

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



In the Matter of)
)
Otto Bock HealthCare North America,)
Inc.,)
)
a corporation,)
)
Respondent.)

Docket No. 9378

ORIGINAL

RESPONDENT'S POST-TRIAL BRIEF

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INTRODUCTION

Respondent Ottobock HealthCare North America, Inc.'s ("Ottobock") acquisition of FIH Group Holdings, LLC ("Freedom") (the "Acquisition") has not, and will not, harm competition in any relevant antitrust market. In attempting to prove claims under Section 7 of the Clayton Act, as amended 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended 15 U.S.C. § 45 (the "Claims"), Complaint Counsel alleges an untenable market consisting of every prosthetic knee that contains a microprocessor ("MPK") sold in the United States. Despite 13 weeks of trial, the testimony of 68 witnesses live and by deposition, and the introduction of 2198 exhibits, Complaint Counsel has failed to establish that market and that the Acquisition would harm competition in that, or any other, market for at least the following reasons:

- Complaint Counsel's alleged market is simultaneously overly broad and narrow and ignores both the economics and practical realities of the prosthetic industry.
- The Acquisition will not have anticompetitive effects in any relevant market because none of the very high quality, cutting edge MPKs manufactured by Ottobock (most notably, the "C-Leg") are close competitors with Freedom's lone and obsolete MPK (the "Plié") with respect to functionality, quality, or price.
- The Acquisition will not have anticompetitive effects because at least four existing participants in the alleged market have the ability, desire, and incentive to continue ongoing expansion of MPK sales far in excess of Freedom's average annual output of MPKs in the United States.
- The Acquisition will not have anticompetitive effects because sophisticated, powerful buyers and the third-party reimbursement system in the United States sufficiently discipline and constrain manufacturers with respect to price increases.
- Because Ottobock and Freedom have agreed to divest 100% of the assets in the alleged relevant market – *i.e.*, all of Freedom's MPK-related assets – the Acquisition poses no harm to competition in Complaint Counsel's alleged market and serves as an appropriately narrow remedy, any broader remedy being unnecessary and unduly punitive.
- The Acquisition will not have anticompetitive effects because Freedom was a "flailing firm" as a result of insurmountable debt, terrible financial performance, inability to meet financial forecasts, and gross mismanagement.

- The failing firm defense serves as a complete defense to Complaint Counsel's Claims because, for the same reasons that Freedom was "flailing," at the time of the Acquisition, Freedom was unable to meet its financial obligations in the near future, had no ability to successfully reorganize under Chapter 11 of the Bankruptcy Act, and exhausted good faith efforts to elicit reasonable alternatives to the Acquisition.

For these reasons, which are explained at length below, the Court should find that the Acquisition has not, and will not, lessen competition in any relevant market, and accordingly reject Complaint Counsel's Claims.

SUMMARY OF ARGUMENT

First, Complaint Counsel has failed to carry its burden of establishing a relevant antitrust market. Because this case is solely one of alleged unilateral effects and because prosthetic knees are highly differentiated products, the burden on Complaint Counsel to properly and specifically define a market is decidedly high: "[T]o make a sharp distinction between products 'in' and 'out' of the market can be misleading if there is no clear break in the chain of substitutes." *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1120 (N. D. Cal. 2004). The market alleged in this case – one that is "no broader than the manufacture and sale of [MPKs] to prosthetic clinics in the United States" (Complaint ¶ 17) – is fatally too narrow and overbroad.

Complaint Counsel's market is too narrow because it ignores a significant number of competing products that are indisputably medically appropriate for the same patients that benefit from MPKs simply because those products do not contain a microprocessor (prosthetic knees that do not contain a microprocessor, "Non-MPKs"). The evidence introduced at trial was overwhelming, however, that certain sophisticated Non-MPKs whose "swing and stance" phases are controlled by complex hydraulic and/or pneumatic systems ("Sophisticated Non-MPKs") are medically appropriate, and often chosen as superior, for the very same patient population – higher activity patients receiving so-called "K-3" and "K-4" mobility designations – that is eligible to

receive MPKs. Indeed, the evidence at trial was undisputed that these patients routinely compare and contrast MPKs and Sophisticated Non-MPKs with some patients choosing the former and some choosing the latter after consultation with clinicians and consideration of other factors, including cost.

The evidence was also clear that prosthetic clinics – the primary consumers of prosthetic knees – would respond to a small but significant and non-transitory increase in price (“SSNIP”) in MPKs by switching at least some patients to Sophisticated Non-MPKs. Clinics operate on very thin margins as a result of a third-party payer reimbursement system that places a cap on the amount any clinic is paid for prosthetic device fittings. The consequence of that system is that most clinics in the United States would be very sensitive to a SSNIP because it could lead to prosthetic knee fittings that are simply unprofitable. Therefore, a SSNIP on MPKs would not be profitable for a manufacturer because, among other reasons, Sophisticated Non-MPKs are medically appropriate substitutes that are routinely (and more often) selected by patients and prosthetists.

Complaint Counsel’s alleged market is too broad because it incorrectly includes certain extremely high-end MPKs that are not substitutes for the vast majority of MPKs and Sophisticated Non-MPKs available in the United States with respect to functionality, quality, or price. Only Ottobock and Össur hf. (“Össur”) manufacture such MPKs. Ottobock manufactures the X3 and the Genium while Össur manufactures the Rheo XC and the Power Knee (together, the X3, Genium, Rheo XC, and Power Knee, the “High-End MPKs”). These High-End MPKs can cost three or more times as much as other MPKs, and they provide extremely advanced function and quality. High-End MPKs are only available to a very select patient population, primarily active and retired military through the Department of Defense (“DOD”) and Veterans Administration

(“VA”) because Medicare and most private insurers do not provide additional reimbursement for extra the functionality provided by High-End MPKs. For those rare patients who are eligible to receive High-End MPKs through DOD or VA coverage, there is generally no co-pay, deductible, or other financial obligation on the part of the patient. Significantly, Freedom does not manufacturer any product that would qualify as a High-End MPK and thus does not compete for sales against High-End MPKs. Complaint Counsel’s inclusion of High-End MPKs in the alleged market is wrong and renders its calculation of market shares unreliable. The evidence introduced at trial was uniform that High-End MPKs are not substitutes for other MPKs because they are dramatically different in price and function, and also because Medicare and private insurance payers do not reimburse for High-End MPKs.

In sum, the fundamental flaw in the alleged market definition is Complaint Counsel’s rigid assumption that any prosthetic knee that contains a microprocessor must be included in the market. That assumption was consistently and routinely debunked at trial by witness after witness. Indeed, there can be no reasonable dispute that some MPKs, like the Plié, are more similar in function, quality, and price to Sophisticated Non-MPKs than to other MPKs, like the C-Leg or Ottobock’s High-End MPKs. For these reasons, Complaint Counsel fails to establish a properly defined market because the alleged market excludes Sophisticated Non-MPKs and is too narrow. In addition, the alleged market improperly combines High-End MPKs with other MPKs and is too broad.

Second, there has not been, and will not be, any harm to competition in Complaint Counsel’s alleged market because Freedom and Ottobock are not close competitors generally or with respect to MPKs specifically. Ottobock’s closest competitor is, and always has been, [REDACTED] [REDACTED] Ottobock’s C-Leg’s closest competitor is [REDACTED] These two products

compete most closely on functionality, price, quality, performance, reliability, and innovation. Ottobock and Össur are also the only competitors that offer High-End MPKs.

Freedom's only prosthetic knee, the Plié, has never been in the same league as the knees manufactured by Ottobock or Össur due in large part to its limited functionality, poor quality, and unsustainable value pricing strategy. Freedom's third, and latest, version of the product, the Plié 3, was released in 2014 and is already obsolete at the end of its technological life cycle. The Plié 3 is more similar in function to a Sophisticated Non-MPK because the Plié's resistance levels can only be adjusted manually (*i.e.*, with a wrench and an air pump). The Plié's microprocessor ultimately does very little, acting only as a "switch" between phases. In contrast, the C-Leg's microprocessor controls variation in resistance levels throughout the swing and stance phases of the knee. Further, the MPKs manufactured by Chas. A Blatchford & Sons Ltd., d/b/a/ Endolite ("Endolite"), Nabtesco Corporation ("Nabtesco"), and DAW Industries ("DAW") are all closer substitutes for the C-Leg than the Plié, making the Plié the most distant substitute for the C-Leg in an alleged market consisting of six manufacturers.

Third, the Acquisition poses no harm to competition because existing participants in the alleged relevant market have the capability, incentive, and desire to continue ongoing expansion well in excess of Freedom's annual output. The prosthetics marketplace is particularly accessible for inter-brand switching because of brand-agnostic reimbursement and sophisticated buyers. In the full calendar year prior to the Acquisition, Freedom sold [REDACTED] MPKs in the United States. Össur, Endolite, Nabtesco, and DAW all manufacture MPKs and collectively have additional annual capacity well in excess of [REDACTED]

[REDACTED]

[REDACTED] Nabtesco is also a quickly growing and highly motivated

company that [REDACTED]

Not only do they have the [REDACTED] but Endolite and Nabtesco have consistently priced their respective MPKs at around or below the prices offered by Freedom and below those of Ottobock. Thus, if Freedom were to exit the market or raise the price of the Plié, existing participants would quickly and effectively fill the void for consumers.

Fourth, the Acquisition does not pose harm to competition because power buyers and third-party reimbursement constrain the ability of manufacturers to raise prices. Hanger, Inc. (“Hanger”) is a public company with more than \$1 billion in annual revenue that controls approximately 800 prosthetics clinics of the clinics in the United States, and accounts for a very large portion of nationwide MPK purchases. Hanger has significant buying power and the ability to discipline manufacturers who attempt to impose price increases. For example, following the Acquisition, Hanger [REDACTED]

[REDACTED] Hanger is able to control the purchasing decisions of its clinics because the clinics obtain their prosthetic devices – including MPKs – directly from Hanger instead of the manufacturers. Hanger [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] is strong evidence that Hanger is well-positioned to combat any price increase by switching to other manufacturers.

Similarly, the system of third-party reimbursement in the United States constrains the ability of manufacturers to raise prices and induces inter-brand switching. Virtually all amputee

patients in this country receive prosthetic devices through some form of insurance with the most common types being Medicare and/or private insurance. Unlike other segments of the healthcare industry, Medicare sets the ceiling for insurance reimbursement, and private insurance companies reimburse anywhere from [REDACTED] less than the Medicare-allowable reimbursement. Because prosthetic clinics already operate with very thin margins, small increases in the cost of prosthetic device components, like prosthetic knees, would cause many clinics to operate unprofitably with respect to the very large group of patients covered by private insurance, and thus more likely to surrender to incentives to switch patients to Sophisticated Non-MPKs. Manufacturers, therefore, do not have room to profitably impose price increases, which is why many clinic representatives have testified that they believe the prosthetics industry’s unique third-party payer system constrains the ability of manufacturers to raise prices. Reimbursement is also brand agnostic, meaning it is commonplace for clinics to switch manufacturers.

Fifth, the Acquisition poses no harm to competition because Respondent has agreed to divest 100% of Freedom’s assets in the alleged relevant market (an “MPK Divestiture”).

Respondent has entered into an Asset Purchase Agreement (“APA”) with [REDACTED]

The MPK Divestiture eliminates any perceived harm to competition because it keeps 100% of the assets in the market alleged by Complaint Counsel under the control of a viable competitor to Respondent. In addition, any remedy broader than an MPK Divestiture would be overly broad, plainly punitive, and beyond the scope of legally supportable remedies available under Complaint Counsel's Claims.

And, *sixth*, Freedom's status as a failing business warrants rejection of Complaint Counsel's Claims. At the time of the Acquisition, Freedom owed approximately \$27.5 million to its lenders in September 2017 that it simply could not pay. Not a single witness at trial – including Complaint Counsel's own accounting expert – challenged the fact that Freedom could not meet its financial obligation to repay its enormous debt when due. In addition, Freedom was failing by virtually every financial measure in the months leading up to the Acquisition. Freedom also failed for years to meet its financial forecasts or to timely launch pipeline products. [REDACTED]

[REDACTED]

[REDACTED] Even Freedom's outside auditors had substantial doubt whether Freedom could continue as a going concern. After more than a year of consideration, Freedom was unable to attract refinancing partners, serious strategic acquirers other

than Ottobock, or develop a successfully Chapter 11 reorganization strategy. The only hope to avoid liquidation in September 2017 was the Acquisition by Ottobock. Significantly, the Acquisition was an absolute last resort for Freedom given that its investors and management lost many millions of dollars on the sale – more than [REDACTED] in the case of Freedom’s majority owner. If there had been any viable alternative, there is no reasonable question that such an alternative would have been vigorously pursued.

Freedom’s very unique financial circumstances at the time of the Acquisition destroy Complaint Counsel’s Claims. The “failing firm” defense is a complete defense to the Claims. Freedom easily qualifies for the defense because (i) Freedom could not meet its financial obligations – most notably, its obligation to repay approximately \$27.5 million in debt – in the near future; (ii) Freedom could not have successfully reorganized under Chapter 11 of the Bankruptcy Act because Freedom lacked access to the capital necessary to survive that process; and (iii) substantial good faith efforts to elicit reasonable alternatives to the Acquisition were unsuccessful. In addition to supporting the failing firm defense, the facts surrounding Freedom’s abysmal financial condition also rebut any presumption of harm to competition in the alleged relevant market because Freedom was so weakened that it posed virtually no competitive threat in the alleged market at the time of the Acquisition.

RELEVANT FACTUAL BACKGROUND

I THE PARTIES AND THE ACQUISITION

A. Ottobock

Ottobock was founded in 1919 to help victims of World War I. Respondent’s Proposed Findings of Fact and Conclusions of Law (“FOF”) ¶ 1. Having operated in the United States for over 60 years, Ottobock maintains U.S. headquarters in Austin, Texas with additional facilities in

Kentucky and Utah. FOF ¶ 3. Ottobock employs more than 475 people in the United States. FOF ¶ 3.

Since its founding in 1919, Ottobock has had a long history of disruptive innovation in the area of prosthetics and mobility solutions for amputees. FOF ¶ 2. This disruptive innovation has allowed Ottobock to significantly improve the quality of life and socio-economic welfare of amputees in the United States. FOF ¶ 3, 4. Original prostheses were made of wood. FOF ¶ 3. However, in 1953, the company's found, Otto Bock, began to use synthetic materials, which revolutionized the industry. In the sixties, Otto Bock made another groundbreaking development, which raised the quality of prosthetic fittings to a new level when it introduced the modular system for lower limb prostheses. Otto Bock is viewed by many as the Henry Ford of the prosthetics industry. FOF ¶ 3.

Ottobock has been particularly innovative with respect to prosthetic knees. Ottobock introduced the very the first microprocessor-controlled "swing-and-stance" phase knee, the C-Leg, to the United States in 1999. FOF ¶¶ 191, 610, 611. Since that time, Ottobock's C-Leg has become the "gold standard" MPK. FOF ¶¶ 610, 611, 615. The C-Leg is a "swing-and-stance" MPK because the C-Leg's microprocessor controls both the switch from swing to stance phase and also controls the variable resistance of the knee while engaged in each respective phase. FOF ¶¶ 193, 195. The C-Leg was quickly a huge success.

