserts only that Nabtesco/Proteor "has taken the necessary steps to timely, likely, and sufficiently compete for market share." RB at 69.

The greater weight of the evidence is contrary to a conclusion that Nabtesco is capable of replacing lost competition. Nabtesco has an insignificant presence in the United States MPK market, with less than a [redacted] share. F. 479-480. In 2017, Nabtesco sold [redacted] MPKs in the United States, while Freedom sold [redacted] MPKs. F. 666. Bradley Mattear, managing director of Proteor (F. 36), described Nabtesco as a "tadpole in the ocean" and "[i]n the grand scheme of things," nobody knew who they were. F. 675. Jeffrey Collins, the president of Cascade, a distributor of the Allux, did not anticipate increasing its sales of the Allux in 2018 over sales in 2017, explaining, "[t]here are very well-established brands and commonly used microprocessor knees that are available in the market today . . . at a competitive price, so it is difficult to bring in a new product at a price point that's similar to those existing products in the market and expect significant sales increases." F. 674. Many of Ottobock's and Freedom's clinic customers are not familiar with MPKs manufactured by Nabtesco. F. 667. Of the prosthetists who have heard of Nabtesco, many testified that they would not fit a Nabtesco MPK on a patient because of difficulties with customer service or concerns about the reliability of the MPK. F. 668.

For all the foregoing reasons, Respondent's rebuttal argument based on repositioning or expansion by MPK competitors is rejected.

### 2. Market constraints

Respondent contends that the MPK market is characterized by the existence of power buyers and by price ceilings associated with insurance reimbursement, both of which constrain Respondent's ability to impose price increases post-Acquisition. These arguments are addressed in turn below.

#### a. Power buyers

The "power buyer" defense is grounded in the theory that large, sophisticated buyers may have the bargaining power to resist anticompetitive price increases and thereby counter any anticompetitive effects of a merger. *Baker Hughes*, 908 F.2d at 986-87. *See also* Merger Guidelines § 8 ("The Agencies consider the possibility that powerful buyers may constrain the ability of the merging parties to raise prices.").

Respondent argues that Hanger is a power buyer that can prevent any reasonably likely anticompetitive effects. RB at 70-74.[27] Complaint Counsel argues that Hanger would be harmed by removing Freedom as an independent competitor for Hanger's business, and that, in any event, the existence of Hanger as a power buyer says nothing about the likelihood of anticompetitive effects for smaller buyers in the market who may not have Hanger's buying power. CCB at 140-42.

Courts do not consider proof of the existence of power buyers "as itself independently adequate to rebut a *prima facie* case." *Chicago Bridge*, 534 F.3d at 440. As the court noted in *Chicago Bridge*, "the economic argument for even partially rebutting a presumptive case, because a market is dominated by large buyers, is weak." 534 F.3d at 440 (citing 4 Areeda & Hovenkamp at ¶ 943 ("[I]t would be inappropriate to give formal recognition to buyer concentration and related factors in the ordinary run of merger cases."). Courts have credited the existence of power buyers as a defense only where there is also proof of ease of entry and likely efficiencies. *Chicago Bridge*, 534 F.3d at 440; *Cardinal Health*, 12 F. Supp. 2d at 58. Consistent with the foregoing, the Merger Guidelines state that "the Agencies do not presume the presence of powerful buyers alone forestalls adverse competitive effects flowing from the merger. Even buyers that can negotiate favorable terms may be harmed by an increase in market power." Merger Guidelines § 8.

Respondent asserts that Hanger is a large and important customer that has significant leverage in negotiations with MPK manufacturers. RB at 71-72. The evidence tends to support this proposition. Hanger represents a large portion of the prosthetic clinics in the United States, with 800 clinics across the country and about 1,500 clinician employees. F. 713. By comparison, there are approximately 3,400 clinics and 6,500 clinicians in the United States. F. 713. Hanger is Ottobock's largest United States customer for MPKs. F. 715. A little more than half of Freedom's sales in the United States are to Hanger. F. 717. Hanger is also the largest United States lower-limb prosthetic customer of Össur and a very important customer of Endolite. F. 719-720. Hanger's bargaining power is manifested in the fact that [redacted]

[27] Although Respondent alludes to the buying power of Hanger "and other" unnamed "sophisticated customers," Respondent's evidentiary assertions are limited to Hanger. RB at 71; RFF section IV.G.

Moreover, Hanger has acknowledged its purchasing power as a competitive strength. F. 721.

The evidence further shows that Ottobock and Freedom are Hanger's top two suppliers of MPKs in terms of volume. F. 501. In 2017, Hanger purchased approximately of its MPKs from Ottobock and from Freedom, for a total of F. 499. Maynard Carkhuff, Freedom's chairman, testified that Hanger's ability to threaten to move Plié volume to C-Leg allows Hanger to negotiate lower prices from Freedom. F. 496 (citing Carkhuff, Tr. 404). Vinit Asar, Hanger's CEO (F. 44), testified that even if the price of the C-Leg and Plié increases post-Acquisition, Hanger plans to continue offering both products to patients because "both these products are good products, our clinicians like them, our patients use them. We would see no reason not to offer them." F. 727. The foregoing evidence supports the conclusion that Ottobock's acquisition of Freedom is likely to increase Ottobock's bargaining leverage post-Acquisition, regardless of Hanger's pre-Acquisition power as a large, important customer.

Respondent further asserts that Hanger has "structures and tools in place" to constrain future MPK prices. RB at 72. Respondent argues that Hanger is capable of defeating a price increase and shifting volume to other manufacturers by changing its internal pricing that it charges its clinics for MPKs to incentivize Hanger clinicians to shift volume away from the combined Ottobock/Freedom to Össur and Endolite. RB at 73. Respondent points to a Hanger document titled "Supplier Consolidation Presentation – The Path Forward," which Hanger prepared in February 2018 after the Acquisition ("Supplier Consolidation Presentation"). *See* F. 722.

After learning about the Ottobock/Freedom transaction, Hanger undertook an assessment of the potential impact of the Acquisition on Hanger. F. 722. The resulting Supplier Consolidation Presentation outlined "a couple of scenarios that [Hanger staff] modeled out." F. 723. Under the scenario relied on by Respondent, RB at 72-73, Hanger modeled reducing the combined share of Ottobock and Freedom from of Hanger's MPK sales to with a reduction in volume of units and a shifting of that volume to Össur and Endolite. F. 725. Under this scenario, based on Ottobock pricing, Hanger calculated it would save per year. F. 725. However, Hanger did not assess the feasibility of any of the scenarios described in

the Supplier Consolidation Presentation. F. 726. Vinit Asar described the assessment as "a small survey of a bunch of clinicians to figure out just why are you picking Otto Bock" MPKs. F. 726. The only identified plan to resist post-Acquisition price increases is to ensure Hanger clinicians "are fully aware of the features, the benefits, and the economics" of MPKs offered by other MPK manufacturers. F. 726. Based on the foregoing, Respondent's characterization of the Supplier Consolidation Presentation as a structure in place that is likely to defeat an anticompetitive price increase to Hanger overstates the case. In any event, a customer's effort to plan a way to avoid acceding to a price increase does not render it a power buyer. *Polypore*, 2010 WL 9549988, at *32.

Respondent also contends that Hanger has the "demonstrated ability and willingness" to sponsor expansion by competing MPK manufacturers, and thereby defeat any post-Acquisition anticompetitive effects. RB at 73. To support this contention, Respondent asserts that Hanger invited representatives of Ottobock, Freedom, Össur and Endolite to its 2018 "Hanger Education Fair" to familiarize Hanger clinicians with their products and that Hanger clinics bought more Endolite Orion 3 MPKs after becoming more familiar with the product. RB at 73-74. However, Respondent fails to cite to the record or to any proposed findings to support this argument. In any event, the assertions, even if supported by the record, fall short of demonstrating that Hanger is able and willing to sponsor expansion so as to defeat any post-Acquisition anticompetitive effects.

In addition, approximately 60% of Ottobock's sales are to customers other than Hanger and approximately half of Freedom's sales are to customers other than Hanger. F. 728-729. Even if Hanger would be able to avoid price increases as a result of its size and sophistication, Respondent cites no evidence suggesting that any other clinic customers would be able to do so. In *Polypore*, 2010 WL 9549988, the Commission rejected the respondent's power buyer defense, in part because even if it were "assume[d] that the four claimed power buyers somehow would be able to avoid price increases as a result of their size and sophistication, there is no reason to believe that other . . . customers would fare as well." 2010 WL 9549988, at *32. In the instant case, as in *Polypore*, pricing is individually negotiated. *Id.*; F. 315. In addition, MPK manufacturers charge different prices to different clinic customers, and different clinic customers have different bargaining leverage in negotiations with MPK suppliers, and different abilities to

negotiate lower prices. F. 316, 730. In these circumstances, there is no reason to believe that "smaller buyers will be protected by the resistance offered by larger, more powerful customers." 2010 WL 9549988, at *32 (citing *United States v. United Tote, Inc.*, 768 F. Supp. 1064, 1085 (D. Del. 1991); *FTC v. Bass Bros. Enterprises, Inc*., 1984 U.S. Dist. LEXIS 16122 (N.D. Ohio 1984)). *See also* Merger Guidelines § 8 ("[E]ven if some powerful buyers could protect themselves, the Agencies also consider whether market power can be exercised against other buyers.").

Finally, as noted above, courts typically do not credit a power buyer defense absent additional proof of ease of entry and likely efficiencies. *Chicago Bridge*, 534 F.3d at 440; *Cardinal Health,* 12 F. Supp. 2d at 58. As set forth in section II.E.1 above and section II.E.6 below, the evidence fails to prove either.

For all the foregoing reasons, Respondent's rebuttal argument based on the power buyer theory is rejected.

**b. Insurance reimbursement cap as constraint**

Respondent next argues that the insurance reimbursement rate for an MPK has the effect of constraining manufacturer price increases, by acting as a cap on pricing. RB at 74-75. According to Respondent, because of the cap on allowable reimbursement for an MPK, and what Respondent asserts are "very thin margins" for clinics, manufacturers "do not have room to profitably impose price increases." RB at 74. A price increase would encourage clinics to change MPK brand, Respondent argues, because the allowable reimbursement for an MPK is the same regardless of MPK brand. Complaint Counsel replies that the evidence fails to show that reimbursement rates will prevent post-Acquisition price increases. CCB at 138-40; CCRB at 80-82.

Respondent cites the testimony of Cali Solario, senior prosthetics marketing manager of Ottobock (RFF 963-64), who stated that, in determining what to charge a customer for an MPK, the amount of allowable reimbursement "creates kind of the ceiling for what [the manufacturer's] price could be." (Solario (Ottobock) Tr. 1624). Ms. Solorio further testified that Ottobock then looks at its "manufacturing costs, . . . the competitive landscape, and all of

those things together kind of work to help establish the market price" to charge its customers. *Id*. Ms. Solorio explained that Ottobock's pricing must "play within that space[.] . . . [I]f you . . . don't give your customers an opportunity to have a healthy margin" on the purchase of an MPK, the manufacturer risks "pricing [it]self out" of the market. (Solario (Ottobock) Tr. 1624-25). Even if Ottobock views reimbursement amounts as its price ceiling, and sets its prices "within that space" below the ceiling, it does not logically follow that there is no room in the space between the price of the MPK and the ceiling for reimbursement for Respondent to impose a price increase. Moreover, as discussed below, the evidence suggests that there is room for Respondent to raise the price of the Plié 3 post-Acquisition, contrary to Respondent's assertion.

A clinic's margin is not dictated only by the price of the MPK. The components of the overall lower-limb prosthetic, in addition to the knee, such as the foot, socket, suspension mechanism, adapters, hardware, and liners, have additional L-Codes for which clinics obtain reimbursement and which allow some amount of margin for the clinic. F. 732. A clinic's profit for fitting an MPK takes into account the reimbursement on all components of the lower-limb prosthetic, not solely the reimbursement on the MPK. F. 731. As Respondent's expert witness Dr. David Argue agreed, a clinic may earn a profit on the prosthetic leg as a whole even if the clinic does not make a profit on the MPK component. F. 739.

Moreover, the evidence shows that customers typically pay anywhere from [redacted] less for the Plié 3 than for the C-Leg 4. F. 493. Dr. Argue estimated that the average price of a Plié 3 in 2016 was [redacted] and the average price of an Ottobock C-Leg 4 in 2016 was [redacted] F. 794. The evidence further shows that it is profitable for clinics to fit a C-Leg today. F. 735. For at least some clinic customers, based on the price differential between the Plié 3 and the C-Leg 4, Respondent could impose a 10% increase in the price of the Plié 3 post-Acquisition, and the cost would still be lower than a C-Leg 4 (F. 736-737), which suggests there is room to raise the price of the Plié 3, notwithstanding the insurance reimbursement ceiling.

Finally, Respondent's argument that a price increase will encourage clinics to change MPK brand, because insurance reimbursement is the same regardless of which brand of MPK is selected, rests only on certain cited testimony of Scott Sabolich of Scott Sabolich Prosthetic & Research. RB at 75. Mr. Sabolich testified that if Ottobock were to increase the price of the

C-Leg 4 by 10%, he "would still have a profit" on the product, but he "wouldn't be very happy about" the price increase and "might want to start using an Endolite knee." (Sabolich (SSPR), Tr. 5915). This testimony is insufficiently definite or substantial to sustain Respondent's argument.

For all the foregoing reasons, Respondent's rebuttal argument that the allowable insurance reimbursement for MPKs will constrain Ottobock from imposing MPK price increases post-Acquisition is rejected.

### 3. Failing company defense

The failing company doctrine, recognized as a valid defense to a Section 7 suit in *Brown Shoe*, was first announced by the Supreme Court in *International Shoe Co. v. FTC*, 280 U.S. 291 (1930). *United States v. General Dynamics Corp.*, 415 U.S. 486, 506 (1974). "A company invoking the defense has the burden of showing that its 'resources [were] so depleted and the prospect of rehabilitation so remote that it faced the grave probability of a business failure . . . ,' and further that it tried and failed to merge with a company other than the acquiring one." *Id.* at 507 (citations omitted). The burden of proving that the conditions of the failing company doctrine have been satisfied is on Respondent. *Citizen Pub. Co. v. United States*, 394 U.S. 131, 138-39 (1969).

The underlying rationale for the failing company defense, as explained in *General Dynamics*, is that "the effect on competition and the 'loss to [the company's] stockholders and injury to the communities where its plants were operated' will be less if a company continues to exist even as a party to a merger than if it disappears entirely from the market. It is, in a sense, a 'lesser of two evils' approach . . . ." *General Dynamics*, 415 U.S. at 507 (internal citation omitted). In *Michigan Citizens for an Independent Press v. Thornburgh*, the court explained that the Supreme Court's decision in *Citizen Publishing* "narrowly confined the scope of the doctrine," by holding that a financially troubled company may not employ the failing company defense unless it meets three conditions: the owners of the merger target are contemplating liquidation; the prospects for successful reorganization under the bankruptcy laws are "dim or nonexistent"; and the acquiring company was "the only available purchaser." 868 F.2d 1285, 1288 (D.C. Cir. 1989) (citing *Citizen Pub.*, 394 U.S. at 137-38), *aff'd*, 493 U.S. 38 (1989).

A failing company defense is also recognized in Section 11 of the Merger Guidelines, which states:

> The Agencies do not normally credit claims that the assets of the failing firm would exit the relevant market [absent the merger] unless all of the following circumstances are met: (1) the allegedly failing firm would be unable to meet its financial obligations in the near future; (2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act; and (3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger.

Merger Guidelines § 11.

The forgoing criteria for establishing a failing company defense are addressed in turn below.

**a. Imminent danger of failure**

The first requirement to justify an acquisition under the failing company doctrine is that the proponent of the acquisition must show that the company to be acquired is in imminent danger of failure. *Dr. Pepper/Seven-Up Cos. v. FTC*, 991 F.2d 859, 864 (D.C. Cir. 1993) (citing *General Dynamics*, 415 U.S. at 507); *see also Michigan Citizens*, 868 F.2d at 1288 ("[I]ndeed, [the acquisition] must be the 'last straw' at which the company can grasp."). "The most important factor that courts have considered in determining whether a firm faces the 'grave possibility of business failure' is whether the firm is insolvent or on the brink of insolvency either in the bankruptcy sense, that the firm has no net worth, or in the equity sense, that the firm is unable to meet its debts as they come due." *California v. Sutter Health Sys*., 84 F. Supp. 2d 1057, 1081-82 (N.D. Cal. 2000) (citing *Crown Zellerbach Corp. v. FTC*, 296 F.2d 800, 831-32 (9th Cir. 1961) (holding that a firm was not in a failing condition were it had a positive net worth); *United States v. M.P.M., Inc.*, 397 F. Supp. 78, 100 (D. Co. 1975) (finding that a firm passed the first prong of failing company defense where the defendant was insolvent in the equity sense)).

Respondent argues that Freedom would have been unable to meet its financial obligations in the near future. In support of this argument, Respondent asserts that, in the period preceding the Acquisition, Freedom was failing by virtually every financial measure, that Freedom's debt was insurmountable, and that, according to Freedom's CEO at the time, Freedom was on the verge of liquidation, without capital, and about to terminate all of its employees in March 2017. RB at 93-112.

### i. Financial measures

Respondent points out, and the evidence does show, that Freedom's EBITDA,[28] operating income, and gross profit percentage fell every year from 2012 to 2016. F. 764-766[29]; RB at 94-95. From early 2015 through early 2016, internal and external factors lead to a decline in Freedom's financial performance. F. 771-773. Some of the reasons for this decline, as noted in Freedom's ordinary course of business documents, were that, internally, Freedom failed to keep costs in line with forecasted revenue growth and the launch of its new microprocessor ankle, the Kinnex, was delayed (F. 771-772); and externally, Ottobock had released the C-Leg 4, which cut into sales of Freedom's Plié 3. F. 771. To address these and other issues, effective April 2, 2016, Freedom's majority equity owner, Health Evolution Partners ("HEP") and board of directors replaced Freedom's then-CEO Maynard Carkhuff, with David Smith, an HEP partner with significant operating experience. F. 774.

David Smith promptly took several steps to improve Freedom's business, including replacing the company's chief operating officer and head of sales, revamping Freedom's sales and service structure, and enhancing the productivity of its research and development pipeline. F. 775, 777. In September 2016, Mr. Smith presented a 2017 Strategic Plan to Freedom's board of directors that detailed Freedom's shortcomings and plans for improvement through 2017.

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[28] EBITDA, which stands for earnings before interest, (income) taxes, depreciation, and amortization, is an acronym used by analysts to focus on a particular measure of cash flow used in valuation. F. 761. EBITDA is an important metric in measuring the financial health of a company because it is an approximation of the operating cash flow generated by the business of the company. EBITDA needs to be high enough to cover debt service and capital expenditures, which are cash outflows, as well as provide positive net cash flow, which is an indicator of the value of the business. F. 762.

[29] Freedom's EBITDA was $6,347,000 in 2012; $4,180,000 in 2013; $3,414,000 in 2014; [redacted] in 2015; [redacted] in 2016; and [redacted] (annualized) for 2017 to June 30, 2017. F. 764.

F.778. To help implement the 2017 Strategic Plan, Mr. Smith requested and received [redacted] of additional capital support from Freedom's equity investors. F. 779-780.

As a result of David Smith's efforts, Freedom experienced some improvement in top line revenue during the first two quarters of 2017. RB at 98; *see* F. 781-792. For the first quarter of 2017, Freedom's year-to-date total actual revenue was about [redacted] dollars ahead of plan and about [redacted] dollars ahead of revenue earned in the first quarter of the previous year. F. 787.[30] Respondent argues that top line revenue improvement does not indicate a material change in Freedom's financial health. RB at 98. Indeed, Freedom's gross profit percentage declined every year from 2012 up to and including 2017. F. 767. However, in 2017, Freedom's EBITDA and cash flow were ahead of plan and ahead of the prior year's performance. F.782, 784-785, 787-797. Over the first eight months of 2017, Freedom experienced a [redacted] increase in revenue and a [redacted] increase in EBITDA over the same period in 2016. F. 797. In March 2017, Freedom reported "[s]ignificant revenue turnaround and growth started in September [2016]." F. 781. Although Respondent argues that, because 2016 was Freedom's worst financial year ever, it was not difficult for Freedom to exceed its 2016 financial performance, RRCCFF 1902, this does not undermine the reality that Freedom's financial position had significantly improved in 2017. *See* F. 781-797.

In March 2017, describing its momentum for financial improvement, Freedom identified the release of an improved Plié 3 and Kinterra; release of the Maverick foot line; release of the Kinnex microprocessor-controlled ankle; and alpha testing and fitting of the Quattro MPK. F. 781. *See also* F. 782 (Freedom presentation stating that momentum was expected from Plié 3 product quality improvements already resulting in [redacted] volume increase over last year). Furthermore, Freedom's "[s]ales performance had improved significantly" by March 2017, F. 786, which undercuts Respondent's argument that Freedom was a failing company. *See Olin Corp. v. FTC*, 986 F.2d 1295, 1307 (9th Cir. 1993) (holding that the defendant could not rely on a failing company defense, when there was no dispute that the acquired firm's business in the relevant product market was successful, notwithstanding that performance may not have met the company's expectations). In this case, Freedom's sales performance had improved significantly

[30] For the first quarter of 2017, Freedom's year-to-date total actual revenue was [redacted] planned revenue was [redacted] and previous year first quarter revenue was [redacted] F. 787.

by March 2017 and Freedom experienced a [redacted] year-over-year growth in sales of the Plié MPK from 2016 to 2017. F. 783, 786. *See also* F. 783 (David Smith testifying that the Plié volume increase was "a big reason why the company started to improve").

Respondent also asserts that Freedom's auditor had substantial doubt that Freedom could continue as a going concern in April 2017. RB at 108-12. The audited financial statement for Freedom for the calendar year 2016 does not support Respondent's argument that Freedom would not have been able to meet its financial obligations in the near future. In the process of auditing Freedom in March 2017, Squire & Company ("Squire") considered whether it was appropriate to include a "going concern modification"[31] in its audit opinion of Freedom's 2016 financial statements. F. 806, 808. The lead auditor from Squire, Shane Edwards, worked with Lee Kim, Freedom's chief financial officer ("CFO"). F. 804, 807. Mr. Edwards informed Mr. Kim that Squire was considering including a paragraph in its audit opinion expressing doubt about Freedom's ability to continue as a going concern and asked Mr. Kim to prepare a memorandum to address the conditions and events that raise substantial doubt, provide an evaluation of Freedom's ability to meet its financial obligations, and document the plan to mitigate the problem. F. 808-809. Mr. Edwards told Mr. Kim that if Freedom could alleviate the conditions or events that raise substantial doubt about the entity's ability to continue as a going concern, Squire could remove the going concern paragraph from the audit opinion. F. 809. Mr. Kim provided Mr. Edwards with the requested information in his "Going Concern Memo" (F. 810) and Squire determined that there was no need to include a going concern modification in its audit opinion. F. 813-814.

The auditor's report is inconsistent with Respondent's claim that Freedom would have been unable to meet its financial obligations in the near future. Squire's April 2017 Independent Auditor's Report of Freedom's Consolidated Financial Statements for Years Ended December 31, 2016 and 2015 reported Freedom's net losses, cash used in operations, and accumulated deficit; noted that Freedom entered into a term note and line of credit agreement with financial institutions, to mature September 16, 2017; reported that management believes it is probable that the refinancing and recapitalization process will be successful; and stated that Freedom "believes

[31] A "going concern modification" is a qualification that an auditor has substantial doubt about a company's ability to continue for at least one year after the auditor signs the audit report. F. 803.

that the equity commitment in combination with the current terms and conditions of the term loan and line of credit will be sufficient to fund operations through 2018." F. 818.

Respondent's attempt to challenge the legitimacy of the audit by challenging the competence and veracity of Freedom's CFO (RB at 109-11) is unavailing. The evidence shows that Lee Kim is a licensed certified public accountant with many years of experience in accounting at the Deloitte accounting firm and in-house for numerous private companies (F. 805); Mr. Kim received input from Freedom's sales and marketing management team for the memo he provided to Squire (F. 810); Mr. Kim strived to be truthful in his communications with Squire (F. 807); and when Mr. Kim drafted the Going Concern Memo in March 2017, he believed that the plan Freedom's management team had in place could alleviate the conditions raising doubt about the company's ability to continue as a going concern (F. 812). Respondent also attempts to call into question the legitimacy of the audit based on Shane Edwards' purported failure to take any steps to verify the information provided to him by Mr. Kim. RB at 109. This argument is contradicted by the signed statement in the Independent Auditor's Report that Squire "conducted [its] audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement." F. 819-820. In summary, Respondent's challenges to the legitimacy of the audit fail to detract from the evidentiary value of the conclusions of the independent audit. *Compare Sutter Health*, 84 F. Supp. 2d at 1083 (noting that an "independent auditor's refusal to issue a clean opinion is evidence of a company's failing condition").

**ii. Freedom's debt**

Respondent next argues that Freedom would have been unable to meet its financial obligations in the near future because Freedom's debt was insurmountable. RB at 102-08. In 2012, Freedom entered into a credit agreement with Bank of Montreal ("BMO") and Madison Capital Funding, LLC ("Madison Capital") (collectively, the "Lenders") that provided Freedom with a [redacted] term loan (the "Credit Agreement"). F. 743. The term loan provided under the Credit Agreement contained a "Term Loan Maturity Date," which is the date by which any outstanding amounts under the term loan were due and payable to the Lenders. F. 745. At the

time the Credit Agreement was executed in 2012, the Term Loan Maturity Date was February 16, 2017. F. 745. By the end of 2016, Freedom owed the Lenders approximately [redacted] F. 748.

Freedom failed to pay the outstanding balance on the term loan by the February 16, 2017 Term Loan Maturity Date. F. 749. On April 4, 2017, Freedom and its Lenders entered into a Seventh Amendment to the Credit Agreement, which required HEP (Freedom's majority owner) to invest an additional [redacted] in Freedom and required Freedom to formally engage an investment banker to help Freedom find a refinancing partner or sell the company. F. 750-753. HEP provided the additional [redacted] and Freedom formally engaged Moelis & Company ("Moelis"), an independent investment bank, in May 2017. F. 754. With the conditions satisfied, the Lenders extended the maturity date of the Credit Agreement from February 16, 2017 to September 16, 2017. F. 755, 757.

Respondent asserts that the Lenders "intended to force Freedom into liquidation if they were not paid in the very near future through an acquisition." RB at 102. To support this assertion, Respondent relies on the after-the-fact testimony of Maynard Carkhuff and David Smith. RFF 1527 [redacted] Respondent presented no testimony from the Lenders or documents from the Lenders to support this assertion. Moreover, the evidence is contrary to Respondent's assertion. The evidence shows that the Lenders repeatedly amended the Credit Agreement and twice extended the maturity date of the debt, rather than foreclosing. F. 746-747, 751, 757. When Madison Capital extended the maturity date of the debt in April 2017, Madison Capital believed that "the [redacted] of liquidity forecasted by Freedom should be sufficient for Freedom to continue its operations through a prolonged sale process in the second half of 2017 without the need for additional outside capital. F. 828. In addition, Madison Capital notified Freedom in July 2017 that Madison Capital could not lead refinancing, but that it would participate in someone else's transaction. F. 829. Furthermore, Freedom never calculated the liquidation value of the company. F. 823-825. Based on the foregoing, Respondent has not met its burden of demonstrating that Freedom would have been liquidated, but for the Acquisition. *See Citizen*

*Pub.*, 394 U.S. at 137 (holding that the failing company defense was not met where there was no indication that the owners of the acquired company were contemplating a liquidation).

**iii. Freedom's actions**

Respondent also asserts that Freedom was insolvent and about to terminate all of its employees in March 2017. RB at 111-12. However, the actions taken by Freedom in that timeframe are inconsistent with the conclusion that Freedom was unable to meet its financial obligations or was at risk of imminent failure. For example, Freedom continued to enhance its research and development pipeline. *E.g.*, F. 834 [redacted] F. 831 (Freedom spent [redacted] on research and development in the first eight months of 2017). Freedom also spent more on sales and marketing in the first eight months of 2017 than it had in the first eight months of 2016 and hired five additional sales representatives for its European operations as of April 2017. F. 830, 833. In addition, Freedom had extended the leases for its Irvine, California and Gunnison, Utah facilities for three years each in 2017. F. 836. Finally, although David Smith and Maynard Carkhuff testified that they were concerned about Freedom's ability to make payroll (RRFF 2023), Freedom never missed a payroll and paid out discretionary bonuses to its executives in 2017. F. 837.

For the above stated reasons, Respondent has not met its burden of demonstrating that Freedom was in imminent danger of failure.

**b. Inability to reorganize successfully under Chapter 11 of the Bankruptcy Act**

Section 11 of the Merger Guidelines articulates the second prong of the failing company defense as requiring that the allegedly failing company "would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act." Merger Guidelines § 11. "There is disagreement among the courts as to whether this element is an actual requirement of the failing company defense. *See Citizen*, 394 U.S. at 138 (noting many companies successfully reorganize in bankruptcy and requiring defendant to show prospects of reorganization to be dim or nonexistent); *United States Steel Corp. v. F.T.C.*, 426 F.2d 592, 608 (holding *Citizen* requires showing that prospects of Chapter 11 reorganization must be dim or nonexistent) (6th Cir. 1970);

*United States v. Phillips Petroleum Co.*, 367 F. Supp. 1226, 1259 (C.D. Cal. 1973) (acknowledging reorganization in bankruptcy requirement) . . . . *But see General Dynamics*, 415 U.S. at 507 (omitting bankruptcy reorganization requirement when setting forth failing company defense in dictum); *Black & Decker*, 430 F. Supp. at 778 ('The weight of authority suggests that dim prospects for bankruptcy reorganization are not essential to successful assertion of the failing company defense.'); *M.P.M.*, 397 F. Supp. at 96 ('We conclude that a [] defendant need not be required to show that reorganization prospects under the bankruptcy act were dim or nonexistent in order to discharge its burden of proof as to the "failing company" defense.')." *Sutter Health*, 84 F. Supp. 2d at 1084.

It is not necessary to resolve whether, as a matter of law, Respondent must prove that the prospects for Freedom's reorganization under the bankruptcy laws were dim or nonexistent because Respondent has not proven the other elements of the failing company defense. *FTC v. Harbour Group Invs., L.P.*, 1990 WL 198819, at *2-4 n.4 (D.D.C. 1990) (holding that, where defendants failed to show that the merger was the only available alternative, the court "need not decide whether or not defendants must prove that the prospects of reorganization under the bankruptcy laws are dim or nonexistent"). As set forth above, Respondent has failed to prove the first element of the defense, that Freedom was at risk of imminent failure. As explained below, Respondent has also failed to prove that the Ottobock was "the only available purchaser."

**c. Unsuccessful good-faith efforts to elicit reasonable alternative offers**

The last element that must be proven to establish the failing company defense is that the acquiring company was "the only available purchaser." *Citizen Pub.*, 394 U.S. at 138; *United States v. Greater Buffalo Press*, 402 U.S. 549, 555-56 (1971) (holding that a defendant must show that there was "no other prospective purchaser" for the acquired company, and finding that the acquired company was not within the "failing company" exception to Section 7 of the Clayton Act where only two companies were "considered as prospective purchasers; the numerous other smaller [market participants] were never even approached"). "The 'only' suggests that the burden on the defendant in proving compliance with this requirement is quite heavy." *Harbour Group*, 1990 WL 198819, at *3. The Ninth Circuit has stated that "[m]erely proving that some or all of the most logical purchasers have declined to buy is not enough to

prove that the challenged purchaser was the only prospective purchaser." *Golden Grain Macaroni v. FTC,* 472 F.2d 882, 887 (9th Cir. 1972) (citing *Greater Buffalo Press*, 402 U.S. 549).

In order to prove that no alternative purchaser exists, courts have required the acquired company to demonstrate that it "made a reasonable, good faith attempt to locate an alternative buyer." *Dr. Pepper*, 991 F.2d at 865. *See also Sutter Health*, 84 F. Supp. 2d at 1084-85 (citing *United States v. Diebold, Inc.,* 369 U.S. 654, 655 (1962); *United States v. Pabst Brewing Co.*, 296 F. Supp. 994, 1002 (E.D. Wis. 1969) (holding that a defendant must make "a sufficiently clear showing" that it "undertook a well conceived and thorough canvass of the industry such as to ferret out viable alternative partners for a merger")). To qualify as a "good-faith effort," a company "must make reasonable inquiries within its market . . . ." IV Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 954d1 (4th ed. 2016); *Harbour Group*, 1990 WL 198819, at *6 (declining to apply the failing company defense where the company made minimal efforts to contact obvious companies in its own industry that appear to be willing to at least entertain the notion of purchasing the company). Some courts have also required a defendant to show it has made good-faith efforts to elicit reasonable alternative offers that would keep the acquired company in the relevant market and pose a less severe danger to competition than does the proposed merger. *United States v. Energy Sols., Inc.*, 265 F. Supp. 3d 415, 445 (D. Del. 2017). *See also* Merger Guidelines § 11.

Respondent asserts that Freedom's financial situation left Freedom with two possible avenues to avoid bankruptcy, a refinancing or a sale to a strategic buyer, and that Freedom's preferred avenue was a refinancing. RB at 114; RFF 1453 (citing trial testimony of Freedom's then-chairman and CEO David Smith). The assertion that Freedom's preferred avenue was a refinancing is contradicted by evidence indicating that Freedom's preferred avenue was a sale to a strategic buyer. At an October 7, 2016 board meeting, one key point the participants discussed was that obtaining a "[n]ew investor, if contributing equity will be very painful to both HEP and Parker [Hannifin] [the owners of Freedom] in terms of the dilution impact." F. 841. In addition, when [redacted] was considering replacing half the debt with equity, but with a [redacted] the board viewed this as unfavorable, as compared to an offer of [redacted] by the strategic players (Ottobock and Össur). F. 846-847. When asked about the

efforts that were made to refinance Freedom's debt, board member Achilleas Dorotheou testified, "[a] few players were approached, but the terms of valuation were very unfavorable compared to the strategic bidders . . . . [I]t was evident to us that . . . one of the strategic players and notably Ottobock would have the highest offer." F. 848.

The record further shows that Freedom's sales process focused on Ottobock. In early October 2016, Maynard Carkhuff, Freedom's vice chairman and chief innovation officer at the time, and David Smith, Freedom's CEO at the time, met with Ottobock HealthCare GmbH's chairman and primary owner, Professor Hans Georg Näder, in Berlin, Germany to gauge Ottobock's interest in acquiring Freedom. F. 849. Later in October 2016, Mr. Carkhuff and Mr. Smith had another meeting with Professor Näder in New York, New York. F. 850. At that meeting, Mr. Carkhuff made a presentation to Professor Näder, which provided an overview of the Freedom business in order to try to persuade Ottobock to acquire Freedom. F. 850.

A presentation created in February 2017 by Moelis, Freedom's investment bank, stated that Moelis "presented a preliminary, illustrative valuation to the [b]oard of Freedom Innovations on October 20, 2016[.] Freedom Innovations subsequently entered into bilateral sale negotiations with Ottobock[.]" F. 856.[32] This presentation did not reference any other potential acquirers of Freedom or any refinancing alternatives. F. 856. In the October 2016 timeframe, Moelis had not been asked to conduct any outreach to potential acquirers, to provide any assistance with selling the Freedom business, or to contact any possible refinance partners. F. 853. In March 2017, Maynard Carkhuff, David Smith, and Freedom board member Rolf Classon met with Professor Näder and Otto Bock HealthCare GmbH director of strategy and mergers and acquisitions, Alexander Gück, in Berlin, Germany. F. 857. In April 2017, Ottobock informed Freedom that it viewed Freedom's valuation to be [redacted] F. 859.

From October 2016 to April 2017, neither Freedom nor Moelis contacted any potential alternative strategic buyers besides Ottobock. F. 860. In late April 2017, Moelis contacted Össur and Permobil, a company largely focused on patient lifts, wheelchairs, and mobility aids (F. 861), as potential acquirers of Freedom. Moelis also expanded its outreach in May 2017 to

[32] Freedom formally engaged Moelis in May 2017. F.843. Prior to the formal engagement, Moelis had a number of meetings and discussions with Freedom and Freedom's board of directors regarding a valuation of Freedom. F. 842.

five potential strategic buyers in addition to Össur and Permobil, but none of the five additional potential strategic buyers were in the business of selling prosthetics and none were informed that Freedom was the acquisition target. F. 863. In June 2017, Moelis sent process letters to both Össur and Ottobock seeking "a written, non-binding indication of interest" to acquire Freedom. F. 864. No other companies received a process letter to submit an indication of interest. F. 865.

Freedom's objective was to get bids as high as possible, in order to pay the banks and creditors and provide as much money as possible to Freedom's investors. F. 874. Jon Hammack, managing director at Moelis and the person leading Freedom's sales process, believed that a company would need to have at least [redacted] and therefore Moelis did not contact companies about acquiring Freedom unless the company had access to at least [redacted] F. 873. A search with that purpose may be "typical in the [mergers and acquisitions] field," as asserted by Respondent (RB at 117), but it does not satisfy the legal requirements of the failing company defense. *See Pabst Brewing Co.*, 296 F. Supp. at 1002 (rejecting the failing company defense where the defendant failed to make "a sufficiently clear showing [that] management undertook a well-conceived and thorough canvass of the industry" to find "viable alternative partners for merger"); *Energy Sols.*, 265 F. Supp. 3d at 446 (rejecting the failing company defense where the acquired company was "clearly focused on obtaining what it perceived to be . . . fair value, not an offer above the liquidation value").

In this case, several smaller prosthetics companies testified that they were not contacted during Freedom's sales process, but would have had an interest in acquiring Freedom. F. 883, 885-886. *See also* F. 875-876, 880 (numerous smaller companies in the industry that were never approached). Respondent asserts that, "[a]s a result of the importance of speed and certainty, Freedom was not able to contact every conceivable company in the prosthetics industry that might have made an offer because doing so would have delayed the process and ultimately been fruitless." RB at 117-18. Regardless of whether or not Freedom was legally obligated to contact "every conceivable company," Freedom's failure to contact smaller prosthetics companies to determine their interest in an acquisition undermines Respondent's failing company defense. In *Greater Buffalo Press*, the Supreme Court summarily rejected the adequacy of a search on the ground that "numerous other smaller [companies in the industry] were never approached."

402 U.S. at 556. Similarly, the defendants in *Harbour Group* argued that "it is unreasonable to require it to approach smaller companies in the industry that could not be expected to have an interest or ability to purchase a larger company . . . ." *Harbour Group*, 1990 WL 198819, at *4. Citing the Supreme Court's guidance in *Greater Buffalo Press*, the *Harbour Group* court held that, "at least in some cases, approaching smaller companies in a given industry might be exactly what is required of a company seeking the protection of the failing company defense." 1990 WL 198819, at *4. The failure to approach a single, smaller prosthetics company weighs against a conclusion that Freedom engaged in a good-faith effort to elicit reasonable alternative offers.

Furthermore, Freedom disregarded an expression of interest by Nabtesco. In September 2017, Nabtesco contacted Maynard Carkhuff and expressed an interest in acquiring Freedom. F. 877. Upon learning of Nabtesco's interest, David Smith, Freedom's CEO, informed Mr. Carkhuff that Freedom had several good offers in hand and that there likely would not be enough time to integrate Nabtesco into the process. F. 877. Mr. Carkhuff then informed Nabtesco that Freedom was not interested in Nabtesco buying Freedom. F. 878.

Finally, Respondent cannot show that Ottobock was the "only available purchaser" because Freedom rejected a [redacted] bid from Össur to acquire Freedom. F. 889, 895-896. Respondent asserts that Össur's bid cannot be considered a reasonable alternative offer because it was not sufficiently concrete or binding. RB at 118. This assertion is without merit. The evidence shows that in late July 2017, Ottobock made an initial offer of [redacted] and Össur made an initial offer of [redacted] F. 866-867. On August 1, 2017, Moelis sent identical letters to Ottobock and Össur, seeking their final offers to acquire Freedom. F. 892. Össur conducted limited due diligence, including looking at "high-level sales information" and the "overall cost structure of the company," and inspecting a video of the Quattro MPK's performance. F. 889, 891, 896. On August 31, 2017, Össur submitted a final offer of [redacted] F. 895. Although Össur's August 31, 2017 bid stated that it was non-binding, Össur's offer letter addressed each of the terms Moelis had requested in its August 1, 2017 letter, including that "Össur has received board approval to submit this Proposal and to consummate the transaction on consistent terms" and that Össur was prepared to close the acquisition "within two weeks." F. 896-900. Moreover, Ottobock's August 31, 2017 bid was also non-binding. F. 870.

Ordinary course of business documents from Freedom in September 2017 describe Össur's offer as a "good offer." F. 901. *See also* F. 902.

Respondent next asserts that the dollar amount of Össur's bid "was so unreasonably low that it does not satisfy the liquidation threshold described in the Merger Guidelines." RB at 118-19. The Merger Guidelines define a reasonable alternative offer as "[a]ny offer to purchase the assets of the failing firm for a price above the liquidation value of those assets . . . . Liquidation value is the highest value the assets could command for use outside the relevant market." Merger Guidelines § 11 n.16. Only one case has relied upon this standard. *See Energy Sols.*, 265 F. Supp. 3d at 446. To the extent that there is a liquidation threshold, Freedom's tangible and intangible assets combined would have a liquidation value of at most [redacted] F. 904. Össur's [redacted] bid is well above that amount.

Respondent's last criticism of the Össur offer is that an Össur acquisition of Freedom would have been no less of a danger to competition than the acquisition of Freedom by Ottobock. RB at 118-19, 122-23. The evidence fails to support this claim. Respondent asserts that an acquisition by Össur would be presumptively anticompetitive in the relevant market of MPKs sold in the United States. RB at 122-23. However, the evidence shows that an acquisition of Freedom by Össur would increase the HHI by 339 points, whereas the acquisition of Freedom by Ottobock increases the HHI by 1,522 points. F. 908. Thus, based solely on market structure evidence, the Acquisition of Freedom by Ottobock, poses a substantially greater presumptive threat to competition than an acquisition by Össur, contrary to Respondent's argument. Moreover, Respondent does not point to any other evidence suggesting that an acquisition of Freedom by Össur would pose a likelihood of anticompetitive effects.[33]

Respondent further asserts that an acquisition of Freedom by Össur would be presumptively anticompetitive, based on market shares in "a market for K-3 and K-4 prosthetic

[33] In this regard, it is noted that Respondent's expert witness, James Peterson, was not aware of testimony or documents in the record that indicate that Össur intended to discontinue selling Freedom's microprocessor knee products in the United States. F. 906. In addition, Respondent's other expert witness, Dr. David Argue, did not perform any analysis to determine potential anticompetitive harm in the United States MPK market from an acquisition of Freedom by Össur, beyond finding a presumption of harm under the Merger Guidelines based on levels and changes in the HHI. F. 909.

feet." RB at 123. Respondent relies on the opinion of its expert witness, Dr. David Argue, who testified at trial that for the purposes of analyzing a merger between Össur and Freedom with respect to feet, he defined a foot market consisting of K-3 and K-4 prosthetic feet. F. 910. However, Respondent fails to explain any details of the purported market, or cite to any analysis in Dr. Argue's expert report demonstrating the existence of such a market. *See* RFF 1502. Dr. Argue acknowledged that he did not include any critical loss calculation or a full evaluation of likely predicted loss. F. 910. Based on the foregoing, the evidence fails to prove that the competitive impact of an Össur/Freedom acquisition should be evaluated based on a market defined as K-3 and K-4 prosthetic feet.

In summary, Freedom rejected a reasonable formal offer, ignored expressions of interest, and avoided gauging the interest of smaller companies in the industry. Therefore, Respondent has not demonstrated that Freedom made a reasonable, good faith attempt to locate an alternative buyer.

#### d. Conclusion

For the above stated reasons, Respondent has not met the strict standards of the failing company defense.

### 4. Weakened competitor

Respondent also asserts that Freedom was a "flailing firm" at the time of the Acquisition, for the same reasons that Freedom was assertedly a failing firm, and that because Freedom was a "weakened competitor" of little competitive significance, the Acquisition does not reduce competition. RB at 75-77. "[T]o ensure that competition and consumers are protected, [courts] will credit such a defense only in rare cases, when the defendant makes a substantial showing that the acquired firm's weakness, which cannot be resolved by any competitive means, would cause that firm's market share to reduce to a level that would undermine the government's prima facie case." *Univ. Health*, 938 F.2d at 1221; *see also FTC v. Warner Commc'ns, Inc*., 742 F.2d 1156, 1164 (9th Cir. 1984) (explaining that a weakened competitor defense is disfavored because it "would expand the failing company doctrine, a defense which has strict limits").

"[C]ourts have imposed an extremely heavy burden on defendants seeking to rebut the structural presumption on this ground." *ProMedica*, 2012 FTC LEXIS 293 at *78. For example, in *FTC v. Arch Coal*, 329 F. Supp. 2d 109 (D.D.C. 2004), the court held that "the evidence of financial or other weakness must genuinely undercut the statistical showing of anticompetitive market concentration." *Id.* at 154. "[F]inancial difficulties 'are relevant only where they indicate that market shares would decline in the future and by enough to bring the merger below the threshold of presumptive illegality.'" *Id.* (citation omitted). "[I]ndeed, '[f]inancial weakness, while perhaps relevant in some cases, is probably the weakest ground of all for justifying a merger,' and 'certainly cannot be the primary justification' for permitting one." *Id.* (quoting *Kaiser Aluminum & Chemical Corp. v. FTC*, 652 F.2d 1324, 1339, 1341 (7th Cir. 1981)).

As set forth above, Respondent has not made a substantial showing that Freedom was so weak as to be of little competitive significance. As detailed in F. 740-770 and summarized above, the record shows that Freedom was experiencing financial difficulties in the years prior to the Acquisition. However, as discussed above, the evidence also shows that after David Smith became CEO in April 2016 and implemented a concrete strategic plan, Freedom had months of increased sales and earnings and a research and development pipeline that, just before the Acquisition, was "the best it's ever been in the history of [the] company." F. 835. Thus, this case is not like *General Dynamics*, relied upon by Respondent, in which "the acquired firm, a coal company, 'had no coal reserves and was unable to obtain additional ones.'" RB at 76 (quoting *FTC v. National Tea Co.*, 603 F.2d 694, 699-700 (8th Cir. 1979) (citing *General Dynamics*, 415 U.S. 486)).

Respondent has also failed to show that Freedom's purported financial weakness would cause its market share to decline so precipitously as "to bring the merger below the threshold of presumptive illegality." *ProMedica*, 2012 FTC LEXIS 293 at *89. Although Respondent asserts that "Freedom was days away from liquidation," RB at 76, Freedom never calculated a liquidation value of the company and never missed a payroll (F. 823, 837), and Respondent presented no evidence from Freedom's lenders indicating that they would have forced Freedom into liquidation. Despite its purported weakness, Freedom's market share increased from 2016

to 2017 (based on units sold) from [redacted] in the narrower MPK market and [redacted] in the broader MPK market) and Freedom experienced a [redacted] year-over-year growth in sales of the Plié from 2016 to 2017. F. 480, 484, 783. Based on the foregoing, Respondent has not met its burden of demonstrating that Freedom's financial weakness "genuinely undercut[s] the statistical showing of anticompetitive market concentration." *Arch Coal*, 329 F. Supp. 2d at 154.

Furthermore, Respondent has not made a substantial showing that Freedom's weakness could not be resolved by any competitive means. Whereas in *Arch Coal*, prospects for finding an alternative buyer were "dim," *Arch Coal*, 329 F. Supp. 2d at 156, here that is far from clear. As discussed above, the evidence shows that there were numerous other strategic players interested in acquiring Freedom, including Össur, whose reasonable offer was rejected. Thus, as detailed in section III.E.4.b of the Findings of Fact and summarized above, Respondent has failed to demonstrate that Freedom's financial difficulties could not be addressed "through new financing or acquisition by other than a leading competitor." *Univ. Health*, 938 F.2d at 1221.

For the above reasons, "this is not one of those 'rare cases,' where Respondent has met its burden of showing that financial weakness rebuts the presumption of illegality based on the government's structural case." *ProMedica*, 2012 FTC LEXIS 293 at *97 (internal citation omitted).

**5. Divestiture**

Respondent next contends in rebuttal that Respondent has proposed to divest certain assets of Freedom, limited to assets pertaining to Freedom MPKs, and that such divestiture would counteract any likely anticompetitive effects from the Acquisition of Freedom by Ottobock. RB at 81-90. Complaint Counsel argues that the evidence fails to show that [redacted] Respondent's divestiture [redacted] would fully restore competition; and that even if Respondent's proposed divestiture would fully restore competition in the future, this fact cannot negate liability that Respondent may have for anticompetitive effects occurring after the Acquisition, prior to the completion of [redacted] divesture. CCB at 143-80.

"In rebuttal, a defendant may introduce evidence that a proposed divestiture would 'restore [the] competition' lost by the merger counteracting the anticompetitive effects of the merger." *Aetna*, 240 F. Supp. 3d at 60. In this regard, the standard for evaluating a proposed divestiture, in the context of rebuttal, is the same as would be applied to evaluating a remedy, i.e., it must appear that the proposed divestiture will "effectively preserve competition in the relevant market." *Id*. (citation omitted). In other words, the divestiture must "replac[e] the competitive intensity lost as a result of the merger." *Sysco*, 113 F. Supp. 3d at 72 (internal quotation marks omitted). *See also* U.S. Dep't of Justice, Antitrust Division Policy Guide to Merger Remedies 4 (2004) (stating that relief must be "sufficient to restore competitive conditions the merger would remove. Restoring competition is the 'key to the whole question of an antitrust remedy' and the 'only appropriate goal.'").[34]

To support its rebuttal argument, Respondent relies on [redacted] RB at 89-90; RFF 1283-90. *See* F. 960-962.

A defendant's burden on rebuttal "includes producing evidence that the divestiture will actually occur. . . . [T]he divestiture need not be iron clad for a court to consider it. Rather, once the divestiture is sufficiently non-speculative for the court to evaluate its effects on future competition, then further evidence about the likelihood of the divestiture goes to the weight of the evidence regarding the divestiture's effects." *Aetna*, 240 F. Supp. 3d at 60. In the instant case, [redacted] RRB at 146-47. Under these circumstances, Respondent has

[34] Like the Merger Guidelines, the DOJ remedies guide "is frequently used by courts to guide their analysis, although it is not binding law." *Aetna*, 240 F. Supp. 3d at 60.

failed to demonstrate that [redacted] Accordingly, [redacted] cannot properly be considered.

[redacted] F. 935. Divestiture of an entire existing business entity is the preferred method for restoring competition adversely affected by an acquisition. "Divestiture of an 'existing business entity' might be more likely to 'effectively preserv[e] the competition that would have been lost through the merger'. . . ." *Aetna*, 240 F. Supp. 3d at 60. This is because, with a complete divestiture, the acquirer will have the "'personnel, customer lists, information systems, intangible assets, and management infrastructure' necessary to competition . . . ." *Id.* (quoting DOJ Guide to Merger Remedies 1 (2011)). "[D]ivestiture of some lesser set of assets might be appropriate when the purchaser already has, or could easily attain, the other capabilities needed to compete effectively." *Id*. Respondent asserts that [redacted] RB at 88-89. Based on the current record, as explained below, the evidence fails to prove this assertion.

[redacted]

[35] [redacted]

[redacted]

[redacted]

[redacted]

[36]

For all these reasons, the terms of the agreement have not been sufficiently demonstrated and cannot be properly evaluated.

Furthermore, there are conditions precedent to closing the which affect the likelihood of the divestiture. As noted above, even where a divestiture is sufficiently non-speculative to consider its effects, "further evidence about the likelihood of the divestiture goes to the weight of the evidence regarding the divestiture's effects." *Aetna*, 240 F. Supp. 3d at 60.

[36] Respondent asserts that Freedom "represents and warrants under the that the assets being transferred are sufficient to enable to compete. RB at 88 (citing § 3.20 of the ). Section 3.20 contains no warranty. Section 3.20 simply states that the assets are sufficient. F. 959. The statement is not termed a "representation" and is not expressly, or exclusively, attributed to Freedom. *See* F. 959.

[redacted] F. 958. Given the absence of any settlement to date and the likelihood of administrative and judicial appeals going forward, it is difficult to envision the conditions being fulfilled in the reasonably near future. The conditions precedent to closing [redacted] cast doubt on the likelihood of the divestiture occurring, and thereby detract from the weight to be given any asserted effects of the proposed divestiture.

It is recognized that it is the nature of an asset purchase agreement that the closing takes place in the future, and that some terms may not be finalized until closing appears more certain. In this context, and given the uncertainty in the instant case that the conditions precedent for closing the [redacted] can be met, Respondent's burden on rebuttal is particularly challenging. But this cannot alter the conclusion that the trial record lacks sufficient evidence to conclude that Respondent has met the required burden.

For all the foregoing reasons, Respondent's rebuttal argument based on its proposed divestiture of Freedom's MPK assets is rejected.[37]

### 6. Efficiencies

#### a. Applicable legal standards

Merger-generated efficiencies can "'enhance the merged firm's ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products.'" *H&R Block*, 833 F. Supp. 2d at 89 (quoting Merger Guidelines § 10). Thus, "a defendant may rebut the government's prima facie case with evidence showing that the intended merger would create significant efficiencies in the relevant market." *Univ. Health*, 938 F.2d at 1222. An anticompetitive merger cannot be justified on the basis of asserted efficiencies outside the relevant market. *See Philadelphia Nat'l Bank*, 374 U.S. at 370 (rejecting the defendant's proffered justification that the challenged merger would help the defendant compete in areas outside the relevant geographic market).

[37] Complaint Counsel's argument that, even if Respondent's proposed divestiture would restore competition post-divestiture, Respondent remains liable for violating Section 7 due to anticompetitive effects allegedly having already occurred, is moot because, as set forth above, Respondent's evidence is insufficient to determine whether the proposed divestiture will restore competition. Accordingly, logic dictates that Complaint Counsel's argument need not be, and thus is not, addressed.

Cognizable efficiencies are defined as "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *H&R Block*, 833 F. Supp. 2d at 89 (quoting Merger Guidelines § 10). A cognizable efficiency claim "must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted saving must be reasonably verifiable by an independent party." *Id.* Moreover, the evidence must show that the claimed efficiencies would ultimately benefit customers. *Penn State Hershey Med. Ctr.*, 838 F.3d at 351; *Univ. Health*, 938 F.2d at 1223.

To be verifiable, the claimed efficiencies require "clear evidence showing that the merger will result in efficiencies that will offset the anticompetitive effects and ultimately benefit consumers." *Penn State Hershey Med. Ctr.*, 838 F.3d at 350. A merger-specific efficiency is one that "cannot be achieved by either company alone because, if they can, the merger's asserted benefits can be achieved without the concomitant loss of a competitor." *Heinz*, 246 F.3d at 721-22.

The law requires "a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721. *Accord H&R Block*, 833 F. Supp. 2d at 89. As the court in *H&R Block* explained:

> Efficiencies are inherently "difficult to verify and quantify" and "it is incumbent upon the merging firms to substantiate efficiency claims" so that it is possible to "verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific."

*Id.* (quoting Merger Guidelines § 10).

"High market concentration levels require 'proof of extraordinary efficiencies'" to rebut the presumption of likely anticompetitive effects, and "courts 'generally have found inadequate proof of efficiencies to sustain rebuttal of the government's case.'" *H&R Block*, 833 F. Supp. 2d at 89 (quoting *Heinz*, 246 F.3d at 720); *Sysco*, 113 F. Supp. at 81-82; *CCC Holdings*, 605 F. Supp. 2d at 72. Research does not reveal a case that permitted an otherwise unlawful

transaction to proceed based on claimed efficiencies. *See FTC v. Wilh. Wilhelmsen Holdings ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018) (citing *CCC Holdings*, 605 F. Supp. 2d at 72); *Sysco*, 113 F. Supp. 3d at 82 ("The court is not aware of any case . . . where the merging parties have successfully rebutted the government's *prima facie* case on the strength of the efficiencies.").

**b. Analysis**

Respondent argues that efficiencies to be generated by the Acquisition outweigh any likely anticompetitive effects. RB at 78. Specifically, Respondent asserts that the integration plan for Freedom, developed by Ottobock and Freedom with assistance from an outside consultant, A.T. Kearney (the "integration team"), contemplates a dual brand strategy,[38] which the integration team estimated would result in substantial cost savings through [redacted] RB at 78-79. Respondent further argues that its proffered expert witness on efficiencies, James Peterson, analyzed the integration plan and the cost synergies identified by the integration team and concluded that the Acquisition will result in merger-specific efficiencies in the form of [redacted] RB at 79-80. Complaint Counsel responds that the efficiencies analysis by Mr. Peterson fails to demonstrate any verifiable, merger-specific efficiencies. CCB at 109-14. Complaint Counsel further argues that, even if Respondent's claimed efficiencies were verifiable and merger-specific, the evidence fails to show that Respondent's claimed efficiencies would be passed on to consumers. CCB at 114-16.

The evidence shows that on September 29, 2017, as part of Ottobock's process for the integration of Freedom, Ottobock engaged a third-party consultant, A.T. Kearney, to assist Ottobock with post-Acquisition planning. F. 679-680. A.T. Kearney's responsibilities included

[38] For Ottobock, a dual brand strategy is when a single company has two different brands in the same market. With respect to the Acquisition, the dual brand strategy refers to positioning Freedom in the market as a company with advanced products and positioning Ottobock as a company with premier products. Under a dual brand strategy, the two companies would operate independently with common ownership but would have different value propositions and price points in the same market, with the goal of gaining increased usage of both products. F. 683.

establishing a program for the integration of Freedom, defining synergy targets, identifying synergy opportunities, and developing synergy capture plans. F. 681. An integration team was formed, consisting of personnel from Ottobock, Freedom, and A.T. Kearney. F. 681. The integration team developed a financial model of potential cost savings from the integration of Freedom ("financial model"). F. 684. The financial model prepared by the integration team served as the basis for James Peterson's efficiencies estimates. F. 684. Based on his review of the financial model, Mr. Peterson concluded that, of the six categories of potential cost savings identified by the integration team in the financial model, only three were "potential Ottobock merger-specific efficiencies": [redacted][39] F. 694. Mr. Peterson then calculated the value of those potential merger-specific efficiencies by discounting the figures in the integration team's financial model for each of those categories by 30 and 50%. F. 695. Applying a 30% discount, Mr. Peterson estimated approximately [redacted] as an upper limit of the potential merger-specific efficiencies that Ottobock could achieve by 2022, and, applying a 50% discount, estimated approximately [redacted] as a lower limit of the potential merger-specific efficiencies that Ottobock could achieve by 2022. F. 696-697.

Respondent asserts that the financial model developed by the integration team represents a "detailed plan" that identified and quantified cost savings from the Acquisition of approximately [redacted] per year by 2022. RB at 79. However, the integration team stopped all work in mid-December 2017. F. 685. According to Dr. Juerg Baggenstoss of A.T. Kearney, the integration team leader (F. 682), the team's work relating to identifying synergies opportunities was at an "early stage" and "incomplete." F. 686. Specifically, the integration team's work had progressed only through an initial stage of identifying and estimating synergy opportunities. F. 687. None of the synergy opportunities identified by the integration team progressed beyond this initial stage. F. 688. As Dr. Baggenstoss explained, there "were initial

[39] Mr. Peterson concluded that three other categories of potential cost savings identified by the integration team in the financial model were not merger-specific efficiencies: [redacted] F. 693.

estimates on the opportunity, but a proper target setting was not done." F. 688.[40] A "proper target setting" involves the CFO offering a cost savings target, followed by a "bottom-up assessment" by the integration team as to whether the target is possible, which can lead to readjusting the target. F. 689.

Furthermore, the evidence shows that Ottobock had not yet made decisions regarding integration plans affecting [redacted] which could affect the identified synergy opportunities in these areas. F. 691. Indeed, according to Freedom's current CEO David Reissfelder,[41] no decisions had been made "at any point about . . . any aspect of the integration" of Freedom in the United States. F. 690. Based on the foregoing, Respondent has failed to demonstrate that the integration team sufficiently verified the synergies estimates in its financial model, or that the estimates are non-speculative.

Moreover, contrary to Respondent's argument, the evidence fails to show that James Peterson independently verified the cost savings estimates in the financial model. Respondent contends that Mr. Peterson "further analyzed" the work of the integration team, including through a "sensitivity analysis." RB at 79. The evidence fails to support this contention. The efficiencies estimates provided by Mr. Peterson were derived directly from the estimates in the integration team's financial model (F. 684, 695), which as noted above, were early stage, incomplete assessments. F. 686. The financial model prepared by the integration team relies upon numerous assumptions. F. 701. Although Mr. Peterson altered various assumptions to see how the changes affected the model, ultimately, what Mr. Peterson described as sensitizing of the financial model synergies estimates amounted to simply discounting the synergies estimates to arrive at his efficiencies estimates. F. 703-704. As an example, with respect to the integration team's assumptions affecting gross margins, Mr. Peterson explained that he "relied upon the fact

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[40] [redacted]

[41] Mr. Reissfelder became Freedom's CEO on September 27, 2017, after the Acquisition. F. 690 n.61.

that [Ottobock] hired a third-party consultant [A.T. Kearney] who had done significant work over a significant period of time . . . , then built a model, and then . . . I also took a significant discount on those implied efficiencies." F. 703.

Furthermore, James Peterson's opinion that [redacted] constitute merger-specific efficiencies is vague and unpersuasive. For example, as support for the opinion that [redacted] efficiencies are merger-specific, Mr. Peterson's expert report states only that [redacted] and that "it is unknown if another strategic buyer could achieve such synergies." F. 705. *See also* F. 709 (opinion that the [redacted] efficiencies are merger-specific based on the assertion that they [redacted] Moreover, Mr. Peterson's report does not address whether Freedom could have independently achieved the asserted efficiencies, or achieved them through another type of transaction. F. 706, 708, 710.

In addition, Mr. Peterson assumed that the asserted efficiencies would be passed on to consumers based on the concept that [redacted] . . . enable[] a company to be more flexible when it comes to pricing." F. 711. However, Mr. Peterson did not attempt to calculate an estimate of the efficiencies that would be realized by consumers. F. 711. *See CCC Holdings*, 605 F. Supp. 2d at 74 (rejecting asserted cost savings efficiencies, noting that there was "no evidence to suggest that a sufficient percentage of those savings will accrue to the benefit of the consumers to offset the potential for increased prices. . . . [T]hese advantages could show up in higher profits instead . . . ."). Similarly, Mr. Peterson did not evaluate whether the claimed efficiencies related to [redacted] would be realized in the United States. F. 712. *See Philadelphia Nat'l Bank*, 374 U.S. at 370 (holding that asserted efficiencies outside the relevant market do not justify an anticompetitive merger).

Based on the foregoing, Respondent has failed to demonstrate that its asserted efficiencies are merger-specific or to sufficiently substantiate the asserted efficiencies with independent verification. Furthermore, the evidence is insufficient to justify a conclusion that the asserted efficiencies would benefit consumers in the United States, which is the relevant

geographic market. Accordingly, Respondent's rebuttal argument based on efficiencies is rejected.

#### 7. Conclusion

As shown above, Respondent's rebuttal arguments and defenses are without merit. The evidence proves that the Acquisition may substantially lessen competition in the relevant market for the manufacture and sale of MPKs in the United States in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act.

The analysis now addresses the appropriate remedy.[42]

### F. Remedy

#### 1. Applicable legal principles

Complaint Counsel has proven that Respondent's acquisition of Freedom constitutes an illegal acquisition in violation of Section 7 of the Clayton Act. "The purpose of relief in a Section 7 case is to restore competition lost through the unlawful acquisition. . . . [C]omplete divestiture is generally the most appropriate way to restore competition lost through an unlawful acquisition. *See United States v. E.I. du Pont de Nemours & Co.,* 366 U.S. 316, 329, 81 S. Ct. 1243, 6 L. Ed. 2d 318 (1961); *Chicago Bridge,* 534 F.3d at 441." *Polypore*, 2010 WL 9549988, at *33.

In a merger case, absent "unusual circumstances," it is presumed that total divestiture of the acquired assets is the best means of restoring competition. *In re RSR Corp.,* 88 F.T.C. 800, 1976 FTC LEXIS 40, at *208 (Dec. 2, 1976), *aff'd*, *RSR Corp. v. FTC*, 602 F.2d 1317 (9th Cir. 1979). Accordingly, "the burden rests with respondent to demonstrate that a remedy other than full divestiture would adequately redress any violation which is found." *In re Fruehauf Corp.*,

[42] Because Respondent has failed to successfully rebut the prima facie proof of reasonably likely anticompetitive effects based on market structure and direct competition between Ottobock and Freedom (see section II.D above), Complaint Counsel has met its burden of proving the Acquisition violates Section 7 of the Clayton Act and Section 5 of the FTC Act. *See, e.g.*, *Polypore*, 2010 WL 9549988, at *28-32 (determining that the respondent failed to meet its burden to rebut the prima facie case and entering a remedial order for a violation of Section 7). Accordingly, it is not necessary to analyze Complaint Counsel's additional contentions in support of a finding of likely anticompetitive effects (*see* fn 25 above). Whether or not such additional proof exists would not change the result in this case.

90 F.T.C. 891, 1977 FTC LEXIS 9, at *3 n.1 (Dec. 21, 1977); *In re Chicago Bridge*, 138 F.T.C. 1024, 1373 (June 18, 2003). "[E]xceptions to the general rule [of full divestiture] can be reasonably invoked . . . only when the proof of their probable efficacy is clear and convincing." *In re Diamond Alkalai, Co.*, 72 F.T.C. 700, 1967 FTC LEXIS 44, at *88 (Oct. 2, 1967).

> In the absence of proof to the contrary the assumption of this Commission must be that "only divestiture can reasonably be expected to restore competition and make the affected markets whole again." Moreover, if an order of divestiture appears to the Commission to be in all likelihood the most effective available remedy, the Commission need not justify its order beforehand by showing that it will unquestionably restore competition.

*Id.* at *88-89 (citation omitted).

In addition, it is well settled that once the government "has successfully borne the considerable burden of establishing a violation of law, all doubts as to the remedy are to be resolved in its favor." *du Pont*, 366 U.S. at 334.

### 2. Analysis

#### a. Introduction

As a remedy for the Section 7 violation demonstrated in this case, Complaint Counsel seeks an order requiring Respondent to fully divest Freedom to a Commission-approved acquirer, with two potential exceptions described below. *See* Complaint Counsel's proposed order (Attachment B to Complaint Counsel's Post-Trial Brief) (hereafter, "Proposed Order"), Paragraph II.A.1.

The Proposed Order also contains a number of requirements that Complaint Counsel asserts are reasonably necessary for an effective divestiture, such as requirements for continuing to hold Freedom's assets separate pending divestiture (II.A.3), providing a potential acquirer full due diligence (II.A.4), and allowing an acquirer the right to offer employment to Freedom's employees (II.A.5.c; II.A.9). In addition, the Proposed Order contains various ancillary provisions that Complaint Counsel argues are designed to help ensure that the divested Freedom will be able to compete effectively, including provisions prohibiting Respondent, pending divestiture, from using or disclosing any of Freedom's confidential information (II.A.10-11),

selling or eliminating Freedom's services (III.A,B), or failing to maintain employment of Freedom's employees (II.C). Complaint Counsel briefed each material provision of the Proposed Order, asserting legal and/or record justification. *See* CCB at 179-90 and Attachment A (annotated Proposed Order).

Respondent objects to a complete divestiture and argues that a partial divestiture of Freedom, limited to Freedom's assets related to MPKs (the "MPK Assets" or the "MPK Divestiture"), is a sufficient remedy in this case. RB at 90-91; RRB at 169-76. While Respondent argues these general objections to the scope of the Proposed Order's divestiture requirement, Respondent does not state any objections to any specific provision of the Proposed Order. *See Id.*

Respondent's objections to the Proposed Order and arguments for an MPK Divestiture are addressed below.

**b. Respondent's arguments against the Proposed Order and for partial divestiture limited to Freedom's MPK Assets**

Respondent asserts that Freedom's MPK Assets constitute a discrete set of assets that "can easily be separated" out from the whole of Freedom's business. RRB at 169, 173-74; *see also* RB at 90-91. The evidence fails to support this proposition. [redacted]

[redacted] The foregoing facts contradict the notion that Freedom's MPK assets can be easily separated out from Freedom, as asserted by Respondent.

Respondent further argues that an MPK Divestiture is sufficient to restore any alleged competitive harm from the Acquisition, because the Complaint does not allege, and Complaint Counsel failed to prove, a likelihood of adverse effects on competition in any market beyond the relevant MPK market, and therefore, any broader divestiture remedy is punitive and unnecessary. RB at 90-91; RRB at 174-76. This argument is without merit. In *Chicago Bridge*, 2005 FTC LEXIS 215, to remedy a violation of Section 7 of the Clayton Act, the Commission ordered a complete divestiture of all acquired assets, including a division that built water tanks, even though the relevant product market was cryogenic tanks, because cryogenic tank sales were irregularly timed and water tank sales would provide the regular income stream needed for the divestiture buyer's viability. 2005 FTC LEXIS 215 at **214-16. Similarly, in *In re Olin Corp.,* 113 F.T.C. 400, 1990 FTC LEXIS 234 (June 13, 1990), the Commission ordered the respondent to divest a plant that had facilities to manufacture both the relevant market product and a product outside the relevant market, when the evidence failed to show the plant would be viable if the facilities were separated. 1990 FTC LEXIS 234, at *63-65. The Commission explained: "Since the objective of requiring divestiture is to create a new competitor in this market, we must ensure that the package of assets divested is sufficient to give its acquirer a real chance at competitive success." *Id.* at *65. Furthermore, in *Polypore*, 2010 WL 9549988, the Commission reaffirmed that a remedial order may require "divestiture of assets outside the relevant market where divestiture of those assets is necessary to restore competition within the relevant market." *Id.* at *33. Accordingly, contrary to Respondent's argument, it is well settled that the Commission may order full divestiture in a consummated merger case when a violation of the Clayton Act has been found, even when products outside the relevant product market are implicated.

Moreover, Respondent has failed to demonstrate that a partial divestiture limited to Freedom's MPK Assets would be sufficient to restore competition in the MPK market, and thereby remedy the unlawful Acquisition. The evidence shows that Freedom has leveraged its foot products to stimulate sales of the Plié 3 and compete with Ottobock's C-Leg, F. 976, which

suggests that an MPK divestiture alone may not be sufficient to restore competition and could deprive a potential acquirer of Freedom assets that could help that acquirer compete in the MPK market. *See Polypore*, 2010 WL 9549988, at *33-35 (including divestiture of a European plant, outside the relevant North American geographic market, because the European plant would allow an acquirer to maintain sufficient capacity at a capacity-constrained North American plant, and thereby help the acquirer effectively compete for North American business). The evidence demonstrates that one of Freedom's responses to competitive pressure from the C-Leg 4 was a promotion it called the "ideal combo," which provided a discounted or free prosthetic foot with the purchase of a Plié 3. F. 611-618, 631. The purpose of the ideal combo promotion was to regain Plié's sales lost to the C-Leg 4. F. 616-617. Furthermore, the promotion has been successful in increasing Freedom's Plié 3 sales, including by converting multiple customer accounts to the Plié from other MPKs, and has incentivized customers to buy more Freedom MPKs and feet. F. 617, 624-626. Sales from the ideal combo in the fourth quarter of 2015 accounted for approximately [redacted] of Freedom's total MPK sales in that quarter. F. 625. Prosthetists have responded favorably to the ideal combo. F. 624. Freedom's ideal combo promotion has also impacted Ottobock's sales. F. 637.

In support of its argument for the sufficiency of a partial divestiture, Respondent cites *United States v. Reed Roller Bit Co.*, 274 F. Supp. 573 (W.D. Okla. 1967). RRB at 172. The court in *Reed* held that a remedy of partial divestiture, limited to products in the two relevant markets in which the merging parties competed, would be at least as effective as a divestiture of all of the assets of the acquired company, which included some non-competing products. 274 F. Supp. at 586-89. The court based this conclusion on several factors, including that there was no evidence that the merging parties' competing product lines "can or must be best utilized" with the non-competing products; and that there was no evidence that the operations for the non-competing products were "so interrelated and noncompartmentalized" as to render partial divestiture of the competing products unworkable. *Id.* at 585-87. In the instant case, in contrast, there is substantial evidence, summarized above, that Freedom's MPK can be, and has been marketed to be, utilized with Freedom's prosthetic foot products, notwithstanding such products being outside the relevant product market; and there is substantial evidence, summarized above, that Freedom's operations are interrelated and that MPK operations cannot be easily separated

from the whole of Freedom. Unlike in *Reed*, the evidence in this case fails to demonstrate that a partial divestiture limited to Freedom's MPK Assets would be at least as effective as full divestiture.

Respondent's reliance on *FTC v. PepsiCo, Inc.*, 477 F.2d 24 (2d Cir. 1973) is similarly misplaced. RRB at 172. The issue in that case was whether a preliminary injunction should issue, ordering all assets and management to be kept separate and independent, pending conclusion of an administrative adjudication challenging the defendants' consummated stock acquisition. *Id.* at 25. The court declined to issue the preliminary injunction requested by the FTC, but instead entered an order requiring the parties to enter into a more limited hold separate agreement, proposed by the defendants, along with additional conditions. *Id.* at 30-31. One part of the court's reasoning was that, even if the FTC prevailed in the administrative proceeding, it could not be assumed that a complete divestiture would be ordered as a remedy, and therefore, the Commission had failed to support its argument that, absent the requested injunction, it would be "virtually impossible" to effectuate relief. *Id.* at 28-29. The posture of *PepsiCo* is inapposite and not instructive for the instant case.[43]

Respondent next argues that certain potential exceptions to full divestiture provided under the Proposed Order do not mitigate the full divestiture requirement because, according to Respondent, these provisions are unlikely to result ultimately in anything less than complete divestiture. RRB at 175-76. As shown above, Respondent has failed to demonstrate that complete divestiture is an inappropriate remedy in this case. Moreover, as shown below, Respondent's predictions as to the ultimate effect of the potential exceptions to full divestiture provided in the Proposed Order are speculative.

Paragraph II.A.1 of the Proposed Order contains two potential exceptions to a complete divestiture of all of Freedom. Under the first potential exception, Ottobock *may retain* prosthetic

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[43] Respondent cites various consent orders allowing for partial divestitures in settlement of merger challenges. RB at 90-91; RRB at 171-72. Consent orders do not constitute legal precedent. "[T]he circumstances surrounding . . . negotiated [consent decrees] are so different that they cannot be persuasively cited in a litigation context." *du Pont*, 366 U.S. at 331 n.12; *see In re POM Wonderful, LLC*, 2012 FTC LEXIS 106, at *705 n.27 (May 17, 2012); *see also In re Giant Food, Inc.*, 61 F.T.C. 326, 1962 FTC LEXIS 84, at *63 (July 31, 1962) ("[C]onsent order . . . lacks the precedent value of a litigated case"); *In re Federal Employees Distributing Co.*, 56 F.T.C. 550, 1959 FTC LEXIS 301, at *58 (Nov. 23, 1959) ("[C]onsent order under agreement of parties . . . is not a precedent in other cases for any purpose.").

foot products of Freedom specified in "Divestiture Products Group A," "*unless* the Acquirer demonstrates to the Commission's satisfaction: (i) that any such asset is necessary to achieve the purpose of this Order; and (ii) that the Acquirer needs such asset to effectively operate the Freedom Business in a manner consistent with the purpose of this Order, and the Commission approves the divestiture with the divestiture of such asset." According to Complaint Counsel, Divestiture Products Group A consists of prosthetic feet that [redacted] CCB at 187; Appendix A to Proposed Order. Under the second potential exception, Ottobock *must divest* prosthetic foot products of Freedom specified in "Divestiture Products Group B," "*unless* the Acquirer demonstrates to the Commission's satisfaction: (i) that any such asset is not necessary to achieve the purpose of this Order; and (ii) that the Acquirer does not need such asset to effectively operate the Freedom Business in a manner consistent with the purpose of this Order, and the Commission approves the divestiture without the divestiture of such asset." Divestiture Products Group B consists of Freedom prosthetic foot products that Complaint Counsel asserts [redacted] CCB at 187; Appendix B to Proposed Order.

Regarding Divestiture Products Group A (foot products that were not used by Freedom in the ideal combo promotion), Respondent contends that the Commission is unlikely to approve anything less than complete divestiture because Complaint Counsel did not agree to such terms during pretrial settlement negotiations. RRB at 176. Even assuming that Respondent's assertion as to Complaint Counsel's pretrial settlement position is accurate, given that Complaint Counsel affirmatively interjected a potential pathway for Ottobock to retain some Freedom assets, it should not be presumed that Complaint Counsel's position in post-trial divestiture proceedings will precisely mirror its position in pretrial settlement negotiations.

As to Divestiture Products Group B (foot products that were used by Freedom in the ideal combo promotion), Respondent asserts that it is unlikely that any potential acquirer will agree to forego acquiring less than all the assets of Freedom, even if not all assets are necessary to

compete, especially when the assets will inevitably be offered at a punitive, "fire-sale price." RRB at 175-76. Respondent fails to cite any record evidence or case law to support this assertion. It is speculation at this stage to decide what a future buyer may want or need to acquire, and whether the price will amount to a "punitive" give-away. *In re RSR Corp.*, 1976 FTC LEXIS 40, at *210 ("Certainly it cannot be forecast with absolute assurance that the divested [entity] will find a willing buyer and become the vigorous competitor it once was. But neither is there anything more than speculation to justify the opposite conclusion . . ."). Moreover, the mere fact that divestiture may have an adverse economic impact on Respondent does not compel a lesser remedy. *See du Pont*, 366 U.S. at 326 ("[C]ourts are authorized, indeed required, to decree relief effective to redress the violations, whatever the adverse effect of such a decree on private interests. Divestiture is itself an equitable remedy designed to protect the public interest.").

For all the foregoing reasons, Respondent's objections to complete divestiture provided under the Proposed Order and argument that a partial divestiture limited to Freedom's MPK Assets should be the remedy in this case are rejected.

### 3. Conclusion

All provisions of the Proposed Order, as well as Complaint Counsel's arguments in support thereof, and Respondent's objections and arguments in opposition thereto, have been carefully considered. Complaint Counsel has demonstrated that the divestiture of Freedom, as provided under the Proposed Order, is the appropriate remedy in this case. Moreover, the ancillary provisions in the Proposed Order are supported by the record and applicable case law. Furthermore, as noted above, other than Respondent's general objections to scope of the divestiture required under the Proposed Order, Respondent has not raised objections to any specific provision of the Proposed Order.

Based on the foregoing, the Proposed Order will be issued herewith as the Order in this case.[44] The Order accomplishes the remedial objectives of the Clayton Act and the FTC Act, and is supported by the record and applicable case law.

[44] The provisions of the Order are not substantively different from the Proposed Order.

## III. FACTS

### A. Background to the Litigation

#### 1. The Parties, the Acquisition, and litigation

##### a. Otto Bock HealthCare North America, Inc.

1. Otto Bock HealthCare North America, Inc. ("Ottobock") is a pioneering prosthetics and orthotics company. Ottobock was a subsidiary of Otto Bock HealthCare GmbH at the time of the Acquisition (F. 11) and is now a subsidiary of Otto Bock Healthcare SE & Co. KGaA headquartered in Duderstadt, Germany ("Ottobock Germany"). (PX07049 (Ottobock Amended Answer) at 007-08 ¶ 14; Kannenberg (Ottobock) Tr. 1932-33; Schneider (Ottobock) Tr. 4277-79, 4281-84; Carkhuff (Freedom) Tr. 710-11; PX05155 (Ehrich (Ottobock) Dep. at 60)).

2. Ottobock Germany has over 7,000 employees worldwide and operates in 50 countries. (PX07049 (Ottobock Amended Answer) at 007-08 ¶ 14).

3. Ottobock Germany opened its first foreign branch in 1958 in Minneapolis, Minnesota. (Schneider (Ottobock) Tr. 4279). Ottobock is a Minnesota corporation. (Joint Stipulations of Law and Fact, JX001 at 001 ¶ 5). Ottobock moved its American headquarters from Minneapolis to Austin, Texas in 2014. The Austin headquarters employs about 100 individuals. (Schneider (Ottobock) Tr. 4284, 4285). Ottobock also has manufacturing and research and development facilities in Salt Lake City, Utah that employ between 220 and 250 employees, as well as logistics facilities in Louisville, Kentucky where another 25 people work. (Schneider (Ottobock) Tr. 4284-85). Ottobock also employs between 75 and 100 people that work in the field as sales representatives, clinical specialists, or reimbursement specialists. (Schneider (Ottobock) Tr. 4284-85).

4. Ottobock manufactures and sells "upper and lower limb prosthetics, orthotics, mobility solutions, and medical-related services to customers" in the United States of America ("United States") and around the world. (PX07049 (Ottobock Amended Answer) at 007-08 ¶ 14).

5. Ottobock's lower-limb prosthetics include mechanical knees and microprocessor knees ("MPKs")[45], including the C-Leg 4 MPK, which is presently sold by Ottobock in the United States. (Solorio (Ottobock) Tr. 1633, 1637; Joint Stipulations of Law and Fact, JX001 at 003 ¶ 34).

6. Ottobock began developing an update to the C-Leg 4, referred to as the C-Leg 5 [redacted] (Schneider (Ottobock) Tr. 4353-54, 4539, *in camera*).

[45] The differences between mechanical knees and microprocessor knees are discussed *infra* in section III.C.2.a-d. The microprocessor knees that Ottobock sells in the United States are discussed in section III.B.8.a.

### b. FIH Holdings, LLC

7. FIH Group Holdings, LLC ("Freedom") was founded in 2002. (Carkhuff (Freedom) Tr. 293; PX07049 (Ottobock Amended Answer) at 008 ¶ 15; PX05103 (Kim (Freedom) Dep. at 17)). Freedom is headquartered in Irvine, California, has facilities in California and Utah, and employs approximately 150 people. (Carkhuff (Freedom) Tr. 321, 328-30; PX07049 (Ottobock Amended Answer) at 008 ¶ 15).

8. Freedom sells over 20 different brands of prosthetic feet and 2 prosthetic knees, the Liberty[46] and the Plié, in the United States. (RX0949; Carkhuff (Freedom) Tr. 686). For the first five years of Freedom's existence, Freedom sold exclusively carbon fiber foot products. (Carkhuff (Freedom) Tr. 293). Since 2007, Freedom has manufactured one prosthetic knee, the Plié.[47] (Carkhuff (Freedom) Tr. 294). The Plié 3 is manufactured in Gunnison, Utah, and "is the only American-made [MPK] product." (Carkhuff (Freedom) Tr. 328-29). Freedom has not sold any mechanical knees. (Carkhuff (Freedom) Tr. 323).

9. Freedom's next-generation MPK, the Quattro, was in development at the time of the Acquisition and had not yet launched. (PX05111 (Prince (Freedom) Dep. at 58); PX07049 (Otto Bock Amended Answer) at 004-05 ¶ 6; Carkhuff (Freedom) Tr. 679). At the time of trial, the Quattro was still in development. (Prince (Freedom) Tr. 2673).

10. Prior to the acquisition by Ottobock (F. 11), Freedom had been privately held, and the majority shareholder had been Health Evolution Partners Fund I (AIVI), LP ("HEP"), a private equity firm. (PX05113 (Chung (HEP) Dep. at 12, 119); Kim (Freedom) Tr. 2542).

### c. The Acquisition

11. On September 22, 2017, Ottobock acquired Freedom (the "Acquisition"). (PX07049 (Ottobock Amended Answer) at 003 ¶ 1; Joint Stipulations of Law and Fact, JX001 at 001 ¶ 4). The acquisition price was approximately [redacted] million. (PX05010 (Schneider (Ottobock) IHT at 177), *in camera*; PX05122 (Smith (HEP) Dep. at 179)).

12. Upon consummation of the Acquisition, Freedom became a wholly owned subsidiary of Ottobock. (Joint Stipulations of Law and Fact, JX001 at 002 ¶ 9).

13. Ottobock purchased Freedom from its majority shareholder, Health Evolution Partners and its minority shareholders including Parker Hannifin Corporation ("Parker Hannifin") and various employees and individuals, pursuant to a share tender, which followed a shareholder vote. (Carkhuff (Freedom) Tr. 311-13).

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[46] In 2017, Freedom began distributing a prosthetic knee called the Liberty that is manufactured by ST&G. (Carkhuff (Freedom) Tr. 685-86; Ferris (Freedom) Tr. 2466).

[47] The Plié is discussed in more detail in section III.B.8.b.

#### d. Post-Acquisition events

14. In September 2017, the FTC began a preliminary investigation into the Acquisition. (CCFF 114).

15. On December 19, 2017, Ottobock and the FTC entered into a Hold Separate and Asset Maintenance Agreement ("Hold Separate Agreement"). (CCFF 145; RRCCFF 145; Carkhuff (Freedom) Tr. 703; Schneider (Ottobock) Tr. 4413).

16. Pursuant to the Hold Separate Agreement, Ottobock agreed to restore all services, locations, employees, products, operations or businesses of Freedom that were transferred to or consolidated with Ottobock after the date of the Acquisition. After signing the Hold Separate Agreement, Ottobock and Freedom placed all integration and integration planning work on hold. (CCFF 146; RRCCFF 146; PX05109 (Carkhuff (Freedom) Dep. at 192-93)).

### 2. Witness backgrounds

#### a. Ottobock

17. Dr. Andreas Kannenberg is executive medical director for Ottobock. He has been in that position since 2013. (Kannenberg (Ottobock) Tr. 1819). As executive medical director, Dr. Kannenberg's responsibilities include clinical research and education and reimbursement. (Kannenberg (Ottobock) Tr. 1824). Dr. Kannenberg joined Ottobock as director of medical affairs. In this role, Dr. Kannenberg provided education and training to prosthetists and orthotists,[48] including education about the evidence supporting the use of Ottobock products. (Kannenberg (Ottobock) Tr. 1821-22).

18. Scott Schneider is Ottobock's vice president of government, medical affairs and future development. (Schneider (Ottobock) Tr. 4260). Mr. Schneider is involved in patient care in his role at Ottobock, and is familiar with how prosthetic devices are manufactured by Ottobock and reimbursed by insurance providers. (Schneider (Ottobock) Tr. 4267-68, 4272). As a prosthetist from 1988 to 1995, Mr. Schneider fitted patients with prosthetic devices, including prosthetic knees. (Schneider (Ottobock) Tr. 4261, 4264).

19. Cali Solorio has been the senior prosthetics marketing manager at Ottobock since March 2017. (Solorio (Ottobock) Tr. 1575). Ms. Solorio was involved in the marketing strategy, advertising, product pricing and promotions, and educating the sales team regarding prosthetic knees and assisted with the launch of Ottobock's C-Leg 4 in April 2015. (Solorio (Ottbock) Tr. 1576-78).

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[48] Prosthetists fit prosthetic devices on patients, as discussed in detail in F. 76-83 and F. 143-147. Orthotists fit orthotic devices on patients. A prosthetic device is designed to replace a limb that has been lost either due to amputation or congenital issues. An orthotic device is a bracing system that is designed to help a limb or part of the body that is still intact and needs support. (Schneider (Ottobock) Tr. 4261; Ford (POA) Tr. 915).

20. Matthew Swiggum had been the regional president and chief executive officer ("CEO") of Ottobock from September 2016 until he was terminated. He had been in that position at the time of the Acquisition and was personally involved in meetings regarding the integration of Freedom after it was acquired by Ottobock and involved in analyzing Freedom's Plié 3 business after Ottobock's acquisition of Freedom. (Swiggum (Ottobock) Tr. 3309-10, 3312, 3327-28).

**b. Freedom**

21. Maynard Carkhuff is currently the chairman of Freedom. At the time of the Acquisition, Mr. Carkhuff was on Freedom's board of directors. (Carkhuff (Freedom) Tr. 290-91). Mr. Carkhuff joined Freedom in 2005 as president of the company. In 2012, Mr. Carkhuff became CEO and president, and had responsibility for all aspects of the company's operations. In 2015, Mr. Carkhuff became chairman of the board of directors. (Carkhuff (Freedom) Tr. 291-94). In April 2016, Mr. Carkhuff became vice chairman and chief innovation officer at Freedom, and focused on strategic issues at Freedom, chaired the technology committee, and collaborated with the chairman of Freedom's board and CEO on potential acquisitions and new product development efforts. (Carkhuff (Freedom) Tr. 292, 296). In October 2017, Mr. Carkhuff assumed his current title of chairman. (Carkfuff (Freedom) Tr. 292). Mr. Carkhuff is the manager for the Hold Separate Agreement between the FTC and Ottobock. (Carkhuff (Freedom) Tr. 290-91).

22. Eric Ferris has been the vice president of marketing, customer service and product development at Freedom since February 2018. (Ferris (Freedom) Tr. 2299). From July 2015 through February 2018, he was the director of marketing and customer service. (Ferris (Freedom) Tr. 2298). Mr. Ferris' responsibilities include marketing Freedom's products, promoting the products, messaging, competitive assessments, pricing, education, and strategy regarding messaging for sales into the different sales channels. (Ferris (Freedom) Tr. 2303-05).

23. Lee Kim is the chief financial officer ("CFO") of Freedom and has been since he started working at Freedom in February of 2008. (Kim (Freedom) Tr. 2492). Mr. Kim continues to hold the position of CFO following Freedom's acquisition by Ottobock. (Kim (Freedom) Tr. 2492). As CFO of Freedom, Mr. Kim is the executive responsible for managing Freedom's accounting operations and preparing the company's financial statements. (Kim (Freedom) Tr. 2493). Following Freedom's acquisition by Ottobock, Mr. Kim continues to be the executive overseeing the annual audit process for Freedom. (Kim (Freedom) Tr. 2499-2500).

24. Dr. Stephen Prince is currently the Quattro project manager and technical leader at Freedom. He began working at Freedom in June 2012 and became project manager in 2015. (Prince (Freedom) Tr. 2672-73).

25. David Smith was the chairman and CEO of Freedom from April 1, 2016 to September 2017. (Smith (HEP) Tr. 6408). Mr. Smith's tenure as chairman and CEO of Freedom

ended the Friday before the Acquisition. (PX05122 (Smith (HEP) Dep. at 7)). Prior to the Acquisition, from 2012 until April 2016, Mr. Smith was a partner with Health Evolution Partners, the majority owner of Freedom. (Smith (HEP) Tr. 6409-10; PX05122 (Smith (HEP) Dep. at 126)).

26. Mark Testerman is Freedom's vice president of national and key accounts, a position he has held since February 2014. (Testerman (Freedom) Tr. 1073). Key accounts are the top 50 domestic customers based on volume of products sold. (Testerman (Freedom) Tr. 1073). Mr. Testerman builds relationships with these key accounts and works with them on contracting and pricing. (Testerman (Freedom) Tr. 1079).

**c. Manufacturer witnesses**

**i. Össur hf**

27. Össur hf ("Össur")[49] is headquartered in Reykjavik, Iceland and has a U.S. headquarters in Foothill Ranch, California. (De Roy (Össur) Tr. 3537). Össur manufactures and sells medical devices within the field of prosthetics and noninvasive orthopedics. (De Roy (Össur) Tr. 3526). Össur sells the full range of lower-limb prosthetic products to restore mobility, including non-MPKs and MPKs. (De Roy (Össur) Tr. 3536-37). Össur employs between 300 and 400 employees in the United States. (De Roy (Össur) Tr. 3538). Össur's U.S. sales force consists of 50 employees that educate and assist with reimbursement and fittings. (De Roy (Össur) Tr. 3539).

28. Össur's total U.S. revenue from prosthetic sales in 2017 was in the range of [redacted] million. (De Roy (Össur) Tr. 3601, *in camera*). Of that, approximately [redacted] million came from sales of prosthetic knees. (De Roy (Össur) Tr. 3601, *in camera*). Approximately [redacted] million was generated from sales of all of Össur's MPKs, including the Symbionic Leg. (De Roy (Össur) Tr. 3601-02, *in camera*).

29. Kim Peter Viviane De Roy is the executive vice president of research and development at Össur. (De Roy (Össur) Tr. 3525-27). Mr. De Roy is responsible for overseeing all research and development projects at Össur, including those related to prosthetic knees and feet. (De Roy (Össur) Tr. 3527). Mr. De Roy has been in his current role since November 2017. (De Roy (Össur) Tr. 3527). Mr. De Roy has personal experience with orthotics because he is a below-the-knee amputee. (De Roy (Össur) Tr. 3534-35). His academic background in orthotics includes a bachelor's degree in prosthetics and orthotics and a master's degree in physical therapy and rehabilitation. (De Roy (Össur) Tr. 3536).

**ii. Charles A. Blatchford & Sons Limited d/b/a Endolite**

30. Charles A. Blatchford & Sons Limited ("Blatchford") is a family-owned business that manufactures lower-limb prosthetic devices. (Blatchford (Endolite) Tr. 2089-90, 2093).

[49] Hf (hf) stands for Hlutafelag, the Icelandic corporate designation.

Blatchford was founded in 1890 by Stephen Blatchford's great grandfather and is currently headquartered in Basingstoke, England. (Blatchford (Endolite) Tr. 2090).

31. Blatchford products are sold under the trade name Endolite throughout the world, including the United States. (Blatchford (Endolite) Tr. 2099). Endolite sells a wide range of prosthetics products in the United States, including energy-storing feet, hydraulic ankles, microprocessor-controlled feet, non-MPKs, and MPKs. (Blatchford (Endolite) Tr. 2099-2100). Endolite employs roughly 80 people in the United States, including 60 at its Miamisburg, Ohio headquarters and 15 sales representatives and 5 clinical support specialists that operate throughout the United States. (Blatchford (Endolite) Tr. 2100-01).

32. Stephen Blatchford is executive chairman of Blatchford. (Blatchford (Endolite) Tr. 2091). His main responsibilities include looking at the strategic direction of the company, managing the board of directors, and overseeing the strategic direction of developing products. (Blatchford (Endolite) Tr. 2091).

### iii. Proteor, Inc. d/b/a Nabtesco Proteor USA

33. Proteor, Inc. d/b/a Nabtesco Proteor USA ("Proteor") is a subsidiary of Proteor France. (Mattear (Proteor) Tr. 5516-17). Proteor sells prosthetics products manufactured by Proteor France, based in Dijon, France, and Nabtesco Corporation ("Nabtesco"), based in Kobe, Japan. (Mattear (Proteor) Tr. 5516-17, 5519-22, 5531).

34. In 2018, Proteor acquired Ability Dynamics, the manufacturer of the RUSH Foot, and Ability Dynamics' sales force and clinical team. (Mattear (Proteor) Tr. 5527-28, 5555-61). As of September 1, 2018, Proteor became the exclusive distributor of prosthetic devices manufactured by Nabtesco. (Mattear (Nabtesco) Tr. 5521-22, 5546-47).

35. Proteor has seven sales representatives, a certified prosthetist clinician, and a business development manager. (Mattear (Proteor) Tr. 5527, 5563-64).

36. Bradley Mattear has been the managing director of Proteor since 2016. (Mattear (Proteor) Tr. 5510, 5523-24). Mr. Mattear is a certified prosthetic assistant, and has the ability to evaluate, fit, adjust, and modify prosthetics. (Mattear (Proteor) Tr. 5511-12). From 2011 to 2016, Mr. Mattear was a business development manager in charge of the Midwest region for Cascade, a distributor of prosthetic products. (Mattear (Proteor) Tr. 5514).

### iv. Ohio Willow Wood Company

37. Ohio Willow Wood Company ("WillowWood") was founded in 1907 and manufactures and sells prosthetic products in the United States. (Arbogast (WillowWood) Tr. 4931). WillowWood is a multi-national business that sells its product offerings in over 30 markets. (Arbogast (WillowWood) Tr. 4933-34). WillowWood is one of the leading liner manufacturers in the United States. (Matera (WillowWood) Tr. 5226; Schneider

(Ottobock) Tr. 4304). They also manufacture knees, ankles, feet, sockets, and the LimbLogic vacuum pump. (Matera (WillowWood) Tr. 5226).

38. Ryan Arbogast is majority owner and CEO of WillowWood. (Arbogast (WillowWood) Tr. 4929).

39. John Matera is the chief operating officer ("COO") at WillowWood and has served in that position for the last five years. (Matera (WillowWood) Tr. 5224-25).

#### v. College Park Industries

40. College Park Industries ("College Park") is a prosthetic manufacturer that sells prosthetic feet, knees, liners, endo components,[50] and upper limb products in the United States. (Carver (College Park) Tr. 2003). College Park's only knee is the Guardian knee, which is a "safety knee" for K-2 users. (Carver (College Park) Tr. 2012). College Park is developing the Capital hydraulic knee for K-3 users. (PX05107 (Carver (College Park) Dep. at 81-82)). College Park has approximately 130 employees and had [redacted] in U.S. revenue in 2017. (Carver (College Park) Tr. 2011, 2032, *in camera*).

41. William James Carver, III is president and COO of College Park. (Carver (College Park) Tr. 2003). Mr. Carver began working at College Park in 2009 as College Park's operations manager. (Carver (College Park) Tr. 2003-04). As COO, Mr. Carver assists in developing the strategy and business plan of the company. (Carver (College Park) Tr. 2005).

### d. Clinic witnesses

#### i. Hanger, Inc. and Southern Prosthetic Supply

42. Hanger, Inc. ("Hanger") provides healthcare services through a large network of orthotic and prosthetic clinics in 44 states and Washington, D.C. (Asar (Hanger) Tr. 1307; Testerman (Freedom) Tr. 1259). Hanger fits approximately 1,800 to 2,000 MPKs on patients per year. (Asar (Hanger) Tr. 1373). Hanger has two business segments: (1) its patient care segment, which fits prosthetic knees, and (2) its products and services segment, called Southern Prosthetic Supply, or SPS. (Asar (Hanger) Tr. 1307-09, 1318-19). Hanger has 800 clinics across the country and employs about 1,500 clinicians. (Asar, Tr. 1313, 1379-80). Hanger is the largest U.S. customer of sellers of prosthetics in the United States, including Ottobock, Freedom, Össur, and Endolite. (Carkhuff (Freedom) Tr. 298; Testerman (Freedom) Tr. 1098; Solorio (Ottobock) Tr. 1626; Blatchford (Blatchford) Tr. 2273; DeRoy (Össur) Tr. 3667).

43. Southern Prosthetic Supply ("SPS"), owned by Hanger, distributes orthotic and prosthetic devices from manufacturers to independent clinics outside of Hanger. (Asar (Hanger) Tr. 1319). SPS has a sales force but it does not assist in fittings. (Asar (Hanger) Tr. 1320).

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[50] Endo components refers to endoskeletal connection adapters between the knee and leg or knee and foot. (PX05107 (Carver (College Park) Dep. at 16-17)).

SPS has five distribution centers in the United States and is the largest distributor in the country. (Schneider (Ottobock) Tr. 4401-02; Mattear (Proteor) Tr. 5515; Asar (Hanger) Tr. 1320-21).

44. Vinit Asar is the president and CEO of Hanger and a member of Hanger's executive board. (Asar (Hanger) Tr. 1308). Mr. Asar is responsible for the operational and strategic sides of the business. (Asar (Hanger) Tr. 1310). Mr. Asar visits between 60 and 80 clinics a year and talks with clinicians about the technology and types of fittings they are doing. (Asar (Hanger) Tr. 1322, 1324-25).

**ii. Scheck & Siress Prosthetics, Inc.**

45. Scheck & Siress Prosthetics, Inc. ("Scheck & Siress") is an orthotic and prosthetic provider in the Chicago metropolitan area. (Oros (Scheck & Siress) Tr. 4771). Scheck & Siress currently has 15 locations and employs 32 certified prosthetists and orthotists. (Oros (Scheck & Siress) Tr. 4772-73).

46. Michael Oros is a certified prosthetist and orthotist and is the president and CEO of Scheck & Siress. (Oros (Scheck & Siress) Tr. 4771, 4774). Before he became president of Scheck & Siress, Mr. Oros was a clinical lab manager of one of its facilities for approximately six or seven years. (Oros (Scheck & Siress) Tr. 4773). Mr. Oros is the immediate past president of the American Orthotic and Prosthetic Association ("AOPA"). (Oros (Scheck & Siress) Tr. 4780).

**iii. Scott Sabolich Prosthetic & Research**

47. Scott Sabolich Prosthetic & Research ("SSPR") is headquartered in Oklahoma City, Oklahoma. (Sabolich (SSPR) Tr. 5788). SSPR is a prosthetics-only facility, founded in 1947 by Mr. Sabolich's grandfather. (Sabolich (SSPR) Tr. 5788-89). SSPR employs 50 people, 12 of whom are certified prosthetists and 2 of whom are prosthetic assistants. (Sabolich (SSPR) Tr. 5793). SSPR has two locations, one in Oklahoma City and one in Dallas, Texas. (Sabolich (SSPR) Tr. 5788). SSPR has a running track and golf course so that they can service patients who have goals like running or playing golf. (Sabolich (SSPR) Tr. 5811-13).

48. Mr. Sabolich is a prosthetist and the owner and clinical director of SSPR. (Sabolich (SSPR) Tr. 5788). Mr. Sabolich has been the owner of SSPR since May 1999. (Sabolich (SSPR) Tr. 5790).

49. Mr. Sabolich has been involved in the U.S. Paralympics since 1996. (Sabolich (SSPR) Tr. 5811-12).

**iv. Center for Orthotic and Prosthetic Care**

50. Center for Orthotic and Prosthetic Care ("COPC") is an orthotic and prosthetic company. (Senn (COPC) Tr. 149). COPC operates 25 clinics located in Kentucky, Indiana, North

Carolina, New York, and Pennsylvania, and employs approximately 120 people, including approximately 50 employees who serve as either certified prosthetists, orthotists, or both. (Senn (COPC) Tr. 151, 156-57).

51. Keith Senn is president of the Kentucky and Indiana operations at COPC. (Senn (COPC) Tr. 149). Mr. Senn began working at COPC in January 1997 as its CFO. (Senn (COPC) Tr. 149-50). As CFO, Mr. Senn's responsibilities included establishing guidelines for insurance reimbursement and compliance, as well as establishing a process for purchasing and accounts receivable. (Senn (COPC) Tr. 150-51). As president of COPC's Kentucky and Indiana operations, Mr. Senn oversees the various departments within COPC, and helps create policy manuals to establish set procedures for patient care across the clinics in the Kentucky and Indiana regions. (Senn (COPC) Tr. 151-52). Mr. Senn also meets with sales representatives from MPK manufacturers to discuss products, outreach to COPC's prosthetists regarding training on devices, and other issues involving the sale of MPK products. (Senn (COPC) Tr. 161-62).

### v. Prosthetic and Orthotic Associates

52. Prosthetic and Orthotic Associates ("POA") is an orthotic and prosthetic clinic. (Ford (POA) Tr. 902). POA has three full-time clinics in Middletown, New York, Kingston, New York, and Poughkeepsie, New York and one part-time clinic in Mahwah, New Jersey. (Ford (POA) Tr. 905-06). POA employs 22 people, including 9 prosthetists. (Ford (POA) Tr. 906, 917).

53. Mark Ford has been the president and managing partner at POA since June 2016 and has had almost 20 years of experience in the prosthetics industry. (Ford (POA) Tr. 902, 918).

54. As president and managing partner of POA, Mr. Ford oversees all the business operations and facilities, negotiates with manufacturers, and manages the partner team of the company and the profitability of the business. (Ford (POA) Tr. 902, 904-05). Mr. Ford has discussions with POA clinicians related to MPKs and is generally familiar with the Ottobock C-Leg 4 and Freedom Plié 3 through their marketing, attending MPK seminars at national meetings, and through discussions with POA clinicians. (Ford (POA) Tr. 948-49).

### vi. Mid-Missouri Orthotics and Prosthetics

55. Mid-Missouri Orthotics and Prosthetics ("Mid-Missouri O&P") provides orthotics and prosthetics, artificial limbs, and braces. (Ell (Mid-Missouri O&P) Tr. 1659). Mid-Missouri O&P has four clinics located in Missouri, employs three certified prosthetists and one prosthetic resident. (Ell (Mid-Missouri O&P) Tr. 1660-61). These prosthetists fit between 30 to 50 mechanical knees each year and 10 to 20 MPKs each year. (Ell (Mid-Missouri O&P) Tr. 1676).

56. Tracy Ell is the owner and chief prosthetist at Mid-Missouri O&P. (Ell (Mid-Missouri O&P) Tr. 1659). Mr. Ell has been the owner of Mid-Missouri for 18 years. (Ell (Mid-

Missouri O&P) Tr. 1659). As owner, Mr. Ell coordinates referral sources, coordinates the fabrication facilities, supervises residents, fits orthotics and approves L-Codes (F. 115) prior to submissions for authorization of insurance. (Ell (Mid-Missouri O&P) Tr. 1662). As chief prosthetist at Mid-Missouri O&P, Mr. Ell supervises the majority of all prosthetic fittings and coordinates resident training. (Ell (Mid-Missouri O&P) Tr. 1662-63).

#### vii. Ability Prosthetics and Orthotics

57. Ability Prosthetics and Orthotics ("Ability P&O") provides patient care to amputees and brace wearers in ten facilities across three states. (Brandt (Ability P&O) Tr. 3742). Ability has approximately 43 employees, 18 of whom are certified prosthetists. (Brandt (Ability P&O) Tr. 3743). Once a patient is referred to Ability P&O for its services, Ability P&O evaluates, designs, and fits the prescribed device, and then provides ongoing follow-up care and maintenance for that patient over the course of the lifetime of the device. (Brandt (Ability P&O) Tr. 3742).

58. Jeffrey Brandt is the CEO of Ability P&O. (Brandt (Ability P&O) Tr. 3742). Mr. Brandt founded Ability P&O in 2004, and has worked there for about fourteen and a half years. (Brandt (Ability P&O) Tr. 3742, 3744). As CEO, Mr. Brandt is currently involved in business development and with AOPA. (Brandt (Ability P&O) Tr. 3756).

#### viii. Cascade Orthopedic Supply

59. Cascade Orthopedic Supply ("Cascade") is a wholesale distributor of medical supplies and equipment, specifically serving certified, independently owned, i.e., non-Hanger-owned, orthotic and prosthetic clinics in the United States. (Collins (Cascade) Tr. 3271-72). In addition to private clinics, Cascade has national contracts with large institutions like the Shriners Hospitals and other university hospitals, as well as a number of governmental agencies including the United States Department of Defense and the United States Department of Veterans Affairs. (Collins, Tr. 3272). Cascade's 2017 revenue was approximately [redacted] with [redacted] from sales of prosthetic knees. (Collins (Cascade) Tr. 3288, *in camera*).

60. Jeffrey Collins has been the president of Cascade since 2006. (Collins (Cascade) Tr. 3271). Mr. Collins leads a team of directors, provides strategic planning efforts for the business, and speaks with Cascade's customers at least weekly on topics that are relevant to Cascade's commercial activities. (Collins (Cascade) Tr. 3272-73). Mr. Collins is on the board of the American Orthotic and Prosthetic Association, and in that capacity is aware of reimbursement trends and matters, policy issues, regulatory matters, and industry-related matters. (Collins (Cascade) Tr. 3272-73).

### e. United Healthcare Services, Inc.

61. United Healthcare Services, Inc. ("United Healthcare") is a national health insurance company. (Sanders (United) Tr. 5370-71). United Healthcare provides coverage for

prosthetic devices and related services, including microprocessor knees, and is one of the largest providers of insurance covering prosthetics in the United States. (DeRoy (Össur) Tr. 3631; Sanders (United) Tr. 5465).

62. Jack Sanders is a senior clinical program consultant at United Healthcare and has been in that role for five years. (Sanders (United) Tr. 5370-71). Mr. Sanders' responsibilities include the areas of durable medical equipment, prosthetics, orthotics, and supplies. (Sanders (United) Tr. 5371). Mr. Sanders' responsibilities include training nurses and doctors who perform prior authorization and predetermination insurance reviews, research, and net promoter scores. (Sanders (United) Tr. 5463-64). Mr. Sanders is not and has never been a certified prosthetist. (Sanders (United) Tr. 5377).

#### f. Medical doctor witnesses

##### i. Dr. Benjamin Potter

63. Lieutenant Colonel (P)[51] Benjamin Potter, M.D., is the chief of the department of orthopedics at Walter Reed National Military Medical Center, a tertiary medical treatment facility in Bethesda, Maryland. (Potter (Walter Reed) Tr. 744). Dr. Potter performs surgeries from initial wounding (in the case of a trauma or combat-related amputation), including definitive revision and closure, and additional surgeries for amputees, including reoperations or revision procedures. (Potter (Walter Reed) Tr. 747). Dr. Potter performs the majority of the amputation surgery at Walter Reed National Military Medical Center and has performed over 100 amputations. (Potter (Walter Reed) Tr. 747, 754-55).

##### ii. Dr. Douglas Smith

64. Dr. Douglas Smith is a professor emeritus in the Department of Orthopedic Surgery at the University of Washington in Seattle. (Smith, Tr. 5961). Dr. Smith stopped working as a full time physician in December of 2016. (Smith, Tr. 5964). Dr. Smith estimates that throughout the course of his career as an orthopedic surgeon, he performed 150 amputation surgeries per year for 28 years, about 80 to 85% of which were lower-limb amputations. (Smith, Tr. 5961, 5968, 5979, 6036-37).