In addition to the overwhelming success of the original C-Leg and its subsequent versions, Ottobock has continued to innovate with respect to MPKs by offering customers various tiers of MPKs that suit different levels of patient mobility. FOF ¶¶ 182, 183, 218, 219. For example, Ottobock has developed the Compact and Kenevo for amputees with lower mobility levels than patients who qualify for a C-Leg. FOF ¶¶ 181-188. On the other end of the spectrum, Ottobock

has developed and marketed two High-End MPKs – the Genium and X3 – for the most active amputees, including active and retired U.S. service men and women, through partnership with the DOD and VA. FOF ¶¶ 505-507.

Ottobock also sells Non-MPKs, including Sophisticated Non-MPKs, such as the 3R80 and 3R60. These Sophisticated Non-MPKs may be waterproof, provide greater flexion, or be lighter weight than MPKs. FOF ¶¶ 143, 146, 148. Because they are designed for higher activity patients, these Sophisticated Non-MPKs are more similar in functionality to the C-Leg than they are to Ottobock’s lower activity MPKs, the Compact and Kenevo. FOF ¶ 478.

Despite Ottobock’s successful transformation of prosthetic knees, Ottobock has struggled to develop similarly effective prosthetic feet. FOF ¶¶ 952; 953, [REDACTED].

B. Freedom

Freedom was founded in 2002 by Dr. Roland Christensen and Rick Myers. Freedom is based in Irvine, California with a manufacturing facility in Gunnison, Utah. FOF ¶ 6. Freedom has a portfolio of lower limb prosthetic solutions and support services focusing mostly on prosthetic feet and ankles. FOF ¶¶ 5, 6. In particular, Freedom markets over 20 brands of carbon fiber feet that can be customized to fit any lifestyle from everyday walking to extreme sports. FOF ¶ 6. The vast majority of Freedom’s revenue is derived from the sale of prosthetic feet and ankles, and *not* prosthetic knees. FOF ¶ 6.

For the first five years of Freedom’s existence, it sold exclusively carbon fiber foot products. FOF ¶ 7. Since 2007, Freedom has only manufactured one prosthetic knee, the Plié. The Plié utilizes a microprocessor solely to switch between the stance phase and swing of the knee, but the Plié’s microprocessor does not control the knee’s resistance levels within each phase of walking. Unlike the C-Leg and other swing-and-stance MPKs available in the United States, the Plié’s resistance levels must be adjusted manually using a wrench and a pump.

At the time of the Acquisition, Freedom expected [REDACTED]

[REDACTED] Freedom has claimed to be developing a new MPK known as the “Quattro Project.”

[REDACTED]

The history of Freedom’s founding informs the type of company that it is today, and is therefore important to understand. In 1985, Freedom’s current Chairman, Maynard Carkhuff, joined a one-product company called Flex-Foot, and helped to grow that company to establish a broad portfolio of carbon fiber foot products. FOF ¶ 9. Though Flex-Foot was California-based, it manufactured its carbon fiber foot products in a manufacturing plant owned by Dr. Christensen and his company Applied Composite Technology (“ACT”), in Gunnison, Utah. FOF ¶ 9. Dr. Christensen sat on the Flex-Foot R&D team and produced 90 percent of Flex-Foot’s prototypes, but his company, ACT, was separate from Flex-Foot and acted as Flex-Foot’s vendor. FOF ¶ 9.

After developing its line of foot products, Flex-Foot acquired a knee manufacturing company called Mauch Laboratories, and sold the fluid-controlled Non-MPK that Mauch had developed. FOF ¶ 10. Flex-Foot then entered into a joint venture with MIT to develop an MPK. FOF ¶ 10.

In February 2000, before Flex-Foot could commercialize the MPK, Flex-Foot was sold to Össur. FOF ¶ 11. After that acquisition, Carkhuff worked for Össur as the President and CEO of Össur Prosthetics, and Flex-Foot was merged into Össur’s business. FOF ¶ 11. Össur continued to manufacture Flex-Foot carbon fiber foot products in the ACT manufacturing plant owned by Dr. Christensen. FOF ¶ 11.

Össur continues to sell products from the Flex-Foot acquisition under its brand name today, including a commercialized version of the MIT joint venture MPK, which is now known as the “Rheo.” FOF ¶ 12. [REDACTED]

[REDACTED] Össur has grown significantly since it purchased Flex-Foot in 2000, and it is now a publicly traded company. FOF ¶ 12.

In August of 2001, Össur terminated Mr. Carkhuff’s employment. FOF ¶ 13. Össur then moved the carbon fiber manufacturing from ACT’s plant in Gunnison, Utah to Össur’s headquarters in Reykjavik, Iceland. (Carkhuff, Tr. 306). FOF ¶ 13. That left Dr. Christensen with an empty plant, a large number of employees, and knowledge about carbon foot products. FOF ¶ 13. In 2002, Dr. Christensen formed Freedom with Myers, who was the head of operations for the Flex-Foot, and who was out of a job once Össur moved the manufacturing to Iceland. FOF ¶ 13. Following a contractual non-competition period, Carkhuff became the President of Freedom in 2005. FOF ¶ 13.

Since its inception, Freedom has manufactured its carbon fiber foot products in the same plant that Flex-Foot (and Össur) had previously manufactured carbon fiber foot products. (Carkhuff, Tr. 598). FOF ¶ 14. [REDACTED]

[REDACTED]

C. The Acquisition

Freedom’s abysmal financial state at the time of the Acquisition is discussed in detail in Section V, *infra*. In summary, Freedom was experiencing catastrophic financial problems at the time of the Acquisition and was on the verge of liquidation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] From the time David Smith became CEO in April 2016 until the closing of the Acquisition in September 2017, Freedom exhausted good faith efforts to find both potential investors and potential acquirers. In addition, Freedom formally engaged an international investment bank – Moelis & Company (“Moelis”) – to assist with those efforts. FOF ¶ 1451. [REDACTED]

[REDACTED]

[REDACTED] Freedom’s pending debt payment made time of the essence. FOF ¶ 1313. Ottobock was the only serious potential buyer that was prepared to close an acquisition in time to pay Freedom’s debt. FOF ¶ 1506.

Ottobock acquired Freedom on September 22, 2017 for [REDACTED] pursuant to an Agreement and Plan of Merger (“Merger Agreement”). FOF ¶ 17. From Ottobock’s perspective, the Acquisition’s primary strategic rationale was to [REDACTED]. FOF ¶ 941. [REDACTED]

[REDACTED] This is not surprising given that Freedom only sold one prosthetic knee, the Plié, prior to the Acquisition.

FOF ¶ 7. [REDACTED]

[REDACTED]

[REDACTED]

Freedom has a great line of prosthetic feet, and sells over twenty brands of feet in the United States. FOF ¶ 5. Competing manufacturers consistently rank Freedom among the leading manufacturers of K3/K4 feet. FOF ¶¶ 945, 946. A voice-of-customer survey recently conducted by Freedom confirmed that Freedom’s feet are highly valued by customers. (Ferris, Tr. 2316). Conversely, Ottobock’s feet do not have a good reputation in the industry, and they do not rank highly among manufacturers of K-3/K-4 feet. FOF ¶¶ 947, [REDACTED] Ottobock bought Freedom to boost its reputation for feet, and fill portfolio gaps. FOF ¶ 948. The Acquisition thus made perfect sense with respect to foot products.

During the FTC’s investigation of the Acquisition, on December 19, 2017, Ottobock executed a Hold Separate and Asset Maintenance Agreement, agreeing to hold Freedom separate and maintain its assets (the “Hold Separate Agreement”). FOF ¶ 1115.

II THE PROSTHETICS INDUSTRY

A. The Consumers Of Prosthetic Devices

Manufacturers of prosthetic components typically sell products to prosthetic clinics, which then fit such products on amputee patients. FOF ¶ 113. Patients do not purchase prosthetic devices directly from manufacturers. FOF ¶ 113. Prosthetic clinics can operate as independent entities, through large networks of clinics, or may be affiliated with a hospital. FOF ¶ 113. There are approximately 3,400 prosthetic clinics in the United States. FOF ¶ 113. Prosthetic clinics employ “Certified Prosthetists,” who are certified by the American Board for Certification in Orthotics,

Prosthetics, and Pedorthics to make and fit prostheses and manage comprehensive patient care of amputees. FOF ¶ 114. There are approximately 6,500 Certified Prosthetists in the United States. FOF ¶ 113. Frequently, Certified Prosthetists are also “Certified Orthotists,” and prosthetic clinics also frequently provide orthotic care to patients. FOF ¶¶ 48, 49, 56. Prosthetic clinics purchase most components from prosthetic manufacturers or distributors, but may fabricate certain components themselves, such as sockets. FOF ¶ 89. Typically, clinics do not stock prosthetic components, but purchase them individually for each particular patient. FOF ¶ 89.

B. Above-The-Knee Prosthetic Components

This case concerns prosthetic devices that are fit on above-the-knee amputees because these are the patients who require a prosthetic knee component. FOF ¶ 87. An above-the-knee prosthetic device is typically composed of several prosthetic components, including a liner, socket, prosthetic knee, and prosthetic foot. FOF ¶ 88. The prosthetic foot may also have an ankle component to it. FOF ¶ 88. There may be cosmetic or protective covering on the prosthetic components. Pylons and connectors connect the components of the prosthetic device together. FOF ¶ 88.

Liners: A liner is a product that goes over the patient’s residual limb to shield the residual limb from rubbing against the socket. FOF ¶ 1175. [REDACTED]

[REDACTED]

Sockets: A socket is a device that is typically custom-manufactured by a prosthetist from commodity products, such as plastics, polypropylene or carbon fiber. FOF ¶ 90. That product is custom-made by the prosthetist to fit the patient’s residual limb. FOF ¶ 90. The creation of the socket is important, to make sure that the product is very comfortable to the patient, avoiding nerves and scars that could cause pressures. FOF ¶ 90. The socket goes over the patient’s residual

limb, and the socket provides a means to secure the device to the patient, and then from the bottom of the socket all of the prosthetic components are attached. FOF ¶ 90.

Knees: Prosthetic knees available for sale to prosthetic clinics in the United States range in sophistication from “basic mechanical knees, single-axis brake knees, all the way to knees that are designed for . . . K3 or K4 level ambulatory, so they have swing and stance control, stumble recovery.” FOF ¶ 93. This range in functionality includes knees that contain microprocessors (MPKs), and knees that do not (Non-MPKs). More specific descriptions of those knees can be found in Section II.F., *infra*.

Feet: Prosthetic feet are grouped by mobility level, like other lower-limb prosthetics. Prosthetic feet range from softer, low activity feet to carbon fiber or glass composite feet that have energy return and are appropriate for higher activity K-3/K-4 patients. FOF ¶ 94. [REDACTED]

[REDACTED]

C. Third-Party Payer Reimbursement System

The prosthetics industry is dominated by a government and private insurance payer reimbursement system. Payers reimburse clinics for the provision of prosthetic devices based on the “L-Code” system created by The Centers for Medicare and Medicaid Services (“CMS”). FOF ¶ 124. L-Codes describe certain features or functions of components of a prosthetic device; each structural component of a prosthetic device will have one or more L-Codes for various functional aspects of the device. FOF ¶ 124. CMS establishes an allowed reimbursement amount for each L-Code. FOF ¶ 124. Other public and private insurance payers derive reimbursement amounts for the same devices from the amounts set by CMS with respect to a particular L-Code. FOF ¶ 277, 278. Private insurance payers generally reimburse at amounts below the CMS allowed reimbursement. FOF ¶ 276.

Clinics bill payers for the prosthetic devices they deliver to patients by identifying applicable L-Codes and then adding up the allowed reimbursement correspondence to each identified L-Code for the prosthetic device. FOF ¶ 262. Prosthetic components generally have a base L-Code associated with them, and could have additional codes, depending on functionality. FOF ¶¶ 188, 189, 262.

Manufacturers recommend certain L-Codes for their prosthetic components based on the manufacturers' claims about the functionality of their respective prosthetic devices. FOF ¶ 308. Some manufacturers elect to obtain outside confirmation of those claims by obtaining verification of recommended L-Codes by a Pricing, Data, Analytics Contractor ("PDAC"). FOF ¶ 308. If a manufacturer's product received PDAC verification, prosthetic clinics purchasing the PDAC-verified product from the manufacture security that insurance coverage will not be denied for incorrect L-Coding of the product. FOF ¶ 307.

For prosthetic components with new functionality not captured by established L-Codes, manufacturers can apply for new L-Codes. FOF ¶ 320. [REDACTED]

[REDACTED] In order for an L-Code to be established, the benefits of a particular function must be established and accepted. FOF ¶ 322. Once established, other manufacturers can take advantage of the additional coding obtained and create new products. FOF ¶ 322. Therefore, the presence of an industry leader and innovator, like Ottobock, willing to invest in new products, prove their efficacy, and lobby for additional L-Coding is critically important to improving the lives of amputees. FOF ¶¶ 319-322.

Medicare and private insurance payers do not reimburse at difference rates for different by manufacturers; instead, the payer's focus is the claimed functionality of the device for which a

clinic is seeking reimbursement. FOF ¶ 331. In other words, the amount that a payer will reimburse is determined by the L-Code, not by the particular brand of device or the price the clinic pays for the device. FOF ¶ 331. Without an established L-Code for a particular function, clinics will not be able to obtain additional reimbursement for that function. FOF ¶ 331. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The allowed CMS L-Code reimbursement sets an absolute ceiling on the clinics ability to recover compensation of its services. FOF ¶ 269. The 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. FOF ¶ 269. Fitting prosthetic devices frequently requires several follow-up visits, and can be extremely time-intensive making reliable payer reimbursement very important to the success of prosthetic clinics. FOF ¶ 268.

D. Patient “K-Level” Mobility

Clinics and manufacturers frequently categorize lower-limb prosthetic components by “K-Level,” which reflects the mobility level of an amputee patient. FOF ¶ 91. The patient’s “K-Level” is a very important consideration in deciding what type of prosthetic device is medically appropriate and subject to payer reimbursement. FOF ¶ 91. K-Levels are sometimes referred to as “MFCL levels,” which stands for Medicare Functional Classification Levels. FOF ¶ 91.

A patient is assigned a level between K-0 and K-4 based on the following mobility descriptions:

Level	Description
K-0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
K-1	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K-2	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
K-3	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.
K-4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

FOF ¶ 91-92.

CMS – and as a result, private insurance payers – will only reimburse a clinic for certain L-Codes that correspond to certain K-levels. FOF ¶ 92 For example, the “base” L-Code for a “swing-and-stance” microprocessor knee is L5856, which establishes the reimbursement amount for the swing and stance microprocessor control function of the knee. FOF ¶ 189. Clinics can only be reimbursed through Medicare for L5856 if the patient receiving the device is classified as K-3 or K-4, or if the patient has been determined to have the potential to become classified as K-3.¹ FOF ¶ 191.

¹Medicare has sponsored Recovery Audit Contractors (“RAC”) audits to ferret out clinics fitting more expensive MPKs on patients for whom cheaper Non-MPKs might suffice, which has led to clinics curtailing use of MPKs in favor of Non-MPKs. See also Section II.B.1.b.ii, *infra*. (discussing RAC audits in the context of MPKs and Non-MPKs).