##### iii. Dr. Kenton Kaufman

65. Dr. Kenton Kaufman is employed by the Mayo Clinic in Rochester, Minnesota. (Kaufman (Mayo) Tr. 807). Dr. Kaufman is the W. Wendell Hall, Jr. Musculoskeletal research professor, a professor of biomechanical engineering, and the director of the Motion Analysis Laboratory. He is also on staff in the departments of orthopedic surgery, physiology, and biomechanical engineering at the Mayo Clinic. (Kaufman (Mayo) Tr. 808). As director of the Motion Analysis Laboratory at the Mayo Clinic, Dr. Kaufman is responsible for the operation, the quality of data, the final

[51] The (P) indicates that Dr. Potter had been selected for promotion to Colonel at the time of trial. (Potter (Walter Reed) Tr. 753).

recommendations, the operations and the financial aspects of the laboratory. (Kaufman (Mayo) Tr. 812-13). Dr. Kaufman has published 250 peer-reviewed journal articles to date, of which, 11 involve prosthetic microprocessor knees in the last decade. (Kaufman (Mayo) Tr. 818- 19). Dr. Kaufman occasionally works with clinicians who are fitting prosthetics on patients by providing objective data on a patient's gait to "provide information on things that cannot be seen, like forces, moments, muscle activity, [and] asymmetry." (Kaufman (Mayo) Tr. 814).

#### g. Moelis & Company

66. Moelis & Company ("Moelis") is an independent investment bank that was formally engaged by Freedom in May 2017. (Hammack (Moelis) Tr. 6062-63). Moelis served as Freedom's financial advisor in exploring the sale of the company. (Hammack (Moelis) Tr. 6065). Moelis also advised Freedom on potential refinancing alternatives. (Hammack (Moelis) Tr. 6065).

67. Jon Hammack is currently the managing director at Moelis and was the lead representative from Moelis in charge of its formal engagement with Freedom. (Hammack (Moelis) Tr. 6063-64). Mr. Hammack has worked at Moelis for 5 years, has 16 years experience in the investment bank industry, and has been involved in between 40 and 50 merger and acquisition transactions in his career, with more than 20 of those involving a company that was sold through a bidding process. (Hammack (Moelis) Tr. 6063).

## B. Background on the Process through which a User Obtains a Prosthetic Knee

### 1. Lower-limb prostheses

#### a. Transfemoral amputation

68. Transfemoral, or above-the-knee, amputees and individuals born with partial lower limbs often receive a lower-limb prosthesis to enable them to ambulate. (PX05002 (Asar, Dep. at 16); DeRoy (Össur) Tr. 3540).

69. An estimated 1.9 million individuals in the United States live with the loss of a limb. Of that number, approximately 18.5%, or approximately 350,000 individuals, are transfemoral amputees. (PX08004 (RAND Report) at 007).

70. About 75% of leg amputations occur because of vascular disease like diabetes. Other causes include trauma, cancer, and flesh-eating bacteria. (Schneider (Ottobock) Tr. 4287; Senn (COPC) Tr. 163; Smith, Tr. 5982-83).

71. A lower-limb prosthesis for an above-the-knee amputee consists of (1) either a suspension or a liner, (2) a socket, which is a rigid or semi-rigid negative of the residual limb, (3) a knee, (4) a pylon connecting the knee to a foot, and (5) a foot shell with a covering. (Schneider (Ottobock) Tr. 4303-04; Senn (COPC) Tr. 171).

72. A socket is typically custom-manufactured by a prosthetist from commodity products, such as plastics, polypropylene or carbon fiber, and is custom-fitted by the prosthetist to fit the patient's residual limb. The socket goes over the patient's residual limb, and provides a means to secure the device to the patient. All of the prosthetic components are attached from the bottom of the socket. The creation of the socket is important for the patient's comfort, and should avoid nerves and scars that could cause pressures. (Carkhuff (Freedom) Tr. 600).

73. Following amputation surgery, patients typically stay at an inpatient facility for at least three days to more than a week. (Potter (Walter Reed) Tr. 758-59). While an inpatient, the patient is fitted with a "shrinker" stocking for the residual limb, in order to decrease swelling and mold the limb to prepare it for eventual socket use. After three weeks, a patient is typically ready to have sutures removed, and after six weeks, to be fitted with an initial prosthesis. (Potter (Walter Reed) Tr. 760-62).

74. A surgeon may work with a physiatrist as part of the patient's rehabilitation process. (Ford (POA) Tr. 919). A physiatrist is a medical professional who specializes in rehabilitation. When a physiatrist is involved, the physiatrist analyzes a patient's mobility and functional capabilities, and develops a plan for the patient's rehabilitation. (Ell (Mid-Missouri O&P) Tr. 1680, 1682-83; Sanders (United) Tr. 5381).

75. Once it is determined that a patient is ready for a prosthetic fitting, a surgeon or a physiatrist provides a patient with a referral to a prosthetist (F. 76) and a prescription (F. 135-137) to receive an initial, or temporary, prosthesis. (Potter (Walter Reed) Tr. 762, 764); Ell (Mid-Missouri O&P) Tr. 1681-82; Ford (POA) Tr. 919; PX05002 (Asar (Hanger) IHT at 16-17); Sabolich (SSPR) Tr. 5841).

**b. Prothetists**

76. A prosthetist designs and fits the prosthesis for lower-limb amputees. (Asar (Hanger) Tr. 1314-15; Sanders (United) Tr. 5473-74).

77. Prosthetic clinics typically employ one or more certified prosthetists to make and fit prostheses and manage patient care. These clinics provide comprehensive patient care for amputees, including the fitting of a prosthesis. (Asar (Hanger) Tr. 1312-13; Ford (POA) Tr. 917-18; Senn (COPC) Tr. 152).

78. Prosthetic clinics can be independent entities, networks of clinics, or affiliated with a hospital. There are approximately 3,400 prosthetic clinics in the United States. (Asar (Hangar) Tr. 1379-80; PX05153A (Asar (Hanger) Dep. at 77-78)).

79. A certified prosthetist is an individual who typically has obtained a certification or a masters-level degree in prosthetics, completed a one-year residency in prosthetics, and passed a board exam. (Senn (COPC) Tr. 167; Brandt (Ability P&O) Tr. 3743-44; PX05129 (Ell (Mid-Missouri O&P) Dep. at 17-18)). Certified prosthetists receive

certification by the American Board for Certification ("ABC"). (Ell (Mid-Missouri O&P) Tr. 1663-64; Brandt (Ability P&O) Tr. 3749).

80. Prosthetists fit a final prosthesis following physical rehabilitation and training on the initial temporary prosthesis. (Sanders (United) Tr. 5472-74). Generally, after a patient has been wearing a temporary prosthesis for about six months to a year, the patient is ready to receive the more permanent, or definitive, prosthetic device. (Sabolich (SSPR) Tr. 5842).

81. A prosthetist will fit the prosthesis on the patient once the fabrication process is complete. Following the fitting, the prosthetist will continue to provide follow-up care as necessary for the patient. (PX05108 (Yates (Jonesboro P&O) Dep. at 37-39)).

82. The process for fitting a new transfemoral patient with an above-the-knee prosthesis can take between 10 to 20 visits spread out over six months to a year. (PX05108 (Yates (Jonesboro P&O) Dep. at 43-44)).

83. Prosthetic clinics purchase components used in the prostheses, including the prosthetic knee, socket, and liner. (Solorio (Ottobock) Tr. 1625-26; Kannenberg (Ottobock) Tr. 1825; Blatchford (Endolite) Tr. 2101).

**c. K-Levels**

84. An amputee's current and potential mobility is assessed with reference to certain "Medical Function Classification Levels," referred to as a "K-Levels." The K-Level designations were developed by the Centers for Medicare and Medicaid Services ("CMS"), a United States federal agency in the United States Department of Health and Human Services. (Joint Stipulations of Law and Fact, JX001 at 002 ¶¶ 16-17; PX05145 (Ford (POA) Dep. at 93-95); PX05010 (Schneider (Ottobock) IHT at 46-48)).

85. The K-Level definitions are used throughout the orthotic and prosthetics industry in the United States to classify amputees into five ascending mobility levels, K-Level 0 to K-Level 4. (Joint Stipulations of Law and Fact, JX001 at 002 ¶ 18; PX05108 (Yates (Jonesboro P&O) Dep. at 44-46); PX05143 (Smith, Dep. at 77-78); PX08068 (Michael S. Orendurff, et al., *Functional Level Assessment of Individuals with Transtibial Limb Loss: Evaluation in the Clinical Setting versus Objective Community Ambulatory Activity*, 3 Journal of Rehab. and Assistive Tech. Engineering 1, 2 (2016)) (table showing K level descriptions)).

86. K-Level 0 ("K-0") is described by CMS as nonambulatory: "Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility." (Joint Stipulations of Law and Fact, JX001 at 002 ¶ 19).

87. K-Level 1 ("K-1") is described by CMS as a household ambulator: "Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence." (Joint Stipulations of Law and Fact, JX001 at 002 ¶ 20).

88. K-Level 2 ("K-2") is described by CMS as a limited community ambulator: "Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces." (Joint Stipulations of Law and Fact, JX001 at 002 ¶ 21).

89. K-Level 3 ("K-3") is described by CMS as an unlimited community ambulator: "Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion." (Joint Stipulations of Law and Fact, JX001 at 003 ¶ 22).

90. K-Level 4 ("K-4") is described by CMS as very active: "Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete." (Joint Stipulations of Law and Fact, JX001 at 003 ¶ 23).

### 2. Types of prosthetic knees

#### a. Basic functionality of prosthetic knees

91. A prosthetic knee tries to provide patients with a normal gait cycle when ambulating. (Schneider (Ottobock) Tr. 4308-09).

92. A gait cycle consists of two phases: (i) the "stance" phase, when weight is applied to the leg and the lower-limb prosthesis is in contact with the ground; and (ii) the "swing" phase, when the foot swings forward and the lower-limb prosthesis is in the air. (Schneider (Ottobock) Tr. 4309; Carkhuff (Freedom) Tr. 342-43; PX08013 (Ottobock) at 001).

93. The gait cycle has been described as follows: "When your foot is in contact with the ground, your leg normally flexes, or bends, sometimes even when you are standing still. The amount of flexion (bending) is relatively small – you don't want your knee to buckle under you! The muscles of a biological leg are adding resistance, or support, to prevent buckling. When you take a step and put weight on your foot, your knee flexes a little, acting like a shock absorber. This is another time that your muscles are active to stabilize your knee. This also helps take stress off the rest of the body. . . . When you are in swing phase (your leg swinging forward as you take a step), your knee is also flexed, or bent. But in this case you don't need as much support or resistance, and in fact you want the knee to swing more freely when your foot is off the ground, so you can take that step forward." (PX08013 (Ottobock website) at 001-02).

94. In normal ambulation, individuals spend 60% of the time in the stance phase of the gait cycle and 40% in the swing phase of the gait cycle. (Schneider (Ottobock) Tr. 4308-09).

95. In general, there are two kinds of prosthetic knees: mechanical knees and microprocessor knees. (PX08013 (Ottobock website) at 001; Ell (Mid-Missouri O&P) Tr. 1675; Brandt (Ability P&O) Tr. 3757).

### b. Mechanical knees

96. A mechanical knee is a prosthetic device that uses a mechanical hinge to replace an amputee's knee joint. How quickly or easily the hinge swings is often controlled by friction, some type of hydraulic system or a locking mechanism. Mechanical knees do not have a microprocessor. (PX08013 (Ottobock) at 001). The terms "mechanical knees" and "non-microprocessor knees" are used interchangeably throughout the industry (Carkhuff (Freedom) Tr. 370; Kaufman (Mayo Clinic) Tr. 867) and in this Initial Decision.

97. There are several types of mechanical knees. (Carver (College Park) Tr. 2019-20; Kaufman (Mayo Clinic) Tr. 819-20; PX05148 (Swiggum (Ottobock) Dep. at 181-182)).

98. Mechanical knees are divided into subcategories based on their design and function. (Carver (College Park) Tr. 2019-20; PX05117 (Choi (ST&G) Dep. at 39)). The type of mechanism used to generate the force and resistance in the cylinder of a mechanical knee and the structure of the knee differentiate the types of mechanical knees. (Carver (College Park) Tr. 2019-21; PX05160 (Kaufman (Mayo Clinic) Dep. at 48-49)).

99. Mechanical knees that use friction to provide resistance are known as "friction-brake" or "constant friction" mechanical knees. A friction-brake or constant friction knee provides a uniform resistance level in both the swing and stance phases of the gait cycle. The design of friction-based mechanical knees limits patients to a single walking speed because of the consistent resistance provided during swing phase. These types of knees are fit on K-2 patients more often than K-3 patients. (PX05117 (Choi (ST&G) Dep. at 40-41); PX05160 (Kaufman (Mayo Clinic) Dep. at 49); Ell (Mid-Missouri O&P) Tr. 1771-72).

100. Mechanical knees that use air to regulate the cylinder of the knee are known as "pneumatic" knees. (Carver (College Park) Tr. 2020; PX05160 (Kaufman (Mayo Clinic) Dep. at 49)). The air pressure in the cylinder of a pneumatic mechanical knee regulates the swing of the leg during the swing phase and stabilizes the knee in the stance phase of a user's gait. (Carver (College Park) Tr. 2020).

101. Mechanical knees that use liquids to regulate the cylinder of the knee are known as "hydraulic" or "fluid-controlled" knees. Similar to the function of the air in a pneumatic knee, the pressure from the liquids in the cylinder of an hydraulic knee regulates the swing and stance phases of a user's gait. (PX05160 (Kaufman (Mayo Clinic) Dep. at 48-49); Asar (Hanger) Tr. 1464-65; Carver (College Park) Tr. 2020-21).

### c. Microprocessor knees

102. Prosthetic knees that use a microprocessor to regulate the movement and positioning of the knee are referred to as microprocessor knees, or "MPKs." (De Roy (Össur) Tr. 3542-43; PX05117 (Choi (ST&G) Dep. at 42); PX05119 (Kahle (Prosthetic Design & Research) Dep. at 33-34). The terms "microprocessor knees" and "MPKs" are used

interchangeably throughout the industry (Carkhuff (Freedom) Tr. 370; Kaufman (Mayo Clinic) Tr. 867) and in this Initial Decision.

103. An MPK "relies on a microprocessor or computer to monitor the activity of a patient and steer the function of the knee to ensure appropriate reaction and response of that knee to whatever situation the patient might find themselves in." The sensors embedded in an MPK read a user's movements and positioning of the knee. The sensors then relay the information to the microprocessor in the knee. (De Roy (Össur) Tr. 3542-43).

104. MPKs adjust in real time, as a user walks, by using sensors located in the knee to transmit information to a microprocessor that directs the knee how to respond to a user's motions. (De Roy (Össur) Tr. 3542-43; Kannenberg (Ottobock) Tr. 1946-47; Ell (Mid-Missouri O&P) Tr. 1704; Carver (College Park) Tr. 2018-19; Blatchford (Endolite) Tr. 2104; PX05111 (Prince (Freedom) Dep. at 96; PX05160 (Kaufman (Mayo Clinic) Dep. at 46); PX05107 (Carver (College Park) Dep. at 19-20); PX05119 (Kahle (Prosthetic Design & Research) Dep. at 34-36)).

105. As further detailed in F. 264-266, the microprocessor in the Plié 3 switches the knee from stance to swing or swing to stance, but does not vary the resistance throughout the gait cycle. (Carkhuff (Freedom) Tr. 335; Schneider (Ottobock) Tr. 4310, 4319-20).

### 3. Payment for prosthetics

#### a. Insurance reimbursement generally

106. Prosthetic clinics submit requests for reimbursement to third-party payers ("payers") after the fitting of an above-the-knee prosthesis on a patient. (Senn (COPC) Tr. 171-72; PX05118 (Testerman (Freedom) Dep. at 84-85); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 37-38)).

107. Types of third-party payers include Medicare, private insurance, Medicaid, the Department of Veterans Affairs, the Department of Defense, and workers' compensation programs. (PX01022 (Freedom) at 012; Senn (COPC) Tr. 198; Asar (Hanger) Tr. 1356-58; Oros (Scheck & Siress) Tr. 4812, 4835).

108. Medicare and private insurance are the largest third-party payers, by number of reimbursement claims, in the United States. (PX01022 (Freedom) at 011-12 (pie graph showing that Medicare and private insurance make up 31% and 26%, respectively, of reimbursement claims in the United States)).

109. The five largest insurance providers for prosthetic devices in the United States are Medicare, United Healthcare, Kaiser Permanente, Cigna Health Corporation, and Aetna US Healthcare Inc. (De Roy (Össur) Tr. 3631-32).

110. Insurers offer hundreds of different insurance plans with different coverage criteria for prosthetics devices. (Schneider (Ottobock) Tr. 4307).

111. The percentage of a clinic's patients covered by Medicare varies. (Sabolich (SSPR) Tr. 5822) (testifying that 68% of SSPR's patients are Medicare patients); Oros (Scheck & Siress) Tr. 4835 (estimating that 30% of Scheck & Siress' patients are Medicare patients, 40% of Scheck & Siress' patients have private insurance, and the final 30% is divided between the Department of Veterans Affairs, Department of Defense, and workers' compensation programs); Senn (COPC) Tr. 259-60 (testifying that private insurance reimbursement is the biggest percentage of COPC's clinics' reimbursement at more than 30%)).

112. Hanger, a large provider of orthotic and prosthetic services to patients (F. 42), receives approximately 40% of its reimbursements from private insurers, 30% from Medicare, 15% from Medicaid, 7 or 8% from the Department of Veterans Affairs, and the remaining 7% from private-pay (self-pay) patients. (Asar (Hanger) Tr. 1357).

113. To receive reimbursement, payers often require clinics to obtain prior authorization or predetermination of coverage based on a medical provider's written clinical assessment of the patient. (PX05165 (Sanders (United) Dep. at 44-46). Some clinics seek predetermination from insurance plans before fitting a prosthetic, even if prior authorization is not required. (Sanders (United) Tr. 5375).

114. Prosthetic clinics seek reimbursement from payers only after a prosthetist completes the fitting process and the patient signs a "delivery acknowledgement" affirming receipt of the prosthesis. (Senn (COPC) Tr. 171-72).

**b. L-Codes**

115. Payers reimburse clinics for the provision of prosthetic devices based on "L-Codes," which is a system developed by CMS but is also used by private payers. (Schneider (Ottobock) Tr. 4291; PX05145 (Ford (POA) Dep. at 45); PX05165 (Sanders (United) Dep. at 31)).

116. Each L-Code has a reimbursement rate that is associated with the specific L-Code. (Senn (COPC) Tr. 200-01 or Schneider (OttoBock) Tr. 4291-92; PX05117 (Choi (ST&G) Dep. at 47-49)).

117. The L-Codes for prosthetics are typically a four-digit number representing a function in the prosthesis. A prosthetic component could have multiple functions and therefore use multiple L-Codes. Reimbursement rates are set by combining L-Codes based on product functionality. (De Roy (Össur) Tr. 3558; Schneider (Ottobock) Tr. 4291).

118. Clinics receive reimbursement, in accordance with applicable L-Codes, for all component parts of an above-the-knee prosthesis, including reimbursement for the socket, liner, foot, and other miscellaneous products used in the fabrication of the device. (Brandt (Ability P&O) Tr. 3772-73).

119. A pricing committee within CMS sets the fee or allowable amount for each L-Code. CMS reviews the fee for each L-Code and can decrease or increase the fee associated with each L-Code. CMS can determine whether or not to grant a new L-Code, which may be proposed by a manufacturer. It is rare for CMS to grant new L-Codes. CMS can also eliminate L-Codes. (Schneider (Ottobock) Tr. 4292).

120. The L-Code definitions are not manufacturer-specific. Clinics receive the same reimbursement amount, as established for each L-Code, regardless of the manufacturer of the device provided to the patient. (Joint Stipulations of Law and Fact, JX001 at 003 ¶ 29); Kannenberg (Ottobock) Tr. 1872; Sanders (United) Tr. 5434; Asar (Hanger) Tr. 1382).

121. Clinics receive the same reimbursement amount for each L-Code, regardless of the cost to the clinic of the device purchased. (Senn (COPC) Tr. 203-04; Sanders (United) Tr. 5490-92).

122. Clinics incur costs that are not separately reimbursable through L-Codes, including the cost of marketing, administrative costs, costs associated with the work performed by a clinic's certified prosthetists, costs associated with the technical staff building the leg, overhead costs, human resources, payroll, facility costs, and other operational costs. (Senn (COPC) Tr. 256-57).

123. The CMS reimbursement amounts in 2018, depending on each state, for each L-Code commonly used with MPKs were: L-Code 5856, $20,657 to $27,543; L-Code 5858, $15,970 to $21,293; L-Code 5828, $2,701 to $3,601; L-Code 5845, $1,540 to $2,054; and L-Code 5848, $924 to $1,232. (Additional Joint Stipulations of Fact, JX003 at 2 ¶¶ 9-13).

124. Medicare pays 80% of the allotted L-Code reimbursement amount. The remaining 20% is the patient's responsibility. (Oros (Scheck & Siress) Tr. 4801-02).

125. Private insurance providers typically reimburse at an amount that is discounted off of the amount set by the CMS L-Code. The discount rate varies, but ranges from around 5% to as much as 40% off of the Medicare reimbursement amount. (Oros (Scheck & Siress) Tr. 4802-03 (testifying that private insurance companies typically pay clinics less than the Medicare allowed reimbursement, ranging from 67 or 68% of Medicare allowable up to 95 or 96% of Medicare allowable); Sabolich (SSPR) Tr. 5827 (testifying that United Healthcare is the lowest reimburser for prosthetics in the United States); Senn (COPC) Tr. 261-62 (testifying that Anthem Inc., a large insurer, reimburses COPC at 75% of Medicare); PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 30-31) (testifying that commercial health plans' allowable amounts are generally 10% to 40% below Medicare's)).

126. It is a unique feature of the prosthetics industry that Medicare reimburses at a higher amount than private insurance. (Oros (Sheck & Siress) Tr. 4836).

127. The amount of the patient's financial responsibility depends on the patient's type of insurance, including whether the patient has secondary insurance or is self-insured. (Oros (Sheck & Siress) Tr. 4802).

#### c. Audits

128. Medicare and other payers conduct audits known as recovery audit contractor audits, referred to as "RAC audits." (Senn (COPC) Tr. 210; Brandt (Ability P&O) Tr. 3764).

129. During a RAC audit, the payer reviews a patient file from a prosthetic clinic that is associated with a prior reimbursement claim. If the audit determines that the patient's file does not contain sufficient documentary justification for the claim, the payer recoups the payment from the prosthetic clinic. (Senn (COPC) Tr. 210; Schneider (Ottobock) Tr. 4381; Ford (POA) Tr. 973-74).

130. If a claim fails a RAC audit, the clinic may appeal the decision. Resolution of the appeal can take years. (Sanders (United) Tr. 5447-48; Senn (COPC) Tr. 258; Oros (Scheck & Siress) Tr. 4884-85).

131. The frequency of RAC audits started to increase around 2011 and has increased in the past three years. (Schneider (Ottobock) Tr. 4745; PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 25); Mattear (Nabtesco) Tr. 5654-55).

132. In response to the threat of RAC audits, prosthetic clinics enacted policies and procedures to ensure that claims are properly documented. (Senn (COPC) Tr. 211-12; Ford (POA) Tr. 973-77; Asar (Hanger) Tr. 1364; Carkhuff (Freedom) Tr. 716-17; PX05107 (Carver (College Park) Dep. at 210-12) (stating that prosthetists have "found ways to create better documentation and feel more secure about their billing practices")).

133. Since 2012, prosthetic clinics have, to varying degrees, improved their ability to document and receive reimbursement for MPKs. (Carkhuff (Freedom) Tr. 717).

### 4. Overview of process that determines whether or not a patient receives an MPK

134. There are a number of factors that affect whether a patient will receive an MPK, including: whether the patient's condition and activities of daily living are appropriate for the use of an MPK; whether there is insurance coverage for an MPK; whether the patient has the financial ability to pay any out-of-pocket costs; and, when the payer is Medicare, the patient must be a K-3 or K-4, or have the ability to become a K-3. (PX05010 (Schneider (Ottobock) IHT at 85-87)).

### a. Physician prescription

135. A prosthetic clinic cannot see or evaluate a patient for a prosthetic device without a referring prescription from a physician (usually a surgeon or a physiatrist). (Oros (Scheck & Siress) Tr. 4782-85).

136. There are two instances when a prescription is written for a prosthetic knee: for a patient's initial prosthesis and for a patient's final, definitive prosthesis. (Sabolich (SSPR) Tr. 5843; Potter (Walter Reed) Tr. 764).

137. The prescription for a prosthesis generally includes identifying information, such as the patient's name, date of birth, height, and weight, time since amputation or last surgery, and the "specific goals of and justification for the device." (Potter (Walter Reed) Tr. 766-67).

138. The level of detail in a prescription varies from relatively vague, i.e., "transfemoral or above-knee amputee, fit with prosthesis" to more detailed specifications, such as a particular type of knee, depending on the physician's level of knowledge. (Brandt (Ability P&O) Tr. 3746-47; Sabolich (SSPR) Tr. 5830, 5837-38; Oros (Scheck & Siress) Tr. 4782-83; Potter (Walter Reed) Tr. 774-75; Ell (Mid-Missouri O&P) Tr. 1692, 1761-62; Kannenberg (Ottobock) Tr. 1894; Smith Tr. 6005-06, 6014-15).

139. If the referring physician has a specialty such as physical medicine or rehabilitation, the physician may be more well versed in the different types of prosthetics than a general surgeon, and may take more of a role in determining which prosthetic is appropriate for a particular patient. (Brandt (Ability P&O) Tr. 3751-52).

140. Sometimes the prescription will note the patient's K-Level. (PX05141 (Bright (North Bay) Dep. at 139)).

141. Surgeons rarely include the specific brand of prosthetic knee in prescriptions for prosthetic knees. (Potter (Walter Reed) Tr. 767-68, 770-71).

142. Although prosthetists do not write prescriptions for prosthetics, they help guide what the physician writes on the final prescription for a prosthetic. (PX05141 (Bright (North Bay) Dep. at 134); Ell (Mid-Missouri O&P) Tr. 1688).

### b. Prosthetist role

143. Typically, the prosthetist decides the specific type and brand of knee to fit on a patient using input from the patient, surgeon, physical therapists, and other medical professionals involved in the patient's fitting process. (Ford (POA) Tr. 924, 989; Asar (Hanger) Tr. 1334, 1381, 1546-47; Potter (Walter Reed) Tr. 770-71; Oros (Scheck & Siress) Tr. 4784-86, 4855-56, 4871; Brandt (Ability P&O) Tr. 3751, 3799-3800; Sanders (United) Tr. 5439, 5401-02 (discussing PX03153); PX05119 (Kahle (Prosthetic Design & Research)

Dep. at 38-39); PX05130 (Governor (Ottobock) Dep. at 78); PX05144 (Blatchford (Endolite) Dep. at 151); PX05150 (Kannenberg (Ottobock) Dep. at 23) (agreeing that prosthetists are the "direct customers"); PX05114 (Ferris (Freedom) Dep. at 48-49); PX05141 (Bright (North Bay) Dep. at 136-37); PX05128 (Senn (COPC) Dep. at 87); PX05108 (Yates (Jonesboro P&O) Dep. at 42-43) (explaining that the prosthetist is the "subject-matter expert in terms of the specific componentry" who is "driving that conversation"); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 108-10); PX05116 (Endrikat (Empire Medical) Dep. at 147-48); PX05137 (Matthews (Freedom) Dep. at 152-53)).

144. Prosthetic clinics "play an important role" in determining what prosthetic device the patient will use. "[T]hey work in concert with the prescribers and therapists that are providing the clinical direction, and they translate that into the actual device that the member will use to replace their missing body part." (Sanders (United) Tr. 5379). Although the treating physician will lay out the treatment goal and plan, "[b]y training, you can't expect every physician to know the make and model or technological features of a . . . prosthetic knee." If the physician is unfamiliar, the prosthetist uses his or her "expertise to translate the physician's direction into a tangible product." (Sanders (United) Tr. 5401-02).

145. A patient arriving at a prosthetic facility with a prescription for a new prosthesis will go through multiple evaluations by a clinician. Through these evaluations, the clinician will endeavor to understand the patient's desired outcomes and what the patient would like to try to accomplish. (PX05010 (Schneider (Ottobock) IHT at 46-47)).

146. When evaluating a patient to be fit with a prosthetic knee, the prosthetist will focus in part on the patient's "activities of daily living" to determine the needs of the patient. These activities may include "[w]ashing clothes, driving, cooking, taking kids to school, walking pets, taking care of pets. Anything you do in your day-to-day routine, or sometimes your weekly routine, or monthly routine that you choose to do or want to do." (PX05119 (Kahle (Prosthetic Design & Research) Dep. at 38-40). "Anything that would inform the design of the prosthesis to ensure comfort, safety, and function for the patient in their desired activities of daily living would be considered [as well as] objectively what is their ability to use a prosthesis to accomplish those tasks." (PX05108 (Yates (Jonesboro P&O) Dep. at 40)).

147. As part of the multiple clinical evaluations referenced in F. 145, a patient's socioeconomic position will be assessed. The clinician will inquire as to where the patient lives, and will try to get a full picture of what the patient will have to maneuver and navigate in their activities of daily life by assessing whether there are any barriers, steps, rocks, or similar environmental concerns. (PX05010 (Schneider (Ottobock) IHT at 46-47); Ell (Mid-Missouri O&P), Tr. 1768-70).

#### c. Patient role

148. The patient works with the physician, prosthetist, physical therapist, nurses, and potentially a mental health provider, to decide what type of prosthetic knee is in the best

interest of that particular patient. (Smith, Tr. 6003-04; PX05166 (Watson (Fourroux Prosthetics) Dep. at 180)).

149. The patient has significant input into which knee they get. (Sabolich (SSPR) Tr. 5845; Smith, Tr. 6010-11).

150. Even if an MPK would clinically benefit a patient, the patient has a choice not to get an MPK, based on the patient's lifestyle and activities. (Smith, Tr. 6010; Senn (COPC) Tr. 263). *See* section III.B.7 below.

#### d. Insurance eligibility

151. Insurers play a role in determining which prosthetic device will be selected for a patient by determining coverage eligibility, which greatly influences the decision. (Sanders (United) Tr. 5438-39).

152. As "the person with the checkbook," the insurance company can ultimately control what type of knee a patient receives. (Ford (POA) Tr. 919-20; *see also* PX05141 (Bright (North Bay) Dep. at 144)).

153. Even when a prosthetist believes that an MPK would be appropriate for a patient, "you always have to look at the insurance situation of the patient." (PX05150 (Kannenberg (Ottobock) Dep. at 78-79)).

154. Insurers do not determine the functional needs of the patient. (Sanders (United) Tr. 5402).

155. Össur, the manufacturer of the Rheo MPK, has a "step-by-step guide to a successful claim," which provides prosthetic clinics with an overview of the process for obtaining approval for an MPK from a patient's insurer. (PX03242 (Össur) at 001). The guide instructs, as the first step, "know your payer," and explains: "Before you can do anything for new patients, you must first understand what their insurer will pay for and what the patients' financial responsibility is." (PX03242 (Össur) at 002).

156. For United Healthcare, once a patient satisfies eligibility criteria,[52] the prosthetist and/or physician are the key decision-makers as to which prosthetic knee the patient will receive. (Sanders (United) Tr. 5438-39).

### 5. Healthcare considerations in determining if an MPK is appropriate

#### a. K-Level assessment

157. A patient arriving at a prosthetic facility with a prescription for a new prosthesis will be evaluated for his or her K-Level, based on validated tests. The patient's K-Level

[52] Insurance eligibility criteria are discussed in section III.B.6 below.

assessment is the first task the prosthetist undertakes in order to determine whether to fit the patient with an MPK. (PX05010 (Schneider (Ottobock) IHT at 46-47); PX05145 (Ford (POA) Dep. at 93-94)).

158. Hanger uses a standard questionnaire, which it refers to as its "PAVET" form, to help its clinicians assess or confirm a patient's K-Level. (Asar (Hanger) Tr. 1340; PX05141 (Bright (North Bay) Dep. at 139) (testifying that the prosthetist helps the physician in determining the K-Level when the physician has difficulty)).

159. Hanger's PAVET form (F. 158) has three sections. The first section asks whether the patient can do the basic actions of daily living such as moving in and out of a car or walking on flat terrain. The second section asks about the patient's functionality, such as whether the patient can ambulate the limb or navigate small barriers. The third section tests the strength of the patient. (Asar (Hanger) Tr. 1341-43; PX03207 (Hanger) (PAVET form)).

160. Each of the three sections of Hanger's PAVET form (F. 158) contains several questions. The patients are graded on these questions and their scores are tallied, resulting in a K-Level classification. (Asar (Hanger) Tr. 1345-46; PX03207 (Hanger) at 001, 007 (PAVET form)).

161. In determining whether to fit a patient with an MPK instead of a mechanical knee, North Bay Prosthetics conducts a series of function tests on the patient to assess their K-Level. These include walking tests, standing up tests, and the AMPRO test,[53] which involves "approximately 30 different events you have the patient attempt, and they test their balance, strength, ability to walk at varying cadences, there's many different things, and those all help us guide them to their functional level." (PX05141 (Bright (North Bay) Dep. at 146-47)).

**b. Importance of K-Level**

162. CMS coverage criteria do not allow for reimbursement for an MPK for patients categorized as K-Levels K-0, K-1, or K-2. (Ford (POA) Tr. 990-91). Some commercial payers or workers' compensation payers might reimburse for an MPK for patients at those K-Levels, but most insurers follow CMS guidelines. (Ford (POA) Tr. 990-91; PX05150 (Kannenberg (Ottobock) Dep. at 56-57) ("[L]imited community ambulators usually don't qualify for microprocessor knees.")).

163. Medicare and most third-party payers will only provide reimbursement for MPKs for K-3 or K-4 patients. (Kannenberg (Ottobock) Tr. 1831, 1839; Sanders (United) Tr. 5484-85; PX03219 (Mayo) at 002; PX05141 (Bright (North Bay) Dep. at 67)).

[53] AMPRO refers to amputee mobility predictor with prosthesis. *See* https://www.sralab.org/rehabilitation-measures/amputee-mobility-predictor-0.

164. Almost all insurance policies that provide for reimbursement of MPKs where medically necessary (*see* section III.B.6.b. below) do so only for K-3 or K-4 amputees. (PX05150 (Kannenberg (Ottobock) Dep. at 56-57)).

165. Approximately 35% of new above-the-knee amputees are K-3 patients, and 5% are K-4 patients. (PX03021 (WillowWood) at 026). A patient's K-Level may change over time following rehabilitation because of an improvement or decline in mobility. (Carver (College Park) Tr. 2027-28).

166. Although K-2 patients may benefit medically from using a prosthetic knee that contains a microprocessor, due to reimbursement constraints dictated by insurance providers, K-3 and K-4 patients are the patients that are most often fitted with MPKs. (Carkhuff (Freedom) Tr. 614-15).

167. Ottobock has been working to expand insurance coverage for MPKs for K-2 patients since 2006. Ottobock's vice president of government, medical affairs, and future development does not expect that to happen for at least five to ten years. (Schneider (Ottobock) Tr. 4308, 4532; Kannenberg (Ottobock) Tr. 1995-97).

168. In order for a patient to receive insurance reimbursement for an MPK, the prosthetist or clinic submits various categories of information on the patient's behalf. (Kannenberg (Ottobock) Tr. 1830). It is important that this submission demonstrate that a patient is an unlimited community ambulator, or K-3, because private insurers and Medicare cover MPKs only for K-3 and K-4 patients. (Kannenberg (Ottobock) Tr. 1830-31; Kannenberg (Ottobock) Tr. 1890-91).

**c. Patient-specific factors in addition to K-Level**

169. If the patient meets the appropriate K-Level for an MPK, in order to determine whether to fit the patient with an MPK, the clinician will assess "the specific needs of that individual patient, what are they looking to do in their daily lives, the requirements that the patient may have when it comes to weight, [and] functionality for the entire prosthesis." (PX05145 (Ford (POA) Dep. at 93-95); Ford (POA) Tr. 995-96).

170. Even if a patient's mobility assessment indicates that the patient is a good candidate for an MPK, the clinician works with the patient to determine whether an MPK is appropriate for them. (Asar (Hanger) Tr. 1482).

171. Össur's step-by-step guide to a successful claim (F. 155) for the Rheo MPK instructs, as the second step, to "know your patient," and explains: "What's their story? What kind of life do they want to live with a prosthesis? What's their current and potential functional level? To accurately and completely tell your patient's story, you need both social and personal patient information on the one hand, and clinical information on the other." (PX03242 (Össur) at 003).

172. Össur's step-by-step guide to a successful claim (F. 155) for the Rheo MPK instructs, as the third step, to "match[] the patient & product," and explains: "Every patient has

unique clinical needs. And every product offers unique clinical outcomes. Making sure that you map the two to each other is essential if you want (a) a happy and functional patient, and (b) to process your claim successfully." (PX03242 (Össur) at 005).

173. The choice of prosthetic knee "is based on a number of factors, including the patient's age, weight, etiology [i.e., reason for or cause] of the amputation, physical health, history, functional goals, personal motivation, and medical coverage." (PX08059 (Hafner, B. and Smith, D, *Differences in Function and Safety between Medicare Functional Classification Level-2 and -3 Transfemoral Amputees and Influence of Prosthetic Knee Joint Control*, Journal of Rehabilitation Research & Development, Vol. 46, No. 3, 2009) at 002).

174. In determining what type of knee to select for a patient, prosthetists evaluate the patient's fall risk, walking speed, and gait patterns when sitting and standing. Further, they look at the patient's life, including hobbies, job, lifestyle, and whether the patient may use the prosthetic around water, caustic chemicals, heat, or other situations that can be hazardous. (PX05132 (Sabolich (SSPR) Dep. at 27-28)).

175. Prosthetists evaluate a patient's "overall health profile, age, weight, height, [and] strength." (PX05141 (Bright (North Bay) Dep. at 141-42); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 50); *see also* PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 27) (prosthetist evaluates strength, range of motion, among other factors)).

176. A patient's weight affects whether the patient is a good candidate for an MPK, because MPKs have certain weight ratings which, if exceeded, present a risk of "catastrophic failure." (PX05141 (Bright (North Bay) Dep. at 69-70)).

177. A patient's age will be considered in determining whether an MPK is appropriate because fall risk increases with age. (PX05134 (Oros (Scheck & Siress) Dep. at 67-68)).

178. In determining whether to provide an MPK for a K-3 or K-4 patient, the clinician will assess how much of the patient's day is spent standing, whether they are going into and out of cars, and their daily environment. (Ford (POA) Tr. 995-96).

179. The patient's desire to return to pre-amputation functionality is considered, so the patient's prior activities and functioning will be assessed. For example, if a patient had been "climbing ten flights of stairs" to his or her office before the amputation, returning to that level of functioning will be "really important." (PX05149 (Brandt (Ability P&O) Dep. at 44-46)).

180. To assess whether it can be demonstrated that a microprocessor knee is a medical necessity for a patient for purposes of an insurance coverage submission (F. 188), a prosthetist will typically "have a consultant interview with the patient and ask[] questions around activities of daily living of how they ambulate in their neighborhood, what their neighborhood looks like, does it have an elevator, do they have to ascend or descend stairs, do they have uneven walking terrain that they incorporate in their activity of

church or school or community." The prosthetist may also have the patient take one or more "validated tests like the stand up and go six-minute walk test." (PX05139 (Schneider (Ottobock) Dep. at 89)). The insurance submission can then connect the patient's activities of daily living to peer-reviewed articles showing the benefits of microprocessor knees to patients engaging in those activities. (PX05139 (Schneider (Ottobock) Dep. at 89-90)).

181. For purposes of an insurance coverage submission arguing for medical necessity for an MPK for a patient, a prosthetist may show that the patient's activities of daily living include "[a]mbulating uneven terrain, ambulating in very confined spaces, ambulating over a greater distance, the requirement of greater balance, the requirement of stress relief to the spine and/or hip on the sound side or on the amputated side[.]" (PX05139 (Schneider (Ottobock) Dep. at 91)).

182. In making a clinical decision whether or not to fit a patient with an MPK, prosthetists at Fourroux Prosthetics, Inc., a prosthetic clinic, will ask, among other things, whether the patient experiences falls or stumbles, or is unable to change gait speed. (PX05166 (Watson (Fourroux) Dep. at 34-37)).

183. Glenn Choi, president of ST&G, a prosthetic clinic, believes that MPKs are likely beneficial for the subset of K-3 amputees that engage in such activities as "going up the stairs, going down the stairs with variable speed[,] . . . [g]oing down a hill, walking down a hill with variable speed, climbing up sometimes, . . . [or] jump[ing] from curb to the street . . . ," as well as navigating environmental barriers, crowded areas, icy streets, going through shrubs and leaves, and having to regularly walk on mulch or uneven ground. (PX05117 (Choi (ST&G) Dep. at 192-93)).

184. Michael Fillauer, CEO of Fillauer Companies, Inc., a manufacturer and distributor of prosthetic and orthotic supplies, believes that patients who are looking to reduce likelihood of stumbles and falls or who need stumble recovery assistance would greatly benefit from an MPK because the system adjusts automatically to their gait as they go through different gait cycles. (PX05105 (Fillauer (Fillauer) Dep. at 23)).

185. North Bay Prosthetics believes that K-3 and K-4 patients who "are able to move at varying cadences," "go up stairs and go down ramps and step over curbs," "walk in the outside community," or like to hike or dance would benefit from an MPK rather than a mechanical knee. (PX05141 (Bright (North Bay) Dep. at 149-50)).

186. When a patient has used a mechanical knee as an initial prosthesis for a while and "experiences frequent stumbles and falls, and is not able to do activities that he needs to do or wants to do on a regular basis," a microprocessor knee will be considered. (PX05150 (Kannenberg (Ottobock) Dep. at 78)).

### 6. Obtaining insurance reimbursement

#### a. Medical necessity justification

187. If the prosthetist determines that a patient is a K-3 or K-4 ambulator, and would benefit from an MPK, in order to obtain insurance reimbursement for an MPK, the prosthetist must demonstrate the "medical necessity" of an MPK over a mechanical knee. (Kannenberg (Ottobock) Tr. 1890-91; Carkhuff (Freedom) Tr. 346; Ell (Mid-Missouri O&P) Tr. 1694; *see also* PX05165 (Sanders (United) Dep. at 43-46); PX05109 (Carkhuff (Freedom) Dep. at 49)).

188. Medical necessity refers to eligibility for a particular device or the criteria that have been established by insurance companies to determine eligibility to receive an MPK. For example, CMS deems MPKs to be medically necessary for K-3 and K-4 patients. This means that MPKs are available to that patient population, but does not mean that every eligible patient must get an MPK. (Schneider (Ottobock) Tr. 4405; Kannenberg (Ottobock) Tr. 1833, 1944).

189. Medical necessity involves demonstrating that the patient has unmet needs with their current prosthesis, which can be fulfilled by an MPK, but not by a less expensive alternative, such as a mechanical knee. (Kannenberg (Ottobock) Tr. 1891-94; PX01543 (Ottobock) at 030).

190. Medical necessity refers to insurance coverage determinations and eligibility. Medical necessity in this context is not a clinical determination. (Smith, Tr. 6016-17).

191. United Healthcare requires pre-authorization for all MPKs. Documentation submitted with the pre-authorization request typically includes a clinical note from the patient's physician, and a narrative from the prosthetist or vendor, describing any impairments to mobility the patient has, as well as general information about the patient's capabilities. For a new amputee, the narrative would also include the prosthetist's specific recommendation for what type of prosthetic they think the patient should receive, such as an MPK. However, the recommendation does not need to indicate the specific manufacturer or brand of MPK. (Sanders (United) Tr. 5476-79).

192. In justifying medical necessity for purposes of insurance reimbursement, the focus is on what functionality the microprocessor knee would provide that is not provided by a mechanical knee. This is equally true under both Medicare and private insurance coverage requirements. (Kannenberg (Ottobock) Tr. 1834-35; PX05150 (Kannenberg (Ottobock) Dep. at 100-01)).

#### b. Demonstrating medical necessity

193. To demonstrate medical necessity for purposes of obtaining insurance reimbursement, prosthetists have to demonstrate certain criteria such as variable cadence, "the 400 yards criterion," and the regular need to ambulate on uneven terrain, slopes and stairs.

Additionally, a prosthetist will need to "explain why [a] patient needs a microprocessor knee over a mechanical knee." (Kannenberg (Ottobock) Tr. 1891; *see also* Kannenberg (Ottobock) Tr. 1831-33; PX05150 (Kannenberg (Ottobock) Dep. at 83-84) (discussing PX01543)).

194. Ottobock identifies "[s]afety," "[s]lope negotiation," "[s]tair negotiation," and "[n]egotiation of uneven terrain/obstacles in the walkway" as factors that prosthetists must demonstrate to establish the medical necessity of an MPK for a patient when seeking reimbursement from insurance providers. (PX01489 (Ottobock) at 033-34; PX01543 (Ottobock) at 001-02; PX05150 (Kannenberg (Ottobock) Dep. at 83-84)).

195. The most important unmet need that could be argued to justify medical necessity of an MPK over a less costly mechanical knee is a need for more safety, by documenting that a patient has experienced frequent falls. (Kannenberg (Ottobock) Tr. 1834-35).

196. Ottobock assists customers in demonstrating the medical necessity of an MPK to insurance providers, including by giving presentations to clinics. (Kannenberg (Ottobock) Tr. 1849-50, 1887-89; PX05139 (Schneider (Ottobock) Dep. at 96) (Ottobock conducts presentations "on several reimbursement topics, including claim submittals, new coding, reimbursement systems"); PX01543 (Ottobock) (presentation on medical justification)).

197. Ottobock advises physicians that "[m]edical necessity for a microprocessor knee is based on the beneficiary's 'potential' functional ability. Potential functional ability is based on the reasonable expectation of the ordering physician and prosthetist, considering factors including, but not limited to:" "[t]he beneficiary's past history," "[t]he beneficiary's current condition[,]" and "[t]he beneficiary's desire to ambulate." (PX01489 (Ottobock) at 003 (Microprocessor Knees Physician's Documentation Guide for Medicare)).

198. Ottobock recommends that medical necessity submissions "refer to publications of studies that have demonstrated superior safety and/or function of the requested device," such as studies showing that the requested MPK reduces falls compared to a mechanical knee. The submission should "[b]ack the claims on a device with evidence whenever possible, and tie it to the patient's unmet needs." (PX01543 (Ottobock) at 060-61, 065).

199. Ottobock provides customers with clinical research articles and other academic literature showing the benefits of MPKs in order to support customers' justification of medical necessity. These articles are provided on Ottobock's website and directly to customers via email. (Kannenberg (Ottobock) Tr. 1850, 1893; *see also* PX01543 (Ottobock) at 067-68 (collecting studies on the superiority of the C-Leg to mechanical knees); PX05150 (Kannenberg (Ottobock) Dep. at 91-92)).

200. Ottobock provides evidence to prosthetists to help them convince physicians of the benefits of MPKs, because "when the prosthetist wants to fit a microprocessor knee and the physician of the patient is not on board, it's almost impossible to get an approval." (PX05150 (Kannenberg (Ottobock) Dep. at 105-06)).

201. Ottobock assists its clinic and prosthetist customers by offering to review their reimbursement claims prior to submission to insurers. (PX05150 (Kannenberg (Ottobock) Dep. at 25)).

202. Ottobock assists its customers by analyzing "the requirements of the insurance plan and coverage of the patient and help[ing] the prosthetist to produce the documentation that is needed to meet these criteria that the insurance companies have defined." (PX05150 (Kannenberg (Ottobock) Dep. at 89)).

203. Clinics have begun using internal procedures to ensure prosthetists comply with payers' documentation requirements for the reimbursement of MPKs and only fit those products on patients who meet eligibility criteria. (PX05134 (Oros (Scheck & Siress) Dep. at 46-47; 228-29); Ford (POA) Tr. 972-75 (explaining POA's internal 27-step reimbursement process before releasing a claim to be billed to an insurer)).

204. Clinics may submit clinical research showing the benefits of MPKs to insurance providers when submitting paperwork to establish the medical necessity of an MPK. (*See* PX05119 (Kahle (Prosthetic Design & Research) Dep. at 53-54); Kannenberg (Ottobock) Tr. 1850; PX05139 (Schneider (Ottobock) Dep. at 89-90)).

205. Anthem, a large health insurance company, views MPKs as medically necessary for K-3/K-4 amputees when four criteria are met: (1) the patient is physically and mentally capable of using an MPK to walk faster; (2) the patient will be able to walk faster with an MPK than with a "standard prosthetic application," such as a mechanical knee; (3) the patient has a "documented need for daily long distance ambulation" at variable rates; and (4) the patient has a "demonstrated need for regular ambulation on uneven terrain or regular use on stairs." Only where each of these criteria are met and documented will an MPK be reimbursed. (PX01543 (Ottobock) at 042).

206. United Healthcare reimburses MPKs for K-3 patients for whom an MPK would make a clinically significant difference in their lives, which must be supported by documentation in order to demonstrate medical necessity. (Sanders (United) Tr. 5485-86).

207. Össur's step-by-step guide to a successful claim (F. 155) for the Rheo MPK instructs, as the fourth step, to "get physician confirmation," and explains: "Getting documentation from a physician confirming the prosthetist's findings and recommendations is an important Medicare requirement. A huge percentage of denied claims since 2011 result from prosthetists' failure to make sure that the physician's records validate their own." (PX03242 (Össur) at 007).

208. Össur's step-by-step guide to a successful claim (F. 155) for the Rheo MPK instructs, as the fifth step, to perform a "final review before claim submission," and explains: "You've collected all the necessary patient information. You've confirmed that other health care providers' notes corroborate yours. You're ready to proceed to delivery and filing the claim for reimbursement. But you still need to verify that: (1) your patient

delivery sheet contains all of the required information, and (2) you have filled out the claim form completely." (PX03242 (Össur) at 008).

209. To document unmet safety and mobility needs, Ottobock suggests that the prosthetist or clinic should "[d]escribe difficulties, such as stumbles, falls, compensatory movements, not making it across the street before light changes, inability to change walking speed when needed, etc." The submission should then describe "[h]ow will the patient be able to do this activity safer/better with the new prosthesis[.]" It should include "[w]hat function(s) does the new prosthesis offer that will support the patient in doing this activity? Is there published evidence to support this?" (PX01543 (Ottobock) at 039).

210. At Hanger clinics, the PAVET form, which evaluates a patient's ability to partake in activities of daily living, their functionality, and strength (F. 158-159), is submitted with a physician's notes regarding a patient. (Asar (Hanger) Tr. 1341-43). Because the form has been around for "a couple of decades," some payers use the form to determine if a patient has the appropriate device. (Asar (Hanger) Tr. 1340-41).

211. Ottobock's "Physician's Documentation Guide for Medicare," in a section titled "Evidence for the C-Leg," lists documentable patient needs to justify the medical necessity of the C-Leg and secure Medicare reimbursement. (PX01489 (Ottobock) at 033-35). The patient needs that are enumerated include: "Safety," "Slope negotiation," "Stair negotiation," and "Negotiation of uneven terrain." (PX01489 (Ottobock) at 034).

**c. Effect of insurance claim disapproval**

212. Some insurance plans do not provide any coverage for MPKs. (PX05150 (Kannenberg (Ottobock) Dep. at 78-79) ("[P]rivate health insurance may consider a microprocessor knee medically necessary for certain patients in their policy, but . . . they may sell plans that don't cover microprocessor prosthetic components.").

213. Not all K-3 patients are able to demonstrate medical necessity. (Sanders (United) Tr. 5486). Patients designated by a physician as K-3 patients who do not meet medical necessity requirements for a microprocessor knee generally get a non-microprocessor, or mechanical knee. (Ell (Mid-Missouri O&P) Tr. 1723-24); *see also* Carver (College Park) Tr. 2055-56 (testifying that mechanical knees are "the next best option" if payers will not reimburse a prosthetist for an MPK).

214. "If the patient doesn't have to negotiate uneven terrain, slopes and stairs outside the home of the patient on a regular basis, then the insurance usually denies the claim for a microprocessor knee." (PX05150 (Kannenberg (Ottobock) Dep. at 83-84).

215. Patients not receiving coverage for an MPK very rarely purchase one out-of-pocket. Dr. Andreas Kannenberg of Ottobock estimated that fewer than 1% of MPKs are paid for entirely out of pocket. (PX05150 (Kannenberg (Ottobock) Dep. at 60)).

216. Most users' insurance providers only provide reimbursement for one prosthetic knee at a time. (Senn (COPC) Tr. 182). Patients typically use a prosthetic knee until it needs to be replaced. (Senn (COPC) Tr. 181).

217. In instances where the patient does not have insurance coverage or the insurance company does not approve reimbursement for a microprocessor knee, clinics fit their patients with a mechanical knee. (Brandt (Ability P&O) Tr. 3800; PX05151 (Patton (Prosthetic Solutions) Dep. at 24-25); PX05134 (Oros (Scheck & Siress) Dep. at 91); PX05107 (Carver (College Park) Dep. at 95-97); PX05108 (Yates (Jonesboro P&O) Dep. at 161); PX05128 (Senn (COPC) Dep. at 93); PX05141 (Bright (North Bay) Dep. at 68)).

### 7. Patient-specific reasons patients may prefer mechanical knees

218. Lack of available insurance reimbursement is a reason a patient may choose a mechanical knee over an MPK. (F. 212-217).

219. A K-3 or K-4 patient who is more active, runs often, or plays soccer may be better served by a light-weight mechanical knee. (Sanders (United) Tr. 5388; De Roy (Össur), Tr. 3580; PX05151 (Patton (Prosthetic Solutions) Dep. at 24-25); PX05134 (Oros (Scheck & Siress) Dep. at 91-92); PX05105 (Fillauer (Fillauer) Dep. at 21-23); PX05150 (Kannenberg (Ottobock) Dep. at 51-52); PX05141 (Bright (North Bay) Dep. at 156-57)).

220. Mechanical knees may be preferable to MPKs for patients engaging in certain sports and activities such as cycling, weightlifting, and CrossFit. Mechanical knees are more appropriate than MPKs for these activities because they are cheaper, more durable, and easier to replace if they break. (Potter (Walter Reed) Tr. 783-84; PX05150 (Kannenberg (Ottobock) Dep. at 51-52)).

221. Some K-3 or K-4 patients may prefer mechanical knees to MPKs when they work in "environmental conditions that are not suitable" for MPKs, or when they are "highly active people that are involved with working with large weight." (Sanders (United) Tr. 5390-91). Amputees who work in construction often do not wear MPKs. (Asar (Hanger) Tr. 1479-80).

222. If a patient's lifestyle involves being in or near water on a regular basis, the patient is better served with a mechanical knee than a microprocessor knee. For example, fishermen almost always get mechanical knees because they do not want their microprocessor knees to short out on the water. (Smith, Tr. 6007-09; Ell (Mid-Missouri O&P) Tr. 1723; PX05134 (Oros (Scheck & Siress) Dep. at 91-95); Ford (POA) Tr. 993-95).

223. Some mechanical knees are waterproof, or even salt-waterproof, making them preferable for fishermen, or others who engage in water activities. (Kannenberg (Ottobock) Tr. 1985; PX05150 (Kannenberg (Ottobock) Dep. at 54)).

224. Hunters may prefer non-MPKs to avoid the need to recharge the knee, and may prefer a mechanical knee's ability to handle wet or cold environments. (Sanders (United) Tr. 5391).

225. Some K-3 or K-4 patients with young children prefer mechanical knees to MPKs. Mechanical knees may provide greater knee flexion angle, which may make them preferable for parents who want the ability to kneel on the ground. Mechanical knees also better enable a parent to enter water to teach a child to swim or to rescue them. (Kannenberg (Ottobock) Tr. 1984-85; Sanders (United) Tr. 5396; *see also* Sanders (United) Tr. 5389).

226. Because MPKs need to be charged, patients with cognitive deficits are often fitted with a mechanical knee. (PX05134 (Oros (Scheck & Siress) Dep. at 91-93); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 37-38); PX05145 (Ford (POA) Dep. at 93-95)).

227. Some patients may do better with a mechanical knee because it is simpler to operate than an MPK. (PX05121 (Potter (Walter Reed) Dep. at 76-77)).

228. Patients who do not have access to chargers for their knees may be better suited for mechanical knees because they do not need to be charged. (Smith, Tr. 6011-12; Ell (Mid-Missouri O&P) Tr. 1722-23; Asar (Hanger) Tr. 1482 (testifying that farmers who work in the field may receive a mechanical knee)).

229. When a transfemoral amputee gets his or her initial, temporary prosthesis, it is usually a simpler mechanical knee designed for K-1 or K-2 patients because the patient is learning to walk on their amputated stump. (Sabolich (SSPR) Tr. 5841-42; Smith, Tr. 5999-6000).

230. Patients typically receive mechanical knees before being fitted with a microprocessor knee because of insurance criteria. "It's pretty tough to convince an insurance company to pay for a microprocessor knee as the first knee after an amputation . . . . [I]nsurance companies usually say the patient has to try a mechanical knee first, and only if that is functionally and safety-wise insufficient, then we may discuss if a microprocessor knee is medically necessary." (PX05150 (Kannenberg (Ottobock) Dep. at 54-55); *see also* PX05150 (Kannenberg (Ottobock) Dep. at 79-80)).

231. Some patients prefer to use a mechanical knee, even if they might be eligible for an MPK, because they have worn a mechanical knee for many years and prefer not to change. (PX05141 (Bright (North Bay) Dep. at 68-69) ("We have patients that are amputees from World War II that are still using metal and leather joints on their prosthesis. It's just – it's antiquated technology, but they just – it's what's always worked for them, and . . . they don't want to change."); PX05164 (Highsmith (VA) Dep. at 148-50) (describing study showing that 26% of mechanical knee wearers who were trained on a C-Leg returned to a mechanical knee, mostly because they were "long time users" who have had a mechanical knee "for at least ten years"); PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 68-69) ("[S]ome people have worn mechanical knees and have no desire to have a microprocessor knee.")).

### 8. Types of MPKs

#### a. OttoBock

232. Ottobock currently manufactures and sells five lines of MPKs – the Kenevo, Compact, C-Leg, Genium, and X3. (PX05133 (Eichler (Ottobock) Dep. at 57-58).

##### i. C-Leg 4

233. Ottobock designed the C-Leg MPK for K-3 level ambulators. (Solorio (Ottobock) Tr. 1634-35). After launching the first version of the C-Leg in 1999, the second version, approximately three to five years later, and the C-Leg 3, approximately five years after the second version, Ottobock launched the C-Leg 4 in 2015. The C-Leg 4 is the current model sold by Ottobock in the United States.[54] (PX05010 (Schneider (Ottobock) IHT at 99-100); PX05162 (Rhul (Ottobock) Dep. at 34, 88-89)).

234. The Ottobock C-Leg is reimbursed as a swing and stance MPK, under L-Code 5856,[55] which is recommended for knees that contain a microprocessor that controls both the swing and stance phases of the gait cycle. (Schneider (Ottobock) Tr. 4322, 4350, 4367; Kannenberg (Ottobock) Tr. 1961-62).

235. The C-Leg's microprocessor controls and modifies the C-Leg's resistance in the swing and stance phases of the knee through sensors in the knee and with C-Soft software for the C-Leg. (Schneider (Ottobock) Tr. 4319-20). The microprocessor in the C-Leg gives variable controls within the parameters set by C-Soft, and it takes into consideration all of the information that is coming from the sensors in real time. (Schneider (Ottobock) Tr. 4320). It is continually adjusting the variability of resistance in both stance and in swing phase. (Schneider (Ottobock) Tr. 4320).

236. The C-Leg's microprocessor is able to process rule sets that take into consideration environmental conditions and put the leg in the right place to enable people to ambulate in a more safe manner. (Schneider (Ottobock) Tr. 4321-22).

237. The C-Leg's microprocessor can adjust the resistances in the hydraulic unit from step to step and also within one step, if necessary. (Kannenberg (Ottobock) Tr. 1846-47, 1963). The C-Leg 4 does not have screws or bezels to adjust resistance manually; instead the prosthetist adjusts settings via software. (Kannenberg (Ottobock) Tr. 1963).

238. The C-Leg is designed for a user that varies their cadence, navigates different terrains, and navigates stairs and ramps. (Solorio (Ottobock) Tr. 1634-35). It allows a patient to walk backwards, and has a feature called intuitive stance that provides relief for the rest

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[54] Unless the context otherwise dictates, the term "C-Leg" refers to the current version of the C-Leg, the C-Leg 4.

[55] L-Codes are discussed above in F. 115-127, and in greater detail below in F. 438-445.

of a patient's body if they have to stand for long periods of time. (Solorio (Ottobock) Tr. 1635). The C-Leg 4 has programmable additional modes that allow for particular activities, such as pushups. (Solorio (Ottobock) Tr. 1635).

239. The C-Leg 4 has an IP67 rating, which means that it can be submerged in water up to one meter deep for 30 minutes. (Solorio (Ottobock) Tr. 1641). Prosthetic knees with an IP67 rating are not designed to be repeatedly submerged or be in corrosive environments like chlorinated water or salt water. (Solorio (Ottobock) Tr. 1641). The C-Leg 3 was not water resistant. (Ford (POA) Tr. 1007; De Roy (Össur) Tr. 3598-99).

240. The C-Leg's battery life is approximately two days. (PX01599 (Ottobock) at 012).

241. The list price of the C-Leg 4 is between [redacted] (PX05010 (Schneider (Ottobock) IHT at 101, *in camera*). After discounts, the average sale price for the C-Leg is between [redacted] (PX05010 (Schneider (Ottobock) IHT at 101, *in camera*); PX05133 (Eichler (Ottobock) Dep. at 70), *in camera*).

242. Based on data analyzed by Dr. David Argue, Respondent's expert witness, Dr. Argue calculated that the average price for Ottobock's C-Leg 4 in 2016 was [redacted] (RX0913 (Argue Expert Report, Table 2) (under "Average Base MPK Price 2016"), *in camera*; Argue, Tr. 6349, *in camera*).

**ii. Kenevo and Compact**

243. The Kenevo was launched by Ottobock in 2015. (Schneider (Ottobock) Tr. 4344; Solorio (Ottobock) Tr. 1634). The Kenevo was designed for a patient who does not vary their cadence and takes "small shuffly steps." (Solorio (Ottobock) Tr. 1634). The Kenevo was designed for K-2 users, but Medicare and most private payers do not reimburse MPKs for K-2 patients. (Schneider (Ottobock) Tr. 4344-45; Solorio (Ottobock) Tr. 1634).

244. The microprocessor in Ottobock's Kenevo knee controls only the stance phase of a user's gait. (Kannenberg (Ottobock) Tr. 1956-57). The Kenevo does not qualify for reimbursement under L5856 (swing and stance phases); instead, it is recommended for reimbursement under L5858 (stance-only microprocessor control). (Kannenberg (Ottobock) Tr. 1999; *see also* PX05133 (Eichler (Ottobock) Dep. at 57)).

245. The Compact was released by Ottobock in 2004. (Schneider (Ottobock) Tr. 4348). The Compact was designed for high K-2 to low K-3 patients and is marketed as a "light C-Leg." (Schneider (Ottobock) Tr. 4349, Solorio (Ottobock) Tr. 1634).

246. The microprocessor in Ottobock's Compact knee controls only the stance phase of a user's gait. (Kannenberg (Ottobock) Tr. 1955-56; Solorio (Ottobock) Tr. 1634). The Compact does not qualify for reimbursement under L5856 (swing and stance phases); instead, it is recommended for reimbursement under L5858 (stance-only microprocessor control). (Kannenberg (Ottobock) Tr. 1999).

### iii. Genium and X3

247. Ottobock designed the Genium for "higher activity K3 patient[s] into the K4 level." (Solorio (Ottobock) Tr. 1635-36).

248. The Genium has a walk-to-run feature and a feature called optimized physiological gait which allows for the most natural walking experience. (Solorio (Ottobock) Tr. 1635-36). The battery life is five days. (Schneider (Ottobock) Tr. 4391).

249. The average sales price for the Genium is more than [redacted] (PX05141 (Bright (North Bay) Dep. at 55), *in camera*; PX05162 (Ruhl (Ottobock) Dep. at 106-07); PX05129 (Ell (Mid-Missouri O&P) Dep. at 68-69)).

250. Because of reimbursement limitations set by most private insurers, typically only patients at the Department of Defense, Department of Veterans Affairs, and those who receive health benefits paid by some workers' compensation programs have access to insurance reimbursement for the Genium. (Solorio (Ottobock) Tr. 1636-37). The Genium is not billed under L5856 and Medicare does not reimburse for the Genium. (Kannenberg (Ottobock) Tr. 1961-62; Oros (Scheck & Siress) Tr. 4812-13).

251. Ottobock initially developed the X3 MPK for active duty military users. Higher activity users are still the primary users of this MPK. (Kannenberg (Ottobock) Tr. 1959-60).

252. The X3 has all of the features of the Genium, but it is fully corrosion resistant and has a dedicated running mode. (Solorio (Ottobock) Tr. 1636). The X3 has an IP68 rating, which means it is waterproof and can be submerged in fresh water, salt water, and chlorinated water. (Solorio (Ottobock) Tr. 1642; Schneider (Ottobock) Tr. 4338-39). The battery life is five days. (Schneider (Ottobock) Tr. 4391).

253. The average sales price for the X3 is more than [redacted] (PX05133 (Eichler (Ottobock) Dep. at 62), *in camera*; PX05162 (Ruhl (Ottobock) Dep. at 106-07), *in camera*; PX05129 (Ell (Mid-Missouri O&P) Dep. at 68), *in camera*; PX05145 (Ford (POA) Dep. at 59), *in camera*).

254. Because of reimbursement limitations set by most private insurers, typically only patients at the Department of Defense, the Department of Veterans Affairs, and those who receive health benefits paid by some workers' compensation programs have access to insurance reimbursement for the X3. (Solorio (Ottobock) Tr. 1636-37). The X3 is not billed under L5856 and Medicare does not reimburse for the X3. (Kannenberg (Ottobock) Tr. 1961-62; Oros (Scheck & Siress) Tr. 4812).

### b. Freedom's Plié 3

255. Freedom currently sells the Plié 3 for K-3 and K-4 level ambulators. (Carkhuff (Freedom) Tr. 294, 324-25; PX1071 (Freedom) at 023). The original Plié was released in

2007, followed by the Plié 2 in 2010. (Carkhuff (Freedom) Tr. 293-94; PX1071 (Freedom) at 023). The Plié 3 was launched in 2014.[56] (Carkhuff (Freedom) Tr. 293-94; PX1071 (Freedom) at 023).

256. Freedom considers the Plié to be an MPK with swing and stance functionality. (Carkhuff (Freedom) Tr. 350-51; Ferris (Freedom) Tr. 2351; PX05111 (Prince (Freedom) Dep. at 94-97); PX05114 (Ferris (Freedom) Dep. at 141) ("We do actually have swing and stance functionality in our knee."); PX05114 (Ferris (Freedom) Dep. at 159); PX01022 (Freedom) at 063 ("The MPC knee[57] market consists of two major categories: (a) Stance only knees (L-5858) and (b) Swing & Stance knee (L-5856) . . . . Products under the Swing & Stance category are: C-Leg from Otto Bock, Rheo from Össur, Orion from Endolite, and Plié 2.0 from Freedom Innovations."); PX01214 (Freedom) at 025, 035; PX01686 (Freedom) at 011).

257. The Plié is marketed by Freedom as a swing and stance MPK. (Carkhuff (Freedom) Tr. 350-51; Schneider (Ottobock) Tr. 4729-30, 4732; PX01214 (Freedom) at 030, 035).

258. Freedom recommends that customers seek reimbursement for the Plié as a swing and stance MPK under L-Code 5856. (Kannenberg (Ottobock) Tr. 2000; Carkhuff (Freedom) Tr. 350-51; Schneider (Ottobock) Tr. 4651-52, 4727-28; Arbogast (WillowWood) Tr. 5110; PX05137 (Matthews (Freedom) Dep. at 154); PX01214 (Freedom) at 025; PX01732 (Ottobock) at 002, 007; PX01975 (Freedom) at 012; PX07008 (Ottobock) at 004).

259. The Plié is reimbursed as a swing and stance MPK, under L-Code 5856. (Carkhuff (Freedom) Tr. 350, 714-15; Kannenberg (Ottobock) Tr. 1969-70, 2000; Schneider (Ottobock) Tr. 4728; Ell (Mid-Missouri O&P) Tr. 1732; PX05111 (Prince (Freedom) Dep. at 94-96); PX05150 (Kannenberg (Ottobock) Dep. at 76); PX05163 (Stuch (Ottobock) Dep. at 189); PX05108 (Yates (Jonesboro P&O) Dep. at 195-96); PX05144 (Blatchford (Endolite) Dep. at 64-65); PX01975 (Freedom) at 019).

260. Ottobock believes that Freedom's recommendation that the Plié 3 be coded as a L5856 swing and stance microprocessor control is not proper. (Schneider (Ottobock) Tr. 4383-84; Kannenberg (Ottobock) Tr. 1970) ("The Freedom Plié . . . only has a microprocessor switch, but the manufacturer Freedom recommends to bill the microprocessor stance and swing code, which is actually not appropriate.").

261. The battery life of Plié 3 is approximately one day. (PX01025 (Freedom) at 018).

262. The Plié 3 has a customizable stumble recovery feature, variable speeds, the ability to be fully submersed in water, interchangeable batteries, remote access, and real-time data

[56] Unless the context otherwise dictates, the term "Plié" refers to the Plié 3.

[57] The term "MPC knee" is used at times in Freedom documents to refer to a microprocessor-controlled knee and means the same thing as an MPK. (Carkhuff (Freedom) Tr. 482).

display. (PX01181 (Freedom) at 003-04; PX08014 (Freedom) at 002-03; PX08008 at 001 (Plié 3 Fact Sheet); Carkhuff (Freedom) Tr. 348-49).

263. The Plié 3 is water resistant with an IP67 rating. (PX01025 (Freedom) at 018). It is submersible only in freshwater, not chlorinated water or salt water, up to one meter deep for up to an hour. (Schneider (Ottobock) Tr. 4392).

264. The microprocessor in the Plié 3 switches the knee from a fixed stance phase resistance to a fixed swing phase resistance or from a fixed swing stance resistance to a fixed stance phase resistance, but does not vary the resistance throughout the gait cycle. (Carkhuff (Freedom) Tr. 335; Schneider (Ottobock) Tr. 4310, 4320). The hydraulic system and the design controls the resistance throughout the swing and extension by oil flowing through ports. Resistance is controlled during the gait phase, during the swing and extension, by the design of the fluid hydraulic cylinder. (Carkhuff (Freedom) Tr. 335-38).

265. The microprocessor in the Plié 3 is always on and effects changes in the knee from stance to swing and will control the knee when there is some kind of abnormality that the sensors pick up. If there is movement when the user is transitioning in a specific way from stance to swing, the microprocessor will put the knee into a safe stance mode, thereby making real-time adjustments that help reduce falls in patients. (Carkhuff (Freedom) Tr. 336-39).

266. There are two adjustments on the Plié 3 for the swing phase of the knee. (Schneider (Ottobock) Tr. 4312-13). One of them is the hydraulic unit which is preset with an Allen wrench. (Schneider (Ottobock) Tr. 4313-13). The other adjustment is made on the pneumatic cylinder, by inserting a pump that comes with the Plié 3, which is similar to a small bicycle pump. (Schneider (Ottobock) Tr. 4312-13).

267. MPK manufacturers Össur and Endolite consider the Plié to be an MPK. (PX05124 (De Roy (Össur) Dep. at 148); PX05144 (Blatchford (Endolite) Dep. at 74)).

268. Mechanical knee manufacturers consider the Plié to be an MPK. (Arbogast (WillowWood) Tr. 5108; PX05117 (Choi (ST&G) Dep. at 125); PX05124 (De Roy (Össur) Dep. at 148).

269. Prosthetists consider the Plié to be an MPK. (Brandt (Ability P&O) Tr. 3774; *see* PX05108 (Yates (Jonesboro P&O) Dep. at 64); PX05128 (Senn (COPC) Dep. at 76); PX05129 (Ell (Mid-Missouri O&P) Dep. at 64); PX05145 (Ford (POA) Dep. at 142)).

270. Based on data analyzed by Dr. David Argue, Respondent's expert witness, Dr. Argue calculated that the average price for a Plié 3 in 2016 was [redacted] (Argue, Tr. 6301, *in camera*; RX0913 (Argue Expert Report, Table 2) (under "Average Base MPK Price 2016"), *in camera*). *See also* PX01023 (Freedom) at 003, *in camera* (early 2017 presentation noting that the Plié 3 has an average selling price of [redacted]).

### c. Össur

271. In the United States, Össur currently sells the Rheo MPK, Rheo XC MPK, and the Power Knee for K-3 and some K-4 level ambulators. (De Roy (Össur) Tr. 3576, 3579-80). Össur also sells the Symbionic Leg, a combination of the Rheo MPK and Propio ankle. (De Roy (Össur) Tr. 3576).

#### i. Rheo

272. Össur launched the Rheo 3 in the United States in 2014. (De Roy (Össur) Tr. 3640, 3678; PX03245 (Össur) at 005). Össur launched a weatherproof version of the Rheo 3 in 2016. (De Roy (Össur) Tr. 3640-41; PX03245 (Össur)). The current, fourth generation version of the Rheo that was launched by Össur in the United States in September 2017 is marketed as the "Rheo" and is intended for K-3 and K-4 level ambulators. (De Roy (Össur) Tr. 3545, 3640; PX05009 (De Roy (Össur) IHT at 45-48)).

273. The Rheo is reimbursed as a swing and stance MPK, under L-Code 5856. (Kannenberg (Ottobock) Tr. 1961-62; Schneider (Ottobock) Tr. 4352).

274. The Rheo is weatherproof. (De Roy (Össur) Tr. 3581). It cannot be submerged in water but can be exposed to rain or water from a hose or pouring a cup of coffee on it. (De Roy (Össur) Tr. 3582).

275. Össur's Rheo (and Rheo XC, discussed below) use magnetorheologic technology ("MR technology"). (De Roy (Össur) Tr. 3577; Schneider (Ottobock) Tr. 4398-99). Magnetic particles in an oil are kept in a cylinder between blades. The knee creates a magnetic field that aligns the magnetic particles within that fluid between the blades building bridges and providing variable resistance to the swing and stance phases of the knee. (De Roy (Össur) Tr. 3577). The microprocessor and sensors adjust magnetorheological fluid to control the way the knee swings and locks during stance phase. (Blatchford (Endolite) Tr. 2148-49). MR technology in the Rheo and Rheo XC offers variable resistance control in both the swing and stance phases of the knee. (De Roy (Össur) Tr. 3639).

276. The list price of the Rheo is [redacted] which results in an average sales price of approximately [redacted] after discounts. (De Roy (Össur) Tr. 3604, *in camera*).

#### ii. Rheo XC

277. Össur characterizes its Rheo XC as a "step up" from the Rheo. (De Roy (Össur) Tr. 3532). The Rheo XC offers additional features such as walk to run, greater efficiency on stairs, and the ability to ride a bike. (De Roy (Össur) Tr. 3578-79).

278. Össur targets moderate to high-level K-3 and some K-4 users for sales of the Rheo XC. (De Roy (Össur) Tr. 3583).

279. The Rheo XC is not billed under L5856 and Medicare does not reimburse for the Rheo XC. Only the Department of Veterans Affairs, some private payers, and workers'

compensation plans reimburse clinics for the fitting of a Rheo XC. (De Roy (Össur) Tr. 3583-84).

280. The list price of the Rheo XC is [redacted] which results in an average sales price of approximately [redacted] after discounts. (De Roy (Össur) Tr. 3604, *in camera*).

**iii. Power Knee**

281. Össur's Power Knee is a powered microprocessor-controlled device. (De Roy (Össur) Tr. 3576). It is motorized and lifts a user's knee for them. (De Roy (Össur) Tr. 3584-85). The motor in the Power Knee functions like "your quad muscle" to enable a user to rise out of a chair and propel a person "throughout every step." (De Roy (Össur) Tr. 3584-85).

282. Össur recommends the Power Knee for K-3 patients. (De Roy (Össur) Tr. 3585).

283. Private insurers reimburse for the Power Knee only on a case-by-case basis. (De Roy (Össur) Tr. 3585).

284. The Department of Defense and the Department of Veterans Affairs have provided reimbursement for the Power Knee. (De Roy (Össur) Tr. 3586). The Power Knee has a code that is accepted by Medicare and does not rely on the same code positioning as the L-Code 5856 used for microprocessor knees. (De Roy (Össur) Tr. 3660-61).

285. The Power Knee costs approximately twice as much as the Rheo and other MPKs on the market. (De Roy (Össur) Tr. 3585). The list price of the Power Knee is approximately [redacted] which results in an average sales price of around [redacted] after discounts. (De Roy (Össur) Tr. 3604-05, *in camera*).

**d. Endolite's Orion 3**

286. The original Orion knee was launched in 2010, and the Orion 2 was launched in 2014. (Blatchford (Endolite) Tr. 2109-10). Endolite launched the Orion 3 in the United States in September 2016. (Blatchford (Endlolite) Tr. 2109).

287. The Orion 3 is reimbursed as a swing and stance MPK, under L-Code 5856. (Kannenberg (Ottobock) Tr. 1961-62; Schneider (Ottobock) Tr. 4322, 4352).

288. Orion 3 offers MPK control of both the swing and stance phases of the gait cycle. (PX03176 (Endolite) at 009; Blatchford (Endolite) Tr. 2215-16). Orion 3 is able to make adjustments to the friction level of the knee while the knee is either in swing or stance phase. (PX03176 (Endolite) at 009; Blatchford (Endolite) Tr. 2215-16).

289. Orion 3 uses a hybrid cylinder that has two chambers. (Blatchford (Endolite) Tr. 2134-35). The pneumatic chamber controls the resistance level in the swing phase of the knee whereas the hydraulic chamber controls the resistance level in the stance phase of the

knee. (Blatchford (Endolite) Tr. 2134-35). The hydraulic cylinder is the part that would lock under load to make it safe, and the pneumatic cylinder is the part that varies the resistances as it swings to make it react to the user as he or she walks. (Blatchford (Endolite) Tr. 2108).

290. The Orion 3 uses several sensors that determine when to change the resistance levels in the hydraulic and pneumatic chambers depending on how fast the amputee is walking and can lock the knee when the patient is stationary. (Blatchford (Endolite) Tr. 2111). The Orion 3 is also able to detect if a user is walking down a ramp or up a ramp and whether the user is going upstairs or downstairs and can adjust the resistances in the knee accordingly. (Blatchford (Endolite) Tr. 2111).

291. The list price of the Orion 3 is slightly above [redacted] After discounts, clinics typically pay an average sales price between [redacted] (Blatchford (Endolite) Tr. 2155-56, *in camera*).

**e. Nabtesco**

292. Nabtesco Corporation ("Nabtesco") manufactures prosthetic devices including microprocessor knees, non-microprocessor knees, microprocessor feet, and non-microprocessor feet. (PX03004 (Nabtesco) at 001).

293. Nabtesco is headquartered in Kobe, Japan, where the company manufactures all of its products. Nabtesco does not manufacture any products in the United States. (PX03004 (Nabtesco) at 001; PX05161 (Mattear (Nabtesco) Dep. at 26)).

294. Prior to September 2018, Nabtesco's sales in the United States were made through four distributors – Cascade Orthopedic Supply, Inc., Southern Prosthetic Supply, Inc., PEL LLC, and Proteor, Inc. (PX03004 (Nabtesco) at 001).

295. As of September 1, 2018, Proteor, Inc. (d/b/a Nabtesco & Proteor in USA) is the exclusive distributor of prosthetic devices manufactured by Nabtesco Corporation and Proteor S.A. (Mattear (Nabtesco) Tr. 5521-22, 5546-47). Proteor was based out of Muskego, Wisconsin until June 2018 when it acquired Ability Dynamics, including its RUSH foot line of prosthetic products and moved its headquarters to Tempe, Arizona. (Mattear (Nabtesco) Tr. 5510, 5528).

296. Nabtesco currently manufactures and sells three microprocessor knee products – the Intelligent Knee, the Hybrid Knee, and the Allux Knee. (PX05161 (Mattear (Nabtesco) Dep. at 35)).

297. The final version of the Allux was launched in the United States on June 1, 2017. (RX0436 (Nabtesco); Mattear (Nabtesco) Tr. 5598-99; 5775). Before June 1, 2017, Allux was just a beta model. (Mattear (Nabtesco) Tr. 5598-99; 5775-76).

298. The Allux utilizes Nabtesco's proprietary four-bar technology, including a dual safety system, and offers multiaxial, polycentric design. (Mattear (Nabtesco) Tr. 5602; De Roy (Össur) Tr. 3595).

299. The Allux's battery length is four days. (Mattear (Nabtesco) Tr. 5603). The Allux has an internal battery that takes three hours to charge and it also offers a backup battery for emergencies. (Mattear (Nabtesco) Tr. 5621-22).

300. The Allux also comes with a remote control that allows the user to toggle between different preset modes. (Mattear (Nabtesco) Tr. 5604-05).

301. Nabtesco recommends and markets the Allux for K-3 and K-4 users. (Mattear (Nabtesco) Tr. 5607 5780-82).

302. Nabtesco recommends using L-Code 5856 for microprocessor swing and stance control for the Allux. (Kannenberg (Ottobock) Tr. 1961-62; Schneider (Ottobock) Tr. 4352; (Mattear (Nabtesco) Tr. 5607).

303. Complaint Counsel's expert witness, Dr. Fiona Scott Morton, estimated that the average sales price of Nabtesco's MPKs in 2017 was [redacted] (PX06001 (Scott Morton Expert Report at 044 Table 3), *in camera*).

**f. DAW Industries**

304. DAW Industries ("DAW") sells prosthetic components, including MPKs, in the United States. (Joint Stipulations of Law and Fact, JX001 at 004 ¶ 40).

305. DAW does not manufacture its own MPKs. Instead, DAW serves as a distributor of MPKs manufactured by a company named Teh Lin, located in Taipei, Taiwan. (PX05146 (Marquette (DAW) Dep. at 15-17)).

306. DAW markets three microprocessor knee designs: the Self-Learning Knee, the Microprocessor Programmable Knee, and the Multi-Matrix Self-Learning Knee. (PX05146 (Marquette (DAW) Dep. at 21-22); PX04002 (Declaration of Stuart Marquette (DAW) at 002 ¶ 4)). Each of the MPK knees sold by DAW uses a pneumatic system. (PX04002 (Declaration of Stuart Marquette (DAW) at 002 ¶ 6)).

307. DAW markets its MPKs to a subset of K-3 patents whose activity levels fall within the low to mid-level for a K-3 patient and does not market its MPKs to K-4 patients. (PX04002 (Declaration of Stuart Marquette (DAW) at 002 ¶ 6)).

308. DAW recommends using L-Code 5856 for microprocessor stance and swing control for one of its MPKs. (Kannenberg (Ottobock) Tr. 1961-62, 1998).

309. Complaint Counsel's expert witness, Dr. Scott Morton, estimated that the average sales price of DAW's MPKs in 2017 was [redacted] (PX06001 (Scott Morton Expert Report at 044 Table 3), *in camera*).

### g. Integrated microprocessor-controlled leg systems

310. An integrated leg system combines a microprocessor-controlled knee with a microprocessor-controlled ankle. (Blatchford (Endolite) Tr. 2110). The sensors and microprocessor in the knee are able to communicate with the sensors and microprocessor in the ankle. (Blatchford (Endolite) Tr. 2137-39).

311. Endolite's Linx Limb System is an integrated leg system with a microprocessor-controlled knee connected to a microprocessor-controlled foot. (Blatchford (Endolite) Tr. 2110). The list price for the Linx is [redacted] but clinics pay, on average, between [redacted] (Blatchford (Endolite) Tr. 2156, *in camera*).

312. Össur's Symbionic Leg is an integrated leg system. (De Roy (Össur) Tr. 3673). It is a combination of a Rheo knee and a Proprio ankle. (De Roy (Össur) Tr. 3576). The average sales price of the Symbionic Leg is [redacted] (De Roy (Össur) Tr. 3605, *in camera*).

## 9. Role of price

313. Typically, clinics do not stock prosthetic components, but purchase them individually for particular patients. (Oros (Scheck & Siress) Tr. 4778-79).

314. Clinics purchase MPKs from prosthetic manufacturers. (Ell (Mid-Missouri O&P) Tr. 1688; Senn (COPC) Tr. 196-97; PX05128 (Senn (COPC) Dep. at 21, 95); PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 80).

315. Clinics generally negotiate MPK prices with MPK manufacturers on an annual basis during contract renewal negotiations. (Carkhuff (Freedom) Tr. 382-83; Senn (COPC) Tr. 195; PX05116 (Endrikat (Empire Medical) Dep. at 48-49, 53)).

316. MPK manufacturers charge different sales prices to different clinic customers. (PX05007 (Carkhuff (Freedom) IHT at 120-21)).

317. MPK manufacturers make the list prices for their MPKs publicly available, but customers typically pay a negotiated MPK sales price that is below the manufacturer's list price. (Carkhuff (Freedom) Tr. 382; Testerman (Freedom) Tr. 1145; Collins (Cascade) Tr. 3283).

318. The overall volume of MPKs that a clinic customer purchases during the term of the contract affects the discounts they receive from MPK suppliers. (Senn (COPC) Tr. 196-97; PX05004 (Senn (COPC) IHT at 38) ("[W]e could obtain a higher discount from Freedom, if we're able to drive more of the MPK volume to Freedom. Otto Bock has

offered the same thing."); PX05116 (Endrikat (Empire Medical) Dep. at 58) (Empire Medical negotiates the lowest price possible for microprocessor knees through volume by saying "we did X amount of business, and therefore we warrant this amount of discount.")).

319. Clinics recover their costs for the provision of prosthetic devices from insurers, including Medicare, by submitting requests for reimbursement, in accordance with applicable L-Codes. F. 115-119.

320. Clinics get "paid not by brand or by product selected but by function of the product." (PX05010 (Schneider (Ottobock) IHT at 83-84); *see also* Kannenberg (Ottobock) Tr. 1871-72; PX05117 (Choi (ST&G) Dep. at 47-49); PX05165 (Sanders (United) Dep. at 33-34)).

321. Insurers, including Medicare, do not tie the amount of reimbursement to the prices charged by manufacturers for prosthetic devices, but to reimbursable amounts for each L-Code. (Carkhuff (Freedom) Tr. 596-97; PX05165 (Sanders (United) Dep. at 33-34)).

322. There are no L-Codes for aspects of the prosthetic fitting process such as services for the fabrication and fitting of the device or related support services. L-Code reimbursement for the device is supposed to cover the clinic's cost in acquiring the prosthetic device as well as all services and costs related to fitting and servicing that device. (PX05145 (Ford (POA) Dep. at 45-46); Schneider (Ottobock) Tr. 4294-95).

323. Reimbursement for a particular prosthetic device is intended to cover not only the cost of acquiring the prosthesis, but also the prosthetist's labor and overhead, and time spent with the patient over the course of the fitting and adjustment of the device. (Senn (COPC) Tr. 200-01; Ford (POA) Tr. 977-78; Asar (Hanger) Tr. 1359).

324. The difference between the acquisition cost of a prosthetic device and the overall reimbursement allowable goes to the clinic or prosthetist. (PX05124 (De Roy (Össur) Dep. at 135-36)). The reimbursement amount "reflects the time spent in assembling the device and the time spent teaching the patients" as well as time spent by the prosthetist "following up on care with the patient." (PX05124 (De Roy (Össur) Dep. at 135-36)).

325. The gross margin is the allowable reimbursement for a prosthetic less costs like the acquisition cost, staff involved in delivery of care, and technical services. (Oros (Scheck & Siress) Tr. 4823-34).

326. Clinics' margins can increase if prices of MPKs decrease. (Asar (Hanger) Tr. 1484; PX05108 (Yates (Jonesboro P&O) Dep. at 75); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 164-65) (testifying that Sprinkle Prosthetics expects to receive a higher margin for a Plié 3 purchase, as opposed to a C-Leg 4 purchase); PX05128 (Senn (COPC) Dep. at 24)).

327. A 2017 Freedom document shows: the average sales price of the Plié 3 was [redacted] the estimated average sales price of the C-Leg 4 was [redacted] and reimbursement for both MPKs was [redacted] which created an average margin for clinics of [redacted] for each Plié 3 purchased and [redacted] for each C-Leg 4 purchased. (PX01023 (Freedom) at 003, *in camera*; Carkhuff (Freedom) Tr. 387-88).

## C. Relevant Market

### 1. Relevant geographic market

328. Respondent's economic expert witness, Dr. David Argue, agrees that the United States is the relevant geographic market in this case. (Argue, Tr. 6267 (explaining that he "used the United States geographic market for [his] knee and foot markets because clinic customers are not going to go to suppliers outside of the United States to purchase knees or feet"); RX1049 (Argue Expert Report at 0021 ¶ 36) (stating that "[f]or purposes of this report, I do not dispute that the United States is a properly defined geographic market."); PX05173 (Argue (Respondent) Dep. at 91) (explaining that "[t]here's no evidence to indicate that the market, geographic market, was broader than the United States.").

329. Internal Ottobock and Freedom documents distinguish the United States market from the rest of the world. (*See* PX01022 (Freedom) at 007-30 (analyzing the "United States Market" separately from the "European Market"); PX01061 (Ottobock) at 023, 048-57).

### 2. Relevant product market

#### a. Distinguishing physical characteristics

330. The use of a microprocessor in an MPK allows the MPK to function, operate, and perform in a way that is different from how a mechanical knee functions, operates, and performs. (Potter (Walter Reed) Tr. 775-76; Ford (POA) Tr. 916; PX05119 (Kahle (Prosthetic Design & Research) Dep. at 33-34); PX05144 (Blatchford (Endolite) Dep. at 166-67)).

##### i. Ottobock's recognition of the benefits of MPKs over mechanical knees

331. On its publicly available website, Ottobock distinguishes microprocessor knees from mechanical knees as providing a "more sophisticated method of control to a prosthetic knee. These more complex knee joints are designed to help you walk with a much more stable and efficient gait that more closely resembles a natural walking pattern." (PX08013 (Ottobock) at 001).

332. The microprocessor in an MPK reads sensors located throughout the device to help position the knee during a user's gait cycle. These adjustments can predict a user's activities and the walking terrain with each step. (Kannenberg (Ottobock) Tr. 1946-47).

333. Scott Schneider, Ottobock's vice president of government, medical affairs, and future development, believes that "[m]icroprocessors are proven to have stumble recovery, making them very, very safe." According to Mr. Schneider, "microprocessors allow for more cadence variance, so walking fast or slow, . . . the computer can adjust to those speed differences. Microprocessors can enable people to have more comfort because [a microprocessor knee has] additional features and benefits [so] that [the patient does] not have to overcompensate with their muscular structure. So there's many, many ways in which an end user transfemoral amputee can benefit from a microprocessor knee." (PX05010 (Schneider (Ottobock) IHT at 73-74)).

334. Andreas Eichler, head of Ottobock's business unit for prosthetic lower-limb mechatronic systems, believes that the primary benefits of MPKs are "safety and comfort." He elaborated that safety meant "[t]hat patients can rely on their knee joints that it will be stiff when it's supposed to be stiff and it will be pliable when it's supposed to be pliable," and comfort meant "[l]ess pain. So less pain and subsequent damages as a result of everyday use and walking on the prosthetic." (PX05133 (Eichler (Ottobock) Dep. at 4, 43-44)). Mr. Eichler also agreed that microprocessor knees are more responsive than mechanical knees, which, according to Mr. Eichler, "are not responsive at all." (PX05133 (Eichler (Ottobock) Dep. at 51-52)).

335. Dr. Kannenberg, Ottobock's executive medical director, believes that for unlimited community ambulators, MPKs provide a benefit in terms of a reduction in stumbles and falls. For this group, according to Dr. Kannenberg, the benefit is also "about increasing their mobility and being able to do activities that they couldn't do or wouldn't dare to do on a mechanical knee." (PX05150 (Kannenberg (Ottobock) Dep. at 42-43)).

336. Dr. Kannenberg believes that the C-Leg, due to its microprocessor, provides greater mobility than a mechanical knee because "the microprocessor control allows a knee to do more activities without the threat of collapsing and causing a fall." Additionally, according to Dr. Kannenberg, "the resistances that are produced in the knee [are] much more flexible and adaptable to many more activities that you encounter in your daily life than a mechanical control. . . . [A] mechanical knee . . . is usually quite nice for level walking, but as soon as you have to negotiate uneven terrain, slopes and stairs, you're in trouble." (PX05150 (Kannenberg (Ottobock) Dep. at 44-45)).

337. Brad Ruhl, currently Ottobock's managing director for North America, believes that "[t]he benefits of microprocessor control, specifically in C-Leg, [are] that it has features that will help patients avoid stumbles and falls." (PX05162 (Ruhl (Ottobock) Dep. at 35)).

338. Ottobock posted to its website a summary of a publication by Dr. Highsmith, Mr. Kahle, and Dr. Kaufman titled, *Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees.* (PX08007 (Ottobock) at 001). The Ottobock summary quoted the conclusion of the study that, "'[t]hough methodologic quality varied across the selected topic areas, there was sufficient evidence to suggest that the C-Leg provided increased efficacy in safety, energy efficiency, and cost effectiveness when compared

with other [non-microprocessor-controlled] prosthetic knees for transfemoral amputees.'" (PX08007 (Ottobock) at 001 (alteration in the original)).

339. A presentation sent by Ottobock's executive medical director, Dr. Andreas Kannenberg, to Joe Cantwell, a certified prosthetist at Certified Pedorthic Orthotics, highlighted several benefits of MPKs, specifically Ottobock's C-Leg 4 and Compact, over mechanical knees, and represented that such benefits were supported by clinical evidence. The benefits highlighted include: "improved safety – less stumbles and falls (up to 80%!), improved balance and confidence"; "improved and faster slope negotiation"; "improved and faster negotiation of uneven terrain and obstacles"; "improved stair descent"; "reduced cognitive demand to walk and improved multi-tasking"; and "potential to increase overall mobility / K-Level." (PX01543 (Ottobock) at 067; *see also* Kannenberg (Ottobock) Tr. 1895-1901 (discussing PX01543); PX01484 (Ottobock) at 031 (Presentation titled, "Evidence for Microprocessor Controlled Prosthetic Knees")).

340. In a June 2016 email assessing the market and reimbursement potential for a new MPK product, Ottobock research and development prosthetist Greg Schneider wrote, "I think that mechanical knees won't be as much of a factor since there is a pretty big safety gap between the mechanical and MP systems." (PX01878 (Ottobock) at 002).

341. In a letter advocating for Medicare coverage of MPKs for K-2 patients, Ottobock stressed the benefits of MPKs over mechanical knees. (PX01480 (Ottobock) at 004-07). The authors of the letter (Kim Hanson and Dr. Kannenberg of Ottobock) wrote, "While there is no doubt that the unlimited community ambulator receives tremendous benefit from fluid and microprocessor knee control, it is clear that this same technology may equally provide tremendous benefits to patients with [Medicare Functional Classification Level] MFCL-2 mobility grade. In these beneficiaries, stumble recovery and improved stability while ambulating on all terrains create a solid foundation for improvement of overall function and mobility." (PX01480 (Ottobock) at 007)).

342. Over the last several years, Ottobock employees have sent clinical research studies to its customers to market its MPK products. (PX05150 (Kannenberg (Ottobock) Dep. at 193-94); PX05148 (Swiggum (Ottobock) Dep. at 36-38)).

343. Ottobock often provides research studies to clinics with the intention of demonstrating the increased safety or functionality provided by its MPKs relative to mechanical knees. (Kannenberg (Ottobock) Tr. 1893; *see* PX01494 (Ottobock at 001 (May 6, 2015 email from Dr. Kannenberg to Sam Liang, then the president of Hanger, sending an article titled, *Benefits of Microprocessor-controlled Prosthetic Knees to Limited Community Ambulators: Systemic Review,* by Andreas Kannenberg, MD, PhD; Britta Zacharias, Dipl-Ing (FH), CPO; and Eva Pröbsting, Dipl-Ing (FH), CPO); PX00848 (Ottobock) at 001, 040 (August 18, 2015 email from Dr. Kannenberg sending several research articles highlighting the benefits of MPKs to insurer Select Health, including, *Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees: A Review of the Literature,* by M. Jason Highsmith; Jason T. Kahle; Dennis R. Bongiorni; Bryce S.

Sutton; Shirley Groer; and Kenton R. Kaufman (PX08001)); PX00849 (Ottobock) at 001, 022 (September 23, 2015 email from Dr. Kannenberg to Phil Stevens, prosthetist and orthotist at Hanger, attaching several articles highlighting the benefits of MPKs including, *Gait and Balance of Transfemoral Amputees Using Passive Mechanical and Microprocessor-controlled Prosthetic Knees*, by Kenton R. Kaufman; J.A. Levine; R.H. Brey (PX08010)); PX01497 (Ottobock) at 002, 004 (Nov. 3, 2015 email from Dr. Kannenberg attaching several articles highlighting the benefits of MPKs for transmittal to Deanna Hines of Russell Prosthetics including, *Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees: A Review of the Literature,* by M. Jason Highsmith; Jason T. Kahle; Dennis R. Bongiorni; Bryce S. Sutton; Shirley Groer; and Kenton R. Kaufman (PX08016)); PX01620 (Ottobock) at 001 (March 25, 2016 email from Dr. Kannenberg sending several articles highlighting the benefits of MPKs to Lee Childers PhD, MSPO, CP of Alabama State University Prosthetics and Orthotics); PX01480 (Ottobock) at 002, 017 (April 25, 2016 email from Ottobock's Kimberly Hanson, director of reimbursement for North America, attaching several articles highlighting the benefits of MPKs to Stacey Brennan of Anthem, including, *Comparison of Nonmicroprocessor Knee Mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, Stumbles, Falls, Walking Tests, Stair Descent, and Knee Preference,* by Jason T. Kahle, CPO, LPO; M. Jason Highsmith, DPT, CP; and Sandra L. Hubbard, PhD, OTR/L, ATP (PX08018)); PX00852 (Ottobock) at 001 (Nov. 17, 2016 email from Dr. Kannenberg sending several articles highlighting the benefits of MPKs to Courtney Boniello of A Step Ahead Prosthetics)).

**ii. Freedom's recognition of the benefits of MPKs over mechanical knees**

344. Freedom's CEO at the time of the Acquisition, David Smith, believes that Freedom's Plié 3 and mechanical knees are "completely different products [at] completely different price points." (PX05122 (Smith (HEP) Dep. at 106-07)). Distinguishing a mechanical knee from an MPK, Mr. Smith explained: "One is rudimentary and one is sophisticated. One doesn't allow mobility and ambulation and one does. One restricts activity or limits your activity, or you want it limited for safety reasons because the patient is incapable. The other one allows it and facilitates it." The differences are because "one of them has different componentry and different functionality than the other one." (PX05122 (Smith (HEP) Dep. at 202-03)).

345. A document commissioned by Freedom, but drafted by Brian Kaluf of Ability P&O, summarized 29 clinical studies pertaining to MPKs generally, though not to the Plié specifically. (Ferris (Freedom) Tr. 2367, 2370-72; PX01194 (Freedom) ("Draft Summary of Evidence")). The Draft Summary of Evidence used points that validated the use of MPKs generally to support statements made about the Plié. (Ferris (Freedom) Tr. 2367, 2370-72). Freedom intended to provide the document to Freedom's field representatives and prosthetists to assist Freedom's clinic customers with MPK reimbursement. The document had not been finalized for use by Freedom's sales force by October 2017. (Ferris (Freedom) Tr. 2367, 2370-72).

346. The Draft Summary of Evidence states, "The stability and balance confidence provided by the Plié 3.0 and associated reduction in stumbles and falls allows patients to walk more in the community." (PX01194 (Freedom) at 004). Eric Ferris, Freedom's director of marketing and customer service, agreed that this statement is true, both in regards to the Plié 3 and to all MPKs. (Ferris (Freedom) Tr. 2376-77).

347. The Draft Summary of Evidence states, "[N]on-microprocessor controlled prosthetic knees can lead to increased healthcare cost associated to caregiver support and secondary complications associated with falls." (PX01194 (Freedom) at 005). Mr. Ferris agreed that this statement is true, both in regards to the Plié 3 and to all MPKs. (Ferris (Freedom) Tr. 2378).

348. The Draft Summary of Evidence states, "Persons who use a transfemoral prosthesis experience adverse effects and diminished walking ability on level ground due to the shortcomings of a non-microprocessor controlled prosthetic knee. Without a microprocessor, the system provides inappropriate function during swing phase whenever the patient walks slower or faster than their normal comfortable walking speed." (PX01194 (Freedom) at 005). Mr. Ferris explained that this statement means that a mechanical knee will not adjust to changes in terrain like an MPK will, which provides an advantage to some amputees. He agreed that this statement is true, both in regards to the Plié 3 and to all MPKs. (Ferris (Freedom) Tr. 2378-79).

349. The Draft Summary of Evidence states, "A non-microprocessor controlled prosthetic knee limits a patient's function on stairs because the prosthetic knee experiences a great flexion torque[,] which causes it to buckle. This leads to compensatory strategies and reduces mobility on stairs for persons with lower transfemoral amputation." (PX01194 (Freedom) at 006). Mr. Ferris believes this to be a true statement, and that the Plié and other MPKs give a user more confidence as he or she is going down the stairs and more stability than a mechanical knee user would have. (Ferris (Freedom) Tr. 2380; *see also* Ferris (Freedom) Tr. 2382 (the microprocessor in the Plié 3 allows the resistance level of the knee to adjust, thereby providing greater stability than a mechanical knee when walking down a ramp)).

350. The Draft Summary of Evidence states, "Uneven terrain restricts mobility and balance for persons who use a non-microprocessor controlled prosthetic knee, which are designed for level surfaces. . . . This exposes the knee to increased risk of buckling and can lead to a stumble or fall." In contrast, "[t]he sensors and microprocessor in the Plié 3.0 allow it to maintain a high level of knee stability to avoid unintentional buckling on uneven terrain. This allows patients to shift weight onto the prosthesis side without fear of the prosthetic knee buckling and causing a stumble or fall." (PX01194 (Freedom) at 007). Mr. Ferris agreed that an advantage of MPKs over mechanical knees is the former's ability to adjust resistance level based on the terrain the amputee encounters. (Ferris (Freedom) Tr. 2382-83).

351. An August 2016 internal Freedom memo highlights "[k]ey differences between mechanical knee[s] and microprocessor knee[s,]" including improved stability, a

smoother and more natural gait, expenditure of less energy, and the ability to walk with variable cadences for MPK users. (PX01164 (Freedom) at 024).

352. A 2015 Freedom presentation titled "Microprocessor Controlled Knees" includes slides titled, "What makes MPC Knees different?" (PX00814 (Freedom) at 003, 007-08). The listed differences are: "Increases stability and confidence"; "Reduces cognitive burden because of stumble recovery feature"; "Studies have shown that MPC knees can elevate some user's functional abilities (K-level) compared to conventional knees"; "Studies also suggest that [MPKs] actually are responsible for variable cadence achievement"; "Stability can reduce fear of falling"; "Studies show 88.1% increase in confidence"; "Studies also show 88.4% improvement of gait agility compared to non-MPK's"; "Reported that MPC knees can decrease frequency of falls by as much as 64%"; and "Amputees no longer have to watch every step." (PX00814 (Freedom) at 007-08).

353. Freedom's website includes materials for use by Freedom customers seeking reimbursement for the Plié 3 that claim benefits of MPKs over mechanical knees. (PX08009 (Freedom)). The materials include a "Microprocessor Knee Literature Review," which collects and summarizes clinical research articles "in an effort to understand where the research in Microprocessor Knees (MPK) has been focused and to determine where significant outcomes exist." (PX08009 (Freedom) at 017). The Freedom materials state that "research has been able to show that the [MPK] user feels more stable on stairs, inclines, and uneven terrain, while reducing the cognitive demand required for walking" and that "the user experiences less stumbles and falls while expressing a higher level of satisfaction and stability with MPKs." (PX08009 (Freedom) at 017).

#### iii. Recognition by other manufacturers of the benefits of MPKs over mechanical knees

354. Össur highlights the benefits of microprocessor knees compared to mechanical knees to market its MPKs. (*See, e.g.*, PX03097 (Össur) at 010; *see also* De Roy (Össur) Tr. 3549). Benefits highlighted by Össur include "increased quality of life and improved mobility in transfemoral amputees, as measured by transitioning from non-microprocessor, mechanical knees." (PX03097 (Össur) at 006 ("Health Economic Analysis, The case for Rheo Knee 3 | Rheo Knee XC")).

355. According to Kim De Roy, executive vice president for research and development at Össur, research on MPKs "shows that people that transfer from a mechanical knee over to the microprocessor knee experience more safety, experience reduced falls. And in some cases it's even shown that they have reduced comorbidities, such as back pain, because their gait normalizes. They walk better. They don't use their muscles in straining matters; therefore, the risk for developing those types of issues is lower. There's also a benefit to the sound side leg, because typically people are amputated on one side, and the advantages that these types of knees reduce the impact on the sound side, which has proven to be related to or have a positive impact on reducing the chances

of developing knee OA [osteoarthritis] on the sound side . . . ." (De Roy (Össur) Tr. 3546-47).

356. According to Mr. Blatchford, executive chairman of Endolite, Endolite's MPKs provide "several advantages" over its non-MPKs: "If you look at it from the amputee's perspective, the consequence of the fact that the knee reacts to – more exactly to what the user is doing means that the user on average will walk faster – there's clinical studies which will support that – that the user uses less energy, further clinical studies that will support that, that there is less distortion in the gait of the amputee so that when you compare the gait on the sound side with the gait on the amputated side, there's more symmetry . . . [and] because it's more symmetrical, it applies less adverse force on the patient's skeletal system, and therefore, you can get less things like back pain, and so on." (Blatchford (Endolite) Tr. 2114-15).

357. The main clinical benefits that Endolite highlights to market its Orion 3 MPK "are the fact that the user will need less energy to walk with the knee because on average they will walk more quickly, so their self-selected speed . . . is higher than it would be without a microprocessor knee" and also that "[t]he knees reduce the instance of falling very considerably." (Blatchford (Endolite) Tr. 2119-20).

358. According to William Carver, president and COO of mechanical knee manufacturer College Park, "a microprocessor knee offers infinite adjustment and it thinks for you," whereas an hydraulic knee is manually set. In addition, "there's the ability that a microprocessor knee has been shown again and again that it prevents trip-and-fall accidents and can benefit patients, patients' lives and the outcomes." (Carver (College Park) Tr. 2059-60).

359. A microprocessor acts as the "brain" of the knee that "can unleash the potential of that technology" by adjusting the knee to match a user's motions and adapting to the user's environment. In contrast, mechanical knee users instead must rely on a prosthetist to manually "set th[e] knee to a setting" and cannot adjust this setting without a prosthetist. (Carver (College Park) Tr. 2023-24, 2054).

360. According to Ryan Arbogast, CEO of WillowWood, "[m]icroprocessor knees provide additional features and benefits and function that mechanical knees could not." (PX05106 (Arbogast (WillowWood) Dep. at 19)). Mr. Abrogast elaborated that "[m]icroprocessor knees, in general, use sensors to assess what's happening with the knee and make changes in the function of the knee as a result." He further explained that this "could be a benefit when an amputee is changing their mode of activity or has a potential for instability or for a fall." With respect to instability and falling, "[m]echanical knees have certain design characteristics to prevent amputees from falling. Those are called lock or stance phases. Microprocessor knees improve upon that or aim to improve upon that function by using sensors to better understand what's happening with the knee." (PX05106 (Arbogast (WillowWood) Dep. at 19-20)).

361. Glenn Choi, president of mechanical knee manufacturer ST&G, believes that the benefits of having an MPK are that it "[p]rovides stability, safety, and better resistance and adjustments for the patient during gait cycle." (PX05117 (Choi (ST&G) Dep. at 43)). The benefit of an MPK to the amputee is that "[a]s the patient's activity changes or movement changes within the gait cycle, the input of the load forces being applied is not always the same, nor is it predictable, so the microprocessor compensates for the unpredictability in the load that's being applied to the knee in both stance and swing phase" which creates greater safety and stability. (PX05117 (Choi (ST&G) Dep. at 44-45)).

**iv. Recognition by surgeons, prosthetists, and prosthetic clinics of the benefits of MPKs over mechanical knees**

362. Lieutenant Colonel (P) Benjamin Potter, M.D., a surgeon at Walter Reed National Military Medical Center, believes that it is usually in a patient's best interest to receive a microprocessor knee. "I would say at this point it's medical fact that they can provide improved function." (Potter (Walter Reed) Tr. 775). Dr. Potter elaborated that "a well-functioning, well-aligned microprocessor knee attached to a well-designed comfortable socket can provide function that's superior to a mechanical knee or certainly no knee in a peg leg in terms of the patient's ability to walk symmetrically, their balance, their risk for falls, their energy expenditure when walking – you name it – better – better function in activities of daily living like walking, standing and sitting." (Potter (Walter Reed) Tr. 775-76). A more symmetrical gait can, in turn, lead to faster walking as well as a lower "risk for things like low back pain and osteoarthritis in joints above or on the other side of their amputation and for years in the future." (Potter (Walter Reed) Tr. 777). Dr. Potter believes that MPKs provide greater balance than mechanical knees because they are "designed ideally not to buckle or give out on you when they're not supposed to be bending." (Potter (Walter Reed) Tr. 778-79).

363. The Department of Defense and the Department of Veterans Affairs collaborated on a set of Clinical Practice Guidelines for Rehabilitation of Individuals with Lower-Limb Amputation. (PX08005 (VA) at 001). These guidelines "suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction." (PX08005 (VA) at 007). Dr. Michael Highsmith, a contributor to the Clinical Practice Guidelines explained that this is the current recommendation from the Department of Defense and the Department of Veterans Affairs and was based on the best available evidence at the time it was drafted and the consensus of the people that contributed to the recommendation. (PX05164 (Highsmith (VA) Dep. at 28-29) (discussing PX08005)).