K-Level restrictions and classifications are not just limited to MPKs. They apply to all lower-limb prosthetic components. FOF ¶ 240. In fact, Complaint Counsel’s economic expert, Fiona Scott Morton, includes the following description of the prosthetic knees that are appropriate for each K-Level at page 13 of her Opening Report (FOF ¶ 92):

Descriptions for the Medicare Functional Classification Levels and Medicare
Guidelines for Covered Prostheses

K-Level	Description	Medicare Reimbursed Prosthetic Knee
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.”	None
K-1	Household Ambulator: “Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence.”	Constant Friction Knee
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.”	Constant Friction Knee
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.”	Fluid Control Knee, Non-Microprocessor or Microprocessor-Controlled Knee
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.”	Fluid Control Knee, Non-Microprocessor or Microprocessor-Controlled Knee

Because the K-Level classification system plays such a large role in the selection and reimbursement of prosthetic componentry, manufacturers and clinics categorize products by K-

Level. FOF ¶¶ 242, 476. For example, in the product selection guide for one of the prosthetic clinics whose representative testified at trial, Center for Orthotics and Prosthetic Care (“COPC”), the products are segmented by K-Level. FOF ¶ 476. In addition, both Össur and Endolite present their respective products by K-Level. FOF ¶¶ 488, 490. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

E. Prosthetic Knee Fitting Process

Amputee care typically begins with surgery, and thus the surgeon that performs the patient’s amputation. FOF ¶ 96. After surgery, the amputee’s care team may include a physiatrist (a physician with a specialty in rehabilitation), a physical therapist, and a prosthetist. . FOF ¶¶ 127, 115. To understand how prosthetic devices – and prosthetic knees in particular – are selected and fitted, it is critical to understand how the process typically works and also how it varies depending on the particular prosthetic clinics.

1. Amputation Surgery

There are several different conditions that could cause a patient to need an amputation. These conditions include congenital conditions, trauma, or vascular conditions. . FOF ¶ 95. The most common cause of lower-limb amputation in the United States is diabetes, which can cause vascular issues in the patient’s legs, requiring an above-the-knee or below-the-knee amputation. FOF ¶ 95.

When a patient undergoes amputation surgery, the procedure is typically performed by an orthopedic or vascular surgeon. FOF ¶ 96. The surgeon determines where on the limb to do the amputation. FOF ¶ 96. In general, surgeons prefer to leave as long of a residual limb as possible

following amputation and will perform the amputation at the most distal part of the limb that is clinically available. FOF ¶ 96.

An above-the-knee amputation is also referred to as a transfemoral amputation. (Doug Smith, Tr.). FOF ¶ 97. In a typical transfemoral amputation, after a patient is under anesthesia, the surgeon makes a skin incision generally just above the knee level. FOF ¶ 97. He then reflects the skin flaps towards the hip, dissects down and divides the muscle typically a little bit longer than the skin flaps so the muscle would be available to fold over the bone for both residual limb control and padding, and the surgeon transects the muscle at that level. FOF ¶ 97. Then the surgeon isolates the femur and transects the femur with a saw. FOF ¶ 97. The surgeon must next divide the muscles of the posterior leg, get control of the bigger blood vessels which require isolation, and tie those off. FOF ¶ 97. The surgeon then identifies the sciatic nerve and makes sure that it is not at the bottom of the residual limb when the patient is going to be walking. FOF ¶ 97.

After the amputation is complete, the surgeon must make sure that the residual limb is closed up properly, which can be more difficult than removing the leg. FOF ¶ 98. The surgeon endeavors to put the amputation back together in the most functional possible status, typically consisting of tying some critical muscle groups into the bone to allow the amputee to be able to move the residual limb. FOF ¶ 98. The surgeon anchors the muscle groups into the bone for function and for additional padding. FOF ¶ 98. Then, the surgeon trims the skin edges and closes the skin with sutures, after placing a drain in the leg to prevent extra fluid from accumulating. FOF ¶ 98.

2. Patient Rehabilitation And Initial Prosthesis

Following surgery, patients typically stay overnight at an inpatient facility from at least three days to a more than a week. FOF ¶ 99. While inpatient, the patient is fit with a “shrinker”

stocking on the residual limb to decrease the swelling and mold the limb to prepare it for eventual socket use. FOF ¶ 99. After three weeks, a patient is typically ready to have sutures removed, and after six weeks, to be fit with an initial prosthesis. FOF ¶ 99.

About sixty days after surgery, the physician refers the patient to a prosthetist to be evaluated for an initial prosthesis, which is also known as a temporary prosthesis. FOF ¶ 100. Prosthetists typically fit a basic K-1 or K-2 level knee as the initial prosthesis that is stable in design. FOF ¶101. The socket that is created is meant to be used short term, because the residual limb is still swollen from surgery and has not reduced to its final size and shape. FOF ¶101.

3. Definitive Prosthesis

Approximately six months after receiving an initial prosthesis, an amputee is typically ready for a definitive prosthesis. FOF ¶102. In the case of transfemoral amputation, prosthetists help amputees choose the best knee based on the particular patient. FOF ¶ 103. The prosthetist will also teach the amputee how to use that knee properly, which is critical to avoid discomfort, stumbling, and falling. FOF ¶ 268.

Typically, to begin their evaluation for a definitive prosthesis, prosthetists receive a vague referring prescription which does not identify a specific type or brand of knee to be fit on a patient, but may indicate the physician's assessment of mobility level. FOF ¶ 130. Once the treating physician clears a patient to receive a definitive prosthesis, the prosthetist begins consulting with the patient to determine the best prosthetic componentry for that patient. FOF ¶115.

The prosthetist begins the consultation by talking with the patient, understanding their goals, activities of daily living, and history. FOF ¶115. During the initial evaluation, the prosthetist also does functional level testing in order to determine the patient's K-Level, which must be corroborated by the physician. FOF ¶115.

After the K-Level is determined, prosthetists have discretion to choose among different prosthetic knees that are appropriate for the designated K-Level based on financial considerations of the prosthetic clinic and the patient as well as based on myriad other factors, including the patient's mobility level, weight, and vocation, among other things. FOF ¶115 (Sabolich, Tr. 5834 (testifying that there are a hundred knees to choose from and after the consultation he narrows the selection down to a few different options). Both MPKs and Sophisticated Non-MPKs are medically appropriate for patients with K-3 or K-4 mobility levels. FOF ¶115, 449, 451. Patients have discretion to choose among different prosthetic knees that are medically appropriate based on financial considerations as well as the fit and features of the prosthetic knee. FOF ¶ 107.

Sometimes, the treating physician is also involved in the evaluation for a definitive prosthesis to the extent the physician familiar with prosthetic components. FOF ¶ 128. In these cases, the prescription for a prosthetic knee is more detailed, and may contain greater specificity regarding the knee to be fit on the patient. FOF ¶ 128. However, the physician does not prescribe a category of knee to be fit on a patient before speaking with the patient about vocation, activities of daily living, or preferences. FOF ¶ 129.

Once the prosthetist and the patient have selected the components that will comprise the patient's definitive prosthesis, the prosthetist prepares a Detailed Written Order, which lists the L-Codes that correspond to the components that the prosthetist intends to use to create the prosthesis. FOF ¶120. The treating physician must sign off on the Detailed Written Order. FOF ¶ 120.

It takes prosthetists several weeks to fit a patient with a prosthetic device, and can take several visits. FOF ¶ 119. Patients frequently make follow-up visits with their prosthetists after they receive their prosthetic device. FOF ¶ 119.

For Medicare patients, prosthetists do not generally submit documentation to Medicare at the time that the prosthetist delivers the device. FOF ¶ 289. This is because Medicare does not have a predetermination process like those employed by private insurance carriers. FOF ¶ 289. Instead, the paperwork stays with the clinic, and if Medicare identifies something suspicious in the future, the clinic is at risk of a demand for documentation and/or an audit. FOF ¶ 289.

F. Prosthetic Knees For High Activity Patients

K-3 and K-4 patients benefit medically after being fit with both MPKs and Sophisticated Non-MPKs. FOF ¶ 343. There are a wide variety of such knees available in the United States. FOF ¶ 472. MPKs and Sophisticated Non-MPKs are highly differentiated products that patients must compare and contrast before making a selection. FOF ¶¶ 471, 478. For example, these complex prosthetic knees can vary in length, weight, battery life (if applicable), aesthetics, water resistance, flexion angle, and technological platform. FOF ¶ 143.

The functionality of higher activity knees generally relies on resistance provided by fluid (including air or liquid) passing through ports in the mechanical system of the knee. The resistance level depends on the degree to which the ports are open or closed at any given moment. FOF ¶ 139. The resistance level can be set manually or by operation of a microprocessor. FOF ¶¶ 7, 146, 195. Among MPKs, the level of involvement that the microprocessor has in changing the knee's resistance varies. FOF ¶¶ 168, 174, 181, 192. For example, the C-Leg's resistance levels are entirely controlled by its microprocessor while the Plié's resistance levels must be adjusted manually with a wrench or an air pump, depending on the phase (*i.e.*, swing or stance) making it more similar to a Sophisticated Non-MPK than to the C-Leg. FOF ¶¶ 173, 192. Thus, the mechanical platform through which the knee function is more important than the mere presence of a microprocessor because it is that system through which the knee actually functions. FOF ¶ 336.

Hydraulic and pneumatic controls in MPKs and Sophisticated Non-MPKs allow an amputee to walk at a variable cadence, and therefore, from a clinical standpoint, any sophisticated prosthetic knee with a hydraulic or pneumatic system – whether microprocessor-controlled or not – is clinically appropriate for a K3 and K4 amputee. FOF ¶ 335. Consequently, the same patient population would benefit from both the Ottobock 3R80, a Sophisticated Non-MPK, and the C-Leg 4 MPK, ultimately making a choice based on the individual patient’s weighing of the features of both knees. FOF ¶ 393. Both MPKs and Sophisticated Non-MPKs are only available for reimbursement to K-3 and K-4 patients under the payer system in the United States; K-0, K-1, and K-2 patients are not eligible for reimbursement for these knees from public or private payers. FOF ¶ 92.

1. Sophisticated Non-MPKs

There are several Sophisticated Non-MPKs on the market appropriate for K-3 and K-4 patients. These knees utilize hydraulic and/or pneumatic controls for the swing and/or stance phases of the knee. Those swing-only fluid control knees are usually polycentric knees, like Ottobock’s 3R60. FOF ¶ 143. Scott Schneider, Ottobock’s Vice President of Government, Medical Affairs, and Future Development, described the 3R60 as a “super cool knee” with “a lot of sophistication.” FOF ¶ 143.

There are also Sophisticated Non-MPKs with full hydraulic swing and stance phase control, such as Ottobock’s 3R80, the Mauch S&S from Össur, and Endolite’s Mercury Knee. FOF ¶ 143. In the 3R80, for example, the friction that the knee produces for the swing and stance phases can be adjusted manually with turntables and wrenches. FOF ¶ 46. Ottobock’s competitors also offer hydraulic and/or pneumatic knees suitable for K-3 to K-4 activity patients. These knees include Össur’s Mauch Knee, Total Knee, and Medi Knees, as well as Endolite’s Mercury Knee. FOF ¶ 143.

2. Microprocessor-Controlled Switch-Only Knees

A fluid-controlled knee with a microprocessor-controlled switch (“MP-Switch”) uses sensors and a microprocessor to switch the prosthetic knee between swing and stance phase. FOF ¶ 168. The swing and stance phases otherwise offer a predetermined resistance level set by the prosthetist or the patient. FOF ¶¶ 168, 170. The microprocessor in the Plié 3 can switch the knee from a fixed stance phase resistance and a fixed swing phase resistance, but it cannot vary the resistance throughout the gait cycle. FOF ¶ 168. The Plié 3 is the only MPK on the United States market with this limited functionality. FOF ¶ 167.

As Freedom’s current Chairman, Carkhuff, described the Plié 3: “[O]ur microprocessor will switch the product from stance to swing. Other products will control the actual resistance in a continuous manner throughout a range. The Plié microprocessor does not do that. The Plié basically is triggering the knee from stance to swing.” FOF ¶ 606. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The stance flexion resistance on the Freedom Plié 3 is set manually using screws and bezels, very similar to the way the resistance is set on the Ottobock 3R80. FOF ¶ 172. In addition, the Plié 3 uses a pneumatic cylinder to control swing resistance that leaks air over time and must be pumped up manually, using a small pump similar to a bicycle pump that comes with the knee. The knee leaks air often enough that users of the Plié 3 are supposed to carry their pumps around

with them. FOF ¶ 583. One prosthetist expressed annoyance at this design flaw in the Plié 3, saying that “I think it’s very janky, for lack of a better word, to say here’s an expensive knee, but you have to carry this plastic pump around with you. It’s sort of silly.” FOF ¶ 593.

Freedom describes its Plié 3 as obsolete at the end of the product lifecycle, as it is getting a little “long in the tooth.” FOF ¶ 594. In particular, Carkhuff testified that with the Plié 3 alone, without redesigning the product, “it’s going to be very difficult . . . to maintain [knee] sales because competitive brands have continued to innovate and outdistance all of the features that . . . the Freedom product has, so it would be very difficult to gain share.” FOF ¶ 595. Ottobock’s due diligence team agreed at the time of the Acquisition, concluding that among Plié 3’s main limitations was the fact that it had “outdated technology” when compared to other MPK. FOF ¶ 596.

3. Microprocessor-Controlled Swing-Only Knees

A fluid-controlled knee with a microprocessor-controlled swing phase only (“MP-Swing”) uses sensors and a microprocessor to switch the prosthetic knee between swing and stance phase and to provide variable resistance control in the swing phase of the knee. FOF ¶ 174. The resistance in the swing phase of the knee is set to a predetermined level by the prosthetist. FOF ¶ 175. The SmartIP sold by Endolite in the United States is an example of a MP-Swing knee. FOF ¶ 176. The SmartIP was developed in the late 1980’s-early 1990’s with microprocessor-controlled swing technology licensed from Nabtesco. FOF ¶ 176. The SmartIP uses a microprocessor to control the resistance in the swing phase but not the stance phase, and is reimbursed with the base

L-Code L5857. FOF ¶¶ 177, 180. MP-swing only knees are typically fit on patients who are very physically active. (Kannenber, Tr. 1956). FOF ¶ 177.

4. Microprocessor-Controlled Stance-Only Knees

A fluid-controlled knee with a microprocessor-controlled stance phase only (“MP-Stance”) uses sensors and a microprocessor to switch the prosthetic knee between swing and stance phases and to provide variable resistance control in the stance phase of the knee. FOF ¶ 181. The resistance in the swing phase of the knee is set to a predetermined level by the prosthetist. FOF ¶ 181.

The Compact and Kenevo sold by Ottobock in the United States are examples of MP-Stance knees. FOF ¶ 181. Ottobock’s Kenevo and Compact use a microprocessor to control the stance phase of the knee, but the swing phase is set manually. FOF ¶ 181. MP-Stance knees, such as the Kenevo and Compact, are reimbursed under the base L-Code L5858 and suitable for lower activity patients. FOF ¶¶ 183, 186, 187.

5. Microprocessor-Controlled Swing-And-Stance Knees

A fluid-controlled knee with a microprocessor-controlled swing-and-stance phase control (“MP-Swing-and-Stance”) uses sensors and a microprocessor to switch the prosthetic knee between swing and stance phases and to provide variable resistance control in both the swing and stance phases of the knee. FOF ¶ 195. Examples of MP-Swing-and-Stance knees sold in the United States include Ottobock’s C-Leg, Genium, and X3, Össur’s Rheo and Rheo XC, Endolite’s Orion, Nabtesco’s Allux, and DAW’s Stealth Knee. FOF ¶ 190.

6. High-End MPKs

The High-End MPKs are the most technologically state-of-the-art MP-Swing-and-Stance knees. They are characterized by enhanced technological features and by prices two to three times the amount of other MP-Swing-and-Stance knees. FOF ¶ 217. High-End MPKs are typically not

reimbursed by Medicare and private insurers for their enhanced technological features. FOF ¶ 228. The DOD, VA, and Workers' Compensation are the most common sources of reimbursement for High-End MPKs. FOF ¶ 228. High-End MPKs include Ottobock's Genium and X3 and Össur's Rheo XC and Power Knee. FOF ¶ 218, 224.

7. **Integrated MPK Leg Systems**

A fluid-controlled knee and foot integrated together and controlled by microprocessors combine a MP-Swing-and-Stance knee with a microprocessor-controlled ankle. FOF ¶ 235. The sensors and microprocessor in the knee are able to communicate with the sensors and microprocessor in the ankle. FOF ¶ 236. Endolite's Linx and Össur's Symbionic are Integrated Leg Systems. FOF ¶¶ 237, 238.

G. **Interchangeability Of MPKs And Non-MPKs**

The same patient population would consist of target customers for a Sophisticated Non-MPK, like the 3R80, or an MPK, like the C-Leg 4. FOF ¶ 478. However, the same patient population would not consist of target customers for both the C-Leg 4 and the Keveno, even though both knees are MPKs. FOF ¶ 478. Indeed, prosthetists recognize that certain Non-MPKs and certain MPKs are medically appropriate for the same patient population, and that each patient must weigh the pros and cons of all medically appropriate options in consultation with the prosthetist before making a knee selection. FOF ¶¶ 394-397.

LEGAL ARGUMENT

I APPLICABLE LEGAL STANDARD

The "analytical approach to Section 7 cases . . . has traditionally consisted of a burden shifting exercise with three parts." *In re Polypore Int'l*, 149 F.T.C. 486, 798 (F.T.C. March 1, 2010) (Chappell, A.L.J.) (citing *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990)). "First, the government must establish a *prima facie* case that an acquisition is

unlawful.” *Id.* (citing *Baker Hughes*, 908 F.2d at 982; *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 715 (D.C. Cir. 2001)). It is not enough for Complaint Counsel to show some effect on competition. Instead, Complaint Counsel “has the burden of showing that the acquisition is reasonably likely to have ‘demonstrable and substantial anticompetitive effects.’” *New York v. Kraft General Foods, Inc.*, 926 F. Supp. 321, 358 (S.D.N.Y. 1995) (quoting *United States v. Atlantic Richfield Co.*, 297 F. Supp. 1061, 1066 (S.D.N.Y. 1969)).

“Second, once the government establishes the *prima facie* case, the respondent may rebut it by producing evidence to cast doubt on the accuracy of the government’s statistical evidence as predictive of future anticompetitive effects.” *Id.* (citing *Baker Hughes*, 908 F.2d at 982; *Chicago Bridge & Iron Co. N.V. v. Federal Trade Commission*, 534 F.3d 410, 423 (5th Cir. 2008)). “This second step of the analysis requires that the merger be ‘functionally viewed, in the context of its particular industry.’” *Id.* (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 321-22 (1962) and citing *In re Weyerhaeuser Co.*, 106 F.T.C 172, *215 (F.T.C. Sept. 26, 1985)). “Nonstatistical evidence which casts doubt on the persuasive quality of the statistics to predict future anticompetitive consequences may be offered to rebut the *prima facie* case made out by the statistics.” *Id.* (quoting *Kaiser Aluminum & Chem. Corp.*, 652 F.2d 1324, 1341 (7th Cir. 1980)).

“Third, and finally, if the respondent successfully rebuts the *prima facie* case, the burden of production shifts back to the government and merges with the ultimate burden of persuasion, which is incumbent on the government at all times.” *Id.* at 801 (citing *Baker Hughes*, 908 F.2d at 983; *Chicago Bridge*, 534 F.3d at 423; *FTC v. University Health, Inc.*, 938 F.2d 1206, 1218-19 (11th Cir. 1991); *Kaiser Aluminum*, 652 F.2d at 1340); *see also FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 116 (D.D.C. 2004) (“[P]laintiffs have the burden on every element of their Section

7 challenge.”). The legal standards for evaluating Complaint Counsel’s claim under Section 5 of the FTC Act are the same. *Polypore*, 149 F.T.C. at 798.

II COMPLAINT COUNSEL HAS FAILED TO SATISFY ITS BURDEN TO ESTABLISH A CLEARLY DEFINED RELEVANT ANTITRUST MARKET.

Complaint Counsel alleges that the relevant product market is no broader than the manufacture and sale of microprocessor prosthetic knees to prosthetic clinics in the United States. Complaint ¶ 17. That alleged market is impermissibly too broad and too narrow. Complaint Counsel’s assertion that all prosthetic knees that contain a microprocessor somewhere in the knee’s structure constitute a relevant market ignores significant evidence that patients, prosthetists, physicians, and payers consider Sophisticated Non-MPKs to be in the same market as certain MPKs as they are all medically appropriate options for the same patient population. Complaint Counsel’s exclusion of all Non-MPKs from its alleged market renders it fatally narrow. Complaint Counsel also incorrectly includes High-End MPKs, like the Genium and X3, that are about three times the price of a typical MPK and are only available to a very small patient population (*e.g.*, DOD, VA, and Workers’ Compensation patients). For this reason, Complaint Counsel’s alleged market is also far too broad.

A. Complaint Counsel Bears The Burden Of Establishing A Clearly Defined Relevant Antitrust Market.

“The first step in analyzing a Section 7 case is to determine the ‘line of commerce’ and the ‘section of the country.’” *Polypore*, 149 F.T.C. at 799 (quoting 15 U.S.C. § 18). “In other words, the first step is to determine the relevant product and geographic markets.” *Id.* (citing *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1110 (N. D. Cal. 2004); *In re R.R. Donnelley & Sons*, 120 F.T.C. 36, 1995 FTC LEXIS 450, at *37-38 (F.T.C. July 21, 1995); *United States v. General Dynamics Corp.*, 415 U.S. 486, 510 (1974)). “Complaint Counsel bears ‘the burden of

proving a relevant market within which anticompetitive effects are likely as a result of the acquisition.” *Id.* at 799 (quoting *In re R.R. Donnelley & Sons*, 1995 FTC LEXIS 450, at *38).

“A properly defined or relevant product market identifies the products with which the defendants’ products compete and should include those producers that have the actual or potential ability to take significant business from each other.” *Polypore*, 149 F.T.C. at 802-03 (citing *FTC v. CCC Holdings*, 605 F. Supp. 2d 26, 37 (D.D.C. 2009); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978)). “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 also United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 394 (1956). Complaint Counsel bears the burden of establishing a product market by a preponderance of the evidence. *United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 183, 190-91 (N.D. Ill. 2001) (finding that DOJ failed to carry its burden of establishing the relevant product market where customer testimony was found to be at best “equivocal”).

Courts have “traditionally emphasized” two factors in defining a product market: “the reasonable interchangeability of use and the cross-elasticity of demand between the product itself and substitutes for it.” *Polypore*, 149 F.T.C. at 803 (quoting *Arch Coal*, 329 F. Supp. 2d at 119 and *Brown Shoe*, 370 U.S. at 325). “These factors address the question of ‘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.’” *Id.* (quoting *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997)).

“If products can be used for the same purpose, the products are deemed ‘functionally interchangeable.’” *Polypore*, 149 F.T.C. at 804 (quoting *United States v. Chas. Pfizer & Co.*, 246

F. Supp. 464, 468 (E.D.N.Y. 1965) and citing *Arch Coal*, 329 F. Supp. 2d at 119). “Courts generally place functionally interchangeable products in the same product market.” *Id.* (citing *Arch Coal*, 329 F. Supp. 2d at 119). “However, products are only included in the same market if they are both functionally and reasonably interchangeable.” *Id.* (citing *Pfizer*, 246 F. Supp. at 468 n.3); see also *United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 399, 404 (1956)). “Customer preferences for one product versus another do not negate reasonable interchangeability.” *Id.* at 830 (quoting *Oracle*, 331 F. Supp. 2d at 1130-31) (brackets omitted). “[T]he issue is not what solutions the customers would like or prefer for their . . . needs; the issue is what they could do in the event of an anticompetitive price increase by [the merged entity].” *Id.* (quoting *Oracle*, 331 F. Supp. 2d at 1131) (substitutions and omission in original).

In differentiated product markets, market definition is particularly nuanced because “to make a sharp distinction between products ‘in’ and ‘out’ of the market can be misleading if there is no clear break in the chain of substitutes.” *Oracle*, 331 F. Supp. at 1120. The consequences of getting the definition wrong in a unilateral effects case can be severe, because “if products ‘in’ the market are but distant substitutes for the merging products, their significance may be overstated by inclusion to the full extent that their market share would suggest; and if products “out” of the market have significant cross-elasticity with the merging products, their competitive significance may well be understated by their exclusion.” *Id.* (citing Carl Shapiro, *Mergers with Differentiated Products*, 28 *Antitrust* 23).

B. There Is No Relevant Market That Consists Solely Of MPKs That Does Not Also Include Any Non-MPKs.

Complaint Counsel has failed to carry its burden of establishing a properly defined relevant market under both the practical indicia criteria established by *Brown Shoe* and the hypothetical monopolist test. Under the Supreme Court’s decision in *Brown Shoe*, the following factors are

relevant to defining a market, as they illuminate the practical realities underpinning an industry: (1) the product’s peculiar characteristics and uses; (2) distinct customers; (3) distinct prices; (4) sensitivity to price changes; (5) specialized vendors; and (6) industry or public recognition of the market as a separate economic entity. 370 U.S. at 325. These factors do not support exclusion of Sophisticated Non-MPKs from the alleged market by Complaint Counsel.

The hypothetical monopolist test is a leading test used by economists, and is set forth in the 2010 Horizontal Merger Guidelines (the “Merger Guidelines”). The test asks whether a hypothetical monopolist who has control over all of the products in an alleged market could profitably raise prices on those products, by imposing a SSNIP. *Oracle*, 331 F. Supp. 2d at 1111-12). If enough customers would switch to products outside of the proposed relevant market so that the price increase would not be profitable, the proposed relevant market is too narrow. Merger Guidelines § 4.1.3. The number of customers that must switch in order to defeat a price increase is referred to as “critical loss.” *Id.*

Applying the evidence at trial to the *Brown Shoe* factors and the hypothetical monopolist test reveals that any relevant market including both the C-Leg 4 and the Plié 3 must also include Sophisticated Non-MPKs.

1. MPKs And Non-MPKs Are Reasonably Interchangeable.

Prosthetic knees are differentiated products, and range significantly in their features and functions. Sophisticated Non-MPKs and MPKs are the same mechanically; the only difference between them is presence or absence of a microprocessor to control certain functions. FOF ¶ 336. The more complex and important aspects of prosthetic knees are the physical attributes of the mechanics of the knee, such as the hydraulic or pneumatic cylinder systems. FOF ¶¶ 335, 336. To single out one feature, such as the presence or absence of any computer-controlled function, as

definitional and determinative is contrary to the way that prosthetists evaluate and choose prosthetic components and industry participants view the market. FOF ¶ 337. There is no reasonable basis to “make a sharp distinction” between knees that do or do not contain a microprocessor, when the reality is that these are complex products that range in features and functionality. *Oracle*, 331 F. Supp. at 1120.

a. There mere presence of a microprocessor in a prosthetic knee does not render all MPKs functionally or qualitatively similar.

Complaint Counsel failed to show that MPKs have peculiar characteristics and uses. To the contrary, the evidence at trial clearly established that MPKs are not a monolith; MPKs vary significantly in features among each other as some are actually more similar to Sophisticated Non-MPKs than to other MPKs. FOF ¶¶ 383, 596. Moreover, the clinical studies regarding MPK outcomes that Complaint Counsel relies heavily upon to support its flawed alleged market simply do not apply to all MPKs and thus prove nothing regarding the interchangeability of knees that were not part of the research.

i. The Plié 3 is functionally more similar to Sophisticated Non-MPKs than to other MPKs.

The microprocessor in an MPK can provide a spectrum of control ranging from switch-only control (*e.g.*, Plié) to full control throughout swing-and-stance (*e.g.* C-Leg, Orion, Rheo), to a powerd component in the prosthetic. FOF ¶ 164, 192, 229. The evidence at trial establishes that the Plié 3 functions mechanically very similarly to Sophisticated Non-MPKs. FOF ¶¶ 383, 596. For example, the resistance level on the Plié 3 is set using external tools (*i.e.*, a wrench and bicycle pump), unlike the C-Leg 4 which requires no external adjustments because the microprocessor in the C-Leg controls resistance variation. FOF ¶ 599. In fact, the manual resistance settings that the prosthetist makes on a Plié 3 are very similar to the manual resistance settings that the prosthetist makes on the 3R80 (a Sophisticated Non-MPK manufactured by Ottobock), with the exception

that the 3R80 does not require the use of a pump. FOF ¶¶ 146, 172, 173. The very limited “switching” mechanism that the Plié 3 microprocessor performs is performed by mechanical triggers and springs in the 3R80, but otherwise the mechanics of the two knees are very similar.

FOF ¶ 146

- ii. *The Clinical Studies relied upon by Complaint Counsel do not support the conclusion that all MPKs have peculiar uses as compared to Sophisticated Non-MPKs.*

Complaint Counsel has argued that “there is a large body of clinical studies that prove that non-microprocessor knees function very differently than MPKs and cannot achieve the same health and safety outcomes that MPKs have been proven to achieve.” (Opening, Tr. 16). While this may be true for particular MPKs that were actually included in the cited clinical trials and clinical studies (such as the C-Leg), the same conclusion has no applicability to those MPKs that have not been clinically tested.

The vast majority of clinical studies comparing MPKs to Non-MPKs are based on the C-Leg. FOF ¶ 362. Due to the variation in functionality between MPKs, it is not appropriate to extrapolate the results that were obtained with the C-Leg to other prosthetic knees simply because the knee also happens to contain a microprocessor. FOF ¶ 358. Significantly, there are no published studies analyzing the benefits of the Plié 3 compared to Non-MPKs. FOF ¶ 350-355. As the evidence at trial established, the Plié 3 is not particularly close in functionality to the C-Leg, and is in fact the most functionally distant from C-Leg among MPKs. FOF ¶ 577. As previously discussed, the Plié does not provide variable resistance control, requires manual adjustments to the knee, and requires the patient to carry around a pump to refill the leaky pneumatic cylinder controlling the swing phase of the knee. FOF ¶¶ 577-584. Some industry participants describe the Plié 3 as more similar to a Non-MPK than an MPK, and others describe

the Plié 3 as a “hybrid” knee that is somewhere between a Non-MPK and an MPK. FOF ¶¶ 383, 384, 596.

Complaint Counsel will likely point to [REDACTED]

[REDACTED]

[REDACTED] Therefore, to the extent that Complaint Counsel argues that MPKs provide superior functionality to Non-MPKs based on the clinical evidence, the Plié 3 cannot be included in that definition of MPK, and cannot be part of a relevant product market consisting of “clinically proven” MPKs.