364. Dr. Robert Gailey, the director of the Functional Outcomes and Research Evaluation Center at the University of Miami, believes that MPKs "across the board are smoother, they are more responsive to various terrains, going up and down ramps, being able to use stairs and that type of thing." (PX05142 (Gailey (University of Miami) Dep. at 33-36)). "[W]ith prosthetists at both Walter Reed and Center for the Intrepid, [it is] pretty much a standard that a microprocessor knee is given to most veterans coming back and then they

will also, if they choose, have a mechanical knee in case there is failure with the microprocessor knee." (PX05142 (Gailey (University of Miami) Dep. at 86-87)).

365. Clinic customers believe that MPKs provide more safety and stability than mechanical knees, leading to fewer stumbles and falls. As explained by Tracy Ell, owner and chief prosthetist of Mid-Missouri Orthotics and Prosthetics, the inherent stability of microprocessor knees is "far superior" to mechanical knees, and the benefits of MPKs include reducing falls, allowing more variation in walking speed, improving gait patterns and efficiency, and decreasing the wear and tear on a patient's body. (Ell (Mid-Missouri O&P) Tr. 1698-1703). Keith Senn, president of Kentucky and Indiana operations at the Center for Orthotic and Prosthetic Care believes that a "big benefit" of MPKs is "stumble recovery, so there's less falls. They feel more stable." (Senn (COPC) Tr. 174-75). According to Michael Oros, president and CEO of Scheck & Siress Prosthetics, MPKs provide greater safety to amputees because they are more responsive to sudden movements than mechanical knees because of the microprocessor in the knee. (Oros (Scheck & Siress) Tr. 4860-61; *see also* PX05134 (Oros (Scheck & Siress) Dep. at 71-72, 76-77) ("So the microprocessor knee is going to provide the highest level stability of any prosthetic knee."); *see also* Ford (POA) Tr. 996-1000 ("There's no question that [MPKs] reduce the amount of falls that amputees can experience. Their ability to recover from stumbles, toes, hitting your toes, those kind of things, are all benefits that prevent the patient from falling."); PX05132 (Sabolich (SSPR) Dep. at 41-42) (explaining why MPKs are typically a safer choice than a mechanical knee)).

366. Clinic customers believe that MPKs allow patients to more easily traverse everyday environmental barriers, such as curbs, steps, and slopes, as well as walk in crowded areas. Mark Ford, president and managing partner of Prosthetic and Orthotic Associates, finds that an MPK "can accommodate variable cadence, it can accommodate different types of terrain, it can accommodate ramps, steps, much more [quickly] and more responsively than a mechanical knee." (Ford (POA) Tr. 1002). Michael Bright, owner of North Bay Prosthetics and Orthotics, believes that patients who want to maneuver in crowds are "definitely" more likely to benefit from MPKs relative to mechanical knees. (PX05141 (Bright (North Bay) Dep. at 10-11, 149-50); *see also* PX05134 (Oros (Scheck & Siress) Dep. at 75-76)).

367. Clinic customers believe that MPK users demonstrate a much better gait, and are better able to walk with variable cadence, compared with users of mechanical knees. According to Keith Senn of COPC, MPK users "[are] able to have a much better gait, which means to walk better, as well as amputees go, to be able to improve their gait." (Senn (COPC) Tr. 174-75). Michael Oros of Scheck & Siress Prosthetics has found that MPKs respond to variable cadence much faster than mechanical knees, make adjustments more rapidly than mechanical knees, provide a higher level of stability than mechanical knees, and provide benefits walking down slopes relative to mechanical knees. (Oros (Scheck & Siress) Tr. 4858-59; *see also* Ford (POA) Tr. 1002). Jason Kahle of Prosthetic Design and Research describes the "benefit of a microprocessor [as that] it thinks instantaneously," which is attributed to the microprocessor itself. (PX05119 (Kahle (Prosthetic Design & Research) Dep. at 33-35)). The ability to think instantaneously

allows an MPK to respond to a patient's movements. (PX05119 (Kahle (Prosthetic Design & Research) Dep. at 35-36)). Alternatively, a mechanical knee "has to go through a cycle for the knee to figure out what to do" and cannot respond "until it goes through that cycle." (PX05119 (Kahle (Prosthetic Design & Research) Dep. at 33-34)).

368. For patients whose insurance claims are approved, and for whom there are not patient-specific reasons not to select an MPK (*see* F. 218-231), clinics select MPKs as superior to mechanical knees. As explained by Vinit Asar, president of Hanger, "A patient that qualifies for a microprocessor knee based on" the PAVET score and the K-Level "of course, would get a microprocessor knee." Mr. Asar does not think that, under those circumstances, any clinician would say "that a mechanical knee would benefit [the] patient more than a microprocessor knee." He thinks that such a patient "would be shortchanged." (PX05153B (Asar (Hanger) Dep. at 54-55)). Michael Bright, owner of North Bay and a certified prosthetist, would not fit a patient with a mechanical knee instead of an MPK if he determined that the MPK would best serve the patient and the patients' insurance covered the cost, "[b]ecause they will fall and they will hurt themselves, and I don't like it when my patients fall and hurt themselves." (PX05141 (Bright (North Bay) Dep. at 160-61)). As William Carver of College Park explained, if an MPK will be reimbursed by insurance and the patient's care providers believe that the person can benefit from the MPK, the patient is "going to get one, and there's no possible way they would consider that manual knee against that microprocessor knee in that instance." (PX05107 (Carver (College Park) Dep. at 46)). Mr. Senn of COPC explained that it is "rare" for any of COPC's K-3 or K-4 patients to be fit with a mechanical knee instead of a microprocessor knee because the "MPK is the best available knee that's available to those patients, so we want to provide, you know, what those patients deserve and what works best." (Senn (COPC) Tr. 180-81).

### v. Clinical research

369. Peer-reviewed research articles have found increased safety and performance of MPKs over mechanical knees. (Kaufman (Mayo) Tr. 820-21, 826; Blatchford (Endolite) Tr. 2118-20).

370. Authors of clinical research frequently present their findings to prosthetists and clinic owners. (PX05119 (Kahle (Prosthetics Design & Research) Dep. at 53-55) (discussing PX08018); Kaufman (Mayo) Tr. 828).

371. Some prosthetists and clinic owners are aware of clinical research studies demonstrating that a microprocessor knee is effective and prevents falls better than other lower-limb prosthetic devices. (Asar (Hanger) Tr. 1339; PX05108 (Yates (Jonesboro P&O) Dep. at 49-50)).

### (a) Dr. Kaufman's Fast K2 Study

372. [redacted] (Kaufman (Mayo) Tr. 829-30, 841, *in camera*).

373. [redacted] (Kaufman (Mayo Clinic) Tr. 844, *in camera*).

374. [redacted] (PX03219 (Mayo Clinic) at 015, *in camera*; *see also* Kaufman (Mayo Clinic) Tr. 846-51 (discussing PX03219), *in camera*).

375. [redacted] (PX03219 (Mayo Clinic) at 005, *in camera*).

376. [redacted] (Kaufman (Mayo) Tr. 846, *in camera*).

377. [redacted]

[redacted] (PX03219 (Mayo) at 002, *in camera*).

378. [redacted] (Kaufman (Mayo) Tr. 850, *in camera*).

379. [redacted] (Kaufman (Mayo) Tr. 848-49, *in camera*).

380. [redacted] (PX03219 (Mayo) at 013, *in camera*).

**(b) RAND Report**

381. A 2017 report by the RAND Corporation titled, *Economic Value of Advanced Transfemoral Prosthetics*, reviewed existing literature and utilized a simulation model "to assess the differential clinical outcomes and costs of microprocessor-controlled knees compared with non-microprocessor-controlled knees ['NMPKs']." (PX08004 (Liu et al., Economic Value of Advanced Transfemoral Prosthetics, RAND Corporation (2017)) ("RAND Report") at 003).

382. The RAND Report was initiated and funded by AOPA. (Kannenberg (Ottobock) Tr. 1861).

383. Among those acknowledged for contributing to the RAND report were Dr. Kannenberg, executive medical director of Ottobock, Dr. Kenton Kaufman of the Mayo Clinic, Stephen Blatchford of Chas A. Blatchford and Sons, Ltd./Endolite, Kim De Roy of Össur, and Maynard Carkhuff, chairman of Freedom. (PX08004 (RAND Report) at 008).

384. None of the references cited in the RAND Report examines outcomes specifically related to the Freedom Plié. (Kaufman (Mayo) Tr. 878). Ninety-five percent of all the clinical research examined in the RAND Report related to Ottobock's microprocessor knees. (Kannenberg (Ottobock) Tr. 1862-63).

385. The RAND Report concluded that "[o]verall, we found that compared with NMPKs, MPKs are associated with meaningful improvement in physical function and reductions in incidences of falls and osteoarthritis." (PX08004 (RAND Report) at 020). Dr. Kaufman explained, "This is the projection based on the simulation that over time you'll have improved safety by reduction in falls, and because of the improvement of gait, you'll have less arthritis, when using a microprocessor knee compared to a non-microprocessor knee." (Kaufman (Mayo) Tr. 867 (discussing PX08004 at 020)).

386. In a section titled, "Clinical Benefits: Physical Function," the RAND Report states that "[o]verall, there is strong evidence suggesting that compared with NMPKs, MPKs are associated with improvements in walking speed, gait symmetry, and the ability to negotiate obstacles in the environment . . . ." (PX08004 (RAND Report) at 020). Dr. Kaufman explained that "these are some of the biomechanical factors that show improvement when using a microprocessor knee compared to a non-microprocessor knee." (Kaufman (Mayo) Tr. 867-68 (discussing PX08004 at 020)).

387. Elsewhere in the RAND Report, the authors conclude, "In summary, the existing published literature shows that among transfemoral amputees, MPKs are superior to NMPKs in improving parameters of physical function, such as walking speed, gait symmetry, and obstacle assessments. Those improvements lead to fewer falls and lower incidences of osteoarthritis in the intact limb." (PX08004 (RAND Report) at 033; Kaufman (Mayo) Tr. 868 ("These are some of the short-term and long-term benefits of using a microprocessor knee compared to a non-microprocessor knee.")).

388. Maynard Carkhuff, Freedom's chairman, found the RAND Report's findings valuable. For Mr. Carkhuff, the key findings of the RAND Report were that MPKs reduce stumbles and falls and provide greater stability for patients than mechanical knees. Mr. Carkhuff agreed that the findings from the RAND Report are consistent with his experience in the industry. (Carkhuff (Freedom) Tr. 364).

389. Scott Schneider, Ottobock's vice president of government, medical affairs, and future development, presented the results of the RAND Report to multiple members of Congress or their staffs in November 2017. (Schneider (Ottobock) Tr. 4739-40, 4742-44). Mr. Schneider provided a document containing talking points regarding the RAND Report's conclusions to the legislators to highlight that the funds provided by Congress

for prosthetics are helping beneficiaries, cost efficient, and effective. (Schneider (Ottobock) Tr. 4739-40, 4742-44 (discussing PX01380); PX01380 (Ottobock) at 004; PX05139 (Schneider (Ottobock) Dep. at 61-65)). This Ottobock document noted, in its discussion of the RAND Report, that "82% of patients receiving non-MPK limbs will fall compared to only 26% of MPK users." (PX01380 (Ottobock) at 004).

**(c) Other MPK studies**

390. Clinical research based on the Ottobock C-Leg has found that microprocessor knee users improve their gait mechanics and stability as compared to mechanical knee users. (PX08010 at 001 (Kaufman et al., *Gait and Balance of Transfemoral Amputees Using Passive Mechanical and Microprocessor-controlled Prosthetic Knees*, 26 Gait & Posture 489 (2007)) ("Transfemoral amputees using a microprocessor-controlled knee have significant improvements in gait and balance.")). "The overall findings are that [amputees] have improved function, both their gait and their balance, when using a microprocessor knee" rather than a mechanical knee. (Kaufman (Mayo) Tr. 858 (discussing PX08010)).

391. Clinical research based on the Ottobock C-Leg has found that microprocessor knee users have increased ability to walk on difficult terrain as compared with mechanical knee users. (PX08059 at 001 (Hafner and Smith, *Differences in Function and Safety Between Medicare Functional Classification Level-2 and -3 Transfemoral Amputees and Influence of Prosthetic Knee Joint Control*, 46 J. of Rehab. R&D 417) (2009) ("Hafner and Smith")) ("Active knee control [i.e., MPK] was associated with significant improvements ($p < 0.05$) in hill and stair gait, speed (hills, obstacle course, and attentional demand task), and ability to multitask while walking for both cohorts.")).

392. Clinical research based on the Ottobock C-Leg has found that microprocessor knee users experience fewer falls as compared with mechanical knee users. (PX08059 (Hafner and Smith) at 001 ("Results suggest that active knee control [i.e., MPKs] improves function and reduces the frequency of adverse events in a population that is at risk for falls. Use of active knee control may allow persons with amputation to expand their functional domain, transition to a higher MFCL, and access additional prosthetic options.")). Medicare Functional Classification Levels (MFCLs) are effectively equivalent to K-Levels. (PX05150 (Kannenberg (Ottobock) Dep. at 36-37)).

393. Clinical research based on the Ottobock C-Leg has found that microprocessor knee users engage in more physical activity than mechanical knee users and experience overall improvement in quality of life. (PX08011 at 001 (Kaufman et al., *Energy Expenditure and Activity of Transfemoral Amputees Using Mechanical and Microprocessor-Controlled Prosthetic Knees*, 89 Arch Phys Med Rehab. 1380 (July 2008)) ("People ambulating with a microprocessor-controlled knee significantly increased their physical activity during daily life, outside the laboratory setting, and expressed an increased quality of life.")). Dr. Kaufman, the principal investigator for the study, explained that, "[w]hat we showed is that people spontaneously became more active, that is, they burned more energy, when using a microprocessor knee versus the mechanical knee." He noted

that MPK users "burn more energy, which means that they're more active in their free living environment." (Kaufman (Mayo) Tr. 860-61 (discussing PX08011)).

**b. Price differences between MPKs and mechanical knees**

**i. Prices**

394. Prosthetic clinics pay significantly more for microprocessor knees than for mechanical knees. (Blatchford (Endolite) Tr. 2123-24; De Roy (Össur) Tr. 3554-56; PX05109 (Carkhuff (Freedom) Dep. at 112); Schneider (Ottobock) Tr. 4355-56; Senn (COPC) Tr. 197-98); PX05141 (Bright (North Bay) Dep. at 74); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 57-58); PX05108 (Yates (Jonesboro P&O) Dep. at 55, 119-20); Ford (POA) Tr. 945; Asar (Hanger) Tr. 1374; PX05001 (Endrikat (Empire Medical) Dep. at 17-18)).

395. A microprocessor knee costs, on average, anywhere from four to eleven times more than a mechanical knee. (Blatchford (Endolite) Tr. 2123-24; De Roy (Össur) Tr. 3554-56; PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 57-58), *in camera* (the average price for a microprocessor knee is [redacted] and the average [price] for a mechanical knee is [redacted] Ford (POA) Tr. 945 (manufacturers charge "five to eight times" more for MPKs than mechanical knees); Senn (COPC) Tr. 197-98, *in camera* (COPC pays between [redacted] and [redacted] for an MPK and between [redacted] and [redacted] for a mechanical knee); PX05141 (Bright (North Bay) Dep. at 74), *in camera* (average price for an MPK is around [redacted] while mechanical knees range from [redacted] PX05108 (Yates (Jonesboro P&O) Dep. at 55, 119-20), *in camera* (Jonesboro P&O pays between [redacted] and [redacted] for MPKs, which is "significantly higher" than the prices paid for mechanical knees), *in camera*; Asar (Hanger) Tr. 1374, *in camera* (Hanger pays between [redacted] and approximately [redacted] for MPKs and between [redacted] and [redacted] for mechanical knees); PX05001 (Endrikat (Empire Medical) Dep. at 17-18), *in camera* (Empire pays [redacted] on average for MPKs and between [redacted] and [redacted] for mechanical knees)).

396. The list price for the mechanical knees sold by Cascade, a prosthetics distributor, ranges from [redacted] to [redacted] These prices are "[s]ignificantly lower" than the only MPK that Cascade distributes (the Allux). (Collins (Cascade) Tr. 3290, *in camera*).

397. In Fillauer's experience, "a mechanical knee could be anywhere under [redacted] . . . whereas, a microprocessor knee might be close to [redacted] or more. So it's a pretty significant price difference." (PX05105 (Fillauer (Fillauer) Dep. at 97-98), *in camera*).

398. Complaint Counsel's expert witness, Dr. Fiona Scott Morton, estimated that the average sales price of an MPK in 2017 was [redacted] and ranged from [redacted] to [redacted] (PX06001 (Scott Morton Expert Report at 043-44 ¶ 50 & Table 3), *in camera*). Dr. Scott Morton estimated that the average sales price of a mechanical knee from manufacturers that sell both MPKs and mechanical knees was approximately

[redacted] and ranged from [redacted] to [redacted] (PX06001 (Scott Morton Expert Report at 044-46 ¶ 51 & Table 4), *in camera*).

399. Respondent's economic expert witness, Dr. David Argue, agreed that manufacturers charge higher prices for MPKs than non-MPKs. (PX05173 (Argue) Dep. at 134).

**ii. Clinic reimbursements**

400. Clinics submit requests for reimbursement to payers for the fitting of a prosthesis on a patient. PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 37-40).

401. Payers reimburse clinics more money for microprocessor knees than mechanical knees. (PX05109 (Carkhuff (Freedom) Dep. at 112); Kaufman (Mayo) Tr. 834; Senn (COPC) Tr. 250; Ford (POA) Tr. 980 (POA is reimbursed "[f]our to five times" higher for fitting an MPK over a mechanical knee); Asar (Hanger) Tr. 1360 (Hanger clinics are reimbursed "significantly less" for a mechanical knee than they are for a microprocessor knee)).

402. United Healthcare reimburses, on average, typically thousands of dollars more for an MPK than a mechanical knee, to account for the additional technology and the programming required to fit an MPK. (Sanders (United) Tr. 5492-93).

403. Prosthetic manufacturers agree that the reimbursement by both private payers and Medicare is substantially greater for MPKs than it is for mechanical knees. (PX05117 (Choi (ST&G) Dep. at 51-52); Blatchford (Endolite) Tr. 2127 ("[R]eimbursement rates for just the MPK part of it are several times higher than the reimbursement rates for the non-MPK part of a prosthesis which didn't have a microprocessor knee.")).

404. Dr. David Argue, Respondent's economic expert witness, concluded in his expert report that prosthetic clinics receive larger reimbursement amounts for MPKs than non-MPKs. (Argue, Tr. 6270; PX05173 (Argue Dep. at 134); *see also* RX1049 (Argue Expert Report at 0013 ¶¶ 18-19) (estimating that the Medicare reimbursement rate for MPKs ranged from approximately $26,000 to $35,000, while the Medicare reimbursement amount for non-MPKs ranged from approximately $5,000 to $8,000)).

**c. MPK prices not sensitive to mechanical knee prices**

405. In setting the price of its C-Leg 4, Ottobock looked at the prices and reimbursement rates of only three other products, all of which are MPKs – Freedom's Plié 3, Össur's Rheo 3, and Endolite's Orion. (PX01524 (Ottobock) at 004, 007).

406. Freedom does not look at the pricing of mechanical knees when setting the price of the Plié 3. Freedom is "trying to take share from all other microprocessor knees." Freedom therefore looks "at pricing of the Plié 3 versus those [microprocessor] knees." (Testerman (Freedom) Tr. 1144).

407. Össur does not look at the price of mechanical knees when setting the price of its MPKs. (PX05124 (De Roy (Össur) Dep. at 184-85)).

408. Endolite does not consider the price of mechanical knees when setting the price of the Orion 3 because "the pricing of non-MPKs does not affect the pricing of MPKs." Endolite prices its Orion 3 against the C-Leg, the Rheo, and the Plié in particular. (Blatchford (Endolite) Tr. 2155).

409. In the experience of Keith Senn, president of the Kentucky and Indiana operations at the Center for Orthotic & Prosthetic Care, prices of MPKs do not respond to changes in the prices of mechanical knees, and prices of mechanical knees do not respond to changes in the prices of MPKs. (PX05128 (Senn (COPC) Dep. at 150-51); PX05004 (Senn (COPC) IHT at 20)).

410. In the experience of Jonathan Endrikat of Empire Medical, prices of mechanical knees do not respond to changes in the prices charged for microprocessor knees. (PX05001 (Endrikat (Empire Medical) IHT at 18)). Mr. Endrikat uses "ballpark" pricing to play the microprocessor knee manufacturers off of each other during price negotiations and uses only MPK competitor pricing to negotiate extra discounts for MPKs. (PX05116 (Endrikat (Empire) Dep. at 58-59)). Mr. Endrikat explained that he is unable to use pricing of mechanical knees when negotiating with manufacturers for the price of MPKs because "[i]t's a different product category." (PX05116 (Endrikat (Empire Medical) Dep. at 58-59)).

**d. Industry recognition of MPKs as a distinct economic market from mechanical knees**

**i. Ottobock's recognition of MPKs as a separate market**

411. On January 30, 2015, Ottobock estimated its own share (78%) and Freedom's Plié's share (11%) in the United States MPK market. (PX01382 (Ottobock) at 002). The only other products included in Ottobock's estimated market size and share in the MPK market were Össur's Rheo (10% share) and Endolite's Orion (1% share). (PX01382 (Ottobock) at 002).

412. On February 20, 2015, when preparing for the launch of the C-Leg 4, Scott Schneider, Ottobock's vice president of government, medical affairs and future development, sent estimates of shares and positioning in an "MPK market" to his launch team. The analysis did not mention any mechanical knees. (PX01518 (Ottobock) at 001-02, 009).

413. In April 2015, a team of Ottobock sales, marketing, and reimbursement employees recommended initial pricing for the C-Leg 4 "based on competitive analysis and coding strategy." The analysis considered the pricing of the Rheo 3, the Plié 3, and the Endolite Orion. (PX01524 (Ottobock) at 001, 004, 007; PX05162 (Ruhl (Ottobock) Dep. at 109-10)).

414. In a November 18, 2015 presentation, Cali Solorio, Ottobock's senior prosthetics marketing manager, estimated market size and shares of an MPK market that did not include mechanical knees. (PX01002 (Ottobock) at 006 (MPK Portfolio Alignment)). In the presentation, Ms. Solorio estimated Ottobock had an 81% share of the MPK market, Freedom's Plié had a 10% share, Össur's Rheo had an 8% share, and Endolite's Orion had a 1% share. (PX01002 (Ottobock) at 005).

415. In conducting due diligence in connection with the acquisition of Freedom, Ottobock estimated market shares on August 29, 2017. (PX1473 (Ottobock) at 002, 010 (Roosevelt Due Diligence Summary, Integration, Business Plan and Valuation), *in camera*). Ottobock estimated that in 2016 based on United States sales, its C-Leg had a [redacted] market share and Freedom's Plié had a [redacted] market share in a category designated as "Mechatronic knees." (PX1473 (Ottobock) at 010 (Roosevelt Due Diligence Summary, Integration, Business Plan and Valuation), *in camera*). Ottobock also estimated that, in 2016, based on units sold in the United States, its C-Leg had a [redacted] market share and Freedom's Plié had a [redacted] market share of "Mechatronic knees." (PX1473 (Ottobock) at 010 (Roosevelt Due Diligence Summary, Integration, Business Plan and Valuation), *in camera*). Matt Swiggum, Ottobock's CEO at the time of the Acquisition, explained that "mechatronic knees" means MPKs and that this chart only included microprocessor knees. (PX05148 (Swiggum (Ottobock) Dep. at 110, 120-23)).

416. In its 2018 North America Marketing & Sales Plan, Ottobock included a share analysis within the MPK market. (PX00867 (Ottobock) at 002, 021). At trial, Ms. Solorio, Ottobock's senior prosthetics marketing manager, confirmed that this share analysis depicted the "microprocessor knee market." (Solorio (Ottobock) Tr. 1602-06, *in camera*). In an Ottobock document titled, "Share Analysis: MPK," Ottobock estimated it had a [redacted] market share, Freedom had a [redacted] market share, Össur had a [redacted] market share, and Endolite had a [redacted] market share. No mechanical knees were included in the analysis. (PX00867 (Ottobock) at 021, *in camera*).

417. Ottobock tracks sales of its MPKs separately from sales of its mechanical knees. (PX00829 (Ottobock) at 002 (tracking sales separately for MPKs, mechanical knees, and microprocessor feet); PX01326 (Ottobock) at 003 (breaking out MPK sales); PX01597 (Ottobock) (total billings divided between mechanical and MPK sales in both revenue and units); PX01598 (Ottobock) (compilation of reimbursement coverage divided by MPKs and mechanical); PX01718 (Ottobock) at 004 (sales growth divided by MPK and mechanical); PX01730 (Ottobock) at 003 (performance to budget broken out by MPK and mechanical)).

418. As Ottobock was preparing for the international launch of the C-Leg 4, a "C-Leg 4 Global Launch Plan" was circulated in August 2015. (PX01057 (Ottobock) at 001, 012 (email forwarding C-Leg 4 Global Launch Plan)). The "Competitor Analysis" contained within the Global Launch Plan identified only other MPKs. (PX01057 (Ottobock) at 057 (email forwarding C-Leg 4 Global Launch Plan)). A list of competitors to the C-Leg and

a description of how to position the C-Leg against them includes only the Plié 3 and the Rheo 3. (PX01057 (Ottobock) at 054 (email forwarding C-Leg 4 Global Launch Plan)).

419. A draft document, referred to within Ottobock as a "battle card," was circulated within Ottobock in February 2015 to prepare for the launch of the C-Leg 4. (PX01518 (Ottobock) at 001-03 (C-Leg 4 Core Launch Team invitation)). On it, Ottobock compares the C-Leg 4 to three other MPKs, the Plié 3, Rheo 3, and Orion 2. (PX01518 (Ottobock) at 003 (C-Leg 4 Core Launch Team invitation)). Battle cards are used within Ottobock "to show competitive natures and product features for sales representatives" and only those competitors were included because they are the "primary competitors" for the C-Leg 4 in the United States. (Schneider (Ottobock) Tr. 4432-33).

420. In Ottobock's 2018 Prosthetics Roadmap to Success North America Marketing & Sales Plan, the "Competitive Landscape" included only MPKs from Freedom, Össur, and Endolite. (PX00867 (Ottobock) at 002, 022).

421. Ottobock's analyses of competition for its C-Leg analyzed only other MPKs and did not mention mechanical knees. (*See* PX01002 (Ottobock) at 001, 006 (2016 Marketing Plan Lower Limb Mechatronics); Solorio (Ottobock) Tr. 1593-95; PX00872 (Ottobock) at 002, 010 (2016 Market Management Overview Prosthetics); PX01010 (Ottobock) at 014 (chart depicting "Market Overview – Portfolio/Competitive Positioning" includes nine MPKs from four companies, but no mechanical knees); PX01463 (Ottobock) at 002, 023 (2018 Marketing Plans and Calendar); PX01716 (Ottobock) at 003 (comparison of MPKs and mechanical knees in separate sections); PX01871 (Ottobock) at 013-18, 023 ("Competitive Landscape" for C-Leg 4 launch includes only Plié 3, Orion 2, and Rheo 3); PX01874 (Ottobock) at 005 (identifying Plié, Rheo 3, and Orion as similar products to C-Leg 4); PX01875 (Ottobock) at 002 (identifying Plié 3, Rheo 3, and Orion 2 as competitors to C-Leg); PX01752 (Ottobock) at 005 (presentation on mechanical knee sales separates out MPK sales as not mechanical opportunities)).

**ii. Freedom's recognition of MPKs as a separate market**

422. An internal Freedom document included data on a "mechanical knee market," including a market size estimate, a list of differences between microprocessor and mechanical knees, and a look at the competitive landscape a new mechanical knee would face. (PX01164 (Freedom) at 001, 005 (noting that "Freedom currently has no presence in Global $108M Mechanical Knee market"), 016, 024-28 (Mechanical Knee Market Data)).

423. A May 16, 2017 internal Freedom presentation addressing the "Competitive Landscape" showed market shares in a market consisting only of MPKs, including Freedom's Plié ([redacted] share), Ottobock's C-Leg 4 ([redacted] share), Össur's Rheo 3 and XC ([redacted] share), and Endolite's Orion 3 ([redacted] share). (PX01155 (Freedom) at 091, *in camera*).

424. When positioning the Plié against its competition, Freedom primarily targeted "the segment for the Plié's competition, which is other microprocessors." (PX05112

(Ammouri (Freedom) Dep. at 118); *see also* PX01172 (Freedom) at 003-04 (Plié versus Competitors Positioning)).

425. As part of the Plié 3 Selling Guide, Freedom created what it referred to as a "Benefits Matrix," which compares the functionality, adaptability, safety, versatility, and other characteristics of the Plié to the MPKs of its competitors. (PX05112 (Ammouri (Freedom) Dep. at 147-48); PX01182 (Freedom) at 026 ("Benefits Matrix")). The Benefits Matrix lists only microprocessor knees. (PX05112 (Ammouri (Freedom) Dep. at 148-49)).

426. Freedom's analyses of competition evaluated only other MPKs and omitted any comparison to mechanical knees. (*See* Testerman (Freedom) Tr. 1204-05; PX05111 (Prince (Freedom) Dep. at 110-11) ("We were designing a microprocessor knee. We want to compare against other microprocessor knees."); PX01032 (Freedom) at 025 ("Direct Competitors" are only C-Leg 4, Rheo 3 and Orion 2); PX01172 (Freedom) at 004 ("Spec sheet comparing MPC knees"); PX01419 (Freedom) at 006 (comparison of features of MPC knees); PX01847 (Freedom) at 002 (Plié 3 selling guide notes that "Target Customer[s]" are "Clinics known to utilize primary competitors - Otto Bock C-Leg, Genium, and X3, Rheo 3, Endolite Orion")).

### iii. Views of other MPK manufacturers

427. From the perspective of Össur's executive vice president of research and development, Kim Peter Vivianne De Roy, MPKs and mechanical knees "don't really compete for the same population." Mr. De Roy described the patient population for an MPK as "people with access to certain funds," and believes that "[i]f they have access to a microprocessor knee, they'll buy a microprocessor knee." In his view, patients who do not have access to an MPK will buy a mechanical knee. (PX05124 (De Roy (Össur) Dep. at 184-85)).

428. Össur's "Competition Analysis Overview" for its MPK knees, the Rheo and the Power Knee, only included microprocessor knees made by Ottobock, Freedom, and Endolite. (PX03245 (Össur) at 010 (Gate 2 – Business Case Review)). The "Pricing Strategy" slide states, "Need to have a product competing with the mainstream MPK products at the current price level . . . ." (PX03245 (Össur) at 023 (Gate 2 – Business Case Review)).

429. Endolite's sales and marketing materials for the Orion 3 differentiate its MPK from its mechanical knees. Endolite highlights the clinical benefits of MPKs and the "technical features of the knee in terms of how it works, why it works, why it's safe." (Blatchford (Endolite) Tr. 2118).

430. Endolite "only look[s] at other MPKs" and not mechanical knees when analyzing competition for the Orion 3. This is because "the price point is completely different" and "customers don't tend to think of [the two types of knees] in the same way." (Blatchford (Endolite) Tr. 2143-44).

### iv. Views of mechanical knee suppliers

431. Össur, a manufacturer of both mechanical and microprocessor knees, does not consider the prices of MPKs when setting the price for its K-3 mechanical knees because Össur believes MPKs "play in a different segment." (De Roy (Össur) Tr. 3603).

432. College Park, a mechanical knee manufacturer, is currently developing an hydraulic mechanical knee for K-3 users. (Carver (College Park) Tr. 2022-23, 2058). William Carver, the president and COO of College Park, does not believe its hydraulic mechanical knee will compete for patients who qualify for reimbursement of an MPK. He elaborated that "if you were evaluating a microprocessor knee and felt that you could get payment for it, a prosthetist wouldn't order one of our hydraulic knees to compare in that category." (Carver (College Park) Tr. 2058).

433. To College Park, mechanical knees are "not in the same category [as MPKs]. They're not smart. Again, these need manual adjustments within the office." (PX05107 (Carver (College Park) Dep. at 87)).

434. College Park wrote in an internal "Domestic Sales Assessment" that its hydraulic mechanical knee in development "will be an attractive option to US practitioners for their [above-the-knee] amputees that receive Medicare benefits, have limited private insurance or otherwise do not qualify for a Micro Processor controlled knee (first choice)." (PX03025 (College Park) at 002; PX05107 (Carver (College Park) Dep. at 96-97)).

435. College Park is also developing a pneumatic mechanical knee for K-3 users. (Carver (College Park) Tr. 2022-23; PX03030 (College Park) at 003; *see also* PX05107 (Carver (College Park) Dep. at 87)). College Park is using [redacted] mechanical knees [redacted] as its competitive benchmark to beat on price, functionality or features. (PX05107 (Carver (College Park) Dep. at 105-06), *in camera*). College Park did not identify any microprocessor knee as a competitive target for its pneumatic mechanical knee in development because it does not "believe that they compete in the same market." (PX05107 (Carver (College Park) Dep. at 105-06), *in camera*).

436. Michael Fillauer, of Fillauer Companies, believes that Fillauer's mechanical knees do not compete with microprocessor knees. (PX05105 (Fillauer (Fillauer) Dep. at 24-25)). Instead, the company "always, from a marketing and sales standpoint, felt like we would compete with mechanical knees against other mechanical knees." (PX05105 (Fillauer (Fillauer) Dep. at 24-25)).

437. Jeffrey Collins, president of Cascade, a distributor of mechanical knees, believes that the microprocessor knee category is distinct from the mechanical knee category. (PX05120 (Collins (Cascade) Dep. at 50).

### v. L-Codes for MPKs and mechanical knees

438. In the United States, Medicare and private payers use the L-Code system (*see* section III.B.3.b above) to assign reimbursement amounts for microprocessor and non-microprocessor knees. (Sanders (United) Tr. 5489-90; PX05165 (Sanders (United) Dep. at 22-23); PX05141 (Bright (North Bay) Dep. at 62-63)).

439. L-Codes describe the function of specific prosthetic device components. (PX05133 (Eichler (Ottobock) Dep. at 54-56); PX05165 (Sanders (United) at 26-28)).

440. Some L-Codes apply only to MPKs (e.g., L-5856). Some L-Codes apply only to mechanical knees. Some L-Codes apply to features that may be found on either an MPK or mechanical knee. Based on the aggregated set of L-Codes that apply to MPKs and the aggregated set of L-Codes that apply to mechanical knees, reimbursement amounts from Medicare are significantly different for these two types of knees. (PX05150 (Kannenberg (Ottobock) Dep. at 76-77); PX05105 (Fillauer (Fillauer) Dep. at 24); PX05129 (Ell (Mid-Missouri O&P) Dep. at 64-65); PX05151 (Patton (Prosthetic Solutions) Dep. at 70-73); Senn (COPC) Tr. 250; De Roy (Össur) Tr. 3557-60; Sanders (United) Tr. 5491-93).

441. The L-Codes commonly used for an MPK are L5858, L5856, L5828, L5845, and L5848. (PX01062 (Ottobock) at 004; *see* Ell (Mid-Missouri O&P) Tr. 1802-03).

442. L5856 is the base L-Code for swing-and-stance microprocessor knees. L-Code 5856 covers: "lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase." (Carkhuff (Freedom) Tr. 714-15). In order to qualify for reimbursement under L-Code 5856, a knee must have "a microprocessor that controls both the swing and the stance." (PX05010 (Schneider (Ottobock) IHT at 91-92)).

443. The C-Leg, Plié, Rheo, and Orion are reimbursed as swing and stance MPKs, under L-Code 5856. F. 234, 259, 273, 287. Nabtesco recommends using L-Code 5856 for the Allux and DAW recommends using L-Code 5856 for one of its MPKs. F. 302, 308.

444. Mechanical knees do not qualify for reimbursement under L-Code 5856. (PX05129 (Ell (Mid-Missouri O&P) Dep. at 64-65); PX05150 (Kannenberg (Ottobock) Dep. at 76-77); PX05149 (Brandt (Ability P&O) Dep. at 54-55); PX05141 (Bright (North Bay) Dep. at 168-69); PX05116 (Endrikat (Empire) Dep. at 40); PX05117 (Choi (ST&G) Dep. at 47-48)).

445. A clinic cannot use an L-Code for a mechanical knee to seek reimbursement for an MPK. (Ell (Mid-Missouri O&P) Tr. 1730; *see also* PX05130 (Governor (Ottobock) Dep. at 93-94). As Mark Ford of POA explained, "it's against Medicare supplier standards because it doesn't adequately describe what was actually provided, so [the clinic would] be in trouble with CMS." (Ford (POA) Tr. 979-80).

### e. Switching based on price

446. Whether an MPK or a mechanical knee is selected for a patient is a "very patient-specific" determination. (De Roy (Össur) Tr. 3554; Kannenberg (Ottobock) Tr. 1984-85 ("[T]he decision of what prosthetic components are most appropriate for an individual patient is always a very individual one."); *see also* PX05166 (Watson (Fourroux) Dep. at 111) ("Each individual patient's needs are different, and that's the way they're treated, on an individual basis.")).

447. Prosthetists have an ethical and reputational obligation to fit a patient with a prosthetic knee that best meets the patient's medical needs. (PX05129 (Ell (Mid-Missouri O&P) Dep. at 141, 154-55) ("Q. So your ethical duties with regard to maximizing patient outcomes really drives your decision of which knee to fit on a prosthetic patient, correct? A. Yes, sir."); PX05119 (Kahle (Prosthetic Design & Research) Dep. at 66-67); Asar (Hanger) Tr. 1479) ("Q. And to act ethically and, in fact, that's [the clinicians'] ethical responsibility to recommend the knee that is best for the patient? A. Yes, sir."); PX05145 (Ford (POA) Dep. at 95-96 ("Q. Is maximizing patient outcomes the biggest factor in fitting an MPK at POA? A. Yes. Q. Do POA's clinicians have ethical guidelines that factor into their daily work? A. All of our clinicians are certified by ABC, and there are ethical guidelines that are part of that certification.").

448. From the perspective of prosthetists, the choice between fitting a patient with an MPK or a mechanical knee (if insurance coverage were available for both products) is a clinical decision and not based on the relative prices a clinic pays for MPKs and mechanical knees. (PX05105 (Fillauer (Fillauer) Dep. at 24) ("Q. When you were a clinician, did you decide whether to fit your patients in mechanical or microprocessor knees based on – was that a clinical decision, or a price decision? A. I would like to say that it was mostly a clinical decision. Obviously, funding is a factor. If you can't get the device paid for, you can't fit it. But the goal was always for it to be a clinical decision."); PX05166 (Watson (Fourroux) Dep. at 61) ("Q. If the price of these microprocessor knees increased fifteen hundred dollars, would Fourroux clinicians stop fitting patients with these microprocessor knees? A. When I listed all the reasons that a clinician might go through and – with a K-3 or K-4 ambulator to develop a plan of care, none of those factors are financial. Clinicians are clinical. They make clinical decisions based on clinical data. So based on the way [you have] asked that question, I would have to say that it's not relevant to the clinical evaluation and clinical recommendations of a clinician.").

449. Keith Senn, president of Kentucky and Indiana operations at the Center for Orthotic and Prosthetic Care, believes that it "would be a disservice to the patients and poor patient care" to threaten to shift COPC's MPK volume to mechanical knees because MPKs are "a much better knee, and if a patient is [an] eligible candidate for one, that is the knee they would prefer and deserve." (Senn (COPC) Tr. 198).

450. Ability Prosthetics and Orthotics would not move its patients to mechanical knees if the cost of all of the MPKs the clinic currently purchases were to increase by 5%. (PX05149

(Brandt (Ability P&O) Dep. at 68) ("Because clinically we make decisions at Ability about the patient, and so a 5 percent increase would not have me moving my patients to a non-MPK when they, in fact, needed the safety of an MPK.")).

451. The Center for Orthotic and Prosthetic Care would not begin recommending more non-microprocessor mechanical knees if the price charged by manufacturers for MPKs increased by 5 to 10%. (PX05004 (Senn (COPC) IHT at 21)).

452. Sprinkle Prosthetics typically would not switch a patient who would otherwise medically benefit from an MPK and whose insurance provided coverage for an MPK to a mechanical knee if the cost that Sprinkle Prosthetics pays for an MPK were to rise by 5 to 10%. (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 48-49) (explaining, because a microprocessor knee would be a better functional knee for a K-3/K-4 ambulator)).

453. As of March 2018, Jonesboro Prosthetic & Orthotic Laboratory was paying between [redacted] for the "base class" of MPKs that includes Freedom's Plié, Ottobock's C-Leg, Endolite's Orion, and Össur's Rheo. (PX05108 (Yates (Jonesboro P&O) Dep. at 54-56), *in camera*). According to Rob Yates, the president and CEO of Jonesboro P&O, if these manufacturers were to charge Jonesboro [redacted] more for each MPK, Jonesboro "generally" would not stop fitting patients with the MPKs. Mr. Yates elaborated, "There could be specific circumstances that that [redacted] would make the difference between that service being profitable or provided at a loss. But generally speaking, I would not think that a [redacted] change would dramatically shift our selection of components across the patient spectrum." (PX05108 (Yates (Jonesboro P&O) Dep. at 56), *in camera*).

### f. Hypothetical Monopolist Test

454. The U.S. Department of Justice & Federal Trade Commission Horizontal Merger Guidelines (2010) ("Merger Guidelines") provide a test, called the hypothetical monopolist test, for evaluating whether a product or group of products in a particular geographic area is a relevant market. The Merger Guidelines provide that "[t]he hypothetical monopolist test requires that a product market contain enough substitute products so that it could be subject to post-merger exercise of market power significantly exceeding that existing absent the merger. Specifically, the test requires that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products ('hypothetical monopolist') likely would impose at least a small but significant and non-transitory increase in price ('SSNIP') on at least one product in the market, including at least one product sold by one of the merging firms." (PX08040 (Merger Guidelines at 012 § 4.1.1)).

455. The Merger Guidelines provide that "[w]hen the necessary data are available, the Agencies also may consider a 'critical loss analysis.'" The Merger Guidelines describe this analysis as "ask[ing] whether imposing at least a SSNIP on one or more products in a candidate market would raise or lower the hypothetical monopolist's profits." The Merger Guidelines explain, "A price increase raises profits on sales made at the higher

price, but this will be offset to the extent customers substitute away from products in the candidate market." (PX08040 (Merger Guidelines at 015 § 4.1.3)).

456. In the "critical loss analysis," the Merger Guidelines define a "critical loss" as "the number of lost unit sales that would leave profits unchanged." A "predicted loss" is defined as "the number of unit sales that the hypothetical monopolist is predicted to lose due to the price increase." Using these calculations, "[t]he price increase raises the hypothetical monopolist's profits if the predicted loss is less than the critical loss." (PX08040 (Merger Guidelines at 015 § 4.1.3)).

457. Complaint Counsel's economic expert witness, Dr. Fiona Scott Morton, used a critical loss analysis to "test if it would be profitable for a hypothetical monopolist to impose a SSNIP on a candidate market limited to the microprocessor knees sold in the United States by Freedom and Otto Bock." (PX06001A (Scott Morton Expert Report at 075-76 ¶ 93)). If it is profitable for the two firms to raise prices, then that candidate market is a relevant antitrust market. (PX06001A (Scott Morton Expert Report at 075-76 ¶ 93)).

458. To perform a critical loss test, Dr. Scott Morton used as inputs estimates of margin (F. 460) and of diversion (F. 461) derived from Ottobock's and Freedom's ordinary course of business documents, including an August 2017 Ottobock due diligence summary prepared by the head of corporate strategy and mergers and acquisitions at Ottobock in connection with the purchase of Freedom. (Scott Morton Tr. 3882-84). *See* PX06001A (Scott Morton Expert Report at 077-78 ¶ 100 n.195); PX01473 (Ottobock) at 002, 023; (Swiggum (Ottobock) Tr. 3376-80).

459. Dr. Scott Morton explained that she relied upon the August 2017 Ottobock due diligence summary (F. 458) because "this is the kind of document that I would rely on in . . . doing research in my expert witness work because [it is a] . . . board-level document, and I would expect that the people providing the information to this document took some pains to make sure it was correct and accurate." (Scott Morton Tr. 3883-84).

460. Dr. Scott Morton testified that margins in the context of the critical loss analysis means gross margins – "the price less the marginal cost, which in the case of a prosthetic knee would be cost of goods sold only inputs." (Scott Morton Tr. 3876; 3893 (testifying, gross margins indicate how profitable a product is)). In her expert report, margin is "defined as (Price – Variable Cost) / Price." Using this formula, and documents indicating that in 2017, the Plié average sales price is equal to [redacted] and that in 2017, the Plié costs of goods sold are equal to [redacted] the Plié percentage margin is equal to [redacted] (PX06001A (Scott Morton Expert Report at 077-78 ¶ 100 n.193), *in camera*).

461. Dr. Scott Morton explained that diversion in the context of the critical loss analysis is the percentage of the departing customers that go to a particular place. In the example of diversion from Plié to C-Leg, if one were to raise the price of a Plié and 100 people leave, if 50 of those customers then buy a C-Leg, the diversion from Plié to C-Leg is 50%. (Scott Morton Tr. 3875-76).

462. Dr. Scott Morton performed two separate critical loss tests on the candidate market of MPKs sold in the United States by Freedom and Ottobock – an asymmetric critical loss test (F. 463) and a symmetric critical loss test (F. 467). (PX06001A (Scott Morton Expert Report at 076-80 ¶¶ 96-105)).

463. An asymmetric critical loss test "assumes that each firm in the market sells a single product, but allows the prices and margins of those products to differ" and "evaluates the profitability of increasing the price of only one product in the candidate market, rather than all products." (PX06001A (Scott Morton Expert Report at 076 ¶ 96)).

464. Dr. Scott Morton used a margin of [redacted][58] in her asymmetric critical loss analysis, using data from documents produced by Ottobock and Freedom calculating the margin on Freedom's Plié. (PX06001A (Scott Morton Expert Report at 077-78 ¶ 100 n.193), *in camera*; Scott Morton Tr. 3882-84, 3886-88, 3894, *in camera*).

465. Dr. Scott Morton used a diversion rate of [redacted] in her asymmetric critical loss analysis, using data projected by Ottobock of sales of the Plié that would be converted to the C-Leg, should the Plié be discontinued. (PX06001A (Scott Morton Expert Report at 077-78 ¶ 100 n.195), *in camera*; Scott Morton Tr. 3885, 3889, *in camera*; *see* PX01473 (Ottobock) at 023, *in camera*; Swiggum (Ottobock) Tr. 3376-80, *in camera*).

466. In her asymmetric critical loss test, Dr. Scott Morton calculated that for a 10% price increase, the critical loss threshold is 9% and determined that diversion between Freedom's Plié and Ottobock's MPKs must be less than 9% to a make a 10% SSNIP unprofitable, but because the diversion of [redacted] is greater than 9%, the 10% SSNIP would be profitable. She thus concluded that the asymmetric critical loss test confirms that the candidate market consisting of both Ottobock's C-Leg 4 and Freedom's Plié 3 is a relevant antitrust market. (PX06001A (Scott Morton Expert Report at 077-78 ¶ 100), *in camera*; Scott Morton Tr. 3893-96, *in camera*).

467. A symmetric critical loss test assumes "that each firm in the candidate market has a single product with the same price and marginal cost" and "that the hypothetical monopolist imposes a [small but significant price increase] on all products in the candidate market." (PX06001A (Scott Morton Expert Report at 079 ¶ 101)).

468. Dr. Scott Morton used a margin of [redacted] in her symmetric critical loss analysis, assuming that Ottobock's margin is equal to the Plié margin of [redacted] (F. 464). (PX06001A (Scott Morton Expert Report at 080, 082 ¶ 104 & Table 5), *in camera*).

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[58] Respondent's expert witness, Dr. David Argue, testified that he and Dr. Scott Morton used "very similar margins" in their critical loss analyses. (Argue, Tr. 6171). Dr. Argue used [redacted] margin for purposes of his critical loss analysis. (RX1049 (Argue Expert Report at 0021-23 ¶¶ 37-39), *in camera*; Argue, Tr. 6284-85, 6292, *in camera*).

469. Dr. Scott Morton assumed that there was symmetry in diversion and used an aggregate diversion rate of [redacted] in her symmetric critical loss analysis. (PX06001A (Scott Morton Expert Report at 80 ¶ 104), *in camera*).

470. In her symmetric critical loss test, Dr. Scott Morton calculated that for a 10% price increase, the critical loss threshold is 12%. She determined that diversion between Freedom's Plié and Ottobock's MPKs must be less than 12% in order to a make a 10% SSNIP unprofitable, but because the diversion of [redacted] is greater than 12%, the 10% SSNIP would be profitable. She thus concluded that the symmetrical critical loss test confirms that the candidate market consisting of both Ottobock's C-Leg 4 and Freedom's Plié 3 is a relevant antitrust market. (PX06001A (Scott Morton Expert Report at 080 ¶ 104), *in camera*).

471. After reaching the conclusions in F. 466 and F. 470, Dr. Scott Morton concluded that if the narrow candidate market of Ottobock's C-Leg 4 and Freedom's Plié 3 is a relevant antitrust market, then "a wider market consisting of all microprocessor knees sold in the United States is also a relevant antitrust market." (PX06001A (Scott Morton Expert Report at 075-76, 082 ¶¶ 93, 109); Scott Morton Tr. 3895-96 (concluding that if it is profitable for a hypothetical monopolist to impose a SSNIP in the narrow market, then it is profitable for a hypothetical monopolist to impose a SSNIP in the wider market of MPKs manufactured by Össur, Endolite, Nabtesco, and DAW as well)).

### D. Reasonable Likelihood of Anticompetitive Effects

#### 1. Market shares and concentration

472. Complaint Counsel's industry expert witness, Dr. Fiona Scott Morton, calculated market shares in both dollars and unit sales for 2015, 2016, and 2017 for the six providers of microprocessor knees in the United States – Ottobock, Freedom, Össur, Endolite, Nabtesco, and DAW – using sales data provided by these companies. (PX06001A (Scott Morton Expert Report at 083-85 ¶¶ 111-14); *see also* PX06001A (Scott Morton Expert Report at 084, Tables 6 & 7)).

473. Dr. Scott Morton annualized the sales data produced by the parties to reach her 2017 estimated sales figures. (PX06001A (Scott Morton Expert Report at 084, Table 6)).

474. Dr. Scott Morton concluded that it is more appropriate to calculate market shares by revenue because the products in the market are not homogenous – they have different features and price points. (PX06003 (Scott Morton Rebuttal Expert Report at 020-21 ¶ 38)).

475. Dr. Scott Morton explained that, with differentiated products, "we want to account for the value that the firm is delivering to the market." She continued, "If the products are a luxury car versus an inexpensive car or a very expensive knee versus a less expensive knee, we imagine that market forces create quality and that that quality is what's causing the product to be expensive and therefore the value . . . we want to account for the value

that the firm is delivering to the market. And the value the firm is delivering to the market is reflected in dollars, not in units, particularly if the products are differentiated." (Scott Morton, Tr. 4061-62).

476. Dr. Scott Morton explained that it is appropriate to calculate market share based on units sold if the products in the market are homogenous or nearly homogenous because "when you count units, you're implicitly valuing each product in a one-for-one way with all of the other products. So one unit from farmer A is the same as the one unit from farmer B." (Scott Morton, Tr. 4061-62).

477. The federal antitrust agencies measure concentration using the Herfindahl-Hirschman Index ("HHI"). (PX08040 at 021-22 (Merger Guidelines § 5.3)). The HHI is calculated by totaling the squares of the market shares of each firm in the relevant market. (PX08040 at 021-22 (Merger Guidelines § 5.3)).

478. Dr. Scott Morton provided market share and concentration estimates for a market of all MPKs sold in the United States ("all MPK market") that included all Ottobock MPKs, Freedom's Plié, Endolite's Orion, all Össur MPKs, all DAW MPKs, and all Nabtesco MPKs. She also provided market share and concentration estimates for a narrower market that excluded Ottobock's lower-end Kenevo and Compact knees (F. 243-246), Ottobock's higher-end Genium and X3 knees (F. 247-254), and Össur's higher-end XC and Power Knee (F. 277-281) ("narrower market"). (PX06001A (Scott Morton Expert Report at 084 and n.25, Tables 6 & 7, 180-81, Tables A1 & A2)).

479. Dr. Scott Morton's table calculating market shares and HHIs based on revenues in the United States in the "all MPK market" is reproduced below.

(PX06001A (Scott Morton Expert Report at 084, Table 6), *in camera*).

480. Dr. Scott Morton's table calculating market shares and HHIs based on units sold in the United States in the "all MPK market" is reproduced below.

(PX06001A (Scott Morton Expert Report at 084, Table 7), *in camera*).

481. The pre-Acquisition HHIs confirm that the market for all MPKs in the United States was already highly concentrated and that the change in HHIs post-Acquisition establishes a strong presumption that the Acquisition will likely enhance market power in the merged firm. (PX06001A (Scott Morton Expert Report at 085 ¶ 113)).

482. Dr. Scott Morton's "narrower market" includes only sales in the United States of Ottobock's C-Leg, Freedom's Plié, Össur's Rheo (not including sales of its Rheo XC or the Power Knee), Endolite's Orion, each of DAW's MPKs, and Nabtesco's Allux. (PX06001A (Scott Morton Expert Report at 083 n.205)).

483. Dr. Scott Morton's table calculating market shares and HHIs based on revenues in the United States in the narrower market is reproduced below.

(PX06001A (Scott Morton Expert Report at 180, Table A1), *in camera*).

484. Dr. Scott Morton's table calculating market shares and HHIs based on units sold in the United States in the narrower market is reproduced below.

[redacted]

(PX06001A (Scott Morton Expert Report at 181, Table A2), *in camera*).

485. The pre-Acquisition HHIs confirm that the narrower MPK market in the United States is highly concentrated and the change in HHIs post-Acquisition establishes a strong presumption that the Acquisition will likely enhance market power in the merged firm. (PX06001A (Scott Morton Expert Report at 180-81, Tables A1 & A2)).

486. Respondent's economic expert witness, Dr. David Argue, opined that the relevant product market is prosthetic knees for K-3 and K-4 mobility levels. He included in his proposed product market hydraulic and pneumatic non-MPKs and excluded high-end and integrated MPKs (Genium, X3, Rheo XC, Symbionic, and Linx). Dr. Argue calculated shares of market participants using units of production, not sales revenue, from 2016. Under Dr. Argue's proposed market and market share calculations, post-Acquisition, Ottobock and Freedom have a combined market share of [redacted] and the Acquisition would increase the HHI by 599 points, to 4,359. (RX1049 (Argue Expert Report at 0037, Table 3), *in camera*).