- b. There is no record evidence that there exists any patient population for whom MPKs are exclusively medically appropriate and for whom Non-MPKs are not a medically appropriate substitute.**

Complaint Counsel has argued that MPKs are used by a *distinct subset* of K-3 and K-4 amputees who prosthetists determine are healthy enough and regularly engage in activities that

make wearing an MPK a medical necessity. Even after 13 weeks of trial, it is unclear what type of patient would be part of this alleged “distinct subset.” Nevertheless, Complaint Counsel seems to argue that for this undefined class of end-user, Non-MPKs are somehow not a substitute for an MPK. There is simply no support for this in the record.

The mere fact that an MPK must be deemed “medically necessary” in order to be reimbursed by payers does not mean that Non-MPKs are not substitutes for MPKs, as Sophisticated Non-MPKs are also deemed “medically necessary” for the same patient population. In addition, prosthetists and physicians consider both MPKs and Non-MPKs for K-3/K-4 transfemoral amputees and numerous factors influence choice. Very importantly, many patients simply prefer and select Non-MPKs over MPKs for various personal reasons after weighing the pros and cons of all options.

- i. “Medical necessity” concerns payer coverage and not actual medical appropriateness of a particular device.*

“Medical necessity” refers to eligibility for a particular device. FOF ¶¶ 446, 448. 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. FOF ¶¶ 446, 448. Indeed, prosthetists consistently testified that they can establish medical necessity for an MPK or a Non-MPK for all patients designated as K-3. FOF ¶ 457.

The use of the term “medical necessity” itself is misleading, as it is not a health determination that is being made. Medical necessity constitutes a spectrum, and does not have the same meaning in all medical scenarios. FOF ¶ 456. On one end of the medical necessity spectrum is an urgent and emergent medical condition, such as a patient with an appendix about to burst. FOF ¶ 456. No approval from insurance is necessary to perform that emergent procedure. FOF

¶ 456. On the other end of the spectrum relates to prosthetic componentry, where one component may potentially make someone’s life incrementally better and the term “medical necessity” is still used, even though the choice is very different than emergency live-saving surgery. FOF ¶ 456.

If insurance determines that an MPK is “medically necessary” for a patient as defined by the applicable insurance plan, the prosthetist, physician, or patient can still decide to use a Non-MPK. FOF ¶ 459. This happens often. FOF ¶ 459. “The medical necessity is just setting a ceiling to the availability, so medical necessity is usually something that you need to make as a threshold for the coverage criteria which says is the top that you could go. But that does not stop you from going down below.” FOF ¶ 459. By way of example, Dr. Douglas Smith, a highly-experience orthopedic surgeon who has performed more than 4,000 amputation surgeries, has had patients who are initially fit with an MPK later decide that they prefer a Non-MPK. FOF ¶ 460.

ii. Prosthetists and physicians simultaneously consider MPKs and Non-MPKs for the same K-3/K-4 patient population.

Medicare guidelines provide that knees suitable for K-3 patients include fluid-controlled knees that are both Non-MPKs and MPKs. (Senn Tr. 253-54.) Ultimately, whether a patient would prefer from an MPK or a Non-MPK is very patient specific, and comes with tradeoffs. FOF ¶¶ 393-394. The evidence demonstrates that prosthetists and physicians do not think of the fitting selection process as a Non-MPK vs. MPK determination, but instead consider various features and functions that a particular prosthetic knee can provide to a patient. FOF ¶ 337. Sometimes, there are features of a particular prosthetic that become more important to selection than whether or not the knee contains a microprocessor. FOF ¶ 935, 926. As a result, it makes a great deal more practice sense to consider relevant prosthetics market in terms of mobility level, *i.e.*, or K-Level,

which defines the set of products that are available and potentially appropriate for each patient. FOF ¶ 117.

The evidence has demonstrated that Non-MPKs can provide certain advantages over MPKs. FOF ¶ 347, 349. For example, Non-MPKs frequently offer greater flexion than MPKs. FOF ¶ 349. That means that they can bend more, which allows users to kneel on the floor. MPKs do not bend as much. Flexion may be particularly important for a user with small children who needs to get down on the ground. Patients who are athletic and who regularly run, ski, or bike, frequently prefer Non-MPKs over MPKs because these patients prefer the resistance, consistency, lightweight, and predictability of a user-controlled knee rather than a computer-controlled knee. FOF ¶ 156.

The evidence also demonstrates that RAC audits and the increased risk associated with the disallowance of reimbursement for a high-priced prosthetic device, like an MPK, have caused clinics to be more hesitant to fit MPKs. That is, not only do MPKs cost more for prosthetists upfront, they also carry a greater risk that prosthetists will not be able to recover the full cost of the knee through reimbursement. RAC audits can have a significant effect on a clinic's business, no matter how big or small the clinic. Even Hanger, a public company with \$850 million in patient care revenue, has identified RAC audits as a risk facing the company and the industry on its most recent 10-K. FOF ¶ 443. As a response to RAC audit risk, clinics have instituted a procedure of self-auditing claims before submitting to insurance. FOF ¶ 439. For example, at Prosthetic and Orthotic Associates ("POA"), an orthotic and prosthetic clinic, each claim "has to go through a review of 27 different items. If those 27 different items aren't there, the claim doesn't get billed." FOF ¶ 439. [REDACTED] Prosthetists' efforts to police themselves are effective, to a degree. Nonetheless, in 2016, Hanger experienced \$49.3

million of disallowed revenue. FOF ¶ 444. In 2014, Hanger's disallowed revenue was \$82 million. FOF ¶ 444. [REDACTED]

iii. Many patients prefer Non-MPKs to MPKs for a variety of non-medical reasons.

Patients play a large role in the selection of prosthetic componentry, and frequently weigh the pros and cons between Sophisticated Non-MPKs and MPKs, when they are both medically appropriate options. FOF ¶¶ 393, 394. Many of these patients choose Non-MPKs even when they have medical and financial access to MPKs, which further underscores the point that there is no distinct subset of patients who *need* an MPK. FOF ¶ 397.

There is a wide variety of reasons why patients may prefer Non-MPKs to MPKs. FOF ¶¶ 392, 393. Some patients prefer personal control over the knee without microprocessor interference. Non-MPKs are also generally lighter, smaller, and do not require daily charging. FOF ¶ 347. For instance, the C-Leg 4's battery can last up to 48 hours, but it can take a few hours to charge. FOF ¶ 396. Patients who value robustness of a non-MPK, or the voluntary control of the non MPK to the computerized control of an MPK, may weigh the pros and cons of each choice and select a Non-MPK. Sometimes patients choose a Non-MPK over an MPK after being allowed to trial both options. FOF ¶ 395. Similarly situated K-3 patients come to different decisions about whether to get fit with a non-MPK or an MPK, because the same patient can find positive attributes in a fluid-controlled non-MPK and other positive attributes in an MPK, and also find negative attributes in both. FOF ¶ 398. The data bears this out, as many more K-3 and K-4 patients are fit with non-MPKs. FOF ¶ 342.

Patients may also choose Non-MPKs, where clinically appropriate, because of cost. Medicare patients without supplemental coverage are typically responsible for 20% of the

reimbursement amount of a prosthetic device. [REDACTED]

[REDACTED] Given that co-pays are based on reimbursement amount, MPKs generally cost patients more than Non-MPKs. FOF ¶ 401.

c. Variability in prosthetic knee margins cause prosthetists to consider switching patients from MPKs to Non-MPKs for financial reasons.

The relevant economic metric that prosthetists examine is margin, not price. FOF ¶ 407. The evidence at trial revealed that clinics are keenly aware of their respective margins, and often make product selection decisions based on margin. FOF ¶¶ 408, 409. Clinics define margin as the difference between the reimbursement amount related to the applicable L-Codes of the prosthetic component, and the acquisition price of the prosthetic component. FOF ¶ 409. Then, the prosthetist must take into account all costs associated with fitting a particular patient, as the reimbursement amount is intended to cover the entire patient care episode, not just the acquisition of the component. FOF ¶ 269. MPKs are more expensive for the prosthetist to fit and maintain than Non-MPKs, given the number of follow-up visits, and documentation associated with reducing the risk of RAC audits for MPKs. FOF ¶ 273-275. As a result, margins earned by prosthetists are sometimes higher on Non-MPKs than MPKs resulting in a willingness to substitute between both options based on margin.

The evidence establishes that prosthetists are thus sensitive to price changes in MPKs and reimbursement challenges and become more willing to substitute Non-MPKs as fitting MPKs becomes less profitable. In fact, Respondent's economist expert, Dr. David Argue, concluded, based on his review of the evidence, and application of a "Model of Clinic Profitability" that he developed, that clinics can earn little to no margin on MPKs fit on patients with private insurance, which generally reimburses clinics less than the Medicare allowable reimbursement. FOF ¶ 433.

Conversely, Dr. Argue concluded that Sophisticated Non-MPKs almost always earn clinics some margin. The closeness in margin between MPKs and Sophisticated Non-MPKs encourages prosthetists to consider switching to Non-MPKs for certain patients, as it becomes unprofitable to fit such patients with MPKs. FOF ¶ 435.

d. The same prosthetics sales representatives sell both MPKs and Non-MPKs.

There are no specialized sales representatives for MPKs. The evidence at trial established that none of the manufacturers of MPKs in the United States use specialized sales forces to sell MPKs. FOF ¶¶ 463-466. Instead, sales representatives sell a wide range of prosthetic componentry, and manufacturers divide their sales force by geography. There is no evidence that any particular clinics specialize in MPK fittings, instead they provide complete care to all amputees regardless of componentry. Because prosthetic clinics do not typically specialize in a particular type of care that they provide, it would not make sense for manufacturers to segregate their sales forces by product. All prosthetic sales are marketed toward the same customer touchpoint, so it is logical for prosthetics sales reps to carry each manufacturer's full line of prosthetic products. FOF ¶ 465.

e. Industry participants do not separate MPKs and Non-MPKs into Separate Markets.

Industry participants, including Ottobock, Freedom, other manufacturers, prosthetists, payers, and physicians do not recognize MPKs as a distinct market separate from that in which Sophisticated Non-MPKs are sold, because the products are differentiated, and reasonable people could disagree as to what is better. FOF ¶ 398 (Similarly situated K-3 patients come to different decisions about whether to get fit with a non-MPK or MPK). Testimony from prosthetists confirms that they consider Sophisticated Non-MPKs in many cases to be substitutes for MPK's.

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] In addition, both Össur and Endolite present their products by K-Level. FOF ¶¶ [REDACTED] 490. Kim DeRoy of Össur testified that it makes sense for Össur’s product brochure to be segmented by K-Level, because their audience is prosthetic clinics who Össur wants to educate and provide a clear overview of every knee solution that Össur has, and to educate customers on the full range of products offered for K-3 and K-4 patients. FOF ¶ 490.

Carkhuff, Freedom’s current Chairman, acknowledged that there are some Sophisticated Non-MPKs that would benefit K-3 and K-4 patients, including sophisticated hydraulic models. FOF ¶ 340. He testified that “there are a lot of mechanical, hydraulic, fluid-controlled knees . . . that have a geometric design that really is very stable and perfectly appropriate for lots of people.” FOF ¶ 340. “Sophisticated fluid-controlled knees” have “unique geometric designs that . . . provide a very stable stance, sometimes referred to as four-bar or five-bar knees.” FOF ¶ 340. Similarities between the Plié and a sophisticated Non-MPK, like the Mauch, include that “both the Plié and the Mauch use a very sophisticated hydraulic cylinder that the resistance can be adjusted to provide different levels of resistance for different patient categories, be it activity levels or strength. And they control the swing and stance of the knee in a similar way to the Plié.” FOF ¶ 596.

2. The Hypothetical Monopolist Test Confirms That The Relevant Product Market Is Broader Than An MPK-Only Market.

a. Prosthetists will consider switching patients to Non-MPKs when the switch is medically appropriate.

In addition to patient preference, the substitutability of Non-MPKs, combined with their lower price point, puts them in the same market as MPKs under the hypothetical monopolist test. Although prosthetists seek to equip their patients with the most appropriate knee for the needs of

the patients, in many cases, it is medically appropriate to fit a K-3 or K-4 patient either with a Sophisticated Non-MPK or an MPK. FOF ¶ 343. In that case, the lower price point of a Sophisticated Non-MPK might cause the prosthetist or the patient to choose it over an MPK. (FOF 417)(“[P]rice does become an issue between products that are both medically appropriate.”). Individual prosthetists are aware of the costs of knees. At POA, for instance, the company has a profit-sharing program that involves prosthetists. FOF ¶ 758. “[I]n order to really make transparency as powerful as it can be within an organization, it’s important to have a financial aspect to it, so our profit-sharing program involves everybody in the company other than the partners.” (Ford Tr. 928.) POA also has a “monthly scorecard” which includes metrics including “average days to billing, dollars billed, what we call value per visit” FOF ¶ 758.

[REDACTED]

b. The high costs to procure MPKs combined with reimbursement and collection shortfalls incentivize prosthetists to substitute Non-MPKs for MPKs.

There are significant overhead costs in fitting and providing a knee to a patient. Accordingly, for a clinic to operate profitably, the clinic generally requires a gross margin of about \$10,000, as the difference between realized reimbursement and the cost to procure the knee. FOF ¶ 423. There are more overhead costs associated with an MPK than a Non-MPK. In particular, an MPK requires more prosthetist time because of the initial programming of the knee as well as follow-up visits and follow-up programming. FOF ¶ 273, 274. It is not unusual for above-the-knee amputee patients may have up to 24 visits in the first year. FOF ¶ 274.

As described in Section III, *infra*, the reimbursement system is a significant constraint on clinic margins. It is economic reality that if providing an MPK means that the clinic will lose money, the prosthetist would have no choice but to consider substituting a Non-MPK. FOF ¶¶ 425, 426.

The patient's insurance coverage also affects margin. Medicare represents the high-end of reimbursement rates, and many private insurance companies reimburse clinics at a discount significantly below – often 10% to 40% below – the Medicare allowable reimbursement. These lower reimbursements apply significant pressure on clinic margins and can make MPK fittings entirely unprofitable for clinics. For this reasons, the evidence at trial was clear that clinic management and prosthetists take into account the patient's coverage when making product selection decisions. FOF ¶ 427, [REDACTED] 429. (For example, COPC recommends C-Leg to be fit only when a patient is on Medicare and pre-pays their individual obligation).

Not only do MPKs cost more for prosthetists upfront, they also carry a greater risk that prosthetists will not be able to recover the full cost of the knee through reimbursement. “Recovery audit contractors were started by CMS throughout healthcare, and it’s CMS’ attempts to try to find fraud in the billing process for their services.” FOF ¶ 440. If an audit finds that the MPK was not appropriate, then the RAC will recoup its payment to the prosthetist, and the prosthetist will be forced to pursue a Medicare appeal – a process that can take years. FOF ¶ 291. During that process, the prosthetist has to front the cost of the knee itself. FOF ¶ 291. As Asar of Hanger explained, MPKs are “significantly more expensive . . . payers do scrutinize the higher-ticket items.” FOF ¶ 303.

c. Minor changes in purchasing decisions will result in a “critical loss” because of the relatively small number of annual MPK purchases by clinics in the United States.

Many clinics purchase only a small number of MPKs each year. Therefore, clinics would only need to switch a very small number of patients from an MPK to a Sophisticated Non-MPK in order to make a price increase by MPK manufacturers unprofitable. Specifically, as calculated by Dr. Argue, if each clinic, on average, switched one MPK to a non-MPK every four years in response to a five percent increase by a hypothetical monopolist of MPKs, critical loss would be satisfied. FOF ¶ 514.

d. Dr. Argue’s model establishes sufficient substitution between MPKs and Sophisticated Non-MPKs to justify including Sophisticated Non-MPKs in a relevant market that includes MPKs.

As explained above, there is ample record evidence establishing that clinics would switch some patients to Non-MPKs in the face of a price increase on all MPKs. Further, Dr. Argue has created a “Model of Clinic Profitability” which demonstrates that a sufficient number of clinics

would switch some patients to Non-MPKs in the face of a price increase, which confirms that Non-MPKs should be included in the relevant market. FOF ¶ 434.

Simply put, Dr. Argue used the following inputs in his model: the reimbursement that the clinic receives, the cost that it has to pay for the knee, non-billable cost (costs not associated with acquiring the knee), and the profit that comes out at the bottom. Through this model, Dr. Argue determined that costs associated with MPKs were such that a price increase on MPKs would cause clinics to lose money on fitting some patients with MPKs, specifically patients with private insurance reimbursing well-below the Medicare rate. FOF ¶ 434. At trial, clinicians admitted that if they were to lose money on an MPK fitting, they would consider switching some patients to Non-MPKs. Based on that economic reality, Dr. Argue concluded that based on his model and based on the small critical loss number at issue, prosthetists would switch patients in sufficient numbers to Non-MPKs to render a SSNIP unprofitable. FOF ¶ 436. This confirms that Non-MPKs should be included in the relevant market, and that Complaint Counsel's proposed relevant market is too narrow.

C. Complaint Counsel's Alleged MPK-Only Market Is Legally Inadequate.

Complaint Counsel alleges that the relevant product market is "no broader than all microprocessor knees sold in the United States." Complaint Counsel attempts to support its allegation through its Industrial Organization expert, Professor Fiona Scott Morton. Professor Scott Morton concludes, using a series of econometric tests, that the Plié and the Ottobock MPKs somehow constitute a relevant product market. However, that product market is not the one she advances in her report. Instead, Professor Scott Morton opines that once that narrow market test is passed, then any knees can be included and it will still be a relevant product market. As a result, Professor Scott Morton includes all MPKs simply because they contain a microprocessor. Essentially, Professor Scott Morton selects the presence of a microprocessor as the defining

characteristic for her market, without testing whether or not any of those knees should be excluded, or whether any Non-MPKs should be included. The relevant product market advanced by Professor Scott Morton is legally inadequate.

1. Professor Scott Morton Employs A Flawed Economic Approach To Conclude That Ottobock And Freedom MPKs Constitute A Relevant Product Market.

Professor Scott Morton did not perform a hypothetical monopolist test to assess whether Non-MPKs should be included in the relevant market. Instead, Professor Scott Morton uses a flawed economic approach to conclude that Ottobock and Freedom MPKs constitute their *own* relevant product market. After she arrived at this narrow market definition, Professor Scott Morton concludes that it is appropriate to simply start including additional knees in the alleged market, without analyzing whether or not those knees are properly included, or articulating any reason for including them.

Professor Scott Morton relies on the “Lerner Condition” to conclude that Ottobock and Freedom MPKs constitute their own product market. FOF ¶ 540. The Lerner Condition has been criticized in the economic literature, including in articles by FTC Chairman, Mr. Joseph Simons, as resulting in “extremely narrow markets” consisting of “only the two merging firms.” FOF ¶ 541. As a result, according to Mr. Simons and his co-authors on a paper on this topic, “virtually all unilateral effects models utilizing the Lerner Condition produce Price increases for any horizontal merger. That is, every horizontal merger is predicted to raise price, which of course has no empirical support and *would face serious Daubert issues if used in court.*” FOF ¶ 541. (emphasis added).

Applying the Lerner Condition, Professor Scott Morton arrives at the nonsensical conclusion that Ottobock and Freedom MPKs constitute their own relevant antitrust market, a

conclusion that completely lacks support in the record. Having declared this narrow market “proven,” Professor Scott Morton incorrectly claims that it simply does not matter what other knees she adds to the market, because it would still “pass.” She articulates no reason – record-based, economic, or otherwise – for including every knee that contains a microprocessor in her market, and excluding every knee that does not contain a microprocessor on that very fact alone. This proposed market is completely divorced from the economic realities of the market and should not be credited here. Complaint Counsel has fallen well short of their burden to establish a clearly defined relevant antitrust market.

2. The Product Market Advanced By Professor Scott Morton Is Not Consistent With Complaint Counsel’s *Brown Shoe* Arguments.

Professor Scott Morton has not articulate an economic underpinning for the contours of the market she advances, and her market makes no sense as a result. There is no support in the record for a separate product market that includes every knee that contains a microprocessor, regardless of its availability to patients, function, or price. This becomes very clear when comparing Professor Scott Morton’s market to *Brown Shoe* arguments advanced by Complaint Counsel.

Complaint Counsel justifies their market definition, and exclusion of all Non-MPKs, by referring to a “distinct subset” of K-3/K-4 patients for whom a Non-MPK is not a substitute. However, Complaint Counsel does not define who that subset it, or what type of patient would be in that subset. Given the lack of explanation on this subgroup, it is unsurprising that Professor Scott Morton’s market is not limited to knees fit on a “distinct subset” of K-3/K-4 patients. FOF ¶ 543 (An MPK fit on a K-2 patient is in the alleged relevant product market). Instead, Professor Scott Morton appears to state that if an amputee is fit with an MPK, they are in her product market, and if the patient is not fit with an MPK, they are not in her market. FOF ¶ 543. Indeed, Professor Scott Morton opines without support that for *every* person that has been fit with an MPK, a Non-

MPK is somehow not an adequate substitute for that patient. FOF ¶ 543. This is contrary to the evidence in the record, and ignores the head-to-head competition between Non-MPKs and MPKs that often occurs in the prosthetics industry.

Complaint Counsel also points to the clinical studies that have been done on various MPKs to show that MPKs have “peculiar characteristics.” Professor Scott Morton also points to the same studies to justify her choice to exclude Non-MPKs because in her words, MPKs and Non-MPKs have “significant performance differences.” FOF ¶ 544. However, Professor Scott Morton incorrectly claims that the studies she relies on in her report measured patient outcomes for all MPKs, but in reality, the only knees included in those studies were manufactured by Ottobock – none were manufactured by Freedom. FOF ¶ 545. Further, though she agrees that MPKs are differentiated products, Professor Scott Morton testified that she is not aware of the performance differences among MPKs. FOF ¶ 546..

3. High-End MPKs Are In A Separate And Distinct Product Market From Other MPKs.

Professor Scott Morton erroneously includes High-End MPKs in her relevant product market. Because Ottobock has comparatively high sales in this segment, exacerbated by Professor Scott Morton’s use of revenue data rather than unit sales data to calculate market shares, this error biases her market share calculations in favor of higher concentration. It also exposes her fundamental lack of understanding of the realities of prosthetic devices. High-End MPKs should be excluded from the relevant product market because they are not reimbursement by the vast majority of payers, including Medicare or private insurance companies, and they are consequently not an option for most patients. Indeed, Professor Scott Morton admits “if the insurance company is not going to pay for it, then it’s not in the choice set,” yet she inexplicably chose not to exclude High-End MPKs from the alleged relevant market. FOF ¶ 547.

4. MPKs That Are Appropriate For K-2 Patients Are In A Separate And Distinct Product Market From Other MPKs.

Evidence indicates that the Kenevo and Compact are designed for K-2 patients and do not compete against Sophisticated Non-MPKs and MPKs designed for K-3/K-4 patients. FOF ¶ 478. In other words, the C-Leg 4 does not compete against the Kenvo for fittings on the same patient population. Furthermore, Medicare and most private payers do not reimburse K-2 patients for any MPKs, including MPKs designed for K-2 patients. FOF ¶¶ 251-253. Therefore, most of these patients do not have access to K-2 MPKs.

III THE ACQUISITION HAS NOT AND WILL NOT HARM COMPETITION IN ANY ALLEGED RELEVANT MARKET.

In this case, overwhelming evidence rebuts any presumption of a substantial lessening of competition even if the Court were to accept Complaint Counsel’s very flawed alleged relevant market. FOF ¶¶ 565-1290. Market concentration is not a useful gauge of competitive harm in the prosthetics industry generally or the market for prosthetic knees specifically. FOF ¶¶ 565-576. The evidence introduced at trial reflects that there has always been fierce competition, continuous innovation, and rampant inter-brand substitution among several competing firms with respect to MPKs that will continue post-Acquisition. FOF ¶¶ 565-1290. Thus, the Court should conclude that the Acquisition is not likely to harm competition in any alleged relevant market.

A. Market Concentration Is Not A Useful Indicator of Likely Anticompetitive Effects In The Prosthetics Industry.

Only unilateral effects have been alleged in this case. (Compl. ¶ 39-58). However, Complaint Counsel has failed to establish any basis for a legal presumption that Ottobock could exercise unilateral market power post-Acquisition. According to Section 5.3 of the Merger Guidelines, market concentration is just one indicator of likely competitive effects of a merger, and “shares may not fully reflect the competitive significance of firms in the market or the impact

of a merger.” PX08040. Beyond “market share and concentration,” a court must consider the “structure, history and probable future” of the market to determine whether high market shares indicate there are likely to be anticompetitive effects from the transaction.” *General Dynamics*, 415 U.S. at 498 (quoting *Brown Shoe*, 770 U.S. at 322 n.38); *see also Baker Hughes*, 908 F.2d at 992 (“The Herfindahl-Hirschman Index cannot guarantee litigation victories.”) “[M]arket share and concentration data provide only the starting point for analyzing the competitive impact of a merger [The government] also will assess the other market factors that pertain to competitive effects.” *Polypore*, 149 F.T.C. at 849 (quoting Merger Guidelines § 2.1 and citing *In re Weyerhaeuser Co.*, 1985 FTC LEXIS 26, at *215 (F.T.C. Sept. 26, 1985)) (substitutions and omission in original).

Section 2.1.3 of the Merger Guidelines states that “mergers that cause a significant increase in concentration and result in highly concentrated markets are presumed to be likely to enhance market power.” PX08040 Section 2.1.3 of the Merger Guidelines, however, insure against reverting to naked structural analysis by making clear that the role of market shares and market concentration is “not an end in itself,” but rather “one useful indicator of likely anticompetitive effects.” PX08040. Merger Guidelines §§ 4, 5.3. Market concentration is not to be used to “provide a rigid screen to separate competitively benign mergers from anticompetitive ones,” but rather to provide one way to distinguish competitively benign mergers from those that warrant closer scrutiny. PX08040 § 5.3.

“The unifying theme of the unilateral effects analysis contemplated by the Merger Guidelines is that a particularized showing that post-merger competitive constraints are weakened or eliminated by the merger is superior to relying solely upon inferences of competitive effects drawn from changes in market structure.” *In the Matter of Holcim Ltd. and Lafarge S.A.*, 159 F.T.C.

1917, 2013 WL 13021997, *30 (2015) (Comm’r Wright, dissenting) (citing Carl Shapiro, *The 2010 Horizontal Merger Guidelines: From Hedgehog to Fox in Forty Years*, 77 *Antitrust L. J.* 701, 707-08 (2010)).

Complaint Counsel’s only theory of unilateral effects in this case is that the Acquisition reduced the number of competitors in the alleged MPK-only market from six to five, and that the remaining four competitors will not be able or willing to compete for market share, leaving Ottobock with the ability to unilaterally raise prices or curtail innovation. (Compl. ¶ 39-58). This theory of harm requires particularized evidence sufficient to establish reason to believe the Acquisition violates Section 7 of the Clayton Act and should not depend virtually entirely on a “rigid market screen.” PX08040 § 5.3. To the contrary, the evidence at trial revealed that the high market shares of the parties do not accurately reflect the current competitive environment and are not an accurate indicator of the likely effects of the Acquisition on competition and consumers. *See, e.g., General Dynamics*, 415 U.S. 486.

Ottobock’s C-Leg was launched in 1999 and was the predicate device for L5856, the MPK “swing and stance” L-Code. FOF ¶¶ 191,1089, 1023. The C-Leg is widely-recognized for its quality and reliability and has nearly universally been considered the “gold standard” MPK for nearly twenty years. FOF ¶¶ 607-614. Even though at the time of launch, Ottobock had essentially a monopoly position within the alleged market, its C-Leg pricing was constrained by the third-party reimbursement structure and sophisticated buyers. FOF ¶¶ 312-330. Further, despite Ottobock’s initial nearly 100 percent share, five new competitors were able to enter the alleged market, and these firms have repeatedly and continuously innovated their product offerings and increased their market share at the expense of Ottobock. FOF ¶¶ 782-940. Most significantly, post-Acquisition evidence of continued innovation and competition for market share confirms that

the concentration thresholds outlined in the Merger Guidelines should not be used as a “rigid screen” and should not be considered a virtually insurmountable presumption of anticompetitive harm, as claimed by Complaint Counsel. FOF ¶¶ 565-940.

B. Strong Evidence Rebutts Complaint Counsel’s *Prima Facie* Case.

Documents, testimony, and data from Respondent, competitors, prosthetics clinics, physicians, and a leading third-party payer all confirm that unilateral anticompetitive effects are not reasonably likely from the Acquisition for at least the following reasons:

First, Ottobock and Freedom are not close competitors and there is little evidence of direct competition with respect to pricing or innovation between Ottobock’s MPKs, on the one hand, and Freedom’s Plié. FOF ¶¶ 577-746.

Second, Ottobock’s closest competitor, [REDACTED] and Freedom’s closest competitors, [REDACTED] are not only willing and able to expand and compete for share with respect to MPK sales, these firms have already been expanding, competing for share, and continuing to innovate since the Acquisition. FOF ¶¶ 646-687.

Third, Hanger and other sophisticated customers have significant buying power and have promoted expansion and innovation and have [REDACTED]

Fourth, the third-party payer reimbursement system in the United States severely constrains the ability of prosthetic knee manufacturers to raise prices. FOF ¶¶ 240-334.

Fifth, Freedom was a “flailing firm” at the time of the Acquisition as a result of insurmountable debt obligations, terrible financial performance, and gross mismanagement, and as a result of these circumstances, posed no significant competitive threat in the alleged market. FOF ¶¶ 1291-1531.

Sixth, the Acquisition will promote competition through a “Dual Brand Strategy” that would allow Freedom to exist and compete independent of Ottobock, and there has been no evidence of anticompetitive conduct post-Acquisition. FOF ¶¶ 1039-1080

And, *seventh*, the Acquisition will generate substantial cognizable, mergers-specific efficiencies that will benefit consumers. FOF ¶¶ 1532-1570.

1. Ottobock And Freedom Are Not Close Competitors Generally And Their Respective MPKs Are Not Close Competitors Specifically.

Complaint Counsel has failed to show that Ottobock and Freedom are each other’s closest competitors, specifically, or to show any significant head-to-head competition between Ottobock and Freedom, generally, that would be lost by the Acquisition. *See, e.g., ProMedica*, 749 F.3d 559, at 569 (“The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral effects.”); *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 169 (D.D.C. 2000) (“[A] unilateral price increase . . . is likely after the acquisition because it will eliminate one of Swedish Match’s primary direct competitors.”); *Staples*, 970 F. Supp. at 1083 (finding unilateral anticompetitive effects when the transaction “would eliminate significant head-to-head competition” between the merging parties). The evidence shows that Ottobock’s C-Leg successfully targeted customers focused primarily on quality and reliability. FOF ¶¶ 607-660. Freedom, on the other hand, focused mostly on price-sensitive customers. FOF ¶¶ 661-679. Other firms compete more closely with Ottobock and Freedom, respectively, and those firms are innovating and growing. FOF ¶¶ 617-645, 680-687, 789-940.