### 2. Competition between Plié and C-Leg prior to the Acquisition

#### a. Overview

487. Prosthetic industry participants consider Ottobock's C-Leg 4 to be the market leader in the industry. (Collins (Cascade) Tr. 3292; Ferris (Freedom) Tr. 2409; Oros (Scheck & Siress) Tr. 4794-95; Blatchford (Endolite) Tr. 2144-45; Ell (Mid-Missouri O&P) Tr. 1797-98; De Roy (Össur) Tr. 3590-91 (testifying that the C-Leg is the market leader because they were first, and "because it's a really good knee")).

488. Ottobock introduced the first swing and stance MPK to the United States market in 1998 and there was a period of time when Ottobock sold the only swing and stance MPK in the United States, the C-Leg. (Carkhuff (Freedom) Tr. 616).

489. Based on Ottobock estimates, after launches of the Plié in 2007 and the Plié 2 in 2010 (F. 255), Ottobock's United States market share in the MPK market declined from approximately 98% in 2006 to approximately 80% in 2011. (PX01054 (Ottobock) at 005, *in camera*).

490. Prior to the Acquisition, Ottobock was Freedom's biggest competitor in terms of revenue. (Kim (Freedom) Tr. 2538; Carkhuff (Freedom) Tr. 621; PX01087 (Freedom) at 004 (Going Concern Memo)). Freedom's CFO, Lee Kim, referred to Ottobock as Freedom's "main competitor." (Kim (Freedom) Tr. 2595; PX01319 (Freedom) at 001).

491. For United Healthcare, the most common microprocessor knee pre-authorization requests are for the Ottobock C-Leg 4 and the Freedom Plié 3. United Healthcare would not include Össur in the category of most common MPKs submitted to United Healthcare. (Sanders (United) Tr. 5494-95; *see also* (PX05165 (Sanders (United) Dep. at 62) (testifying that "primarily, it's the Ottobock C-Leg and a distant second, the Plié, and then an even more distant third, the Össur.")).

492. Plié 3 pricing tends to be lower than the other manufacturers. (Blatchford (Endolite) Tr. 2148; *see also* PX01004 (Ottobock) at 005 (Due Diligence Report) (noting that Freedom has a "low price strategy with prices below OB [Ottobock], Össur and Endolite prices."

493. Customers generally pay less for the Plié 3 than they do for the C-Leg 4. (PX05141 (Bright (North Bay) Dep. at 125), *in camera* (testifying that North Bay Prosthetics, pays approximately [redacted] for the Plié and about [redacted] more for the C-Leg); Senn (COPC) Tr. 222-23, *in camera* (testifying that COPC paid [redacted] for the Plié 3 and [redacted] for the C-Leg 4 in 2017); Ell (Mid-Missouri O&P) Tr. 1742, *in camera* (testifying that Mid-Missouri O&P pays "[redacted] less" for the Plié 3 than the C-Leg 4); Ford (POA) Tr. 947, *in camera* (testifying that POA pays "[redacted] less" for the Plié than the C-Leg"); PX05166 (Watson (Fourroux Prosthetics) Dep. at 48), *in camera* (testifying that Fourroux Prosthetics pays [redacted] for Ottobock's C-Leg 4 and [redacted] for Freedom's Plié 3.)). *See also* F. 502, 556, 558.

494. Respondent's expert witness, Dr. David Argue, performed an analysis of the average sale prices of the C-Leg 4 and the Plié 3 in 2016, based on actual sales data from Ottobock and Freedom. Dr. Argue calculated that the average sale price of the C-Leg 4 in 2016 was [redacted] and the average sale price of the Pliè 3 in 2016 was [redacted] (Argue, Tr. 6300-01, *in camera*; RX0913 (Argue Expert Report, Table 2), *in camera*).

**b. Clinic perspective**

**i. Overview**

495. A clinic has greater bargaining leverage in negotiations with an MPK supplier if it can credibly threaten to switch some portion of its purchases to another MPK. (PX05007

(Carkhuff (Freedom) IHT at 121-22) (testifying that if the threat is credible, the clinic may use that to negotiate lower prices from Freedom for the Plié 3)).

496. During price negotiations with MPK manufacturers, clinic customers will use a competitor's MPK prices to negotiate for lower prices. (Blatchford (Endolite) Tr. 2163; Ford (POA) Tr. 1004-05; PX05108 (Yates (Jonesboro P&O) Dep. at 115); PX05116 (Endrikat (Empire Medical) Dep. at 34); Ell (Mid-Missouri) Tr. 1751). *See also* Carkhuff (Freedom) Tr. 404 (acknowledging that Hanger's ability to switch to another MPK manufacturer gives Hanger bargaining leverage against Freedom to obtain lower prices); Carkhuff (Freedom) Tr. 383 (acknowledging that Freedom frequently provides lower prices to customers in response to competition from other microprocessor knee manufacturers).

497. Customers use the presence of Freedom as a competitor to help them negotiate with MPK manufacturers. (Senn (COPC) Tr. 227; PX05001 (Endrikat (Empire Medical) IHT at 35-36) (testifying that "[i]t has happened" that his Ottobock sales representative will cut him a deal on the C-Leg if he says that he will buy Pliés instead); Ford (POA) Tr. 1004-05 (testifying that having both Freedom and Ottobock allows him to "negotiate with both companies knowing there are alternatives, that our clinicians . . . are comfortable with both alternatives, so it allows us to negotiate.")).

498. Freedom's chairman, Mr. Carkhuff, acknowledged that when a competing MPK manufacturer offers Freedom customers a lower price, customers often seek to renegotiate their contracts with Freedom. Freedom has lowered the price of its MPK during these negotiations due to competitive pressures from other MPK manufacturers. (Carkhuff (Freedom) Tr. 382-83).

**ii. Hanger**

499. In 2017, Hanger, Inc.'s fittings of MPKs were as follows: Ottobock C-Legs, [redacted] Freedom Pliés, [redacted] Össur Rheos, [redacted] and Endolite Orions, roughly [redacted] (PX03205 (Hanger) at 008, *in camera*; Asar (Hanger) Tr. 1439-43, *in camera*).

500. Ottobock and Freedom are Hanger's top two suppliers of MPKs in terms of money spent. In 2016, Hanger spent [redacted] on Ottobock MPKs and [redacted] on Freedom MPKs. (Asar (Hanger) Tr. 1564-66, *in camera*).

501. Ottobock and Freedom are Hanger's top two suppliers of MPK's in terms of volume. The C-Leg 4 is the most widely used MPK at Hanger, followed by the Plié. The next most purchased MPK is the Endolite MPK, followed by the Össur MPK. There are also a "handful" of purchases each year [redacted] from Nabtesco. (Asar (Hanger) Tr. 1374, 1380-81, *in camera*).

502. Hanger's average acquisition price is currently in the range of [redacted] for the C-Leg and in the range of [redacted] for the Plié 3. (Asar (Hanger) Tr. 1381-82, *in camera*).

503. The Plié 3 is Hanger's second-highest volume purchase. Hanger's reasons for purchasing the Plié are that Freedom is based in the United States and that the Plié is a good product with good technology. Hanger increased its purchases of the Plié after the Plié 3 was released. (Asar (Hanger) Tr. 1389-90).

504. Vinit Asar, Hanger's president and CEO, believes that the C-Leg and Plié are "pretty equivalent" in terms of functionality and patient satisfaction. In addition, as Mr. Asar explained, both knees are "coded the same way," so Hanger receives the same reimbursement for the C-Leg as it does for the Plié. (Asar (Hanger) Tr. 1393).

505. In Mr. Asar's experience as president and CEO of Hanger, "there's always technology leapfrogs happening . . . . [E]very time a new generation from one manufacturer comes out, the other manufacturer is working on something to leapfrog it. . . . [T]hat's the general nature of medical devices . . . ." (Asar (Hanger) Tr. 1408-09).

506. As Mr. Asar explained, "each competitor makes the other competitor stronger in a way, . . . so if somebody comes out with a certain type of product one year, you know that competitor, the other competitor, is likely working on adding one more feature or one more benefit or one more service offering." (Asar (Hanger) Tr. 1458).

507. Hanger believes that competition between Ottobock and Freedom has resulted in better technology and lower pricing. Lower prices have resulted in expanded margins for Hanger, which allows Hanger to reinvest in its business, for example, by investing in an electronic medical records system. (Asar (Hanger) Tr. 1411-12).

**iii. COPC**

508. In 2017, [redacted] of the MPKs purchased by the Center for Orthotic and Prosthetic Care ("COPC") were purchased from Ottobock or Freedom. COPC purchased [redacted] its MPKs from Freedom [redacted] Approximately [redacted] of COPC's MPK purchases were from Ottobock. (Senn (COPC) Tr. 190, *in camera*).

509. COPC prosthetists prefer the functionalities of Freedom and Ottobock knees over Össur's Rheo knee. (Senn (COPC) Tr. 223).

510. Comparing the Ottobock C-Leg and the Freedom Plié knees, for most uses, feedback from COPC prosthetists was that they "like both knees, . . . [and are] happy with both." (Senn (COPC) Tr. 208-09).

511. For COPC, "[i]f . . . two knees are essentially clinically the same, [and] are good for a patient and one is substantially cheaper than the other one," it is beneficial for the clinic's business to take the cost savings. (PX05128 (Senn (COPC) Dep. at 24)).

512. The MPK preferred by COPC's practitioners for K-3 amputees is the Plié 3. Feedback received by Keith Senn, president of Kentucky and Indiana operations at COPC, from

COPC practitioners was that "they like the Plié 3" and it "works well with their patients." In addition, COPC has "a discount arrangement with Freedom based on number o[r] volume of knees" purchased. COPC tries "to drive volume towards . . . that knee, if it's appropriate for the patient." (Senn (COPC) Tr. 180).

513. COPC began purchasing more Plié 3 MPKs in 2015 because of "pricing and the clinical preferences of the Plié, advantages to the Plié the practitioners liked." After COPC increased Plié purchases in 2015, Ottobock responded with greater price discounts on the C-Leg 3 and C-Leg 4. (PX05128 (Senn (COPC) Dep. at 23-25)).

514. In an August 2016 email from president and CEO of COPC, David Sickles, to Keith Senn and other COPC executives, Mr. Sickles wrote, "Last year we pushed hard for Freedom to give us a good deal on their Plié knees. They came through and we bought a large amount of knees from them. [Ottobock] lost out and saw the effect on sales. [Ottobock] lowered their price and made the C-Leg 3 available to us." (PX03118 (COPC) at 001).

515. COPC began shifting more volume to the Plié 3 in 2016, and increased its purchases of the Plié 3 in 2017. These increased purchases were due to Freedom having increased its price discount to COPC substantially from 2016. (Senn (COPC) Tr. 191, 221-22).

516. COPC purchased [redacted] its MPKs from Freedom in 2017 because prosthetists like the Plié 3 and COPC has "a very good discount agreement with them." (Senn (COPC) Tr. 190, *in camera*; *see also* Tr. 191, *in camera* (stating that Freedom's increased purchases in 2017 were due to "[t]he competitive pricing that we received from them")).

517. COPC provides a purchasing guideline for prosthetists, which seeks to drive volume to vendors with which COPC has contracted discounts. (Senn (COPC) Tr. 179). The COPC purchasing guideline is based upon practitioner preference and the cost that COPC is able to negotiate with the manufacturers. (Senn (COPC) Tr. 208-09; *see also* Tr. 154-55 (testifying that, in determining a purchasing guideline, COPC works with practitioners to determine their preferred products that they feel work well with their patients and then negotiates with the vendors to "try to arrange the best pricing")).

518. COPC currently designates the Plié 3 as its preferred knee for its purchasing guideline. (F. 517; Senn (COPC) Tr. 208). COPC prefers the Plié for its purchasing guideline because COPC has a lower cost and obtains a higher margin on the Plié and because it works well for the majority of patients. (Senn (COPC) Tr. 208-09).

519. The COPC purchasing guideline is not mandatory, "so if another knee or foot would be appropriate for that patient, that is fine as well . . . ." (Senn (COPC) Tr. 179). COPC prosthetists are not incentivized by the profits of the company, so choosing a knee other than what is on the guideline does not affect a prosthetist's salary or job. (Senn (COPC) Tr. 206-07).

520. If a prosthetist selects a knee for a patient other than the preferred knee in the guideline, the prosthetist must send a request for approval to the general manager, which explains

the need for a different knee. Such requests are "almost always approved." (Senn (COPC) Tr. 209-10; *see also* Tr. 207 (COPC "want[s] to drive the volume as much as we can, but it's still about the patient care experience.")).

521. Since COPC began shifting more volume to Freedom, COPC has had discussions with Ottobock about increasing their price discounts "to try to move volume back" to Ottobock. COPC was able to obtain a larger discount from Ottobock for the C-Leg 4 in 2017 than COPC had in 2016. (Senn (COPC) Tr. 221-22; *see also* PX05128 (Senn (COPC) Dep. at 24-25) (testifying that after COPC increased its purchases of Plié 3 in 2015, Ottobock responded with "increasingly more aggressive pricing on . . . their C-Leg 3 and C-Leg 4," meaning greater discounts, in order to encourage volume)).

522. In 2016, COPC paid Freedom [redacted] for each Plié 3. As a result of [redacted] COPC currently pays [redacted] for the Plié 3. COPC pays [redacted] for the C-Leg 4 and [redacted] for the Össur Rheo MPK. COPC's price for the Orion 3 in 2017 was [redacted] (Senn (COPC) Tr. 220, 222-23, 236-37, *in camera*).

523. Mr. Senn believes that competition between Ottobock and Freedom has resulted in COPC receiving a higher price discount from Freedom. This benefits COPC and supports hiring, facilities, and various programs that support patient care, such as compliance. (PX05128 (Senn (COPC) Dep. at 34)).

524. Mr. Senn is concerned about the effect that the acquisition of Freedom by Ottobock could have on COPC's ability to negotiate discounts and on continued innovation for MPKs. (Senn (COPC) Tr. 227-28).

**iv. Scheck & Siress**

525. [redacted] of MPK purchases by Scheck & Siress ("S&S") are approximately evenly split between Ottobock and Össur. Most of S&S' Ottobock MPK purchases are C-Legs. The remaining [redacted] of MPK purchases are of the Plié, the Orion, and the Allux. (Oros (Scheck & Siress) Tr. 4815-16, *in camera*).

526. Michael Oros, a certified prosthetist and orthotist and president and CEO of S&S, does not believe that the Plié 3 provides the same amount of stability or the same stumble recovery benefits as the C-Leg and the Rheo. (Oros (Scheck & Siress) Tr. 4821).

527. S&S fits the Plié 3 on a different patient population than the C-Leg 4 and Rheo. S&S "think[s] of the Plié as a knee that's for someone that's on the higher end of that K3 towards K4 status. So an individual that enjoys more . . . voluntary control . . . [is] a better candidate for a Plié than a C[-Leg] 3 or 4." S&S believes that the Plié is better for more active patients because "patients that have better voluntary control, meaning longer residual limbs, more muscular strength, they want to be able to control - often times they want to be able to control their gait or how they move." (Oros (Scheck & Siress) Tr. 4817-18).

528. S&S'current average price for a C-Leg 4 is [redacted] and its average price for a Rheo is [redacted] S&S' price for a Plié 3 is less than that for a C-Leg or a Rheo. (Oros (Scheck & Siress) Tr. 4821, *in camera*).

529. S&S would more likely fit a Rheo or a C-Leg than a Plié on a "high K2/low K3, although we're all calling them K3s," because those patients "don't have the ability necessarily with their muscular strength and coordination to be able to keep themselves from falling; hence that benefit of that microprocessor-controlled knee." Patients with longer residual limbs and strength are better able to control the stumbling sensation. (Oros (Scheck & Siress) Tr. 4818-19).

### v. Scott Sabolich Prosthetic & Research

530. The "main three [MPKs] that are used in the United States" by Scott Sabolich Prosthetic & Research ("SSPR"), with Medicare reimbursement, are the Ottobock C-Leg, the Össur Rheo, and the Freedom Plié. (PX05132 (Sabolich (SSPR) Dep. at 69)).

531. From 2015 through March 2018, the [redacted] of MPKs purchased by SSPR were C-Legs. Össur Rheo followed next, and then Freedom Plié. (Sabolich (SSPR) Tr. 5857, *in camera*).

532. SSPR considers the Rheo 3 to be the closest substitute for a C-Leg 4. (Sabolich (SSPR) Tr. 5858).

533. If SSPR could not have a C-Leg or a Rheo for a patient, Mr. Sabolich would "maybe look at . . . the [Endolite] Orion knee," although "it would be tough" because SSPR has not had very good luck with the Orion MPKs that they have tried. (Sabolich (SSPR) Tr. 5858-59).

534. [redacted]

535. SSPR fits more C-Legs because the C-Leg has been around the longest and has been the most tested. Scott Sabolich, a prosthetist and the owner of SSPR, considers the C-Leg to be a better product and typically better for the patient. (Sabolich (SSPR) Tr. 5857-58).

536. At SSPR, many people request particular componentry, based on advertising or information from the Internet. If what the patient wants is the clinic's least profitable component, the clinic will consider whether the component is "really the best thing for the patient or [if] there [is] an alternative, effective alternative device" for the patient that the clinic could "bill out reasonabl[y]." (Sabolich (SSPR) Tr. 5873-74).

### vi. Mid-Missouri O&P

537. Mid-Missouri Orthotics and Prosthetics ("Mid-Missouri O&P") generally purchases its MPKs from Ottobock and Freedom. From Ottobock, Mid-Missouri O&P purchases C-Leg 4s, Compacts, Geniums, and X3s. From Freedom, Mid-Missouri O&P purchases Plié 3s. Mid-Missouri O&P buys from Ottobock and Freedom because "[t]hey have clearly defined themselves as providing and servicing a better product for [its] patients. The inherent stabilities are far greater in those knees, . . . as well as generalized gait and efficiency." (Ell (Mid-Missouri O&P) Tr. 1731-32).

538. Ottobock and Freedom compete for Mid-Missouri O&P's business. Both companies have offered Mid-Missouri O&P discounts and Ottobock has at times matched Freedom's prices to Mid-Missouri O&P for MPKs. Tracy Ell, the owner and chief prosthetist at Mid-Missouri O&P, believes Freedom and Ottobock MPKs present "similar componentry." (Ell (Mid-Missouri O&P) Tr. 1750-51).

539. Mid-Missouri O&P pays approximately [redacted] for the C-Leg 4 and about [redacted] for the Plié 3. (Ell (Mid-Missouri O&P) Tr. 1744), *in camera*).

540. Tracy Ell, Mid-Missouri O&P's owner and chief prosthetist, believes competition between Ottobock and Freedom has reduced pricing and helped the general progression of technology. (Ell (Mid-Missouri O&P) Tr. 1750-51; PX05129 (Ell (Mid-Missouri) Dep. at 78-79 (referring to "the continued evolution of technology in microprocessor control knee field, [which] then benefits my business as well as the patients").

541. With respect to product innovation, Mr. Ell of Mid-Missouri O&P explained, "Generally, if you have a design of a component and their competitor exceeds the design by some characteristic, then it's only common nature to evolve your product, as in the C-Leg 1 through 4 and the Plié 1, 2 and 3." (Ell (Mid-Missouri O&P) Tr. 1750-51).

### vii. POA

542. Prosthetic and Orthotic Associates ("POA") clinicians prefer C-Legs and Pliés. Mark Ford, president and managing partner at POA, believes, based on marketing materials, training he has attended, and feedback from his prosthetists, that Ottobock's C-Leg 4 and Freedom's Plié 3 "have a lot of similarities in terms of the base function that they work off of using hydraulic cylinders, the microprocessor." (Ford (POA) Tr. 937, 948-49).

543. Mark Ford of POA sees Freedom and Ottobock MPKs as based on "on similar ideas and similar platforms," resulting in "an inherent stronger competition between those two companies . . . ." (Ford (POA) Tr. 1015-16).

544. POA's price for the Plié 3 is [redacted] and its price for the C-Leg 4 is between [redacted] (Ford (POA) Tr. 1024, *in camera*).

545. POA has not purchased a Plié since June 2015, except for one unit it purchased in 2018 as part of a bundled offering by Freedom for a patient that lacked insurance and needed water resistance. POA's prosthetists believe that the C-Leg is a better product and that Ottobock provides better service. (Ford (POA) Tr. 1030-31, 1034-35, 1044).

546. POA has not purchased any MPKs from Össur, Endolite, Nabtesco, or DAW since 2015. (Ford (POA) Tr. 1024).

547. Ottobock and Freedom compete for POA's business. Because POA's "clinicians are . . . comfortable with both alternatives," competition has allowed POA "to negotiate with both companies," on such terms as "cooperative marketing, credit terms, shipping terms, [and] price discounts." (Ford (POA) Tr. 1004-05).

548. POA has used the presence of the option of purchasing the Plié 3 in negotiations with Ottobock "to get better pricing for the C-Leg 4." (Ford (POA) Tr. 1005).

549. POA uses the profit it earns from the difference between its cost for an MPK and the reimbursement it receives to reinvest in POA, including training, new technology systems, and expansion into more offices. (Ford (POA) Tr. 1005).

550. Mark Ford has observed Freedom and Ottobock compete "in a back-and-forth manner" over the years on the basis of product innovation in MPK features, including water resistant features and processor speeds, which make the products better and "grab attention" from POA's clinicians. (PX5145 (Ford (POA) Dep. at 64-69)).

551. Mr. Ford of POA is concerned that, with Ottobock owning Freedom, POA will lose leverage in negotiations with Ottobock for MPKs, prices will increase, and, because reimbursement levels are largely fixed, POA's margins will go down. Mr. Ford is also concerned that if there is less competition, this will slow product improvements, which Freedom and Ottobock have used to "one-up" each other and keep the attention of clinicians. (Ford (POA) Tr. 1014-16).

#### viii. Jonesboro P&O

552. In the experience of Rob Yates, president and CEO of Jonesboro Prosthetic & Orthotic Laboratory ("Jonesboro P&O"), as a clinician and in overseeing purchases for Jonesboro P&O, Ottobock competes with Freedom for sales of MPKs to Jonesboro P&O, including on product features, clinical research, support, customer service, and "certainly they compete on price." (PX05108 (Yates (Jonesboro P&O) Dep. at 72-73)). This competition has benefitted Jonesboro P&O, including by enabling Jonesboro P&O to obtain "relatively competitive pricing structures from both manufacturers" and to use the increased margins for investing in facilities and technology, hiring staff, and providing patient support services that are not reimbursable, such as peer counseling. (PX05108 (Yates (Jonesboro P&O) Dep. at 74-77)).

553. Freedom has provided Jonesboro P&O with "more competitive pricing" for the Plié, which results in a "significantly less acquisition cost" for Jonesboro P&O on the Plié than on the C-Leg, or any other product. While Ottobock has "certainly not sought to try to match" Jonesboro P&O's Plié pricing, it has obtained "a healthy," "pretty aggressive discount structure" from Ottobock. Jonesboro P&O recognizes that "it's not Otto Bock's practice to be a low-cost provider" to purchasers like Jonesboro P&O, as opposed to purchasers with greater volume such as Hanger. (PX05108 (Yates (Jonesboro P&O) Dep. at 73-74)).

554. In Mr. Yates' experience, for most users, the C-Leg is functionally similar to the Plié. (PX05108 (Yates (Jonesboro P&O) Dep. at 64-65)).

555. Mr. Yates has observed that "over time the [C-Leg and Plié] products have become better," to the benefit of Jonesboro P&O's patients. The products "have become more reliable [and] more feature-rich . . . ." (PX05108 (Yates (Jonesboro P&O) Dep. at 77-78)).

556. Jonesboro P&O pays approximately [redacted] for Freedom's Plié 3 and "in the range of [redacted] for Ottobock's C-Leg 4. (PX05108 (Yates (Jonesboro P&O) Dep. at 29), *in camera*).

**ix. Ability Prosthetics & Orthotics**

557. Jeffrey Brandt, CEO of Ability Prosthetics & Orthotics ("Ability P&O"), has observed the price of the C-Leg go down significantly in the past six or seven years, which Mr. Brandt attributes in part to competition from the Plié. To Mr. Brandt, it is "common knowledge" among providers and manufacturers that Freedom and Ottobock have been "one-upping each other and trying to . . . pack more into a knee for the same price or less." (PX05149 (Brandt (Ability P&O) Dep. at 71-72)).

558. Ability P&O currently pays [redacted] for the Ottobock C-Leg and [redacted] for the Plié 3. (Brandt (Ability P&O) Tr. 770-71, *in camera*).

**c. Launch of Plié 3 in 2014**

559. Freedom launched the Plié in 2007 and the Plié 2 in 2010. (PX05007 (Carkhuff (Freedom) IHT at 155-56)).

560. The Plié 3 was the successor to Freedom's prior generation MPK, the Plié 2. To differentiate the Plié 3 as improved over the Plié 2, Freedom marketed the Plié 3 as "stronger, smarter, submersible," as compared to the Plié 2. "Stronger" referred to improvements to reliability; "smarter" referred to consistency of performance with improved software; and "submersible" referred to the ability to "be safely submer[g]ed in fresh shallow water for up to 30 minutes at a time." These were the three major improvements to the Plié 3 compared to the Plié 2. (Carkhuff (Freedom) Tr. 331-33; PX08008 (Freedom) at 002).

561. In a 2012 "product pipeline" presentation, Freedom described its planned "next generation MPC knee" as providing "superior swing and stance phase performance," over the prior Plié, and "designed to be a C-Leg killer." The presentation identified its competitors for the new knee as "C-Leg from Ottobock, Rheo from Össur [and] Orion from Endolite. Not intended to compete directly against Genium." (PX01165 (Freedom) at 005 (Freedom's product pipeline presentation, Nov. 15, 2012).

562. Freedom launched its current generation MPK, the Plié 3, in September 2014. (PX07049 at 004 (Ottobock Amended Answer); PX05112 (Ammouri (Freedom) Dep. at 107)).

563. Freedom marketed as features of the Plié 3 that the Plié 3 enables patients to walk more effectively with a variable gait and helps reduce patient falls. (Carkhuff (Freedom) Tr. 333-35).

564. In marketing the Plié 3, Freedom emphasized water resistance heavily. The Plié 3 is waterproof, which refers to it being submersible in up to a meter of fresh water for as long as 30 minutes. This is a feature the C-Leg 3 did not have. (Carkhuff (Freedom) Tr. 331-32; Ford (POA) Tr. 1007; De Roy (Össur) Tr. 3598-99; PX05010 (Schneider (Ottobock) IHT at 115-16)).

565. The water resistance feature of the Plié 3 was particularly attractive to MPK customers. (Testerman (Freedom) Tr. 1174; PX05162 (Ruhl (Ottobock) Dep. at 93-94); PX05112 (Ammouri (Freedom) Dep. at 96-97); PX05001 (Endrikat (Empire) IHT at 21); PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 34)).

566. Freedom used the technological advancements of the Plié 3 to sell the product to customers. (Testerman (Freedom) Tr. 1180-81).

567. Clinicians at POA noted as improvements in the Plié 3, as compared to Ottobock's C-Leg 3, better battery life and a full waterproof warranty. (Ford (POA) Tr. 1007-08).

568. Hanger believes that the Plié 3 included features that were better than the previous versions of the Plié, such as water resistance and higher weight limits. (Asar (Hanger) Tr. 1414-15).

569. The feedback received by Vinit Asar of Hanger after the launch of the Plié 3 was that the Plié 3 was "very competitive . . . a good product." (Asar (Hanger) Tr. 1389-90).

570. Freedom adopted a "penetration pricing" strategy for the Plié 3, pricing it lower than the C-Leg 3, Ottobock's MPK at the time of the Plié 3 launch. (Carkhuff (Freedom) Tr. 388; PX01023 (Freedom) at 003-04).

571. The launch of the Plié 3 in September 2014 increased Freedom's MPK sales and share of the MPK market in the United States and worldwide. (Carkhuff (Freedom) Tr. 491-92; PX02025 (HEP) at 003). Freedom's largest customer, Hanger, increased its volume of

purchases of Freedom's MPK following the launch of the Plié 3. (Asar (Hanger) Tr. 1389-90).

### d. Pricing and promotions for C-Leg 3

572. In the years prior to the September 2014 launch of the Plié 3, Ottobock estimated that it had a United States market share of at least 90% in each year from 2006 through 2009. Ottobock estimated that, during the years 2010 through 2013, its market share was at least 80% in the United States. (PX05162 (Ruhl (Ottobock) Dep. at 92-93); PX01054 (Ottobock) at 005).

573. After the September 2014 launch of the Plié 3, Ottobock's MPK sales decreased. Ottobock attributed its sales decline to the launch of Freedom's Plié 3. (PX05162 (Ruhl (Ottobock) Dep. at 92-93 (explaining that improvements to the Plié allowed it to "gain market share" at the same time Ottobock was "steadily losing market share"); PX01506 (Ottobock) at 001-02 (March 2015 email noting Freedom made "inroads" with the Plié 3)).

574. Ottobock monitored Freedom's marketing claims for the Plié 3 because it saw Freedom "as one of [Ottobock's] two most viable competitors, next to Össur [and because] Freedom was driving a very aggressive marketing and promotional campaign with pretty high discounts and giveaways of additional products." (PX05150 (Kannenberg (Ottobock) Dep. at 126-27)).

575. In February 2015, Ottobock provided its sales force with a presentation titled "Responding to Marketing Claims Freedom Innovation Plié," in order to assist its sales force. (PX01499 (Ottobock); Schneider (Ottobock) Tr. 4728-31). The presentation identified and provided responses to Freedom's claims, among others, that the Plié 3's microprocessor was faster, that Plié 3 had been clinically validated, and that Plié 3 was properly eligible for reimbursement as a swing and stance microprocessor-controlled knee under L-Code 5856. (PX01499 (Ottobock) at 009-10, 019-23, 026-30). Responses by Ottobock included that the Plié is "basically a mechanical knee with a microprocessor switch" that does not control resistance through the entire gait cycle and that there is a risk of overbilling "since the payer is billed for functionality the patient doesn't get!" (PX01499 (Ottobock) at 013, 026).

576. In the first quarter of 2015, Ottobock sold 44 C-Leg 3 MPKs, based on a promotion, to customers that had not purchased any MPK from Ottobock in 2014. Twenty-one of those sales included a $2,500 discount. Ottobock executives viewed these results as a positive development, referring to the increased sales as "momentum." (PX01519 (Ottobock at 001)).

577. One customer saw the price of Ottobock's C-Leg 3 decrease from [redacted] after the September 2014 launch of the Plié 3. (PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 40), *in camera*).

578. In August 2015, Ottobock determined that Ottobock's C-Leg 3 year-over-year unit sales had been going down in part because the Plié 3 was taking units from the C-Leg 3, through effective and aggressive promotion and selling. In addition, the Plié 3 had a better water resistance than the C-Leg 3. (Schneider (Ottobock) Tr. 4556-58; PX05010 (Schneider (Ottobock) IHT at 121-22)).

579. Ottobock provided its sales and marketing team with "arguments to convince customers to not walk away from the C-Leg and continue to buy C-Legs and fit C-Legs on their patients instead of Pliés." (PX05150 (Kannenberg (Ottobock) Dep. at 128-29); PX01499 (Ottobock) (February 2015 presentation titled, "Responding to Marketing Claims Freedom Innovation Plié")).

**e. Launch of C-Leg 4**

580. Ottobock began a project for developing the C-Leg 4 in December 2012 and finalized its requirements in April 2013. (PX1057 (Ottobock) at 016, 020 (Global Launch Plan)).

581. On April 27, 2015, Ottobock announced it was launching the C-Leg 4 in North America. The C-Leg 4 was released in the United States in July 2015. (PX08077 (Ottobock) at 001 (Press release); Carkhuff (Freedom) Tr. 468).

582. In February 2015, prior to the launch of the C-Leg 4, a cross-functional team consisting of Ottobock sales, marketing, clinical, and service employees created various launch materials for the C-Leg 4. These materials contained information on the C-Leg 4's benefits, features, functions, reimbursement opportunities, launch tasks and timeline, and marketing materials. (PX01518 (Ottobock)). These materials also contained a chart comparing the features of the C-Leg 4 to those of the Plié 3, the Össur Rheo 3, and the Endolite Orion 3. The comparison chart represented that the C-Leg 4 had a greater knee flexion angle than the Plié 3, had a greater battery capacity than the Plié 3, and had Bluetooth compatibility and a protective cover, which the Plié 3 did not. (PX01518 (Ottobock at 003)).

583. Bradley Ruhl, then-president of Ottobock's North American prosthetics business unit, led the C-Leg 4 launch in the United States. The purpose of the launch materials referenced in F. 582 was "to prepare our employees, our sales team, our professional and clinical service team, marketing teams, to ultimately be in a position to launch product in the market and help customers learn and become educated . . . about the product." (PX05162 (Ruhl (Ottobock) Dep. at 8-11, 51-52)).

584. Ottobock's February 2015 C-Leg 4 launch materials described messaging for the C-Leg, including "C-Leg is the best selling and most-proven MPK in the world. Research studies have repeatedly substantiated the C-Leg's reliability . . . . The development of the C-Leg 4 marks the next stage of evolution, ringing in the fourth generation of a new technological era. The C-Leg 4 is quite simply the best C-Leg of all time, significantly improving users' ability to handle their daily activities." (PX01518 (Ottobock) at 024).

585. The C-Leg 4's new features included a lower system height, new carbon frame construction, integration of all sensors, Bluetooth compatibility, and a knee-bending angle of 130 degrees. The C-Leg 4 also added a weatherproof feature. (PX01518 (Ottobock) at 027; PX05162 (Ruhl (Ottobock) Dep. at 42)).

586. Ottobock incorporated waterproof functionality into the C-Leg 4 in response to the launch of the Plié 3. (Solorio (Ottobock) Tr. 1641-43 (referencing IP67 rating and waterproof marketing claims of Plié)).

587. Ottobock's February 2015 C-Leg 4 launch materials estimated that Ottobock had a 78% share of what it described as the "MPK" market and identified Freedom as the next-largest competitor with an 11% share. (PX01518 (Ottobock) at 009, 050).

588. Written notes of an April 2015 internal Ottobock conference call included the comment, "C-Leg 4 is going to blow the Plié out of the water - no comparison - Brad wasn't excited before - but is very excited about this MPK - your customers will be blown out of the water." (PX01570 (Ottobock) at 001).

589. A June 2015 memo from Freedom's marketing and clinical services department to Freedom's sales team acknowledged, "With the introduction of the C-Leg 4, two of the [prior C-Leg's] major shortcomings were addressed - the ability to walk backwards and weather proofing." (PX01213 (Freedom) at 001; Testerman (Freedom) Tr. 1175-77).

590. Ottobock's August 2015 C-Leg 4 launch plan included as sales and marketing goals to "[r]egain market share from competitors especially from Plié in the US and expand the market penetration in the MPK segment" and to "counteract competitors like Plié 3, Rheo 3, Orion 2. Aggressive competitor strategy." (PX01057 (Ottobock) at 023; PX05157 (Pfuhl (Ottobock) Dep. at 70)).

591. Ottobock was trying to regain market share especially from the Plié because Freedom "did a very effective job promoting their product and selling their product, and we had seen a decline in sales of the C-Leg 3." (PX05010 (Schneider (Ottobock) IHT at 121); Schneider (Ottobock) Tr. 4556-57).

#### f. Plié 3 sales and marketing after launch of C-Leg 4

##### i. Sales of Plié 3

592. After the July 2015 launch of Ottobck's C-Leg 4 in the United States, Freedom's sales of the Plié 3 in the United States significantly declined. Prior to the release of the C-Leg 4, Plié 3 direct sales in the United States had been increasing. (Carkhuff (Freedom) Tr. 484, 492; PX02025 (HEP) at 003) (sales chart); PX05007 (Carkhuff (Freedom) IHT at 160-61)).

593. Freedom's Plié 3 sales took a "big hit" following the C-Leg 4 launch. (Carkhuff (Freedom) Tr. 478).

594. Freedom recognized that, with the introduction of the ability to walk backwards and weather proofing in the C-Leg 4, the Plié 3 lost two important selling advantages. "The absence of these two features [had] allowed [Freedom] to highlight the function and features of the Plié 3 when compared to a C-Leg and gain market share over the past several months." (PX01213 (Freedom) at 001; Testerman (Freedom) Tr. 1175-77).

595. In August 2015, Lee Kim, Freedom's CFO, sent a report to the Freedom board of directors, called a monthly flash report, for July 2015. Mr. Kim wrote in his cover email "[t]he new Otto Bock C-Leg 4 is adversely impacting Plié sales. We have developed a sales promotion to regain Plié units (the 'Ideal Combination' of Plié and Kinterra[59]) which will launch in August." (PX01158 (Ottobock) at 001; Kim (Freedom) Tr. 2552; Carkhuff (Freedom) Tr. 408). Also in August 2015, Mr. Kim sent a management report to Freedom's creditor that stated, "Plié sales in the U.S. were impacted by the introduction of the updated Otto Bock MPC knee." (PX02016 (HEP) at 006 (Management Report for July 31, 2015); Carkhuff (Freedom) Tr. 467-68).

596. Ottobock's July 2015 launch of the C-Leg 4 contributed to reduced sales of Freedom's Plié 3 to Hanger from 2014 to 2015, although Hanger sales had been declining prior to that launch. (PX01013 at 021 (January 2016 board of directors presentation); Carkhuff (Freedom) Tr. 493, 504-05).

597. A December 2015 email from a Hanger executive to Brad Ruhl, Ottobock's then-president of its North America prosthetics business noted that the launch of the C-Leg 4 and replacement of the C-Leg 3 in October 2015 resulted in stopping "practitioner migration to competitor knees." (PX01520 (Ottobock) at 001).

598. In March 2016, Ned Brown, a member of Freedom's board of directors, wrote to Thomas Chung, vice president of Health Evolution Partners ("HEP"), and others at HEP, that he would emphasize additional points in a draft presentation, including that the "softness" of sales to Hanger "is related primarily to knees . . . I would be more specific, and I would highlight the impact of [Ottobock]'s new C-Leg launch which correlates exactly with the decline in [Freedom's] Hanger knee business. We didn't respond fast enough to their competitive attack, and we are seeing a broadening competitive impact across our knee business into 2016." (PX02071 (HEP) at 001; *see also* Carkhuff (Freedom) Tr. 497-98; PX02025 (HEP) at 004).

599. The July 2015 launch of the C-Leg 4 was largely responsible for the decline in Freedom's Plié sales. Other competitive factors contributing to the decline in Plié 3 sales identified by Freedom included the fiberglass RUSH Foot by Ability Dynamics. The C-Leg 4 launch also coincided with some quality issues experienced by customers with the Plié 3 (*see* F. 639). (Kim (Freedom) Tr. 2511-13; PX1087 (Freedom) at 002 (March 2017 going concern memo); Carkhuff (Freedom) Tr. 485-86).

[59] The Kinterra is an hydraulic ankle and foot manufactured by Freedom. (Carkhuff (Freedom) Tr. 419).

600. One of Freedom's lenders, Madison Capital Funding (F. 743), attributed a decline in Plié 3 unit sales from September 2015 to April 2016 to Ottobock's release of the C-Leg 4, which it called a "direct competitive product to Freedom's Plié 3." (PX03008 (Madison Capital Funding) at 005, *in camera* ("Otto Bock released its 'C-Leg 4' in [fourth quarter] 2015, a direct competitive product to Freedom's Plié 3 MPC knee product (released in [third quarter] 2014). While the product does not have any distinctive advantages over the Company's Plié 3, the introduction of the new C-Leg 4 resulted in a [redacted] decline in Freedom's knee unit sales from September 2015 to April 2016 compared to the same period for the prior year.")).

### ii. Plié 3 marketing versus C-Leg 4

601. After the July 2015 launch of the C-Leg 4, Freedom's marketing team brainstormed various ideas as to "how to best combat the launch of the C-Leg 4." These included: "Initiate a value-added selling model vs. C-Leg 4," "Revisit P[lié] 3 pricing structure and overall terms," and "Launch a P[lié] 3 demo program with our top Key Accounts." (PX01247 (Freedom) at 001; Testerman (Freedom) Tr. 1190-94).

602. Freedom employees "spent a lot of time discussing" the C-Leg 4 versus the Plié 3 at a fall 2015 sales meeting, which was attended by members of Freedom's sales, marketing, and executive teams. Meeting attendees reviewed a document titled "Competitor Info," which highlighted various features of the Plié 3 and described C-Leg 4 marketing claims and Freedom's responses. This document was created to help Freedom's sales and marketing teams convince customers to buy the Plié 3 rather than the C-Leg 4. (PX01168 (Freedom) at 002; PX05112 (Ammouri (Freedom) Dep. at 107-08, 114)).

603. Freedom developed promotions and other sales materials in order to regain momentum in Plié sales, which had been adversely impacted by the launch of the C-Leg 4. (PX02016 at 006-07 (Freedom) (July 2015 management report); Carkhuff (Freedom) Tr. 468-69, 485-86; Testerman (Freedom) Tr. 1187).

604. After the July 2015 launch of the C-Leg 4, Freedom marketing and clinical teams created presentations comparing the features of the Plié 3 to the C-Leg 4 to make sure the sales team understood how to compete against the C-Leg 4. (Testerman (Freedom) Tr. 1178-79) (discussing PX01213 (Freedom)).

605. In June 2015, Freedom provided its sales team with marketing materials listing a "feature/benefit" comparison of the Plié 3 against the C-Leg 4. (PX01213 (Freedom)). The accompanying memo asserted that even with the addition to the C-Leg 4 of the ability to walk backwards and waterproofing, the absence of which was advantageous to selling the Plié 3, "the Plié 3 still offers meaningful advantages both for patients and prosthetists at a competitive price point." The memo further noted that "[t]he presence of new competition means we/you have made an impact – now go defend it!" (PX01213 (Freedom) at 001, 003).

606. A July 15, 2015 management report to Freedom's creditors stated that, in light of the decline in Plié sales as a result of the C-Leg 4 launch, Freedom has "developed promotions and other sales materials to regain momentum in knee sales." (PX02016 (HEP) at 006).

607. In 2015, Freedom published on its website a document titled "Plié 3 Microprocessor Knee Fact Sheet" that compares the Plié 3's functions directly to the functions of Ottobock's C-Leg 4. (PX08008 at 001 (Freedom); Carkhuff (Freedom) Tr. 348-50).

608. The Plié 3 fact sheet (F. 607) markets the Plié 3 as having comparable functions to the C-Leg 4, including real-time swing and stance control, reliable stance release on challenging surfaces, clinically proven stumble recovery, weatherproof with IP67 rating (submersible up to 3 feet for up to 30 minutes), adjustable modes for special activities, and no-charge reimbursement support. (PX08008 (Freedom)).

609. The Plié 3 fact sheet (F. 607) markets the Plié 3 as having features not possessed by the C-Leg 4, including a faster microprocessor, customized stumble recovery, variable speeds, full submersibility, the ability to make manual adjustments, interchangeable batteries, and remote access. (PX08008 at 001; Carkhuff (Freedom) Tr. 348-49).

610. The Plié 3 fact sheet (F. 607) responds to an Ottobock marketing claim that the C-Leg is PDAC[60] verified, and that the Plié 3 is not, by asserting that "PDAC is not required for reimbursement." (PX08008 (Freedom) at 001).

### iii. Pricing and promotions for Plié 3

611. Ottobock executives recognized that "[p]ressure from the C-Leg 4" drove Freedom to lower prices and "bundle promotions with feet." (Solorio (Ottobock) Tr. 1596; PX01002 (Ottobock) at 006; PX5010 (Schneider (Ottobock) IHT at 123); PX05123 (Solorio (Ottobock) Dep. at 116) ("Freedom seemed to be dropping their pricing most aggressively post C-Leg 4 launch, and they were the ones that were the most active in dropping price and having some sort of additional element to their promotion, whether that be a free foot or an additional discount on their higher-end feet.")).

612. One of Freedom's responses to the July 2015 C-Leg 4 launch was a promotion it called the "ideal combo," which bundled a discounted or free prosthetic foot with the purchase of a Plié 3. (Testerman (Freedom) Tr. 1145-46, 1201; Ferris (Freedom) Tr. 2395; Solorio (Ottobock) Tr. 1588, 1607; PX01158 (Freedom) at 001 (Freedom July 2015 Flash

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[60] A prosthetic manufacturer may submit a prosthetic device to the Medicare Pricing Data Analysis and Coding (PDAC) organization for review and confirmation of its L-Code recommendations ("PDAC verification"). (Solorio (Ottobock) Tr. 1623; PX05139 (Schneider (Ottobock) Dep. at 27-28); PX05165 (Sanders (United) Dep. at 75-76); De Roy (Össur) Tr. 3609; Schneider (Ottobock) 4587). PDAC verification is only directly applicable to reimbursement under Medicare and is not required for prosthetic devices, including MPKs. (PX05114 (Ferris (Freedom) Dep. at 161-62); Sanders (United) Tr. 5495-96; Carkhuff (Freedom) Tr. 352-53; Solorio (Ottobock) Tr. 1623; Kannenberg (Ottobock) Tr. 1970; Schneider (Ottobock) Tr. 4747-48; Oros (Scheck & Siress) Tr. 4877; PX05166 (Watson (Fourroux Prosthetics) Dep. at 182-83)).

Report, reporting on the introduction of the ideal combination in response to the C-Leg 4 launch)). *See also* PX00833 (Freedom) at 007 (advertisement for "The Ideal Combo at the Ideal Price").

613. Ottobock's Scott Schneider, vice president of government, medical affairs, and future development, believes that the bundling promotions of Freedom were one of Freedom's responses to competition from the C-Leg 4. (PX05010 (Schneider) IHT at 123-24).

614. One version of the ideal combo promotion involved offering a discount off of Freedom's Kinterra prosthetic ankle/foot system with the purchase of a Plié 3. (PX01181 (Freedom) at 005; Testerman (Freedom) Tr. 1145-46; PX01158 (Freedom) at 001). The discount off of the Kinterra has at times been as high as $1,000. (PX00824 (Freedom) at 002).

615. One version of Freedom's ideal combo promotion involved offering any Freedom graphite prosthetic foot for free with the purchase of a Plié 3. (PX00824 (Freedom) at 002).

616. The ideal combo promotion sought to regain Plié's lost sales from the C-Leg 4. (PX01158 (Freedom) at 001 (email regarding July 2015 flash report) ("The new Otto Bock C-Leg 4 is adversely impacting Plié sales. We have developed a sales promotion to regain Plié units (the 'Ideal Combination' of Plié and Kinterra) which will launch in August.")).

617. The ideal combo promotion was implemented by Freedom in order to take market share and stay competitive. The ideal combo promotion has been helpful in increasing Plié sales and has been successful in converting multiple customer accounts to the Plié from other MPKs. (Testerman (Freedom) Tr. 1147-48).

618. Freedom created the ideal combo promotion in the summer of 2015, and continued it until at least the time of the Acquisition. (Carkhuff (Freedom) Tr. 408, 417; PX01680 (Freedom) (summarizing 2017 1st quarter promotions); PX01256 (Ottobock) at 001 (stating that, "free foot or $1000 off their higher end feet [with purchase of a Plié] is pretty much a continuous promo for" Freedom); PX05010 (Schneider) IHT at 123-24 (testifying that Ottobock saw knee/foot bundling promotions being offered by Freedom through September 2017)).

619. The Agilix, DynAdapt, Highlander, and Kinterra are the top selling Freedom foot products in the ideal combo promotion. (Carkhuff (Freedom) Tr. 712-13 (discussing RX0439 (Freedom) at 0004, 0005, 0007)).

620. The combination of the Kinterra and the Plié 3 accounts for the majority of Freedom's ideal combo sales. (PX01681 (Freedom) at 011 (Operating Committee Meeting Presentation dated February 2016), *in camera*).

621. After Freedom released its Maverick foot in 2017, Freedom added the Maverick foot to the ideal combo promotion, providing it for half off the price with the purchase of the

Plié 3. Freedom planned to offer the Maverick for free as part of the ideal combo promotion beginning in April 2018. (PX05137 (Matthews (Freedom) Dep. at 168-69); PX02034 (HEP) at 50).

622. Freedom offered the ideal combo promotion nationwide and made it available to all of its customers. (Solorio (Ottobock) Tr. 1611; PX05116 (Endrikat (Empire) Dep. at 61)).

623. Freedom advertised and promoted its ideal combo at the October 2015 conference of the American Orthotic and Prosthetic Association. Freedom's "show book" for this conference stated, "Discover why the 'ideal combo' of pairing the Kinterra foot/ankle system with a Plié 3 MPC Knee provides AK users [above-the-knee amputees] with rock solid stability and safety, while maintaining a gait that is fluid and natural on all terrains. The features and benefits of the Kinterra and the Plié 3 will be closely examined in an interactive hands-on setting with patient models along with a live demonstration of the Plié 3 MPC Knee programming." (PX00803 (Freedom) at 003; Testerman (Freedom) Tr. 1119).

624. Eric Ferris, Freedom's vice president of marketing and product development, believes that the ideal combo promotion drives value and utilization for Freedom. Prosthetists have responded favorably to the ideal combo, and Freedom's sales force has informed Mr. Ferris that the ideal combo has been a well-received promotion. (Ferris (Freedom) Tr. 2395-96).

625. In the fourth quarter of 2015, Freedom's MPK sales from its ideal combo promotion totaled [redacted] (PX01681 (Freedom) at 011 (providing sales in units and dollars of Plié knees sold as part of a promotion with prosthetic feet), *in camera*). Freedom's total MPK sales in the fourth quarter of 2015 totaled approximately [redacted] (PX01160 (Freedom) at 023 (providing Freedom's total revenue for fourth quarter 2015), *in camera*).

626. The ideal combo promotion is an effective marketing tool for Freedom that incentivizes customers to buy more Freedom MPKs and feet. (Swiggum (Ottobock) Tr. 3340; Carkhuff (Freedom) Tr. 408; Solorio (Ottobock) Tr. 1648).

627. Bundling feet together with prosthetic knees provides value to clinics because clinics receive reimbursement for both the Plié 3 and the free foot that they receive. (Solorio (Ottobock) Tr. 1648; Ferris (Freedom) Tr. 2395-96; Swiggum (Ottobock) Tr. 3340-41, 3343).

628. The prosthetic clinic does not need to inform the insurance company that a prosthetic foot was provided for free, so the clinic receives the entire reimbursement, which can be used for the clinic's bottom line. (Solorio (Ottobock) Tr. 1613-14).

629. The free foot promotion provides "more margin for [the prosthetic] practice" than a promotion offering another free item, such as a Yeti cooler, with the purchase of the Plié. (Solorio (Ottobock) Tr. 1614).

630. Respondent's expert witness, Dr. David Argue, concluded, based on the case record, that bundling Freedom's feet with its Plié positively impacts sales of the Plié. (Argue, Tr. 6387-88).

631. Writing to her sales team in September 2015, Cali Solorio, Ottobock's senior prosthetics marketing manager, characterized the Freedom promotion, "Buy a Plié 3 and 50% off a Kinterra," as a result of competitive pressure from C-Leg 4. Referencing this promotion, Ms. Solario wrote: "C-Leg 4 has undoubtedly put considerable pressure on the competition – just look at the unique promos they've been running." (PX01272 (Ottobock) at 001; Solorio (Ottobock) Tr. 1589-91).

632. In September 2015, Ms. Solario provided advice for the Ottobock sales team for "Countering Freedom's Latest Promo" of "Buy a Plié 3 and get 50% off a Kinterra" foot. Setting out a comparison chart of likely customer margins, Ms. Solario wrote, "You'll see that even with a hefty 50% discount on Kinterra, C-Leg 4 combined with Triton Smart Ankle or Triton Harmony still offers a better margin for your customer!" (PX01272 (Ottobock) at 001).

633. Freedom lowered the price of the Plié 3 in response to the July 2015 launch of the C-Leg 4. Freedom sold the Plié 3 at a price that was significantly lower than the C-Leg 4. (PX05114 (Ferris (Freedom) Dep. at 174-76); Solorio (Ottobock) Tr. 1588; Carkhuff (Freedom) Tr. 485; Swiggum (Ottobock) Tr. 3344; PX01173 (Freedom) at 004, *in camera*; PX05153B (Asar (Hanger) Dep. at 103-04)). *See also* PX00859 (Freedom) at 003; Testerman (Freedom) Tr. 1203-04 (discussing plan to reduce pricing of the Plié for Hanger "to be on par with" the C-Leg 4).

634. Ottobock saw Freedom's pricing reduction of the Plié 3 as a reaction to competition from the C-Leg 4. (Solorio (Ottobock) Tr. 1588; PX01269 (Ottobock) at 001 (August 2015 email stating that Freedom is "surely feeling the pressure and as a result, dropping prices"); PX05010 (Schneider) IHT at 123-24 (testifying that Freedom responded to competition from Ottobock's C-Leg 4 with "reduced price or aggressive pricing" as well as an increased discount structure).

635. A November 2015 Ottobock marketing plan noted that "[p]ressure from C-Leg 4 has driven lower [Plié 3] prices and bundle[d] promotions with feet (50% off a Kinterra); consistently seeing prices as low as [redacted] (PX01002 (Ottobock) at 006, *in camera*).

636. An internal Ottobock marketing plan for 2018 noted that Freedom is "[p]laying on price" with an average sales price of [redacted] (PX00867 (Ottobock) at 002, 022 (2018 North America Marketing & Sales Plan), *in camera*).

637. Freedom's price discounting and promotions "definitely" impacted Ottobock's sales. (PX01278 (Ottobock) at 001 ("Freedom's price erosion is definitely impacting sales.

They almost always have a knee+foot promo running now."); Solorio (Ottobock) Tr. 1616-18).

638. Eric Ferris of Freedom wrote in April 2017, "Plié is significantly ahead of plan – thanks largely to the pricing changes – but the continuation of that momentum is at risk, as we know [Ottobock] will be responding in kind." Mr. Ferris was concerned that if Ottobock lowered its price on the C-Leg, Plié sales would decrease. (PX01184 (Freedom) at 001; Ferris (Freedom) Tr. 2411-12; PX05114 (Ferris (Freedom) Dep. at 164-66)).

**g. Plié 3 quality issues**

639. In September 2016, Mark Testerman, Freedom's vice president of national and key accounts, identified some quality issues that contributed to a decline in Plié 3 sales in the United States, including "some out-of-the-box failures," which were costing Freedom "some crediblity in the marketplace." In addition, there were issues regarding the time it took for a loaner knee to get to a practitioner when the knee needed repair, and the time to return the repaired knee to the patient. (Testerman (Freedom) Tr. 1296-97, *in camera*).

640. After the September 2014 launch of the Plié 3, some users were experiencing problems with "the battery lid, that was breaking or it may not have been waterproof." In addition, the battery itself was "too thick" which resulted in the battery getting stuck inside the battery compartment. (PX05115 (Robertson (Freedom) Dep. at 102-03).