Section 6.1 of the Merger Guidelines states (emphasis added):

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 buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice A merger is *unlikely to generate substantial unilateral price increases* if non-merging parties offer

very close substitutes for the products offered by the merging firms.
PX08040.

Closeness of substitution is implied by the willingness of buyers to switch brands of a product. FOF ¶¶335-468. Competition among MPK brands occurs within two general dimensions: functionality and price. FOF ¶¶ 747-772. Freedom's Plié 3 is not the closest competitor to any of Ottobock's MPKs in either context. FOF ¶¶ 577-687.

Freedom's Plié functions most similarly to Sophisticated Non-MPKs, such as the Ottobock's 3R80 and Össur's Mauch Knee. FOF ¶¶ 577-602. Sophisticated Non-MPKs use complex hydraulic and/or pneumatic fluid to provide swing and stance control in the patient's gait cycle. FOF ¶¶ 140-163. The resistance levels in each phase, swing and stance, respectively, of these Sophisticated Non-MPKs are pre-set by the prosthetist or patient using various tools, typically a wrench. FOF ¶¶ 140-163. As such, Sophisticated Non-MPKs do not offer variable resistance control in the swing and stance phases of the knee – the fundamental feature of true swing-and-stance MPKs, like the C-Leg 4. FOF ¶¶ 140-163, 189-239. Freedom's Plié 3 functions virtually identically to the Sophisticated Non-MPKs and not like swing-and-stance MPKs. FOF ¶¶164-173. The Plié 3's stance phase resistance is pre-set by a wrench, and its swing phase is pre-set by the combination of a wrench and an air pump to offer fixed flexion and extension resistance. FOF ¶¶ 164-173. The sole function of the Plié's microprocessor is to switch the knee between the fixed stance and swing phases, a function performed mechanically in other Sophisticated Non-MPKs.² FOF ¶¶ 164-173.

²The fact that Freedom has recommended that the Plié receive reimbursement under the for L-Code for "swing-and-stance" MPKs known as L5856 does not rebut the overwhelming evidence – including the admission of Freedom's own Chairman – that the Plié 3 does not in fact offer microprocessor-controlled swing-and-stance variable resistance. Freedom's overly aggressive coding of the Plié is well-recognized in the industry and most likely explains its popularity among

The Plié's functionality is significantly inferior to other MPKs sold in the United States that offer variable resistance control in either or both the swing and stance phases of the knee, respectively. FOF ¶¶ 168-173, 191-239, 577-602. Endolite's SmartIP has fixed stance resistance control, but offers variable resistance swing phase control of the knee, and Ottobock's Compact and Kenevo have fixed swing resistance control but offer variable resistance stance phase control. FOF ¶¶ 174-188. These products are functionally more similar to the Plié than other MPKs that offer variable resistance swing and stance phase control, yet they have not been as successful in the marketplace as Freedom's Plié because Endolite and Ottobock, respectively, do not recommend that their products be reimbursed for base code L5856. FOF ¶¶ 174-188. Endolite recommends that the SmartIP be reimbursed with base code L5857 for microprocessor swing phase only control; whereas Ottobock recommends that the Compact and Kenevo be reimbursed with base code L5858 for microprocessor stance phase only control. FOF ¶¶ 174-188. L-Codes L5857 and L5858 provide clinics with smaller reimbursement amounts, respectively, than L5856, thus incentivizing price-sensitive clinics to choose the low-cost Plié over knees that provide less margin. FOF ¶¶ 174-188, 661-679.

Other MPK manufacturers agree that Plié 3 does not have the functionality of microprocessor-controlled swing-and-stance control. [REDACTED] has a similar view, arguing that Plié 3 lacks the microprocessor-controlled swing mode that is included in C-Leg 4, Orion 3 and Rheo 3. FOF ¶¶ 619-622. [REDACTED] also questioned the appropriateness of reimbursing Plié 3 for microprocessor swing-and-stance control and expressed concern about [REDACTED]

[REDACTED] FOF ¶

price-sensitive customers that are choosing between an MPK and a Non-MPK for financial considerations.

311. It specified [REDACTED]
[REDACTED] FOF ¶ 311. An Össur executive acknowledged that the Plié 3 is functionally inferior to other MPKs on the market. FOF ¶ 667.

Testimony from clinicians further establishes this point. [REDACTED]
[REDACTED] describes the Plié 3 as having a mechanical stance feature that is [REDACTED]
[REDACTED]
[REDACTED] explains that [REDACTED]
[REDACTED] making billing it with an L5856 code questionable. A [REDACTED] explained that [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

MPKs that provide variable swing-and-stance phase resistance control offer even greater functionality relative to the Plié. FOF ¶¶ 189-216. Swing-and-stance controlled MPKs provide unique functionality for patients who wear them, resulting in significant safety, health, and quality of life benefits. FOF ¶¶ 189-216. A large body of clinical research studying the swing-and-stance MPKs offered by Ottobock, Össur, and Endolite demonstrates the benefits related to this functionality relative to knees that do not offer variable resistance control for K-3 and K-4 patients. FOF ¶¶ 350-381. There is no evidence, however, that any of the features and functions of Freedom’s Plié have increased the safety, health, and quality of life for amputees. FOF ¶¶ 350-381. Thus, to the extent that an MPK is “medically necessary” for a patient and a Non-MPK would not be appropriate for that patient, a Plié 3 would also not be appropriate for the same patient. FOF ¶¶ 350-381, 440-460.

The Plié's lack of functionality has forced Freedom to offer discounts on the product. FOF ¶¶ 661-679. This strategy has been particularly necessary for Freedom in more recent years, as the market has increasingly considered the Plié an inferior product with obsolete technology that is at the end of its life cycle. FOF ¶¶ 577-602, 661-679. There is evidence of [REDACTED] [REDACTED] discounting their MPKs to prices at or below Freedom's price for the Plié; however, there is scant evidence of head-to-head price competition between Freedom's Plié, on the one hand, and Ottobock's C-Leg or [REDACTED] on the other hand. FOF ¶¶ 607-616, 640-660. According to Dr. Argue, the fact that some prosthetics clinics prefer to sell only the C-Leg and Plié is consistent with Ottobock and Freedom offering meaningfully different price points for customers with different price sensitivity. FOF ¶ 533.

Freedom has also failed to meaningfully participate in the significant innovation that has characterized the MPK marketplace over the last three years. FOF ¶¶ 565-576. The latest version of the Plié, the Plié 3, was introduced in 2014. FOF ¶ 595. Freedom internally acknowledges, and the external market agrees, that the Plié 3 was already at the end of its life cycle at the time of the Acquisition in September 2017. FOF ¶¶ 577-602. Since the Plié 3's introduction, the other MPK manufacturers have all released innovative, new MPK products. FOF ¶ 576. Ottobock launched the C-Leg 4 in 2015 and is in development of the [REDACTED] FOF ¶¶ 1920, 1074-1075. Össur introduced the Rheo 3 in 2015, the weatherproof Rheo 3 in 2016, the fourth generation Rheo in 2017, and [REDACTED] [REDACTED] FOF ¶¶ 789-807. Endolite launched the Orion 3 and Linx in 2016, [REDACTED] FOF ¶¶ 789-807. Nabtesco fully launched the Allux in 2017, which is the first MP swing-and-stance knee to also utilize four-bar technology for additional safety and stability. FOF ¶¶ 860-926. Even

DAW, which lacks the resources of the other MPK manufacturers, launched the MTX. FOF ¶¶ 927-940.

Since 2015, Freedom has been attempting to develop an MP-swing-and-stance knee through the Quattro Project, but any future competitive impact of that project is speculative at best. FOF ¶¶ 688-746. Freedom has a track record of delayed and unsuccessful research and development projects, and [REDACTED]

[REDACTED]

Ottobock has not been particularly aggressive against Freedom with respect to MPKs. FOF ¶¶ 607-616. Prior to Freedom's launch of the Plié 3 in 2014, Ottobock already offered the only dustproof and waterproof MPK sold in the United States, the X3. FOF ¶ 217. Freedom's Plié 3 did offer an IP67 rating that many other MPKs sold in the U.S. market, including the C-Leg 3, did not offer at the time, but Freedom's Plié 3 still lacked microprocessor-controlled swing-and-stance variable control. FOF ¶¶ 594, 609. After Ottobock launched its C-Leg 4, Ottobock began discounting its artifact C-Leg 3 because the market was demanding Ottobock's new product. There is no evidence that the discounting of the C-Leg 3 was related to Freedom's pricing strategy

for the Plié 3. Ottobock did send letters to insurers specifically stating that the Plié 3 did not have MP swing-and-stance variable resistance control because Ottobock was concerned that Freedom's aggressive coding recommendations for the Plié 3 was wrongly costing U.S. taxpayers money. FOF ¶ 615. Ottobock did not send similar letters regarding the products sold by Össur and Endolite at the time because Ottobock considered those products properly coded. FOF ¶ 626. Since the C-Leg 3 was moved off of the market in 2015, there is no evidence of Ottobock aggressively discounting its C-Leg 4, or any other MPK, against Freedom's Plié 3. FOF ¶ 607-616.

The timing of Ottobock's C-Leg 4 launch in 2015 was consistent with its longstanding product development plans and unrelated to the timing of the Plié 3's launch in 2014. FOF ¶ 192. Moreover, Ottobock's C-Leg 4 launch materials focused much more heavily on the other MP-swing-and-stance knees that were sold at the time from Össur and Endolite than it does the Plié 3. Indeed, the initial price for the C-Leg 4 of approximately \$15,800 was much more competitive with Össur's Rheo 3 than with Endolite's Orion 2 and Freedom's Plié 3. The launch of the C-Leg 4 had an immediate impact on the sales of Össur, Endolite, and Freedom.

The lack of aggressive head-to-head competition between Ottobock and Freedom was highlighted and explained by a 2016 email from Freedom's Vice President of National and Key Accounts, Mark Testerman. FOF ¶¶ 643, 671. Testerman had been asked by his boss, Freedom's Vice President of Sales, Jeremy Matthews, to provide the top reasons for the decline in Plié 3 sales in 2016. FOF ¶¶ 643, 671. Testerman's first two reasons related to serious quality and durability issues related to the Plié 3 at the time. FOF ¶¶ 643, 671. The third reason related to Nabtesco's launch of its new MP swing-and-stance technology in the United States, the Allux, which offered four-bar technology in an MPK for the first time. FOF ¶¶ 643, 671. The fourth reason related to new, aggressive discounting from Endolite on the Orion 3, which Endolite had just launched that

year in the United States. FOF ¶¶ 643, 671. Endolite was discounting the Orion 3 at or below Freedom's Plié 3 and was causing a decline in Plié 3 sales. FOF ¶¶ 643, 671. The fifth and final reason for the decline in Plié 3 sales in the United States in 2016 was the impact that reimbursement and audits were having on prosthetics clinics that were induced to switch patients from the Plié 3 to Non-MPKs for financial reasons. FOF ¶¶ 643, 671. According to Testerman, competition from Ottobock's C-Leg 4 was not a top reason for the decline of Plié 3 sales in 2016. FOF ¶¶ 644.

Finally, Freedom's aggressive discounting of the Plié 3 in 2017 related to Freedom's effort to drive up top-line revenue to make the company look more attractive in the sale process that was going on at that time and related to the fact that the market considered the Plié 3 to be obsolete in 2017. FOF ¶¶ 1346-1348. Freedom's own assessments of the Plié 3 in due diligence documents show that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Össur, Endolite, Nabtesco, And DAW Offer Very Close Substitutes For Knee Products Offered By Ottobock And Freedom.

Overwhelming evidence shows that Ottobock's closest competitor, [REDACTED] and Freedom's closest competitors, [REDACTED] are not only willing and able to expand and compete for share in the marketplace, they have been have been doing exactly that since the Acquisition. FOF ¶¶ 565-940. As Dr. Argue Testified, there are "sufficient alternatives for customers, and the aggregate effect of this expanded competition post-Acquisition completely

mitigates any likelihood of potential anticompetitive harm from the Acquisition. FOF ¶¶ 565-940 (Argue, Tr. at 6148, 6208-14).

A merger is not likely to enhance market power if expansion in the alleged market is so easy that respondent and its remaining rivals in the market, either unilaterally or collectively, could not profitably raise prices or otherwise reduce competition compared to the level that would have prevailed in the absence of the acquisition. Merger Guidelines § 9.1.³ “The Agencies consider whether repositioning would be sufficient to deter or counteract what otherwise would be significant anticompetitive unilateral effects from a differentiated products merger.” Merger Guidelines § 6.1. The evidence must be sufficient to demonstrate the ability of other suppliers to fill the competitive void that could potentially result post-Acquisition. *See Swedish Match*, 131 F. Supp. 2d 151, 169 (D.D.C. 2000).

Here, Respondent will continue to face strong competition on functionality, quality, reliability, innovation, and price from Össur, Endolite, Nabtesco/Proteor, and DAW. FOF ¶¶ 789-940. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

³ “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 a supply-side response that is evaluated much like entry, with consideration given to timeliness, likelihood, and sufficiency. *See* Section 9.” Merger Guidelines § 6.1.

The alleged market is particular suitable for timely, likely, and sufficient expansion to counteract any anticipated competitive effects. FOF ¶¶ 747-940. Medicare and private payers are manufacturer agnostic when it comes to reimbursement to clinics – the function is what is important. FOF ¶¶331-334. Though some manufacturers will seek certification that a certain device contains the function that corresponds to a particular L-Code, other manufacturers develop their recommended coding for a particular product without external verification. 307-311. The amount that payers reimburse a clinic is determined by that code, not by the particular brand of knee or the price the clinic pays for the knee. FOF ¶¶ 259-266. Once established, other manufacturers can take advantage of the additional coding obtained and create new products. FOF ¶¶ 259-266.

The evidence confirms that prosthetics clinics regularly switch between various brands depending on discounts, promotions, clinical education, and different sales techniques. FOF ¶¶ 747-776. There is no evidence that market forces, such as brand loyalty, would defeat other competitors’ expansion efforts. FOF ¶¶ 747-776, 341-334. Indeed, recent expansion by Endolite and Nabtesco/Proteor, in particular, substantiate the likelihood that new competition will counteract any potential anticompetitive effects. FOF ¶¶ 808-926. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Other clinic representatives have consistently testified that they would be willing to switch to other MPK providers in the face of any price increases. FOF ¶¶ 747-772. Expansion by a single firm that will replicate at least the scale and strength of one of the merging firms is considered “sufficient” under the Merger Guidelines, and expansion by “one or more firms operating at a smaller scale may be sufficient if such firms are not at a competitive

[REDACTED]

3. Sophisticated Buyers Can Discipline And Constrain Manufacturers From Increasing Prices.

The existence of a powerful buyer may mitigate the anticompetitive effects of a merger:

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 anticompetitive effects of a merger. In *Baker Hughes* . . . the Court of Appeals for the D.C. Circuit relied upon the findings of the district court regarding the buyers' sophistication and large order sizes, coupled with their ability to 'closely examine available options' while 'typically insisting on multiple, confidential bids for each order,' as convincing evidence of bargaining power, which would allow customers to resist anticompetitive price increases that might result from the merger.