641. In 2016, Freedom undertook to improve the quality of the Plié 3. Actions taken included addressing the length of time it took to program the Plié 3 and making the Plié 3 more durable. (Kim (Freedom) Tr. 2515; PX05114 (Ferris) Dep. at 175-76) *see also* PX02034 (HEP) at 049 (stating "Enhancement of Plié 3 product quality and service" as an action that Freedom took in 2016).

642. Freedom "redesigned that battery lid to eliminate the failures" seen in the field. Freedom also "found a new battery [for the Plié 3] that was thinner to begin with and remained thinner during subsequent discharge cycles" so that batteries would not get stuck inside the battery compartment. (PX05115 (Robertson (Freedom) Dep. at 102-03)).

643. Dr. Stephen Prince, a Freedom project manager, worked on "sustaining engineering" for the Plié 3 after its release, including assisting with "the diaphragm material improvements" and improving the battery lid, and helped guide "some new engineers working on the electrical system" for the Plié 3. (Prince (Freedom) Tr. 2674-75; PX05111 (Prince (Freedom) Dep. at 12); *see also* PX05115 (Roberts (Freedom) Dep. at 101-02) (testifying that most notable improvements to improve the quality of the Plié 3 were improving the battery, the battery compartment, and the battery lid)).

644. Freedom's most recent improvement to the Plié 3 is the unibody frame design. The design "went from a frame design that had . . . a lower attachment that was screwed in, an end cap[,] . . . to a single unibody frame that doesn't require that separate mechanical

attachment end cap. That was made to address a very limited number of failures in the field." (PX05115 (Robertson (Freedom) Dep. at 103)).

645. Freedom's revenues during the first six months of 2017 increased [redacted] over the prior year, which was driven significantly by sales of the Plié 3. David Smith, Freedom's CEO from April 2016 until the Acquisition, attributed these increased sales to "huge improvements" in the Plié 3 and having "fixed the product." (Smith (HEP) Tr. 6537, 6543, 6545-46, *in camera*; *see also* PX01842 (Freedom) at 002 (August 2017 email from Lee Kim commenting that "Plié quality improvements are driving new growth, as opposed to declining.")).

646. Jeremy Mathews, Freedom's senior vice president of sales and marketing, believes that Freedom's fixing of service and quality issues contributed to increased sales beginning in late 2016. (PX05137 (Mathews (Freedom) Dep. at 196)).

## E. Rebuttal and Defenses

### 1. Expansion

#### a. Össur

647. For many clinicians and patients, Össur's Rheo 3 is an unattractive alternative to the C-Leg 4 and the Plié 3. (F. 648-653. *See also* F. 500-501, 508, 537, 542).

648. COPC "practitioners do not like the Rheo knee" and believe that "the functions or the capability of that knee" do not "compare to the Freedom and Ottobock knees at this time." (PX05128 (Senn (COPC) Dep. at 44).

649. COPC prosthetists find the Rheo to be heavier and not as good at stumble recovery, which are disadvantages compared to the Plié and the C-Leg. (Senn (COPC) Tr. 223-24).

650. COPC is not presently willing to move volume to Rheo because of the preference for the functionality of the Freedom and Ottobock knees over the Rheo knee. (Senn (COPC) Tr. 223).

651. Mid-Missouri O&P has not purchased any MPKs from Össur because, based on the practice's experience with the demonstration models and personal preferences, Tracy Ell of Mid-Missouri O&P, believes that Össur's MPK is "not as inherently safe throughout all its usage." (Ell (Mid-Missouri O&P) Tr. 1732).

652. Mark Ford of POA has found that there are fundamental differences in design between the C-Leg 4 and the Rheo MPK. The Rheo uses magnetic fluids, versus using a hydraulic fluid system, which changes the way the knee operates. The Rheo MPK is also larger than preferred by POA's prosthetists and the Rheo's software works differently than what is preferred by POA's prosthetists. (Ford (POA) Tr. 950-51).

653. In the view of Mark Ford of POA, while Össur's Rheo MPK is used by "a lot of practices" and provides competition for the C-Leg, "for many clinicians," the Rheo MPK is "viewed as a different product than the C-Leg or the Plié knee because of the platform, the functional platform that it's built on." (Ford (POA) Tr. 1015-16).

654. [redacted] (De Roy (Össur) Tr. 3626, *in camera*).

655. If demand for Össur's Rheo Knee increased in the United States, Kim De Roy believes that Össur would be able to expand to produce an additional [redacted] Rheos; however, such expansion would require "more than some investment" and "a year [would be] a tight time frame" for such an expansion. (De Roy (Össur) Tr. 3691-92, *in camera*).

**b. Endolite**

656. Endolite has been selling MPKs for more than 20 years. (PX04001 (Blatchford (Endolite) Decl. at 002 ¶ 8)).

657. In 2016, Endolite sold [redacted] MPKs in the United States, while Freedom sold [redacted] In 2017, Endolite sold [redacted] MPKs in the United States, while Freedom sold [redacted] (PX06001A (Scott Morton Expert Report at 084, Table 7), *in camera*).

658. Prior to the release of the Orion 3 in September 2016, Endolite had technical and service issues that suppressed interest in its MPK products. (PX01075 (Freedom) at 109 (Freedom presentation detailing issues with Endolite's Orion); Blatchford (Endolite) Tr. 2170-71; Senn (COPC) Tr. 194; PX05128 (Senn (COPC) Dep. at 44)).

659. Prior to the release of Orion 3 in September 2016, Endolite "suffered" from having a reputation of "having a product that isn't very reliable, British engineering at its worst." (PX05144 (Blatchford (Endolite) Dep. at 237)).

660. Endolite has "suffered from a legacy of launching our first microprocessor-controlled swing and stance knee . . . . [R]eliability was atrocious, so it has taken us awhile to overcome that, and prosthetists do seem to have quite long memories." (Blatchford (Endolite) Tr. 2170-71).

661. COPC has no plans to move volume to the Orion at this time because, to COPC, "the two primary knees that we use [the C-Leg and the Plié] are better than their [Orion] knee, and so there's no reason today to try to move patients to their knee." (Senn (COPC) Tr. 225).

662. Endolite is a "smaller company," with a small sales force and few clinicians which makes it more challenging for POA to get support from Endolite in a timely manner and with the level of support that POA gets from Ottobock, Freedom, and Össur. (Ford (POA) Tr. 946, 956-57).

663. Hanger makes fewer MPK purchases from Endolite than from Ottobock and Freedom in part due to Endolite's lack of presence in the United States. Hanger sees Endolite sales representatives less frequently, and has found that Endolite offers less support in the United States for its products. (Asar (Hanger) Tr. 1390-91).

664. Stephen Blatchford, executive chairman of Blatchford, explained that in 2014, Endolite developed a strategic plan to double its revenues over a five-year period by 2020, and to double it again by 2025, but he did not specifically attribute the planned growth to growth in sales of MPKs in the United States. (Blatchford (Endolite) Tr. 2209).

665. [redacted]

**c. Nabtesco**

666. In 2016, Nabtesco sold [redacted] MPKs in the United States, while Freedom sold [redacted] In 2017, Nabtesco sold [redacted] MPKs in the United States, while Freedom sold [redacted] (PX06001A (Scott Morton Expert Report at 084, Table 7), *in camera*).

667. Some clinic customers are not familiar with MPKs manufactured by Nabtesco. (*See* Senn (COPC) Tr. 194; PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 61); PX05151 (Patton (Prosthetic Solutions), Dep. at 32); PX05149 (Brandt (Ability P&O), Dep. at 241-42); PX05167 (Filippis (Wright & Filippis) Dep. at 115)).

668. Some clinic customers who had heard of MPKs manufactured by Nabtesco would not fit a Nabtesco MPK on a patient because of difficulties with customer service or concerns about the reliability of the MPK. (Ford (POA) Tr. 959; PX05141 (Bright (North Bay) Dep. at 87-88)).

669. North Bay Prosthetics "tried to do a trial fit one time" on the Nabtesco Allux "and it didn't work, like the electronics didn't function, so we weren't even able to begin the trial because it didn't work, and that was our last attempt at it. It was something we did not – it's a lot cheaper, I believe, but it wasn't worth the risk of outcomes for us." (PX05141 (Bright (North Bay) Dep. at 87-88)).

670. POA has not purchased an MPK from Nabtesco. For POA, Nabtesco's level of service and technical support is "not nearly to the degree that Össur or Ottobock and Freedom have." (Ford (POA) Tr. 958-59)).

671. Scott Sabolich Prosthetics and Research has not fit an Allux MPK on any patients and Mr. Sabolich characterized it as a "very janky knee." (Sabolich (SSPR) Tr. 5861, 5889-90).

672. COPC had not purchased any MPKs from Nabtesco in 2017 and does not have any plans to shift purchases of MPKs from Freedom to Nabtesco because Keith Senn of COPC is not familiar with their knee. (Senn (COPC) Tr. 194).

673. Nabtesco can manufacture approximately [redacted] Allux MPKs worldwide each year. (Mattear (Nabtesco) Tr. 5753, *in camera*).

674. Jeffrey Collins, the president of Cascade, a distributor of prosthetic devices, had estimated its projected sales of the Allux in 2018 to be the same number as it sold in 2017. Cascade made a conservative projection for Allux sales because of "the relative newness of the product and the amount of time that it takes to bring awareness to a new product to the marketplace." Mr. Collins further explained, "There are very well-established brands and commonly used microprocessor knees that are available in the market today . . . available at a competitive price, so it is difficult to bring in a new product at a price point that's similar to those existing products in the market and expect significant sales increases." (Collins (Cascade) Tr. 3290-91).

675. Bradley Mattear of Proteor described Nabtesco as a "tadpole in the ocean" and "[i]n the grand scheme of things," nobody knew who they were. (Mattear (Nabtesco) Tr. 5744-45).

#### d. DAW

676. DAW's MPK sales have been decreasing since 2015. DAW sold [redacted] MPKs in 2015, [redacted] MPKs in 2016, and [redacted] MPKs as of December 15, 2017. (PX04002 (Marquette (DAW) Decl. at 001-02 ¶ 5), *in camera*).

677. Many clinic customers have never fit a DAW MPK. (*See* Ford (POA) Tr. 958; Ell (Mid-Missouri O&P) Tr. 1736; Oros (Scheck & Siress) Tr. 4811; Sabolich (SSPR) Tr. 5891; PX05108 (Yates (Jonesboro P&O) Dep. at 57-58, 64); PX05149 (Brandt (Ability P&O) Dep. at 243-44); PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 35-36)).

678. Many clinic customers would not fit a DAW MPK on a patient because of difficulties with customer service, interactions with sales representatives, or concerns about the reliability of the MPK. (*See* Ford (POA) Tr. 957-58; Ell (Mid-Missouri O&P) Tr. 1736; PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 35-36)).

### 2. Efficiencies

#### a. Ottobock synergies evaluation

679. [redacted]

680. On September 29, 2017, Ottobock engaged an outside consultant, A.T. Kearney (International) AG ("A.T. Kearney") to assist in post-acquisition planning. (RX0616 (Ottobock)).

681. A.T. Kearney's responsibilities included establishing a program for the integration of Freedom, defining synergy targets, identifying synergy opportunities, and developing synergy capture plans. (RX0616 (Ottobock) at 00004). An integration team ("Integration Team") was formed, consisting of personnel from Ottobock, Freedom, and A.T. Kearney. (PX05127 (Röessing (Ottobock) Dep. at 50-51); PX05154 (Baggenstoss (A.T. Kearney), Dep. at 27, 33)).

682. Dr. Juerg Baggenstoss, an external consultant from A.T. Kearney, was the Integration Team leader. (PX01310 (Ottobock) at 005; PX05127 (Röessing (Ottobock) Dep. at 34, 50-51)).

683. For Ottobock, a dual brand strategy is when a single company has two different brands in the same market. With respect to the Acquisition, the dual brand strategy refers to positioning Freedom in the market as a company with advanced products and positioning Ottobock as a company with premier products. Under a dual brand strategy, the two companies would operate independently with common ownership but would have different value propositions and price points in the same market, with the goal of gaining increased usage of both products. (Schneider (Ottobock) Tr. 4414; Carkhuff (Freedom) Tr. 650-51).

684. [redacted]

685. In mid-December 2017, the Integration Team stopped all work on evaluating any potential efficiencies or cost savings from the Acquisition. (PX05127 (Röessing (Ottobock) Dep. at 36-37); PX05154 (Baggenstoss (A.T. Kearney) Dep. at 26); PX05170 (Schneider (Ottobock) Dep. at 22-23)).

686. At the time the Integration Team stopped all work in mid-December 2017, the work relating to identifying synergies opportunities was at an "early stage" and "incomplete." The work regarding integration planning was either not started or in an early stage. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 27-28, 33)).

687. [redacted]

688.

689.

690. David Reissfelder, Freedom's CEO,[61] does not believe that "any decisions" were made "at any point about . . . any aspect of the integration" in the United States. (PX05138 (Reissfelder (Freedom) Dep. at 125)).

691.

**b. James Peterson's efficiencies estimates**

692.

[61] David Reissfelder is Freedom's current CEO. He became CEO on September 27, 2017. Prior to joining Freedom, Mr. Reissfelder was the vice president and general manager for Bionics Medical Technologies in Bedford, Massachusetts ("Bionics"), which was acquired by Ottobock in March 2007. (PX05138 (Reissfelder (Freedom) Dep. at 4, 8)).

693. [redacted]

694. [redacted]

695. Mr. Peterson presents in Table 9 of his expert report the value of the potential merger-specific efficiencies that Ottobock could achieve if it realized 30% or 50% of the synergies estimates contained in the Financial Model. (RX1048 (Peterson Expert Report at 0053-54 ¶ 133 & Table 9); Peterson, Tr. 6727-28).

696. Mr. Peterson estimated approximately [redacted] as an upper limit of the potential merger-specific efficiencies that Ottobock could achieve by 2022. (RX1048 (Peterson Expert Report at 0049, Table 8), *in camera*; Peterson, Tr. 6671-72, *in camera*; PX05174 (Peterson Dep. at 49-50, 53), *in camera*).

697. Mr. Peterson estimated approximately [redacted] as a lower limit of the potential merger-specific efficiencies that Ottobock could achieve by 2022. (RX1048 (Peterson Expert Report at 0054, Table 9), *in camera*; Peterson, Tr. 6728, *in camera*; PX05174 (Peterson, Dep. at 53), *in camera*).

698. Mr. Peterson estimated that [redacted] would yield between [redacted] in cost savings by 2022. (RX1048 (Peterson Expert Report at 0054, Table 9), *in camera;* Peterson, Tr. 6673-76, *in camera*).

699. Mr. Peterson estimated that [redacted] would yield between [redacted] in cost savings by 2022. (RX1048 (Peterson Expert Report at 0054, Table 9), *in camera*; Peterson, Tr. 6673-76, *in camera*).

700. Mr. Peterson concluded based on the financial model that [redacted] would produce cost increases – a "dis-synergy" – ranging from [redacted] by 2022, but also concluded that [redacted] would "result in overall enhancements to gross margin." (Peterson, Tr. 6729-30, *in camera*; RX1048 (Peterson Expert Report at 0054, Table 9), *in camera*).

701. The Financial Model prepared by the Integration Team and relied upon by Mr. Peterson, relies upon numerous assumptions. (Peterson, Tr. 6669; PX05174 (Peterson, Dep. at

269-70) (referring to Financial Model's "running list of certain . . . assumptions"); *see also* PX03185 (Ottobock) at 004 (Financial Model listing assumptions)).

702. Mr. Peterson acknowledged that verification of efficiencies claims usually includes an evaluation of the reasonableness of the parties' assumptions and their analysis. (Peterson, Tr. 6736).

703. Mr. Peterson evaluated the Financial Model by altering various assumptions to see how the alterations impacted the model. Mr. Peterson then discounted the synergies amounts in the model to arrive at his efficiencies estimate. (Peterson, Tr. 6736-37). As an example, with respect to the Integration Team's assumptions about gross margins, Mr. Peterson explained that he "relied upon the fact that [Ottobock] hired a third-party consultant [A.T. Kearney] who had done significant work over a significant period of time in connection with direction and input from management over an extended period of time, then buil[t] a model, and then . . . I also took a significant discount on those implied efficiencies." (PX05174 (Peterson, Dep. at 271-72)).

704. Mr. Peterson described what he referred to as his "sensitizing" of the Financial Model, which consisted of discounting the assumed efficiency benefits by various percentages. (Peterson, Tr. 6673-75; PX05174 (Peterson, Dep. at 276) (stating that he "relied more on just giving the overall efficiencies a haircut")).

705. As support for the opinion that asserted [redacted] efficiencies are merger-specific, Mr. Peterson's expert report states: "The [redacted] projected at New Freedom are driven by the existing manufacturing infrastructure and expertise resident at Ottobock. Absent this specific capability, it is unknown if another strategic buyer could achieve such synergies." (RX1048 (Peterson Expert Report at 0052-53 ¶ 132), *in camer*a).

706. Mr. Peterson's expert report does not assess whether Freedom could have achieved [redacted] efficiencies through independent cost-savings initiatives. (RX1048 (Peterson Expert Report at 0052-53 ¶ 132), *in camera*).

707. As support for the opinion that asserted [redacted] efficiencies are merger-specific, Mr. Peterson's expert report states: "In order to execute on some of the [redacted] summarized above, New Freedom planned to invest in its existing [redacted] This was anticipated to result in overall enhancements to [redacted] (RX1048 (Peterson Expert Report at 0052-53 ¶ 132), *in camera*).

708. Mr. Peterson's expert report does not assess whether Freedom could have achieved [redacted] efficiencies through independent cost-savings initiatives. (RX1048 (Peterson Expert Report at 0052-53 ¶ 132), *in camera*).

709. [redacted]

710. Mr. Peterson's expert report does not explain why Freedom could not have achieved efficiencies through another type of transaction. (RX1048 (Peterson Expert Report at 0052-53 ¶ 132)).

711. Mr. Peterson assumed that the asserted efficiencies would be passed on to consumers based on the concept that . . . enable[] a company to be more flexible when it comes to pricing." Mr. Peterson did not attempt to calculate an estimate of the efficiencies that would be realized by consumers. (PX05174 (Peterson, Dep. at 284, *in camera*); Peterson, Tr. 6746-49, *in camera*).

712. Mr. Peterson did not evaluate whether the claimed efficiencies with respect to the would be realized in the United States. (Peterson, Tr. 6746-49; PX05174 (Peterson, Dep. at 281-82)).

### 3. Market constraints

#### a. Power buyers

713. Hanger represents a large portion of the prosthetic clinics in the United States. Hanger has 800 clinics across the country and employs about 1,500 clinicians. By comparison, there are about 3,400 total clinics in the United States and about 6,500 total clinicians in the United States. (Asar (Hangar) Tr. 1312-13, 1316-17, 1379-80; *see also* Blatchford, Tr. 2273 (testifying that Hanger controls between 25 to 30% of U.S. prosthetic clinics); Carkhuff (Freedom) Tr. 298 (testifying that Hanger is virtually every manufacturer's biggest customer in the United States); Sanders (United) Tr. 5379 (testifying that Hanger is the largest orthotics and prosthetics network that has a contract with United Healthcare in the United States)).

714. In 2017, Hanger purchased approximately of its MPKs from Ottobock and approximately of its MPKs from Freedom, for a total of (Asar (Hanger) Tr. 1444, *in camera*; PX03205 (Hanger) at 008-09 (Supplier Consolidation Presentation), *in camera*).

715. Hanger is Ottobock's largest United States customer for MPKs. (Schneider (Ottobock) Tr. 4401).

716.

717. A little over half of Freedom's sales in the United States are to Hanger or to Southern Prosthetic Supply ("SPS"), which is owned by Hanger (F. 43). (Carkhuff (Freedom) Tr. 695).

718. [redacted]

719. Hanger is Össur's largest lower-limb prosthetics customer in the United States. (De Roy (Ossür) Tr. 3667).

720. Hanger is a very important customer to Endolite, and Endolite gives Hanger its highest discount for MPKs. (Blatchford (Blatchford) Tr. 2273).

721. Hanger is aware that the volume of its purchases improves its negotiating ability with suppliers. Hanger lists as "competitive strengths" on its SEC form 10-K that Hanger has purchasing power for orthotics and prosthetic components and that its purchasing power promotes the usage by its patient care clinics of clinically appropriate products that also enhance Hanger's profit margins. (Asar (Hanger) Tr. 1554-56; RX0341 at 00008-09).

722. After learning about the Acquisition, Hanger undertook an assessment of the potential impact of the Acquisition on Hanger. A presentation regarding the assessment was given in February 2018 and titled, "Supplier Consolidation – The Path Forward" ("Supplier Consolidation Presentation"). (Asar (Hanger) Tr. 1432-34; PX03205 (Hanger) (Supplier Consolidation Presentation)).

723. The Supplier Consolidation Presentation outlined "a couple of scenarios that [Hanger staff] modeled out for us in terms of what the impact would be." (Asar (Hanger) Tr. 1433; PX03205 (Hanger) at 009-10 (Supplier Consolidation Presentation)).

724. In one scenario from the Supplier Consolidation Presentation, Hanger modeled reducing its Ottobock MPK purchases from [redacted] of Hanger's total MPK purchases to [redacted] (Asar (Hanger) Tr. 1433-34, *in camera*; PX03205 (Hanger) at 009 (Supplier Consolidation Presentation), *in camera*).

725. Under one scenario modeled in the Supplier Consolidation Presentation, if Hanger were able to reduce Ottobock's and Freedom's combined share of Hanger MPKs to [redacted] reduce volume by [redacted] units, and shift that volume to Össur and Endolite, Hanger would save [redacted] per year, based on Ottobock's pricing. (PX03205 (Hanger) at 011 (Supplier Consolidation Presentation), *in camera*; Asar (Hanger) Tr. 1506, *in camera*).

726. Hanger did not assess the feasibility or likelihood of any of the scenarios described in the Supplier Consolidation Presentation. Mr. Asar, Hanger's CEO, described the assessment as "a small survey of a bunch of clinicians to figure out just why are you picking

Ottobock" MPKs. (Asar (Hanger) Tr. 1446-47, 1453; PX05153B (Asar (Hanger) Dep. at 147-48) (stating that Hanger has not done any assessment of the likelihood of any of the scenarios in the Supplier Consolidation Presentation and does not have a plan to achieve the Ottobock share decreases aside from ensuring that clinicians "are fully aware of the features, the benefits, and the economics" of other MPKs)).

727. Even if the prices of the C-Leg and the Plié increase post-Acquisition, Hanger plans to continue offering both products to patients because "both these products are good products, our clinicians like them, our patients use them. We would see no reason not to offer them." (Asar (Hanger) Tr. 1457-58).

728. Approximately 60% of Ottobock's United States sales are to customers other than Hanger. (Solorio (Ottobock) Tr. 1626-27).

729. Approximately 50% of Freedom's United States sales are to customers other than Hanger. (Carkhuff (Freedom) Tr. 695).

730. Different clinic customers have different bargaining leverage in negotiations with MPK suppliers, and different abilities to negotiate lower prices. (Carkhuff (Freedom) Tr. 402; PX05007 (Carkhuff (Freedom) IHT at 122); Testerman (Freedom) Tr. 1280-81; PX01023 (Freedom) at 004).

**b. Insurance reimbursement**

731. A clinic's profit for fitting an MPK takes into account the reimbursement on all components of the lower-limb prosthetic, not solely the reimbursement on the MPK. (Brandt (Ability P&O) Tr. 3771-73; PX05141 (Bright (North Bay) Dep. at 178-79); Ell (Mid-Missouri O&P) Tr. 1815).

732. The components of the overall lower-limb prosthetic have additional L-Codes that provide reimbursement to clinics and allow some amount of margin for the clinic, such as the foot, socket, suspension mechanism, adapters, hardware, and liners. (Senn (COPC) Tr. 275-76; Brandt (Ability P&O) Tr. 3772-73; PX05140 (Weott (Orthotic & Prosthetic Centers) Dep. at 44-45); RX0863 (SSPR); PX03282 (Ability P&O)).

733. The reimbursement on a prosthetic knee is a significant percentage of the reimbursement for the overall lower-limb prosthetic. (Senn (COPC) Tr. 275). For example, for COPC, roughly half of the overall reimbursement for a lower-limb prosthesis comes from reimbursement for the MPK. (Senn (COPC) Tr. 200).

734. The total allowable Medicare reimbursement for an entire lower-limb prosthetic, including an MPK, is approximately $45,000. As of 2018, the Medicare reimbursement rate for MPKs under L-Code 5856 ranges from $20,657 to $27,543. (Senn (COPC) Tr. 200; PX05132 (Sabolich (SSPR) Dep. at 190); Additional Joint Stipulations of Fact, JX003 at 2 ¶ 9).

735. For Hanger and COPC, it is currently profitable to fit a C-Leg 4. (Senn (COPC) Tr. 275; Asar (Hanger) Tr. 1382.

736. With Hanger's current acquisition price of the Plié of [redacted] it would still be profitable for Hanger to prescribe the Plié if the price increased by a thousand dollars. If the price for the C-Leg were to increase by a thousand dollars from Hanger's current acquisition price of [redacted] Vinit Asar of Hanger believes it would still be profitable for Hanger to fit a C-Leg, although the margins would be "getting tighter" with the increase. (Asar (Hanger) Tr. 1382-83, *in camera*).

737. For COPC, based on the Plié 3's current price of [redacted] if the price of the Plié increased by almost 10%, or [redacted] it would still be profitable for COPC to fit the Plié 3 on its patients. (Senn (COPC) Tr. 276-77), *in camera*).

738. Respondent's expert witness, Dr. David Argue, estimated that the average price of a Plié 3 in 2016 was [redacted] and the average price for Ottobock's C-Leg 4 in 2016 was [redacted] (F. 242, 270).

739. Dr. David Argue agrees that it is possible that a clinic may earn a profit on the prosthetic leg as a whole even if the clinic does not make a profit on the MPK component. (Argue Tr. 6315-16, *in camera*).

#### 4. Failing company defense

##### a. Freedom's financial situation

###### i. Freedom's debt

740. Freedom was founded in 2002. (Carkhuff (Freedom) Tr. 293). Since its founding, Freedom has recapitalized twice, in 2008 and in 2012. (PX05007 (Carkhuff (Freedom) IHT at 25); PX05103 (Kim (Freedom) Dep. at 17-18)). In 2008, two private equity firms, Tailwind Capital Partners and Telegraph Hill, "bought 80 percent of the company . . . and, basically, provided additional capital for the company to achieve its growth plans." (PX05103 (Kim (Freedom) Dep. at 17-18); Carkhuff (Freedom) Tr. 304).

741. In 2012, Health Evolution Partners ("HEP"), a private equity firm, purchased about a 95% interest in Freedom for [redacted] (PX05103 (Kim (Freedom) Dep. at 18-19), *in camera*; Carkhuff (Freedom) Tr. 310, 631, *in camera*).

742. At the time of the Acquisition, HEP was the majority shareholder of Freedom and Parker Hannifin Corporation ("Parker Hannifin") was a minority shareholder. (Carkhuff (Freedom) Tr. 311). Parker Hannifin employee Achilleas Dorotheou was on the board of directors of Freedom from 2014 through October 2017. (PX05125 (Dorotheou (Parker Hannifin) Dep. at 10); PX05103 (Kim (Freedom) Dep. at 113-14)).

743. Freedom entered into a Credit Agreement, dated February 16, 2012 (the "Credit Agreement"), that provided Freedom with a [redacted] term loan. (RX0826 (Freedom) at 00001, 00028, *in camera*). The term loan was provided by two lenders: Bank of Montreal ("BMO") and Madison Capital Funding, LLC ("Madison Capital") (collectively, the "Lenders"). (Kim (Freedom) Tr. 2602, *in camera*; RX0826 (Freedom) at 00001 & 00095-96, *in camera*).

744. BMO and Madison Capital each held 50% of Freedom's outstanding debt under the Credit Agreement. (Kim (Freedom) Tr. 2602).

745. The Credit Agreement contained a "Term Loan Maturity Date," which is the date by which any outstanding amounts under the term loan were due and payable to the Lenders. At the time the Credit Agreement was executed in 2012, the Term Loan Maturity Date was February 16, 2017. (RX0826 (Freedom) at 00028; Kim (Freedom) Tr. 2602).

746. The Credit Agreement was ultimately amended eight times. (Kim (Freedom) Tr. 2602-03).

747. The first through sixth amendments to the Credit Agreement were executed on March 31, 2013, June 7, 2013, November 24, 2014, June 30, 2016, August 15, 2016, and August 22, 2016. (RX0831 (First Amendment); RX0832 (Second Amendment); RX0829 (Third Amendment); RX0827 (Fourth Amendment); RX0830 (Fifth Amendment); RX0828 (Sixth Amendment)). None of the first six amendments changed the Term Loan Maturity date of February 16, 2017. (Kim (Freedom) Tr. 2603).

748. By the end of 2016, Freedom owed the Lenders approximately [redacted] (Kim (Freedom) Tr. 2604, *in camera*).

749. [redacted]

750. [redacted]

751. [redacted]

752. [redacted]

753. [redacted]

754. HEP invested an additional in Freedom and Freedom formally engaged Moelis & Company ("Moelis") in May 2017 in compliance with the Seventh Amendment. (Smith (HEP) Tr. 6446-47, *in camera*; Kim (Freedom) Tr. 2605-08, *in camera*).

755.

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758.

759. Ottobock satisfied Freedom's debt obligation to the Lenders at the closing of the Acquisition. (Kim (Freedom) Tr. 2668-69, *in camera*).

**ii. Freedom's financial metrics**

760. Respondent's expert witness, James Peterson, calculated Freedom's revenues, gross profits, operating expenses, EBITDA (F. 761), and operating income for 2012 through the first six months of 2017 using Freedom's audited consolidated income statements for 2012 through 2016 and an unaudited consolidated income statement the first six months of 2017 from which he calculated annualized year-to-date figures for 2017. (RX1048 (Peterson Expert Report at 0007 ¶ 15 & n.25-27) (relying on RX0822, RX0823, RX0824, and PX1292)). These calculations are reflected in his expert report as "Table 1 Freedom's Historical Income Statement." (RX1048 (Peterson Expert Report at 0008)).

761. EBITDA, which stands for earnings before interest, (income) taxes, depreciation, and amortization, is an acronym used by analysts to focus on a particular measure of cash flow used in valuation. (RX1048 (Peterson Expert Report at 0007 n.27)).

762. EBITDA is an important metric in measuring the financial health of a company because it is an approximation of the operating cash flow generated by the business of the company. EBITDA needs to be high enough to cover debt service and capital expenditures, which

are cash outflows, as well as providing positive net cash flow, which is an indicator of the value of the business. (Kim (Freedom) Tr. 2622).

763. Freedom's EBITDA, operating income, and gross profit percentage fell every year from 2012 to 2016. (F. 764-766; RX1048 (Peterson Expert Report at 0008, Table 1) (Freedom's Historical Income Statement)).

764. Freedom's EBITDA was $6,347,000 in 2012; $4,180,000 in 2013; $3,414,000 in 2014; [redacted] (RX1048 (Peterson Expert Report at 0008, Table 1) (Freedom's Historical Income Statement), *in camera*; Kim (Freedom) Tr. 2622-23, *in camera*).

765. Freedom's operating income was ($836,000) in 2012; ($4,061,000) in 2013; ($4,815,000) in 2014; [redacted] (RX1048 (Peterson Expert Report at 0008, Table 1) (Freedom's Historical Income Statement), *in camera*).

766. Freedom's gross profit percentage was 69.2% in 2012; 66.1% in 2013; 65.9% in 2014; [redacted] (RX1048 (Peterson Expert Report at 0008, Table 1) (Freedom's Historical Income Statement), *in camera*).

767. From 2012 through the first six months of 2017, Freedom's gross profit percentage fell by approximately [redacted] (F. 766; Kim (Freedom) Tr. 2621, *in camera*; Carkhuff (Freedom) Tr. 643, *in camera*).

768. Respondent's expert witness, James Peterson, calculated Freedom's cash flow statements for 2012 through 2016 using Freedom's audited consolidated income statements for 2012 through 2016. (RX1048 (Peterson Expert Report at 0016-17 n.83) (relying on RX0822, RX0823, and RX0824)). These calculations are reflected in his expert report as "Table 3 Freedom's Audited Historical Cash Flow Statement." (RX1048 (Peterson Expert Report at 0016)).

769. Freedom experienced a net loss of [redacted] in 2015 and 2016, respectively, from a cash flow perspective. (RX1048 (Peterson Expert Report at 0017, Table 3) (Freedom's Audited Historical Cash Flow Statement), *in camera*).

770. Freedom's net cash provided (used) by operating activities was [redacted] (RX1048 (Peterson Expert Report at 0017, Table 3) (Freedom's Audited Historical Cash Flow Statement), *in camera*).

[62] The use of parentheses around certain numbers in F. 764-765 means that the number inside the parenthesis is a negative number. *See* Kim (Freedom) Tr. 2623.

### iii. Changes in Freedom's financial situation

#### (a) 2015 and early 2016

771. "[A]number of internal operational missteps and increased market competition in 2015 and early 2016" led to lower sales and a decreasing EBITDA and free cash flow for Freedom. Such increased market competition included increased sales and marketing efforts by Freedom's competitors and Ottobock's release of the C-Leg 4 in the fourth quarter of 2015, which resulted in a [redacted] decline in Freedom's knee unit sales from September 2015 through April 2016 compared to the same time period for the prior year. In addition, Freedom failed to keep "headcount and expenses in-line with forecasted revenue growth." PX03008 (Madison Capital) at 001, 004-06 (June 29, 2016 Fourth Amendment Memo), *in camera*).

772. Freedom delayed the launch of its Kinnex microprocessor ankle from the end of 2015 to the third quarter of 2016, which "resulted in significant project cost overruns as well as unabsorbed FTE[63] costs as the Company had begun to ramp [up its] manufacturing operations 12 months prematurely." (PX03008 (Madison Capital) at 005, *in camera* (June 29, 2016 Fourth Amendment Memo)).

773. Freedom identified the following "2015 and 2016 Events Affecting Performance: Missteps by operational leadership, particularly with service policy; Impact on K-3 revenues of U.S. regulatory audits, which affected all industry players; Product launches by competitors; Issues with durability and service on Plié 3; Settlement of IP litigation on ankle product." (PX02034 (HEP) at 048, *in camera* (March 2017 Freedom presentation to Ottobock)).

774. Due to "a number of [Freedom's] failures over the past 18-months," on April 1, 2016, HEP and Freedom's board of directors replaced Freedom's then-CEO, Maynard Carkhuff with David Smith, "an HEP operating partner with significant operating experience." (PX03008 (Madison Capital) at 005-06).

775. On April 1, 2016, David Smith became Freedom's chairman and CEO and Maynard Carkhuff's role changed from CEO to vice chairman and chief innovation officer. (Smith (HEP) Tr. 6408; Carkhuff (Freedom) Tr. 291-92). David Smith made "[k]ey sales leadership additions with restructure of sales, clinical and marketing structure and compensation." (PX02034 (HEP) at 049 (*in camera*)).

776. David Smith's initial objectives as CEO were to try to "improve product portfolio, improve . . . customer satisfaction, improve profitability, [and] improve innovation." (Smith (HEP) Tr. 6422).

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[63] Full-time equivalent indicates the workload of an employee.

### (b) Late 2016 and 2017

777. Freedom identified the following "2016 Actions: Added David A. Smith as Chairman and CEO; Replacement of COO and Head of Sales; Reversal of service policy errors; Enhancement of Plié 3 product quality and service; Service model improvements and investment; Key sales leadership additions with restructure of sales, clinical and marketing structure and compensation; Significant enhancement of R&D pipeline." (PX02034 (HEP) at 049, *in camera* (March 2017 Freedom presentation to Ottobock)).

778. In September 2016, Freedom's CEO, David Smith, presented a 2017 Strategic Plan to Freedom's board of directors ("2017 Strategic Plan"). This plan detailed Freedom's shortcomings and plans for improvement through 2017. (PX01014 (Freedom). Freedom's financial performance in 2016 was a significant factor that Freedom used in setting its plan for 2017. (Kim (Freedom) Tr. 2623-25).

779. To implement the 2017 Strategic Plan, David Smith requested [redacted] "of incremental equity support from shareholders to provide [Freedom] with liquidity, operating flexibility, and growth capital[.]" (PX03009 (Madison Capital) at 002, *in camera*).

780. In January 2017, HEP committed to provide Freedom with [redacted] of capital support. (PX03009 (Madison Capital) at 002, *in camera*). This commitment was based upon Madison Capital's demands to extend the Term Loan Maturity Date in connection with the Seventh Amendment. (PX03009 (Madison Capital) at 002, *in camera*; Smith, (HEP) Tr. 6463).

781. Freedom identified the following "2017 Momentum & Results: Release of improved Plié 3 and Kinterra; Release of Maverick foot line; Release of Kinnex MPC Ankle; Alpha testing and fitting of Quattro; Significant revenue turnaround and growth started in September [2016] with the last few months results: [redacted] (PX02034 (HEP) at 050 (March 2017 Freedom presentation to Ottobock), *in camera*).

782. In early 2017, Freedom's "January and February revenues were [redacted] ahead of plan"; "EBIT[A was] [redacted] ahead of plan year-to-date, despite accelerated product pipeline"; and Freedom expected "[m]omentum" from "Plié 3 product quality improvements (already resulting in [redacted] volume increase over last year)." (PX02034 (HEP) at 024 (March 2017 Freedom presentation to Ottobock), *in camera*).

783. Freedom experienced a [redacted] year-over-year growth in sales of the Plié from 2016 to 2017. (PX02032 (Freedom) at 038, *in camera*; *see also* Carkhuff (Freedom) Tr. 570-71; Smith (HEP) Tr. 6532, 6496-97, *in camera* (testifying that the Plié volume increase was "a big reason why the company started to turn")).

784. In February 2017, Freedom's "[c]ash was well above plan based on strong sales" during the previous three months and "lower than planned" capital expenditures and operating expenses. (PX01107 (Freedom) at 002 (Freedom Financial Flash Report[64])).

785. In the first quarter of 2017, Freedom had a positive EBITDA of [redacted] exceeding its forecasted EBITDA, and a negative cash flow of [redacted] (PX01105 at 005 (March 2017 Financial Statements), *in camera*).

786. Freedom's "[s]ales performance had improved significantly" by March 2017. (Kim (Freedom) Tr. 2532).

787. For the first quarter of 2017, Freedom's year-to-date total actual revenue was [redacted] planned revenue was [redacted] and previous year first quarter revenue was [redacted] (PX02032 (Freedom) at 005 (Freedom's board of directors meeting presentation, April 19, 2017), *in camera*). Actual revenue for first quarter of 2017 was about [redacted] ahead of plan, and about [redacted] ahead of revenue for the first quarter of the previous year. (Smith (HEP) Tr. 6514, *in camera*).

788. In May 2017, "[c]ash before series B equity contribution of [redacted] [was] ahead of plan due to operating results better than plan and control of cap ex." (PX01293 (Freedom) at 001, *in camera*; *see also* Kim (Freedom) Tr. 2557-58, *in camera* (testifying that Freedom's cash balance was above where it was expected to be when the annual plan was developed in late 2016 and that "operating results better than plan" means that Freedom's profit was above plan)).

789. May 2017 revenues were [redacted] of plan and [redacted] over the prior year; year-to-date revenues were [redacted] of plan and [redacted] over the prior year; and year-to-date EBITDA was [redacted] ahead of plan. (PX01103 (Freedom) at 001, *in camera*).

790. June 2017 revenues were [redacted] of plan and [redacted] over the prior year. "June 2017 was the highest revenue month in Freedom's history." Year-to-date revenues were [redacted] of plan and [redacted] over the prior year. (PX01292 (Freedom) at 001, *in camera*; *see also* Kim (Freedom) Tr. 2566, *in camera*).

791. In June 2017, year-to-date EBITDA was [redacted] ahead of plan. Year-to-date adjusted EBITDA was [redacted] ahead of plan. (PX01292 (Freedom) at 001, *in camera*; *see also* Kim (Freedom) Tr. 2566-67, *in camera*).

792. In June 2017, cash before year-to-date equity contribution was approximately [redacted] ahead of plan, "primarily due to favorable operating results and cap ex below plan." (PX01292 (Freedom) at 001, *in camera*; *see also* Kim (Freedom) Tr. 2567, *in camera*).

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[64] Freedom's CFO, Lee Kim, drafted "flash reports" updating Freedom's board of directors and executives about the company's performance. Mr. Carkhuff would occasionally review and provide input to the flash reports before they were circulated. (Carkhuff (Freedom) Tr. 406-07).

793. In July 2017, "[c]ash before year to date series B equity contribution of [redacted] ahead of plan due to operating results better than plan and control of cap ex." (PX01312 (Freedom) at 001, *in camera*; *see also* Kim (Freedom) Tr. 2569, *in camera*).

794. In August 2017, "[c]ash before [year-to-date] series B equity contribution of [redacted] ahead of plan due to operating results better than plan and control of cap ex." (PX01313 (Freedom) at 002, *in camera*; Kim (Freedom) Tr. 2571, *in camera*).

795. August 2017 revenues were [redacted] of plan and [redacted] over the prior year; year-to-date revenues were [redacted] of plan and [redacted] over the prior year; year-to-date EBITDA was [redacted] ahead of plan; and year-to-date cash balance was approximately [redacted] higher than anticipated by August 31, 2017. (PX02028 (HEP) at 001, *in camera*).

796. Freedom's consolidated income statements for the month ending August 31, 2017 reflected positive EBITDA of [redacted] (PX02028 (HEP) at 003, *in camera*).

797. Over the first eight months of 2017, Freedom saw a [redacted] increase in revenue and a [redacted] increase in EBITDA over the same time period in 2016. (PX02028 (HEP) at 003, *in camera*).

**iv. Independent auditor's report**

798. Prior to the Acquisition, it was Freedom's regular practice to retain independent auditors to conduct an annual audit of Freedom's financial statements. (Kim (Freedom) Tr. 2494-95).

799. Independent auditors typically would audit Freedom's financial statements in mid-February or mid-March of each year and would provide a report on Freedom's financial statements at the end of the audit process. (Kim (Freedom) Tr. 2496-97, 2500-01).

800. The independent auditor's report would include an opinion on whether the financial statements fairly present the financial position of Freedom, in accordance with Generally Accepted Accounting Principles ("GAAP"). (Kim (Freedom) Tr. 2500-01).

801. Under GAAP, "[i]n connection with preparing financial statements for each annual and interim reporting period, an entity's management shall evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable)." (PX06002 (Hammer Expert Report at 024 ¶ 60)).

802. Under GAAP, "[o]rdinarily, conditions or events that raise substantial doubt about an entity's ability to continue as a going concern relate to the entity's ability to meet its obligations as they become due. Accordingly, management's evaluation of an entity's ability to continue as a going concern ordinarily is based on conditions and events that are relevant to an entity's ability to meet its obligations as they become due within one year after the date that the financial statements are issued." (PX06002 (Hammer Expert Report at 024-25 ¶ 61)).

803. A going concern qualification is a qualification that an auditor has substantial doubt about a company's ability to continue for at least one year after the auditor signs the audit report. (Hammer, Tr. 2942, 2946).

804. Lee Kim, Freedom's CFO, was responsible for managing the independent audit process, interacting with the financial auditors that were retained by Freedom for its annual audits, and providing requested financial information to the independent auditors. (Kim (Freedom) Tr. 2495, 2497).

805. Lee Kim is a licensed certified public accountant who, prior to joining Freedom, had worked at the Deloitte auditing firm for six years, and had also worked at seven to eight other companies. (Kim (Freedom) Tr. 2495-96, 2646).

806. The last independent audit of Freedom's financial statements prior to the Acquisition was an audit of Freedom's 2016 financial statements conducted by Squire & Company ("Squire"), which was completed in March 2017 and signed by Squire on April 6, 2017. (Kim (Freedom) Tr. 2501; PX02023 (HEP) at 016).

807. During the course of the independent audit of Freedom's 2016 financial statements, Lee Kim, Freedom's CFO, provided Squire with information regarding the financial state of Freedom and strived to be truthful in his communications with Squire. (Kim (Freedom) Tr. 2502).

808. During the course of the independent audit of Freedom's 2016 financial statements, Shane Edwards of Squire informed Mr. Kim that Squire was considering including a paragraph in its audit opinion expressing doubt about Freedom's ability to continue as a going concern. (Kim (Freedom) Tr. 2502-03).

809. On March 22, 2017, Mr. Edwards of Squire requested that Mr. Kim draft a memorandum that addresses the conditions/events that raise substantial doubt, provides an evaluation of Freedom's ability to meet its financial obligations, and documents the plan to mitigate the problem. Mr. Edwards wrote to Mr. Kim: "If you can alleviate the conditions or events that raise substantial doubt about the entity's ability to continue as a going concern, . . . we can remove the going concern paragraph from the audit opinion." (PX01294 at 002; Kim (Freedom) Tr. 2503).

810. On March 23, 2017, Lee Kim, Freedom's CFO, provided Squire with the memorandum that Squire requested (F. 809) ("Going Concern Memo"). Mr. Kim drafted the Going

Concern Memo with input from Freedom's sales and marketing team, but without input from Freedom's CEO, David Smith. (PX05126 (Kim (Freedom) Dep. at 48-50, 52-55; Kim (Freedom) Tr. 2504, 2510, 2647-48).

811. Mr. Kim sent the Going Concern Memo to Maynard Carkhuff, Freedom's vice chairman, on March 23, 2017. (PX01087 (Freedom) (email attaching Going Concern Memo); Kim (Freedom) Tr. 2505-06). Mr. Kim could not recall if he sent the Going Concern Memo to Freedom's CEO, David Smith, who testified that he had not received or reviewed it. (Kim (Freedom) Tr. 2647; Smith (HEP) Tr. 6451-52).

812. At the time he wrote the Going Concern Memo, Mr. Kim believed that the plan that Freedom management had in place could alleviate the conditions raising substantial doubt about the company's ability to continue as a going concern. (Kim (Freedom) Tr. 2540).

813. On March 23, 2017, Shane Edwards of Squire replied to Mr. Kim as follows: "Great memo Lee . . . and indeed could well be the mother of all going concern memos. We will remove the going concern modification in the audit opinion. However, as required, we will keep the footnote that talks about the issues." (PX01294 (Freedom) at 001 (email chain attaching draft consolidated financial statements)).

814. Squire ultimately removed the going concern modification it had been considering including in its opinion, meaning that Squire's report did not include information about issues relating to Freedom's ability to continue as a going concern. (Kim (Freedom) Tr. 2508).

815. On April 20, 2017, Freedom issued its 2016 Consolidated Financial Statements for the Years Ended December 31, 2016 and 2015. (PX02023 (HEP) at 001, 013-40 (email from Lee Kim, Freedom's CFO, attaching compliance and financial documents)).

816. Lee Kim, Freedom's CFO, certified that Freedom's 2016 annual audited report fairly presents in all material respects the financial condition and results of operations for Freedom and signed the annual Compliance Certificate for 2016 on behalf of Freedom. (Kim (Freedom) Tr. 2591).

817. Note 1 of Freedom's 2016 Consolidated Financial Statements for Years Ended December 31, 2016 and 2015 was based on the Going Concern Memo that Mr. Kim provided to Squire. Mr. Kim helped Mr. Edwards draft Note 1. (Kim (Freedom) Tr. 2592).

818. [redacted]

[redacted]

[redacted]

[redacted]

(PX02023 (HEP) at 021-22, *in camera*).

819. On April 6, 2017, Squire signed its Independent Auditor's Report of Freedom's Consolidated Financial Statements for Years Ended December 31, 2016 and 2015. (PX02023 (HEP) at 015-16 (email from Lee Kim, Freedom's CFO, attaching compliance and financial documents)).

820. Squire's Independent Auditor's Report of Freedom's Consolidated Financial Statements for Years Ended December 31, 2016 and 2015 states that Squire "conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform audits to obtain reasonable assurance

about whether the consolidated financial statements are free from material misstatement." (PX02023 (HEP) at 015 (email from Lee Kim, Freedom's CFO, attaching compliance and financial documents)).

821. David Smith, Freedom's chairman and CEO at the time, received Squire's Independent Auditor's Report of Freedom's 2016 Consolidated Financial Statements for Years Ended December 31, 2016 and 2015 on April 20, 2017. (PX02023 (HEP) at 001).

### v. Liquidation

822. In late September 2017, Freedom had approximately [redacted] (PX05005 (Smith (HEP) IHT at 13-14, *in camera*); *see also* PX02028 (HEP) at 007, *in camera*).

823. Freedom never calculated the liquidation value of the company. (Carkhuff (Freedom) Tr. 552; Smith (HEP) Tr. 6551; PX07028 (HEP) at 002 (Response to CID Specification No. 1)).

824. Neither Freedom nor HEP asked Moelis, the investment banker hired by Freedom to help find a refinancing partner or to sell the company (F. 843), to assist in calculating a liquidation value of Freedom. (PX05110 (Hammack (Moelis) Dep. at 200)).

825. Freedom never employed a liquidation method of accounting and never undertook any efforts to value what its various assets could be sold for through liquidation because Freedom was not going to be liquidated. (Kim (Freedom) Tr. 2548).

826. Freedom's August 31, 2017 monthly balance sheet reflected a book value of tangible assets in the amount of [redacted] (PX02028 (Freedom) at 006, *in camera*; *see also* PX06002 at 051 (Table 2) (Hammer Expert Report), *in camera*).

827. [redacted]

828. When entering into the Seventh Amendment (F. 750), Madison Capital believed that Freedom's forecasted [redacted] of liquidity should be sufficient for Freedom to continue its operations through a prolonged sale process in the second half of 2017 without the need for additional outside capital. (PX03009 (Madison Capital) (Seventh Amendment), *in camera*).

829. In July 2017, Madison Capital advised Freedom that it could not lead refinancing, but would participate in someone else's transaction. (PX02093 (HEP) at 001).

#### vi. Forward looking actions

830. Freedom spent more money on sales and marketing in the first eight months of 2017 than it had spent in the first eight months of 2016. (PX02028 (HEP) at 003, *in camera* (showing sales and marketing spend year-to-date through August 31 of [redacted] in 2017 and [redacted] in 2016)).

831. Freedom spent more money on research and development in the first eight months of 2017 than it had spent in the first eight months of 2016. (PX02028 (HEP) at 003, *in camera* (showing research and development spend year-to-date through August 31 of [redacted] in 2017 and [redacted] in 2016)).

832. In March 2017, Freedom expected to earn net sales of [redacted] in 2018, [redacted] in 2019, and [redacted] in 2020; and expected EBITDA of [redacted] in 2018, [redacted] in 2019, and [redacted] in 2020. (PX02034 (HEP) at 021 (Freedom presentation to Ottobock), *in camera*; Carkhuff (Freedom) Tr. 544, *in camera*).

833. As of April 19, 2017, Freedom had hired fives sales representatives for its European operations. (PX02032 (HEP) at 016).

834. [redacted]

835. On July 15, 2017, David Smith, Freedom's chairman and CEO at the time, conveyed that Freedom's "pipeline is the best it's ever been in the history of the company. That investment will be harvested over the next several years." (PX02010 (HEP) at 001).

836. In 2017, Freedom extended the leases for its Irvine, California and Gunnison, Utah facilities for three years each. (PX05005 (Smith (HEP) IHT at 214-15)).

837. Freedom never missed a payroll and Freedom paid out discretionary bonuses to its executives in 2017. (Kim (Freedom) Tr. 2588; PX05126 (Kim (Freedom) Dep. at 160)).

### b. Freedom's options

#### i. Refinancing

838. Shortly after David Smith became CEO of Freedom in April 2016, he began looking for refinancing sources. (Smith (HEP) Tr. 6472).

839. David Smith believed that "refinancing would have been perfect." (Smith (HEP) Tr. 6463). Mr. Smith explained that with refinancing, as opposed to selling the company, Freedom, "could have had a longer run of recovery in the business, we could have had

more revenue growth, we could have rolled out more products, and we would have looked much better in order to do due diligence in a sale process." (Smith (HEP) Tr. 6463-64).

840. Any refinancing would need to provide Freedom with between [redacted] to pay its debt obligations, plus an additional [redacted] to fund operations and growth initiatives, for a grand total of approximately [redacted] (Hammack (Moelis) Tr. 6072, *in camera*; Smith (HEP) Tr. 6425, 6464-65, *in camera*).

841. In an October 7, 2016 Freedom board meeting, one key point the participants discussed was, "New investor, if contributing equity will be very painful to both HEP and Parker [Hannifin] [the owners of Freedom] in terms of the dilution impact." (PX03092 (Parker Hannifin) at 001).

842. In October 2016, although Moelis had a number of meetings and discussions with Freedom and Freedom's board of directors regarding a valuation of Freedom, Moelis had not been asked to contact any possible refinance partners. (PX05110 (Hammack (Moelis) Dep. at 19-20); Hammack (Moelis) Tr. 6063-65, 6081-82).

843. To fullfill the condition imposed by Freedom's lender Madison Capital in the Seventh Amendment, in May 2017, Moelis was formally engaged as an investment banker to help the company find a refinancing partner or to sell the company. (F. 753-754).

844. Moelis maintained a contact log that listed six refinancing sources contacted by Freedom representatives: [redacted] (PX03264 (Moelis) at 001, *in camera*; Hammack (Moelis) Tr. 6071, *in camera*). In addition to these entities, Moelis or Freedom contacted three other refinancing sources: [redacted] (Hammack (Moelis) Tr. 6071, *in camera*).

845. In July 2017, Moelis continued to be engaged with four potential refinancing parties [redacted] David Smith felt that [redacted] "both were high quality calls and fully engaged." Madison Capital reportedly "can't lead refinancing, but happy to participate in someone else's transaction." (PX02093 (HEP), *in camera*).

846. As of August 1, 2017, [redacted] (PX03087 (Parker Hannifin) at 001, *in camera*).

847. Achilleas Dorotheou, a Freedom board member, viewed as unfavorable [redacted] willingness to replace half of Freedom's debt with equity, with a [redacted] valuation, as compared to an "offer of [redacted] by the strategic players." (PX05125 (Dorotheou (Parker Hannifin) Dep. at 112-13), *in camera*).

848. "A few players were approached," by Freedom to refinance Freedom's debt, "but the terms of valuation were very unfavorable compared to the strategic bidders." It was evident to Freedom's board that "one of the strategic players and notably Ottobock would have the highest offer." (PX05125 (Dorotheou (Parker Hannifin) Dep. at 111)).

### ii. Sale of the company

#### (a) Timeline for eliciting offers

849. In early October 2016, Maynard Carkhuff, Freedom's vice chairman and chief innovation officer at the time, and David Smith, Freedom's CEO at the time, met with the chairman and primary owner of Ottobock Germany, Professor Hans Georg Näder, in Berlin, Germany to gauge Ottobock's interest in acquiring Freedom. (Carkhuff (Freedom) Tr. 648-49).

850. Later in October 2016 (after the earlier meeting (F. 849)), Mr. Carkhuff and Mr. Smith had another meeting with Professor Näder in New York, New York. (Carkhuff (Freedom) Tr. 519, 649). At that meeting, Mr. Carkhuff made a presentation to Professor Näder, which provided an overview of the Freedom business in order to try to persuade Ottobock to acquire Freedom. (PX05109 (Carkhuff (Freedom) Dep. at 46); Carkhuff (Freedom) Tr. 522, 525-26, 649, *in camera*).

851. At the New York, New York meeting in October 2016 (F. 850), David Smith and Professor Näder discussed Freedom's business, products, and plans, as well as "what the combined entity might be able to do together[.]" (PX05122 (Smith (HEP) Dep. at 24-27)).

852. Jon Hammack, managing director at Moelis, knew about Freedom's discussions with Ottobock in the fall of 2016, but did not play a role in them. (PX05110 (Hammack (Moelis) Dep. at 14)).

853. In October 2016, Moelis was not asked to provide any assistance with selling the Freedom business or to conduct any outreach to potential acquirers. (PX05110 (Hammack (Moelis) Dep. at 19-20); Hammack (Moelis) Tr. 6081-82).

854. On or about November 27, 2016, Mr. Carkhuff received a note from Professor Näder advising Mr. Carkhuff that Freedom continues to be a top priority, but that Ottobock was focusing on wrapping up two prosthetic acquisitions before year-end. (PX01111 (Freedom) at 001).

855. In the fourth quarter of 2016, Freedom "initiated a conversation with Ottobock, one of two major competitors, to discuss the potential strategic sale of Freedom to Ottobock in 2017. Per management, Ottobock is very interested in the Freedom platform and is expected to begin formal diligence in [first quarter] 2017. Per Management, Ottobock has been guided to a purchase multiple of [redacted] and remains interested in the potential transaction. This potential purchase

multiple is consistent with the valuation report lenders received from Moelis in October 2016." (PX03009 (Madison Capital Funding) at 003, *in camera*).

856. A presentation created in February 2017 by Moelis, Freedom's investment bank, stated that Moelis "presented a preliminary, illustrative valuation to the [b]oard of Freedom Innovations on October 20, 2016[.] Freedom Innovations subsequently entered into bilateral sale negotiations with Ottobock[.]" This presentation did not reference any other potential acquirers of Freedom or any refinancing alternatives. (PX03002 (Moelis) at 002).

857. In March 2017, Maynard Carkhuff, David Smith, and Freedom board member Rolf Classon met with Professor Näder and the director of strategy and mergers and acquisitions for Ottobock Germany, Alexander Gück, in Berlin, Germany. (Carkhuff (Freedom) Tr. 541-42; Smith (HEP) Tr. 6491-92; PX02034 (HEP) at 001).

858. At the March 2017 meeting in Berlin, Germany (F. 857), Ottobock requested and Freedom agreed to send Ottobock some financial items. Ottobock indicated that "they would in turn send [Freedom] an offer after review." (PX02034 (HEP) at 001).

859. In April 2017, Ottobock informed Freedom that Ottobock viewed Freedom's valuation to be [redacted] (PX02088 (HEP) at 001, *in camera*; PX03084 (Parker Hannifin) at 001, *in camera*).

860. From October 2016 to April 2017, neither Freedom nor Moelis contacted any potential alternative strategic buyers of Freedom besides Ottobock. (PX05110 (Hammack (Moelis) Dep. at 47); PX02089 (HEP) at 001; PX05125 (Dorotheou (Parker Hannifin) at 67)).

861. In late April 2017, Moelis contacted Össur and Permobil, a company largely focused on patient lifts, wheelchairs, and mobility aids, as potential acquirers of the Freedom business. (PX03264 (Moelis) at 001-03; PX05110 (Hammack (Moelis) Dep. at 41)).

862. In May 2017, Permobil informed Moelis that they were not interested in acquiring the Freedom business. (PX03264 (Moelis) at 003).

863. In May 2017, Moelis expanded its outreach to five potential strategic buyers in addition to Össur and Permobil. None of the five additional potential strategic buyers was in the business of selling prosthetics. Moelis told those five potential buyers that an unnamed company in the prosthetics sector was potentially up for sale and provided those potential buyers with a high-level view of the financial profile of the company. Össur, Permobil, and one financial buyer were the only potential buyers contacted by Moelis that were told that Freedom was the acquisition target. (Hammack (Moelis) Tr. 6086-88; PX03264 (Moelis) at 001).

864. In June 2017, Moelis sent process letters to Össur and to Ottobock seeking "a written, non-binding indication of interest" to acquire Freedom. (PX03056 (Moelis) at 003; PX05110 (Hammack (Moelis) Dep. at 79)).

865. Össur and Ottobock were the only companies to which Moelis sent a letter requesting submittal of an indication of interest in acquiring Freedom. Moelis did not send such a letter to any other companies. (PX05110 (Hammack (Moelis) Dep. at 79)).

866. In late July 2017, Ottobock made an initial offer for Freedom of [redacted] (Carkhuff (Freedom) Tr. 660-61, *in camera*).

867. In July 2017, Össur submitted an initial offer of [redacted] for Freedom.[65] (PX03102 (Össur) (Project Roosevelt – Non-Binding Proposal), *in camera*; De Roy (Össur) Tr. 3606-07, *in camera*).

868. In August 2017, Moelis requested that Ottobock and Össur submit their final offer bids. (PX03239 (Moelis) at 007-10; PX03238 (Moelis) at 008-11).

869. On August 31, 2017, Össur submitted its final offer of [redacted] to acquire Freedom. (RX0531 (Össur), *in camera*; F. 895-900).

870. On August 31, 2017, Ottobock submitted a final offer of [redacted] to acquire Freedom. (PX02115 (HEP), *in camera*). Ottobock's August 31, 2017 final offer letter stated that Ottobock "is pleased to submit this non-binding bid package" to acquire Freedom and further stated that "[t]he proposal set forth in this letter is not intended to create any legally binding obligation on any party. Any such binding obligation shall arise only upon the execution and delivery of a Purchase Agreement by the parties thereto." (PX02115 (HEP) at 001, 005, *in camera*).

871. On September 5, 2017, Ottobock submitted an amendment to its August 31 offer letter, which increased its bid to [redacted] and stated, "[n]othing in this letter shall be construed as creating any binding legal obligation on any party." (PX02054 (HEP) at 001-03, *in camera*).

872. On September 22, 2017, Ottobock acquired Freedom. (PX07049 (Ottobock Amended Answer at 003 ¶ 1); Joint Stipulations of Law and Fact, JX001 at 001 ¶ 4).

**(b) Other companies**

873. Jon Hammack, managing director at Moelis and the person leading Freedom's sales process (F. 67), believed that a company would need at least [redacted] and therefore Moelis did not contact companies about acquiring Freedom unless the company had access to at least [redacted] (Hammack (Moelis) Tr. 6091, *in camera*).

[65] Össur's offer to acquire Freedom is discussed in more detail in F. 889-910.

874. It was David Smith's objective when he was Freedom's CEO to get bids as high as possible – to pay the banks and creditors and give as much money as possible to Freedom's investors. (PX05005 (Smith (HEP) IHT at 188-89)).

875. Moelis did not contact the following companies to determine whether they were interested in purchasing Freedom: Hanger, College Park, True Life, Ability Dynamics, ST&G, Fillauer, and WillowWood. (PX05110 (Hammack (Moelis) Dep. at 61-63)).

876. Nabtesco was not contacted by Moelis or Freedom before September 2017 regarding any interest Nabtesco might have in acquiring Freedom. (Smith (HEP) Tr. 6551, 6559; PX02033 (HEP) at 021; Hammack (Moelis) Tr. 6093; Carkhuff (Freedom) Tr. 727-28).

877. In a September 7, 2017 email, Mr. Carkhuff wrote to David Smith that Nabtesco had approached him regarding Nabtesco's interest in acquiring Freedom. Mr. Smith replied to Mr. Carkhuff that he believed that Freedom had several good offers in hand through the process that the board started many months ago and that there likely would not be enough time to integrate Nabtesco in the process. Mr. Smith then informed a Freedom board member that Freedom could validate Nabtesco's interest if the current "process falls apart." (PX01288 (Freedom) at 001-02).

878. Maynard Carkhuff responded to Nabtesco's inquiry (F. 877) that Freedom was not interested in Nabtesco buying Freedom. (Carkhuff (Freedom) Tr. 450-51).

879. Mr. Carkhuff believes that [redacted] (Carkhuff (Freedom) Tr. 451, *in camera*).

880. Proteor was not contacted by Moelis or Freedom before September 2017 regarding any interest Proteor might have in acquiring Freedom. (Smith (HEP) Tr. 6551, 6559; PX02033 (HEP) at 021; Hammack (Moelis) Tr. 6093-94).

881. According to Bradley Mattear, managing director of orthotics and prosthetics at Proteor, [redacted] (Mattear (Proteor) Tr. 5761-62, *in camera*).

882. College Park was not contacted by Moelis or Freedom before September 2017 regarding any interest College Park might have in acquiring Freedom. (Hammack (Moelis) Tr. 6093; PX02033 (HEP) at 021).

883. William Carver, College Park's president and COO, was "unaware" that Freedom was for sale in 2017. According to Mr. Carver, no one from Freedom ever approached College Park about submitting a bid for the Freedom business. (PX05107 (Carver (College Park) Dep. at 118-19)).

884. David Smith believed that reaching out to College Park, or another small competitor, would be "the worst thing to do" because it "would have alerted a small competitor that

[Freedom] was being sold" and would waste time with "a partner that couldn't buy us." (PX05122 (Smith (HEP) Dep. at 174-75)).

885. Fillauer was not contacted by Freedom or Moelis before September 2017 regarding any interest Fillauer might have in acquiring Freedom. (Smith (HEP) Tr. 6551, 6556; PX02033 (HEP) at 021; Hammack (Moelis) Tr. 6094; PX05105 (Fillauer (Fillauer) Dep. at 45)).

886. WillowWood was not contacted by Freedom or Moelis before September 2017 regarding any interest WillowWood might have in acquiring Freedom. (Smith (HEP) Tr. 6551, 6557; PX02033 (HEP) at 001-21; Hammack (Moelis) Tr. 6094; Carkhuff (Freedom) Tr. 728; Arbogast (WillowWood) Tr. 5087).

887. [redacted]

888. [redacted]

**(c) Össur's offer**

889. In July 2017, Össur submitted an initial offer of [redacted] for Freedom. (PX03102 (Össur) (Project Roosevelt – Non-Binding Proposal), *in camera*; De Roy (Össur) Tr. 3606-07, *in camera*). Prior to its initial bid, Össur conducted limited due diligence into a potential acquisition of Freedom, including looking at "high-level sales information" and the "overall cost structure of the company." (De Roy (Össur) Tr. 3607, *in camera*).

890. Össur was interested in acquiring Freedom because part of Össur's "strategy [is] to grow through acquisition and through organic growth." (De Roy (Össur) Tr. 3606).

891. Össur "requested the opportunity to test the Quattro" MPK being developed by Freedom (F. 9) but Freedom "did not feel comfortable" allowing them to do so. (De Roy (Össur) Tr. 3608-09). Össur was able to inspect a video of the Quattro's performance. (RX0526 at 00001).

892. On August 1, 2017, Moelis sent identical letters to Ottobock and Össur, seeking their final offers to acquire Freedom. (PX03239 (Moelis) at 007-10; PX03238 (Moelis) at 008-11).

893. Moelis' August 1, 2017 letter (F. 892) directed that the final offers for the Freedom business should include the following terms: valuation, financing, management, due diligence, approvals and conditions, and agreement. (PX03239 (Moelis) at 007-10; PX03238 (Moelis) at 008-11).

894. Based on its due diligence, Össur estimated that Freedom's valuation was "most likely in the range" of [redacted] (PX03012 (Össur) at 023, *in camera*).

895. On August 31, 2017, Össur sent Moelis a final offer to acquire Freedom for [redacted] (RX0531 (Össur) at 00001-02, *in camera*). Össur did not increase the amount in its final offer from the amount it had proposed in its initial offer. (*See* F. 889).

896. Össur's August 31, 2017 final offer letter accompanying its final offer to acquire freedom addressed each of the terms Moelis had requested in its August 1, 2017 letter (F. 892-893). (RX0531 (Össur) at 00001-03).

897. Össur's August 31, 2017 final offer letter stated, "Össur has received board approval to submit this Proposal and to consummate the transaction on consistent terms." (RX0531 (Össur) at 00002).

898. Össur's August 31, 2017 final offer letter stated, "In order to provide a quick and streamlined path to closing, we have proposed a simultaneous signing and closing as opposed to signing an agreement providing for a waiting period and a deferred closing." (RX0531 (Össur) at 00002).

899. Össur's August 31, 2017 final offer letter stated, "Össur has provided a mark-up of the proposed agreement concurrently herewith" and clarified that the final offer letter "does not constitute a binding commitment on our part to enter into a definitive agreement for a transaction . . . ." (RX0531 (Össur) at 00002-03).

900. Össur's August 31, 2017 final offer letter stated that it was prepared to close the acquisition "within two weeks." Össur specifically noted that "Össur understands [Freedom's] financial circumstances and lending timeline and is committed and prepared to close quickly and cooperate with [Freedom's] efforts to manage lender requirements." (RX0531 (Össur) at 00001, 00003).

901. Össur's vice president of corporate and strategy development wrote on September 8, 2017 to Jon Hammack, managing director of Moelis, "We think that our offer is a good one based on the information shared by the target to date. Össur management agreed to the most favorable deal structure for the sellers, and in the interest of all parties, was ready to move extremely fast to conclude the transaction within two weeks." (RX0536 (Össur)).

902. David Smith, Freedom's CEO at the time, described Freedom as having "several good offers in hand" on September 8, 2017. (PX01288 (Freedom) at 001).

903. [redacted]

904. Freedom's tangible and intangible assets combined would have a liquidation value of at most [redacted] (PX06002 (Hammer Expert Report at 049, 056 ¶¶ 124, 142), *in camera*; Hammer Tr. 2979-80, *in camera*).

905. Respondent's expert witness, James Peterson, did not perform a liquidation analysis of Freedom's business and did not offer an opinion on whether Össur's offer exceeded the liquidation value of Freedom. (PX05174 (Peterson, Dep. at 126-27); RX1048 (Peterson Expert Report at 0045 ¶ 115); Peterson, Tr. 6691).

906. Respondent's expert witness, James Peterson, is not aware of testimony or documents in the record that indicate that Össur intended to discontinue selling Freedom's microprocessor knee products in the United States. (PX05174 (Peterson, Dep. at 133)).

907. Market shares based on all revenues from MPKs sold in the United States in 2017 were as follows: Ottobock [redacted] Freedom [redacted] Össur [redacted] Endolite [redacted] DAW [redacted] and Nabtesco [redacted] (F. 479).

908. Using the market shares in F. 479 and F. 907, the acquisition of Freedom by Ottobock would increase the HHI by 1,522 points, to 6,767 points (F. 479) and an acquisition of Freedom by Össur would increase the HHI by 339 points, to 5,584 points. (RX1049 (Argue Expert Report at 0078-79)).

909. Respondent's expert witness, Dr. David Argue, did not perform any analysis to determine potential anticompetitive harm in the United States MPK market from an acquisition of Freedom by Össur, beyond finding a presumption of harm under the Merger Guidelines based on levels and changes in the HHI. (RX1049 (Argue Expert Report at 0078-79); Argue, Tr. 6381).

910. Dr. Argue analyzed an acquisition of Freedom by Össur in a purported market consisting of all K-3 and K-4 feet. (Argue, Tr. 6374; RX1049 (Argue Expert Report at 0081-82 ¶¶ 174-75)). Dr. Argue did not include a hypothetical monopolist test to assess whether a monopolist of K-3/K-4 feet could profitably impose a SSNIP, any critical loss calculation, a full evaluation of likely predicted loss, an analysis on the constraints on the ability of existing K-3/K-4 foot suppliers to expand, or an analysis of conditions of entry into the K-3/K-4 prosthetic foot market. (Argue, Tr. 6374-79).

### 5. Divestiture

#### a. [redacted]

911. [redacted]

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**i.**

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921. [redacted]

922. [redacted]

923. [redacted]

924. [redacted]

925. [redacted]

926. [redacted]

927. [redacted]

928. [redacted]

929. [redacted]

**ii.** [redacted]

930. [redacted]

931.

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**iii.**

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**iv.**

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[redacted].

938. [redacted]

939. [redacted]

940. [redacted]

941. [redacted]

942. [redacted]

943. [redacted]

944. [redacted]

945. [redacted]

946. [redacted]

947. [redacted]

948. [redacted]

949. [redacted]

**v.** [redacted]

950. [redacted]

951. [redacted]

952. [redacted]

953. [redacted]

954. [redacted]

**vi.** [redacted]

955. [redacted]

956.

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**vii.**

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959. [redacted]

**b.** [redacted]

960. [redacted]

961. [redacted]

962. [redacted]

963. [redacted]

## F. Remedy

964. [redacted]

965. [redacted]

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973. Freedom manufactures the Plié 3 and its carbon fiber foot products, and also assembles the for the Kinterra ankle, at Freedom's facilities in Gunnison, Utah. (Carkhuff (Freedom) Tr. 598; PX05138 (Reissfelder (Freedom) Dep. at 28, 34), *in camera*).

974.

975. Freedom uses promotions with its prosthetic feet to stimulate sales of its Plié 3 MPK. (PX05138 (Reissfelder (Freedom) Dep. at 77-79); PX01391 (Freedom) at 002. *See* F. 612-626).

976. Mr. Schneider of Ottobock acknowledged that Freedom "leveraged [its] very popular foot portfolio in combination with their microprocessor knee" to compete with Ottobock's C-Leg. (PX05010 (Schneider (Ottobock) IHT at 115-16).

977. The ideal combo promotion "has been successful" in increasing Freedom's Plié 3 sales. (Testerman (Freedom) Tr. 1147-48; F. 612, 614-626).

## IV. SUMMARY OF CONCLUSIONS OF LAW

1. The Commission has jurisdiction over Respondent and the Acquisition pursuant to Section 5 of the FTC Act, 15 U.S.C. § 45, and Sections 7 and 11 of the Clayton Act. 15 U.S.C. §§ 18, 21(b).

2. Section 7 of the Clayton Act prohibits mergers or acquisitions "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or . . . activity affecting commerce in any section of the country." 15 U.S.C. § 18.

3. It is not necessary to demonstrate certainty that a proposed merger will produce anticompetitive effects, or even that such effects are highly probable, but only that the loss of competition is a sufficiently probable and imminent result of the merger or acquisition.

4. To establish a prima facie case of a violation of Section 7, the plaintiff may rely on a presumption of anticompetitive effects, by defining a relevant market and showing that the transaction will lead to undue concentration in that market.

5. A plaintiff may bolster a prima facie case based on a market concentration presumption by adducing evidence showing that anticompetitive unilateral or coordinated effects are likely.

6. If the plaintiff establishes a prima facie case, the burden shifts to the defendant to show that traditional economic theories of the competitive effects of market concentration are not an accurate indicator of the merger's probable effect on competition in the relevant market or that the procompetitive effects of the merger are likely to outweigh any potential anticompetitive effects.

7. Although the courts have not defined a precise standard that must be met to rebut a prima facie case, the courts advise that the more compelling the prima facie case, the more evidence the defendant must present to rebut the presumption successfully.

8. If the defendant successfully rebuts the presumption of a violation of Section 7, the burden of producing additional evidence of anticompetitive effects shifts to the plaintiff, and merges with the ultimate burden of persuasion, which remains with the plaintiff at all times.

9. The relevant market in which to assess the likely effects of the Acquisition is the sale of MPKs to prosthetic clinics in the United States.

10. Complaint Counsel established a presumption of liability, by showing that the Acquisition will lead to undue concentration in the relevant market.

11. Under the unilateral effects theory, a merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising the price of one or both products above the pre-merger level.

12. The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects. Unilateral price effects are greater, the more the buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice.

13. For a merger to raise concerns about unilateral effects, not every consumer in the relevant market must regard the products of the merging firms as his or her top two choices. It is sufficient that a significant fraction of the customers purchasing that product view products formerly sold by the other merging firm as their next-best choice, and the significant fraction need not approach a majority.

14. Complaint Counsel bolstered the presumption of anticompetitive effects by demonstrating that, for a significant fraction of clinic customers, the Ottobock C-Leg and the Freedom Plié are the two top choices for MPKs; that Ottobock and Freedom are direct competitors in the MPK market; and that such competition has helped clinic customers negotiate lower prices and has spurred MPK innovation.

15. In some cases, non-merging firms may be able to reposition their products to offer close substitutes for the products offered by the merging firms. Repositioning is evaluated much like entry, with consideration given to timeliness, likelihood, and sufficiency.

16. Respondent bears the burden of demonstrating that other competitors have the ability to fill the competitive void that will result from the Acquisition. Existing competitors must be poised to expand in a way that is timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract any potential anticompetitive effects resulting from the merger.

17. The evidence fails to justify a conclusion that MPK competitors are poised to expand in a way that is timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract any potential anticompetitive effects resulting from the Acquisition.

18. A "power buyer" defense is grounded in the theory that large, sophisticated buyers may have the bargaining power to resist anticompetitive price increases and thereby counter any anticompetitive effects of a merger.

19. Courts do not consider proof of the existence of power buyers as itself independently adequate to rebut a prima facie case. Courts have credited the existence of power buyers as a defense only where there is also proof of ease of entry and likely efficiencies.

20. To establish a failing company defense, the defendant must demonstrate that the resources of the acquired company were so depleted as to be in imminent danger of business failure and the prospect of rehabilitation so remote that it faced the grave

probability of a business failure, and that the acquired company made unsuccessful good faith efforts to merge with a company other than the acquiring one. Some courts and the Merger Guidelines also require proof that the allegedly failing company would not be able to reorganize successfully in bankruptcy.

21. A weakened competitor defense is credited only in rare cases, when the defendant makes a substantial showing that the acquired firm's weakness, which cannot be resolved by any competitive means, would cause that firm's market share to reduce to a level that would undermine the government's prima facie case. Financial weakness, while perhaps relevant in some cases, is probably the weakest ground of all for justifying a merger, and certainly cannot be the primary justification for permitting one.

22. A defendant may introduce evidence in rebuttal that a proposed divestiture would restore the competition lost by the merger, and thereby counteract the anticompetitive effects of the merger.

23. The standard for evaluating a proposed divestiture, in the context of rebuttal, is the same as that for evaluating a remedy, i.e., it must appear that the proposed divestiture will effectively preserve competition in the relevant market. In other words, the divestiture must replace the competitive intensity lost as a result of the merger.

24. Cognizable efficiencies are defined as merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service.

25. To be cognizable, an asserted efficiency must represent a type of cost saving that could not be achieved without the merger and the estimate of the predicted cost saving must be reasonably verifiable by an independent party.

26. To be verifiable, any asserted efficiencies require clear evidence showing that the merger will result in efficiencies that will offset the anticompetitive effects and ultimately benefit consumers.

27. The law requires a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those efficiencies represent more than mere speculation and promises about post-merger behavior.

28. An anticompetitive merger cannot be justified on the basis of asserted efficiencies outside the relevant market.

29. It is incumbent upon the merging firms to substantiate efficiency claims, so that it is possible to verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific.

30. High market concentration levels require proof of extraordinary efficiencies to rebut the presumption of likely anticompetitive effects, and courts generally have found inadequate proof of efficiencies to sustain rebuttal of the government's case.

31. Respondent failed to successfully rebut Complaint Counsel's prima facie case.

32. The evidence proves that the Acquisition may substantially lessen competition in the relevant market for the sale of MPKs to prosthetic clinics in the United States in violation of Section 7 of the Clayton Act and Section 5 of the FTC Act.

33. The purpose of relief in a Section 7 case is to restore competition lost through the unlawful acquisition. Complete divestiture is generally the most appropriate way to restore competition lost through an unlawful acquisition.

34. Absent unusual circumstances, it is presumed that total divestiture of the acquired assets is the best means of restoring competition. Exceptions to the general rule of full divestiture can be reasonably invoked only when the proof of their probable efficacy is clear and convincing.

35. It is well settled that the Commission may order full divestiture in a consummated merger case when a violation of the Clayton Act has been found, even when products outside the relevant product market are implicated.

36. The burden is on the defendant to demonstrate that a remedy other than full divestiture would adequately redress any violation which is found.

37. Respondent failed to demonstrate that complete divestiture is an inappropriate remedy in this case.

38. Respondent failed to demonstrate that a partial divestiture limited to Freedom's MPK Assets would be sufficient to restore competition in the MPK market, and thereby remedy the unlawful Acquisition.

39. The Order accomplishes the remedial objectives of the Clayton Act and the FTC Act, and is supported by the record and applicable case law.

## ORDER

### I.

**IT IS ORDERED** that, as used in the Order, the following definitions apply:

A. "Ottobock" or "Respondent" means Otto Bock Healthcare North America, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Otto Bock Healthcare North America, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Commission" means the Federal Trade Commission.

C. "Acquirer" means the Person that acquires, with the prior approval of the Commission, the Freedom Assets and Business from Ottobock pursuant to Paragraph II, or from the Divestiture Trustee pursuant to Paragraph VII of this Order.

D. "Acquisition" means the acquisition of the Freedom Assets and Business by Respondent Ottobock pursuant to the Agreement and Plan of Merger dated September 22, 2017 and subsequent amendments and schedules.

E. "Acquisition Date" means September 22, 2017, the date on which Ottobock acquired the Freedom Assets and Business.

F. "Confidential Business Information" means any non-public information relating to the Freedom Assets and Business either prior to or after the Effective Date of Divestiture, including, but not limited to, all customer lists, price lists, distribution or marketing methods, or Intellectual Property relating to Freedom Assets and Business and:

1. Obtained by Ottobock prior to the Effective Date of Divestiture; or,

2. Obtained by Ottobock after the Effective Date of Divestiture, in the course of performing Ottobock's obligations under any Divestiture Agreement.

*Provided, however*, that Confidential Business Information shall not include:

1. Information that Ottobock can demonstrate it obtained prior to the Acquisition Date, other than information it obtained during due diligence pursuant to any confidentiality or non-disclosure agreement;

2. Information that is in the public domain when received by Ottobock;

3. Information that is not in the public domain when received by Ottobock and thereafter becomes public through no act or failure to act by Ottobock;

4. Information that Ottobock develops or obtains independently, without violating any applicable law or this Order; and

5. Information that becomes known to Ottobock from a third party not in breach of applicable law or a confidentiality obligation with respect to the information.

G. "Direct Cost" means the cost of direct material and direct labor used to provide the relevant assistance or service.

H. "Divestiture Agreement" means any agreement, including all exhibits, attachments, agreements, schedules and amendments thereto, that has been approved by the Commission pursuant to which the Freedom Assets and Business are divested by Ottobock pursuant to Paragraph II, or by the Divestiture Trustee pursuant to Paragraph VII in this Order.

I. "Divestiture Products Group A" means all Freedom Assets and Business related to the products listed in Appendix A of this Order.

J. "Divestiture Products Group B" means all Freedom Assets and Business related to the products listed in Appendix B of this Order.

K. "Divestiture Trustee" means the Person appointed pursuant to Paragraph VII of this Order to divest the Freedom Assets and Business.

L. "Effective Date of Divestiture" means the date on which the divestiture of the Freedom Assets and Business to an Acquirer pursuant to Paragraph II or Paragraph VII of this Order is completed.

M. "Freedom Assets" means all of Ottobock's right, title, and interest in and to the Freedom Business and all related assets, tangible or intangible, business, and properties, including any improvements or additions thereto made subsequent to the Acquisition, relating to the operation of the Freedom Business, including, but not limited to:

1. All Real Property of the Freedom Business;

2. All Tangible Personal Property;

3. All Intangible Property;

4. All consumable or disposable inventory;

5. All rights under any contracts and agreements, including, but not limited to, all

rights to leases, service agreements, supply agreements and procurement contracts;

6. All rights and title in and to the use of the Freedom Business name and marks on a permanent and exclusive basis;

7. All Intellectual Property;

8. All governmental approvals, consents, licenses, permits, waivers, or other authorizations to the extent transferrable;

9. All rights under warranties and guarantees, express or implied;

10. All items of prepaid expense; and

11. Books, records, files, correspondence, manuals, computer printouts, databases, and other documents relating to the operation of the Freedom Business, electronic and hard copy, located on the premises of Freedom Business Real Property or in the possession of any Ottobock Employee (or copies thereof where Ottobock has a legal obligation to maintain the original document), including, but not limited to:

    a. Customer files and records, including customer lists, customer product specifications, customer purchasing histories, customer service and support materials, and customer information;

    b. Research and development data and files;

    c. Financial records;

    d. Personnel files;

    e. Maintenance records;

    f. Advertising, promotional and marketing materials, including website content;

    g. Documents relating to policies and procedures;

    h. Documents relating to quality control;

    i. Documents relating to Payors; and

    j. Documents relating to Suppliers.

*Provided, however*, Freedom Assets does not include any assets exclusively related to the Ottobock business (including prosthetic products sold or marketed by Ottobock) prior to

the Acquisition Date, unless such assets were also used by the Freedom Business after the Acquisition Date.

M. "Freedom Business" means all activities relating to the manufacture and sale of prosthetics and other related products and services.

*Provided, however*, the Freedom Business does not include any activities relating to Ottobock's manufacture and sale of prosthetics and other related products and services prior to the Acquisition Date.

N. "Freedom Assets and Business" means the Freedom Assets and the Freedom Business.

O. "Freedom Employee(s)" means Any Person:

1. Employed by the Freedom Business as of the Acquisition Date; and/or

2. Employed by the Freedom Business at any time from the Acquisition Date through the Effective Date of Divestiture.

Q. "Freedom Key Employee(s)" means any Person listed in Confidential Appendix C Attached to this Order.

R. "Hold-Separate Agreements" means the Letter Agreement and Hold Separate and Asset Maintenance Agreement signed by Ottobock and Bureau of Competition Staff on December 20, 2017, attached as Confidential Appendix D to this Order, and the Procedures, Terms and Conditions Agreement.

S. "Hold-Separate Manager Agreement" means the Agreement signed by Ottobock and the Hold Separate Manager on December 22, 2017, attached as Confidential Appendix E to this Order.

T. "Hold-Separate Monitor Agreement" means the Agreement signed by Ottobock and the Hold Separate Monitor on December 27, 2017, attached as Confidential Appendix F to this Order.

U. "Intangible Property" means intangible property relating to the operation of the Freedom Business including, but not limited to, Intellectual Property, the Freedom name and marks, trademarks, logos, and the modifications or improvements to such intangible property.

V. "Intellectual Property" means, without limitation: (i) all patents, patent applications, inventions, and discoveries that may be patentable; (ii) all know-how, trade secrets, software, technical information, data, registrations, applications for governmental approvals, inventions, processes, best practices (including clinical pathways), formulae, protocols, standards, methods, techniques, designs, quality-control practices and information, research and test procedures and information, and safety, environmental and

health practices and information; (iii) all confidential or proprietary information, commercial information, management systems, business processes and practices, patient lists, patient information, patient records and files, patient communications, procurement practices and information, supplier qualification and approval practices and information, training materials, sales and marketing materials, patient support materials, advertising and promotional materials; and (iv) all rights in any jurisdiction to limit the use or disclosure of any of the foregoing, and rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.

W. "Licensed Intangible Property" means Intangible Property licensed to Ottobock or to the Freedom Business from a third party relating to Freedom Assets and Business including, but not limited to, Intellectual Property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality-control information, trademarks, trade names, service marks, logos, and the modification or improvements to such intangible property that are licensed to Ottobock or to the Freedom Business ("Licensed Intangible Property" does not mean modifications and improvements to intangible property that are not licensed to Ottobock).

X. "Monitor" means the Person appointed pursuant to Paragraph VI of the Order and with the prior approval of the Commission.

Y. "Monitor Agreement" means the agreement Ottobock enters into with the Monitor and with the prior approval of the Commission.

Z. "Payor" means any Person that purchases, reimburses for, or otherwise pays for medical goods or services for themselves or for any other person, including, but not limited to: health insurance companies; preferred provider organizations; point-of-service organizations; prepaid hospital, medical, or other health-service plans; health maintenance organizations; government health-benefits programs; employers or other persons providing or administering self-insured health-benefits programs; and patients who purchase medical goods or services for themselves.

AA. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.

BB. "Procedures, Terms and Conditions Agreement" means the Procedures, Terms and Conditions Regarding Access to the Held-Separate Business for FTC Litigation Purposes Pursuant to Hold Separate and Asset Maintenance Agreement dated December 20, 2017, between Bureau of Competition Staff and Ottobock, signed on January 31, 2018, and attached as Confidential Appendix G to this Order.

CC. "Real Property" means all real property interests (including fee simple interests and real property leasehold interests including all rights, easements and appurtenances, together with all buildings, structures, facilities) that Ottobock acquired pursuant to the

Acquisition and/or that Ottobock acquired after the Acquisition to the extent the interests relate to the operation of the Freedom Business. Real Property includes, but is not limited to, the assets, which are identified and listed on Appendix H to this Order.

DD. "Supplier" means any Person that has sold to the Freedom Business or Ottobock any goods or services for use in connection with the operation of the Freedom Business; provided, however, that "Supplier" does not mean an employee of Ottobock.

EE. "Tangible Personal Property" means all machinery, equipment, spare parts, tools, and tooling (whether customer specific or otherwise); furniture, office equipment, computer hardware and software; supplies and materials; vehicles and rolling stock; and other items of tangible personal property of every kind whether owned or leased, together with any express or implied warranty by the manufacturers, sellers, or lessors of any item or component part thereof, and all maintenance records and other documents relating thereto.

FF. "Technical Services Agreement" means the provision by Ottobock at Direct Cost of all advice, consultation, and assistance reasonably necessary for any Acquirer to receive and use, in any manner related to achieving the purposes of this Order, any asset, right, or interest related to the Freedom Business.

GG. "Transitional Services" means the Technical Services Agreement and the Transition Services Agreement.

HH. "Transition Services Agreement" means an agreement requiring Ottobock to provide at Direct Cost all services reasonably necessary to transfer administrative support services to the Acquirer, including, but not limited to, such services related to payroll, employee benefits, accounts receivable, accounts payable, and other administrative and logistical support.

## II.

**IT IS FURTHER ORDERED** that:

A. Ottobock shall:

1. No later than ninety (90) days from the date this Order becomes final and effective, divest absolutely and in good faith, and at no minimum price, the Freedom Assets and Business to an Acquirer that receives the prior approval of the Commission and in a manner, including pursuant to a Divestiture Agreement, that receives the prior approval of the Commission;

*Provided, however,* that Ottobock may retain any or all of the Divestiture Products Group A *unless* the Acquirer demonstrates to the Commission's satisfaction: (i) that any such asset is necessary to achieve the purpose of this Order; and (ii) that the Acquirer needs such asset to effectively operate the Freedom Business in a manner consistent with the

purpose of this Order, and the Commission approves the divestiture with the divestiture of such asset.

*Provided, however*, that Ottobock must divest any or all of the Divestiture Products Group B *unless* the Acquirer demonstrates to the Commission's satisfaction: (i) that any such asset is not necessary to achieve the purpose of this Order; and (ii) that the Acquirer does not need such asset to effectively operate the Freedom Business in a manner consistent with the purpose of this Order, and the Commission approves the divestiture without the divestiture of such asset.

2. Comply with all terms of the Divestiture Agreement approved by the Commission pursuant to this Order, which agreement shall be deemed incorporated by reference into this Order; and any failure by Ottobock to comply with any term of the Divestiture Agreement shall constitute a failure to comply with this Order. The Divestiture Agreement shall not reduce, limit or contradict, or be construed to reduce, limit or contradict, the terms of this Order; *provided, however*, that nothing in this Order shall be construed to reduce any rights or benefits of any Acquirer or to reduce any obligations of Ottobock under such agreement; *provided further*, that if any term of the Divestiture Agreement varies from the terms of this Order ("Order Term"), then to the extent that Ottobock cannot fully comply with both terms, the Order Term shall determine Ottobock's obligations under this Order. Notwithstanding any paragraph, section, or other provision of the Divestiture Agreement, any failure to meet any condition precedent to closing (whether waived or not) or any modification of the Divestiture Agreement, without the prior approval of the Commission, shall constitute a failure to comply with this Order.

3. Prior to the Effective Date of Divestiture, Ottobock shall not rescind the Hold-Separate Agreements, the Hold-Separate Manager Agreement, the Hold-Separate Monitor Agreement, or the Procedures, Terms, and Conditions Agreement or any term of the above Agreements necessary to comply with any Paragraph of this Order.

4. No later than thirty (30) days from the date this Order becomes final and effective, Ottobock shall offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Freedom Assets and Business customarily provided in a due diligence process except such information or documents subject to the attorney-client privilege or work-product doctrine.

*Provided further* that Ottobock shall permit prospective Acquirers of the Freedom Assets and Business to have reasonable access to personnel and to make inspections of the physical facilities; and access to any and all financial, operational, or other documents and information customarily provided as part of a due diligence process; *provided, however*, that Ottobock shall require all prospective Acquirers to sign a confidentiality agreement pursuant to which that prospective Acquirer shall be required to maintain all

Confidential Business Information obtained as part of the due diligence process as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the potential Acquirer that were not involved in the due diligence process. Ottobock shall require, as part of a confidentiality agreement, that the potential Acquirer limit access to Confidential Business Information to only those employees necessary to conduct sufficient due diligence.

5. Take all actions and shall effect all arrangements in connection with the divestiture of the Freedom Assets and Business necessary to ensure that the Acquirer can conduct the Freedom Assets and Business in substantially the same manner as operated prior to the Acquisition, including, but not limited to:

    a. Complying with the Hold-Separate Agreements, the Hold-Separate Manager Agreement, the Hold-Separate Monitor Agreement, or the Procedures, Terms, and Conditions Agreement or any term of the above Agreements,

    b. Providing Transitional Services,

    c. Providing the opportunity to recruit and employ all Freedom Employees.

6. Convey as of the Effective Date of Divestiture to the Acquirer the right to use any Licensed Intangible Property (to the extent permitted by the third-party licensor), if such right is needed for the operation of the Freedom Business by the Acquirer and if the Acquirer is unable, using commercially-reasonable efforts, to obtain equivalent rights from other third parties on commercially-reasonable terms and conditions.

7. Ottobock shall:

    a. Place no restrictions on the use by the Acquirer of the Freedom Assets and Business, including any Intangible Property;

    b. On or before the Effective Date of Divestiture, provide to the Acquirer contact information about customers, Payors, and Suppliers for the Freedom Assets and Business;

    c. With respect to contracts with Freedom Business Suppliers, at the Acquirer's option and as of the Effective Date of Divestiture:

        i. If such contract can be assigned without third-party approval, assign its rights under the contract to the Acquirer; and

        ii. If such contract can be assigned to the Acquirer only with third-party approval, assist and cooperate with the Acquirer in obtaining:

(a) Such third-party approval and in assigning the contract to the acquirer; or

(b) A new contract.

8. At the request of the Acquirer, for two (2) years from the Effective Date of Divestiture, with the option of the Acquirer to renew for two six (6) month periods with written notification to Commission staff, except as otherwise approved by the Commission, and in a manner (including pursuant to an agreement) that receives the prior approval of the Commission:

a. Ottobock shall provide Transitional Services to the Acquirer sufficient to enable the Acquirer to conduct the Freedom Business in substantially the same manner that the Freedom Business was conducted prior to the Acquisition and during the Hold-Separate Period.

b. Ottobock shall provide the Transitional Services required by this Paragraph II.A.8 at substantially the same level and quality as such services are provided by Ottobock in connection with the Hold-Separate Agreements.

*Provided, however*, that Ottobock shall not (i) require the Acquirer to pay compensation for Transitional Services that exceeds Direct Cost of providing such goods and services, (ii) terminate its obligation to provide Transitional Services because of a material breach by the Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) include a term in any agreement to provide Transitional Services that limits the type of damages (such as indirect, special, and consequential damages) that the Acquirer would be entitled to seek and in event of Ottobock's breach of such agreement.

9. Ottobock shall allow the Acquirer an opportunity to recruit and employ any Freedom Employee in connection with the divestiture of the Freedom Assets and Business, including as follows:

a. No later than five (5) days after execution of a divestiture agreement, Ottobock shall (i) identify each Freedom Employee, (ii) allow the Acquirer an opportunity to interview any Freedom Employee, and (iii) allow the Acquirer to inspect the personnel files and other documentation relating to any Freedom Employee, to the extent permissible under applicable laws.

b. Ottobock shall (i) not offer any incentive to any Freedom Employee to decline employment with the Acquirer, (ii) remove any contractual impediments that may deter any Freedom Employee from accepting employment with the Acquirer, including, but not limited to, any non-

compete or confidentiality provisions of employment or other contracts with Ottobock that would affect the ability of the Freedom Employee to be employed by the Acquirer, and (iii) not otherwise interfere with the recruitment of any Freedom Employee by the Acquirer.

c. Ottobock shall (i) vest all current and accrued pension benefits as of the date of transition of employment with the Acquirer for any Freedom Employee who accepts an offer of employment from the Acquirer no later than thirty (30) days from the Effective Date of Divestiture and (ii) if the Acquirer has made a written offer of employment to any Key Employee, as identified and listed on Confidential Appendix C to this Order, provide such Key Employee with reasonable financial incentives to accept a position with the Acquirer at the time of the Effective Date of Divestiture, including, but not limited to (and subject to Commission approval), payment of an incentive equal to up to three (3) months of such Key Employee's base salary to be paid only upon such Key Employee's completion of one (1) year of employment with the Acquirer.

*Provided, however*, that Ottobock and the Acquirer will work together in good faith to determine whether any additional Freedom Employee should be identified as a Key Employee and subject to the provisions of this Paragraph II.A.9.c.

d. For a period ending two (2) years after the Effective Date of Divestiture, Ottobock shall not, directly or indirectly, solicit, hire, or enter into any arrangement for the services of any Freedom Employee employed by the Acquirer, unless such Freedom Employee's employment has been terminated by the Acquirer; provided, however, this Paragraph II.A.9.d shall not prohibit Ottobock from: (i) advertising for employees in newspapers, trade publications, or other media not targeted specifically at the Freedom Employees, (ii) hiring employees who apply for employment with Ottobock, as long as such employees were not solicited by Ottobock in violation of this Paragraph II.A.9.d, or (iii) offering employment to a Freedom Employee who is employed by the Acquirer in only a part- time capacity, if the employment offered by Ottobock would not, in any way, interfere with that employee's ability to fulfill his or her employment responsibilities to the Acquirer.

10. Ottobock shall submit to the Acquirer, at Ottobock's expense, all Confidential Business Information, and:

a. Deliver such Confidential Business information as follows: (i) in good faith; (ii) as soon as practicable, avoiding any delays in transmission of the respective information; and (iii) in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

b. Pending complete delivery of all such Confidential Business Information

to the Acquirer, provide the Acquirer and Monitor with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order.

11. Except in the course of performing its obligations under this Order, Ottobock shall:

    a. Not provide, disclose, or otherwise make available any Confidential Business Information, including trade secrets or any sensitive or proprietary commercial or financial information relating to the Acquirer or the Freedom Business to any Person other than the Acquirer, and shall not share such information for any reason or purpose;

    b. Disclose any Confidential Business Information trade secrets or any sensitive or proprietary commercial or financial information related to the Acquirer or the Freedom Business to any Person other than the Acquirer (1) only in the manner and to the extent necessary to satisfy Ottobock's obligations under this Order and (ii) only to Persons who agree in writing to maintain the confidentiality of such information; and

    c. Enforce the terms of this Paragraph II.A.11 as to any Person and take such action as is necessary, including training, to cause each such Person to comply with the terms of this Paragraph II.A.11, including any actions Ottobock would take to protect its own trade secrets or sensitive or propriety commercial or financial information.

*Provided, however*, that Ottobock may provide, disclose, use, or otherwise make available any Confidential Business Information relating to any of the Divestiture Products Group A or Divestiture Products Group B retained under Paragraph II.A.1 of this Order to the extent that such Confidential Business Information is solely under the use or control of Ottobock.

12. Ottobock shall, no later than five (5) days after the date this Order becomes final and effective:

    a. Require that each employee of Ottobock, including the Hold-Separate Manager and the Hold-Separate Monitor, who has, had, or may have had access to Confidential Business Information relating to the Freedom Assets and Business, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Freedom Assets and Business as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of Ottobock (other than as necessary to comply with the

requirements of this Order), or the use of such Confidential Business Information in any way.

b. Cause all Persons under Ottobock's control, including all Ottobock employees, the Hold-Separate Manager, and the Hold-Separate Monitor, having access to Confidential Business Information of or pertaining to the Freedom Assets and Business to submit a signed statement to the Commission's staff that the individual will maintain the confidentiality required by this Order.

c. Provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Freedom Assets and Business by Ottobock's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Ottobock shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for two (2) years after the date this Order becomes final and effective. Ottobock shall maintain complete records of all such notifications at Ottobock's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program.

B. The purpose of the divestiture of the Freedom Assets and Business is to ensure the continued operation of the Freedom Business by the Acquirer, independent of Ottobock, and to remedy the lessening of competition resulting from the Acquisition.

## III.

**IT IS FURTHER ORDERED** that from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein) until the Effective Date of Divestiture, Ottobock shall abide by the Hold-Separate Agreements and shall not:

A. Sell or transfer any Freedom Assets;

B. Eliminate, transfer, or consolidate any service offered in connection with the Freedom Business;

C. Fail to maintain the employment of all Freedom Employees or otherwise fail to keep the Freedom Business staffed with sufficient employees; provided, however, that Freedom Employees may be terminated for cause as provided by the Hold-Separate Agreements (in which event Ottobock shall replace such employees).

## IV.

**IT IS FURTHER ORDERED** that:

A. From the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein) until the Effective Date of Divestiture, Ottobock shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Freedom Assets and Business, as provided in the Hold-Separate Agreements. Among other things that may be necessary, as provided for in the Hold-Separate Agreements, Ottobock shall:

1. Maintain the operations of the Freedom Business relating to the Freedom Assets in the ordinary course of business and in accordance with the Hold-Separate Agreements;

2. Use best efforts to maintain and increase revenues of the Freedom Business, and to maintain at budgeted levels for the year 2018 or the current year, whichever are higher, all administrative, technical, and marketing support for the Freedom Business and in accordance with the Hold-Separate Agreements;

3. Use best efforts to maintain the current workforce and to retain the services of employees and agents in connection with the Freedom Business, including payments of bonuses as necessary, and maintain the relations and goodwill with customers.

B. No later than thirty (30) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), Ottobock shall file a verified written report to the Commission that identifies (i) all assets included in the Freedom Assets, (ii) all assets originally acquired or that replace assets originally acquired as a result of the Acquisition, and (iii) all services, functions, and agreements that Ottobock discontinued after the Acquisition.

## V.

**IT IS FURTHER ORDERED** that no later than five (5) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), Ottobock shall provide a copy of this Order to each of Ottobock's officers, employees, or agents having managerial responsibility for any of Ottobock's obligations under Paragraphs II, III, and IV of this Order.

## VI.

**IT IS FURTHER ORDERED** that:

A. At any time after this Order becomes final and effective (without regard to the finality of

the divestiture requirements herein), the Commission may appoint a Person ("Monitor") to monitor Ottobock's compliance with its obligations under this Order, consult with Commission staff, and report to the Commission regarding Ottobock's compliance with its obligations under this Order.

B. If a Monitor is appointed pursuant to Paragraph VI.A of this Order, Ottobock shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

1. The Monitor shall have the power and authority to monitor Ottobock's compliance with the terms of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor pursuant to the terms of this Order and in a manner consistent with the purposes of this Order and in consultation with the Commission or its staff.

2. Within ten (10) days after appointment of the Monitor, Ottobock shall execute an agreement that, subject to the approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Ottobock's compliance with the terms of this Order in a manner consistent with the purposes of this Order. If requested by Ottobock, the Monitor shall sign a confidentiality agreement prohibiting the use or disclosure to anyone other than the Commission (or any Person retained by the Monitor pursuant to Paragraph VI.B.5 of this Order), of any competitively-sensitive or proprietary information gained as a result of his or her role as Monitor, for any purpose other than performance of the Monitor's duties under this Order.

3. The Monitor's power and duties under this Paragraph VI shall terminate three (3) business days after the Monitor has completed his or her final report pursuant to Paragraph VI.B.8 of this Order or at such other time as directed by the Commission.

4. Ottobock shall cooperate with any Monitor appointed by the Commission in the performance of his or her duties, and shall provide the Monitor with full and complete access to Ottobock's books, records, documents, personnel, facilities, and technical information relating to compliance with this Order, or to any other relevant information, as the Monitor may reasonably request. Ottobock shall cooperate with any reasonable request of the Monitor. Ottobock shall take no action to interfere with or impede the Monitor's ability to monitor Ottobock's compliance with this Order.

5. The Monitor shall serve, without bond or other security, at the expense of Ottobock, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of Ottobock, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses

incurred, including fees for his or her services, subject to the approval of the Commission.

6. Ottobock shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or willful misconduct. For purposes of this Paragraph VI.B.6, the term "Monitor" shall include all Persons retained by the Monitor pursuant to Paragraph VI.B.5 of this Order.

7. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute to serve as Monitor in the same manner as provided by this Order.

8. The Monitor shall report in writing to the Commission (i) every sixty (60) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), (ii) no later than thirty (30) days from the date Ottobock completes its obligations under this Order, and (iii) at any other time as requested by the staff of the Commission, concerning Ottobock's compliance with this Order.

C. Ottobock shall submit the following reports to the Monitor: (i) no later than twenty (20) days after the date the Monitor is appointed by the Commission pursuant to Paragraph VI.A of this Order, a copy of the Accounting required by Paragraph IV.B of this Order; and (ii) copies of all compliance reports filed with the Commission.

D. Ottobock shall provide the Monitor with: (i) prompt notification of significant meetings, including date, time and venue, scheduled after the execution of the Monitor Agreement, relating to the regulatory approvals, marketing, sale and divestiture of the Freedom Assets and Business, and such meetings may be attended by the Monitor or his representative, at the Monitor's option or at the request of the Commission or staff of the Commission; and (ii) the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of Ottobock.

E. The Commission may, on its own initiative or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

F. The Monitor appointed pursuant to this Order may be the same Person appointed as Divestiture Trustee pursuant to Paragraph VII of this Order.

## VII.

**IT IS FURTHER ORDERED** that:

A. If Ottobock has not divested, absolutely and in good faith, the Freedom Assets and Business pursuant to the requirements of Paragraph II of this Order, within the time and manner required by Paragraph II of this Order, the Commission may at any time appoint one or more Persons as Divestiture Trustee to divest the Freedom Assets and Business, at no minimum price, and pursuant to the requirements of Paragraph II of this Order, in a manner that satisfies the requirements of this Order.

B. In the event that the Commission or the Attorney General of the United States brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Ottobock shall consent to the appointment of a Divestiture Trustee in such action. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph VII shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including appointment of a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Ottobock to comply with this Order.

C. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph VII, Ottobock shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to effect the divestiture pursuant to the requirements of Paragraph II of this Order and in a manner consistent with the purposes of this Order.

2. Within ten (10) days after appointment of the Divestiture Trustee, Ottobock shall execute an agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture and perform the requirements of Paragraph II of this Order for which he or she has been appointed.

3. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the agreement described in Paragraph VII.C.2 of this Order to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period the Divestiture Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court.

4. Ottobock shall provide the Divestiture Trustee with full and complete access to the personnel, books, records, and facilities related to the assets to be divested, or to any other relevant information, as the Divestiture Trustee may request. Ottobock shall develop such financial or other information as the Divestiture Trustee may reasonably request and shall cooperate with the Divestiture Trustee. Ottobock shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Ottobock shall extend the time for divestiture under this Paragraph VII in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

5. The Divestiture Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, but shall divest expeditiously at no minimum price. The divestiture shall be made only to an Acquirer that receives the prior approval of the Commission, and the divestiture shall be accomplished only in a manner that receives the prior approval of the Commission; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity or entities selected by Ottobock from among those approved by the Commission; provided, further, that Ottobock shall select such entity within ten (10) business days of receiving written notification of the Commission's approval.

6. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Ottobock, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Ottobock, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of Ottobock, and the Divestiture Trustee's power shall be terminated. The Divestiture Trustee's compensation may be based in part on a commission arrangement contingent on the Divestiture Trustee's divesting the assets.

7. Ottobock shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph VII.C.7, the term "Divestiture Trustee"

shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph VII.C.6 of this Order.

8. If the Divestiture Trustee ceases to act or fails to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VII for appointment of the initial Divestiture Trustee.

9. The Divestiture Trustee shall have no obligation or authority to operate or maintain the assets to be divested.

10. The Divestiture Trustee shall report in writing to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

D. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

E. The Divestiture Trustee appointed pursuant to this Paragraph VII may be the same Person appointed as the Monitor pursuant to Paragraph VI of this Order.

## VIII.

**IT IS FURTHER ORDERED** that:

A. Ottobock shall submit the complete Divestiture Agreement to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

B. Ottobock shall submit verified written reports ("compliance reports") in accordance with the following:

1. Ottobock shall submit:

a. Interim compliance reports (i) no later than thirty (30) days after the Order becomes final and effective (without regard to the finality of the divestiture requirements herein), and every thirty (30) days thereafter until the divestiture of the Freedom Assets and Business is accomplished, and (ii) thereafter, every sixty (60) days (measured from the Effective Date of Divestiture) until the date Ottobock completes its obligations under this Order; and

b. Additional compliance reports as the Commission or its staff may request.

2. Ottobock shall include in its compliance reports, among other things required by the Commission, a full description of the efforts being made to comply with the

relevant Paragraphs of this Order, the identity of all parties contacted, copies of all written communications to and from such parties, internal documents and communications, and all reports and recommendations concerning the divestiture, the date of divestiture, and a statement that the divestiture has been accomplished in the manner approved by the Commission. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Ottobock is in compliance with each Paragraph of the Order. Conclusory statements that Ottobock has complied with its obligations under the Order are insufficient.

C. Each compliance report shall be verified in the manner set forth in 28 U.S.C. § 1746 by the chief executive officer or another officer or employee specifically authorized to perform this function. Ottobock shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Ottobock shall provide a copy of each compliance report to the Monitor.

## IX.

**IT IS FURTHER ORDERED** that Ottobock shall notify the Commission at least 30 days prior to:

A. Any proposed dissolution of Ottobock;

B. Any proposed acquisition of, or merger or consolidation involving Ottobock, or

C. Any other change in Ottobock including assignment and the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

## X.

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and 5 days' notice to Ottobock, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, Ottobock shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of Ottobock and in the presence of counsel for Ottobock, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of Ottobock related to compliance with this Order, which copying

services shall be provided by Ottobock at the request of the authorized representative of the Commission and at the expense of Ottobock; and

B. To interview officers, directors, or employees of Ottobock, who may have counsel present, regarding such matters.

**XI.**

**IT IS FURTHER ORDERED** that this Order shall terminate 10 years from the date it is issued.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date: May 6, 2019

# APPENDICES TO ORDER

REDACTED