Polypore, 149 F.T.C. at 899 (citing *Baker Hughes*, 908 F.2d at 986-87) (brackets omitted); see also *Archer-Daniels-Midland*, 781 F. Supp. at 1416 ("The existence of large, powerful buyers of a product mitigates against the ability of sellers to raise prices."); *FTC v. RR Donnelley & Sons Co.*, No. 90-1619, 1990 U.S. Dist. LEXIS 11361, at *10-11 (D.D.C. Aug. 27, 1990) (holding that powerful customers exerted economic power that "make any anti-competitive consequences very unlikely."); *United States v. Country Lake Foods*, 754 F. Supp. 669, 679 (D. Minn. 1990) ("The market power of buyers is demonstrated in the declarations of fluid milk purchasers . . . in which they described their swift and aggressive response to a price increase unrelated to normal market conditions as well as their willingness to seek out suppliers who would sell fluid milk at lower prices."); Merger Guidelines § 8.

Hanger and other sophisticated customers in the prosthetics industry have significant buying power and have promoted expansion and innovation and have demonstrated the ability and willingness to prevent any reasonably likely anticompetitive effects. FOF ¶¶ 967-1003. Hanger is the largest network of prosthetic clinics in the United States, with 800 clinics across the country, employing about 1,500 clinicians. FOF ¶ 971. [REDACTED]

[REDACTED] Hanger is the largest MPK customer of Ottobock, [REDACTED] and [REDACTED]

[REDACTED]

[REDACTED]

FOF ¶¶ 977-978. [REDACTED]

[REDACTED]

Hanger's size gives it significant leverage over manufacturers. FOF ¶¶ 976-990. In fact, Hanger lists as a "competitive strength" on its 10-K the fact that they have purchasing power for O&P components and that its purchasing power promotes the usage by its patient care clinics of clinically appropriate products that also enhance its profit margins. FOF ¶ 980. Hanger's CEO, Vinit Asar, testified that he expects to get better pricing and discounts from manufacturers as a result of Hanger's purchase volume. FOF ¶¶ 976-990. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Not only is Hanger a large and important customer, it has structures and tools in place that will enable it to constrain MPK prices moving forward. FOF ¶¶ 985-990. As Dr. Argue testified, upon learning of the Acquisition, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4. The Third-Party Payer Reimbursement System In The United States Constrains The Ability Of Manufacturers To Raise Prices.

The third-party payer reimbursement system in the United States constrains the ability of manufacturers to raise prices and induces inter-brand switching. Unlike other segments of the healthcare industry, Medicare sets the ceiling for insurance reimbursement, and private insurance companies reimburse anywhere from [REDACTED] less than the Medicare-allowable reimbursement. (FOF ¶¶ 287-289). Prosthetic clinics have little bargaining power when negotiating with third-party payers for reimbursement contracts. (FOF ¶ 340). As discussed in Section II.B, *supra*, the fixed reimbursement system forces prosthetic clinics to operate with very thin margins, particularly for patients with private insurance. Manufacturers, therefore, do not have room to profitably impose price increases. (Solorio, Tr. 1624; De Roy, 3557-3558).

Unsurprisingly, clinic representatives have confirmed that they believe the prosthetics industry’s unique third-party payer system constrains the ability of manufacturers to raise prices. (Sabolich, Tr. 5866). Reimbursement is such a powerful force in the industry, that it leads some

clinics to feel there is no risk of manufacturers raising prices, because prices are capped by the allowable reimbursement, which is benchmarked off of a CMS-determined fee. (Sabolich, Tr. 5866 (prosthetic clinic owner testifying that because Medicare “sets the price,” that makes him “want to sort of stand up and scream ‘why are we all here.’”).

Manufacturers are well-aware of this dynamic, and take the reimbursement amount into account when setting MPK prices. FOF ¶ 325; ¶ 327 [REDACTED]

[REDACTED] The reimbursement system constrains prices because the manufacturer knows how much Medicare pays for a device . . . and the acquisition price of a device reflects a profit margin that the manufacturer and prosthetist can both live with. Because L-Codes are agnostic as to brand, if one manufacturer raises prices, that will encourage clinics to switch to different brands, which disciplines manufacturer pricing behavior. [REDACTED]

5. Freedom Was A “Flailing Firm” At The Time Of The Acquisition That Posed No Competitive Threat In The Alleged Market.

The evidence introduced at trial was overwhelming that Freedom was a “flailing firm” at the time of the Acquisition. Freedom was unable to satisfy its insurmountable debt obligations after many years of declining financial performance and a consistent inability to meet product or financial forecasts. Freedom’s former CEO even believed that Freedom had been [REDACTED] [REDACTED] for many years. Simply put, at the time of the Acquisition, Freedom was on the verge of liquidation bankruptcy and posed no real threat to competition in the alleged market. A detailed

statement of facts regarding Freedom’s financial condition and the basis for its status as a “failing firm” that was about to exit the alleged market is set forth in Section V, *infra*, which explains why Freedom also qualifies as a “failing firm” that warrants application of the “failing firm” defense as justification of the Acquisition and those facts apply with equal force here.

An acquisition does not reduce competition where the acquired entity’s weakened position makes it of little competitive significance. In *General Dynamics*, the Supreme Court explained that the acquired firm, a coal company, “had no coal reserves and was unable to obtain additional ones. Thus, . . . the acquired company was an insignificant factor as a competitor and the merger did not have an anticompetitive impact on the market.” *FTC v. National Tea Co.*, 603 F.2d 694, 699-700 (8th Cir. 1979) (citing *General Dynamics*, 415 U.S. 486, and affirming district court’s consideration of acquired firm’s probable exit from the market).

The “weakened competitor” defense may be satisfied even where an element of failing firm defense is technically lacking in some respect. For example, in *Arch Coal*, the court found that the failing firm defense was not satisfied, but held that the financially weakened condition of the target was a defense to the government’s case of anticompetitive effects. In that case, the target, a mining company, was showing positive financial measures, but the court held that this ignored that the mine’s reserves were depleted.

As explained at length in Section V, *infra*, Freedom was days away from liquidation at the time of the Acquisition because it could not pay approximately \$27.5 million in debt obligations. Moreover, Freedom had been engaging in an unsustainable pricing strategy that was contributing to [REDACTED]

[REDACTED] In short, Freedom was a poorly

run company that was about to collapse and exit the alleged market entirely before Ottobock saved it.

6. The Acquisition Is Procompetitive With No Evidence Of Unilateral Harm Since The Acquisition.

The evidence introduced at trial consistently established that Acquisition will promote competition and that there has been no evidence of anticompetitive conduct post-Acquisition.

Ottobock's rationale for the acquisition was twofold:

[REDACTED]

Ottobock never planned to eliminate Freedom as a competitor in the United States. On the contrary, Ottobock intended to allow Freedom to independently compete in the United States and to continue to develop not only the Quattro Project, but also other R&D projects,

[REDACTED]

[REDACTED] Thus, the Acquisition would not only preserve Freedom as a competitive market participant, it would enhance Freedom's competitive significance through the support of Ottobock's resources. Further, most clinics are not concerned that the combination of Ottobock and Freedom through the Acquisition results in higher prices, lower output, or less innovation.

Indeed, competition and innovation among Respondent and its competitors has continued vigorously since the Acquisition, including with respect to MPKs.

7. Cognizable And Acquisition-Specific Efficiencies Outweigh Any Reasonably Likely Anticompetitive Effects In The Alleged Market.

“[C]ourts and the [FTC] typically consider ‘efficiencies, including quality improvements, after the government has shown that the transaction is likely to reduce competition.’” *Polypore*, 149 F.T.C. 486 (quoting *In re Evanston Northwestern Healthcare Corp.*, No. 9315, 2007 FTC LEXIS 210, at *191 (F.T.C. Aug. 6, 2007)). “The defendant has the burden of production to show that efficiencies offset any likely anticompetitive effects of the increase in market power produced by the merger.” *Id.* (quoting *In re Evanston Northwestern Healthcare Corp.*, No. 9315, 2007 FTC LEXIS 210, at *191 (F.T.C. Aug. 6, 2007)); *see also FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999) (enhanced efficiencies should be considered “in the context of the competitive effects of the merger.”); *Country Lake Foods*, 754 F. Supp. at 674, 680 (efficiencies involving “lower plant and transportation costs and other savings” found as “further evidence that the proposed acquisition will enhance competition.”).

Ottobock and Freedom both analyzed the efficiencies created by the Acquisition, and determined that the Acquisition would result in cognizable efficiencies that are specific to the Acquisition, ranging from [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] AT Kearney and Ottobock identified and quantified substantial efficiencies at approximately [REDACTED] per year by 2022, or approximately [REDACTED] % of Freedom's 2022 revenue. FOF ¶ 1549.

[REDACTED]

These Acquisition-specific efficiencies would result in gross margin improvements allowing both companies to: (i) improve the quality of their respective products through increased spending on research and development; (ii) maintain and/or lower the prices of their current respective prosthetic products, including MPKs; and (iii) develop new technology for future prosthetic devices. FOF ¶ 1554.

Respondent's expert in corporate finance and mergers and acquisition transactions, James Peterson, further analyzed the efficiencies work performed by Ottobock and AT Kearney through,

among other things, an Efficiencies Sensitivity Analysis. FOF ¶ 1555, 1564. Peterson concluded that the Acquisition offered material and achievable efficiencies. FOF ¶ 1569. In reaching his conclusion, Peterson analyzed and critiqued the synergies and efficiencies identified by Ottobock and AT Kearney. FOF ¶ 1555. Peterson concluded that Ottobock management and AT Kearney performed significant work to attempt to quantify the efficiencies of the Transaction and the economic benefits of the Dual Brand Strategy. FOF ¶ 1556. The result of Ottobock’s and AT Kearney’s efficiencies analysis resulted in a robust “Financial Model.” FOF ¶ 1535, 1545.

[REDACTED]

Peterson specifically identified the following Acquisition-specific efficiencies: [REDACTED]

[REDACTED]

Due to Freedom’s history of not meeting financial projections, violating terms of debt covenants, and diminishing cash balances, Peterson was not surprised that Ottobock was able to

identify material and achievable efficiencies through its due diligence and development of the Financial Model. FOF ¶ 1568. [REDACTED]

IV THE ACQUISITION SUBJECT TO THE MPK DIVESTITURE WILL NOT ADVERSELY EFFECT COMPETITION AND ANY REMEDY OUTSIDE THE ALLEGED MARKET WOULD BE PUNITIVE.

[REDACTED] Since then, Respondent has agreed to divest 100% of Freedom’s assets in the market alleged by Complaint Counsel to [REDACTED] through an Asset Purchase Agreement (“APA”) [REDACTED] [REDACTED] (the “MPK Divestiture”). FOF ¶ 1086. As a result, there can be no harm to competition in the alleged market under the Court’s competitive effects analysis, as described in Section III, *supra*. Further, a divestiture that is limited to the sale of Freedom’s MPK assets to [REDACTED] is a remedy available to this Court in lieu of complete divestiture of the entire Freedom business, which would be unnecessary and inappropriately punitive.

A. The Acquisition Coupled With The MPK Divestiture Will Not Harm Competition In Any Relevant Market.

As established in *FTC v. Arch Coal, Inc.*, No. 1:04-cv-00534, at 7 (D.D.C. July 7, 2004), the proper analysis under *General Dynamics* where merging parties have agreed to divest assets is whether the merger with the divestiture will have a substantially adverse effect on competition.

The entire transaction, including the divestiture, must be considered in assessing competitive effects. *Id.*

Here, with [REDACTED]

[REDACTED]
[REDACTED] Looking forward, as *General Dynamics* requires, there is no likely substantially adverse effect on competition. FOF ¶ 1089. The evidence establishes that

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Where a defendant proposes a curative divestiture or other modification to the original transaction, courts will consider the divestment or other modification in assessing whether the government has met its burden of proving anticompetitive effects. *See, e.g., Arch Coal, Inc.*, No. 1:04-cv-00534, ECF No. 67 at 7 (D.D.C. July 7, 2004) (where defendant proposed curative divestiture, court held that it was required “to review the *entire* transaction in question.”); *White Consol. Indus., Inc. v. Whirlpool Corp.*, 781 F.2d 1224 (6th Cir. 1986) (affirming vacating injunctive relief after curative divestiture occurred); *United States v. Conn. Nat’l Bank*, 362 F. Supp. 240 (D. Conn. 1973). Furthermore, “a defendant may introduce evidence that a proposed divestiture would ‘restore the competition’ lost by the merger counteracting the anticompetitive effects of the merger.” *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 60 (D.D.C. 2017) (punctuation omitted) (citing *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 72 (D.D.C. 2015)).

The FTC’s April 18, 2018 opinion and order denying Complaint Counsel’s Motion to Strike Respondent’s Seventh Affirmative Defense (the “April 18, 2018 Order”) confirms that the competitive effect of the acquisition subject to the divestiture must be considered as part of the competitive effects analysis, not just as part of any remedy analysis. Although the FTC held that the planned divestiture was not properly characterized as an affirmative defense, it held that the divestiture:

could potentially be relevant to rebut a showing of likely anticompetitive effects [REDACTED] and Respondent remains entitled to develop and present relevant evidence regarding [REDACTED]. Moreover, in support of its denial, Respondent may develop and present relevant evidence regarding the [REDACTED] for any violation found.

April 18, 2018 Order at 6.⁴

“A divestiture must ‘effectively preserve competition in the relevant market.’” *Aetna*, 240 F. Supp. 3d at 60 (quoting U.S. Dep’t of Justice, *Antitrust Division Policy Guide to Merger Remedies* 1 (2011)). “In other words, the divestiture must ‘replace the competitive intensity lost

⁴The FTC’s conclusion that the divestiture does not constitute an affirmative defense is based on its reasoning that “the planned divestiture cannot eliminate the potential for demonstrating likely anticompetitive effects during the intervening period” before the divestiture. April 18, 2018 Order at 4. However, as stated above, Ottobock entered into a Hold Separate Agreement as of December 19, 2017. Complaint Counsel has introduced no evidence of anticompetitive effects from the Acquisition either before or after the date of the Hold Separate Agreement. To the contrary, the evidence establishes that Freedom has continued to operate independently, price its products independently and run its R&D operations independently, albeit with substantial financial assistance from Ottobock, including by satisfying all of Freedom’s debt. As such, despite the FTC’s refusal to characterize the MPK Divestiture as an “affirmative defense” – a distinction that was appropriate before trial – at this point, it is clear that because the Acquisition subject to the MPK Divestiture is not likely to result in a substantially adverse effect on competition in any relevant market, it is effectively a complete defense to Complaint Counsel’s Claims.

as a result of the merger.” *Id.* (quoting *Sysco*, 113 F. Supp. 3d at 72) (punctuation omitted). “In order to be accepted, ‘curative divestitures’ must be made to a new competitor that is ‘in fact . . . a willing, *independent* competitor capable of effective production in the . . . market.” *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26 (D.D.C. 2009) (quoting *White v. Consol. Indus. v. Whirlpool Corp.*, 781 F.2d 1224, 1228 (6th Cir. 1986)).

“Defendants in a merger challenge bear the burden of producing evidence tending to rebut the government’s *prima facie* case. Part of that burden of production includes producing evidence that the divestiture will actually occur But, of course, antitrust deals in ‘probabilities, not certainties.’ Hence, the 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 61 (citations omitted, quoting *Brown Shoe*, 370 U.S. at 323); *see also United States v. Atlantic Richfield Co.*, 297 F. Supp. 1061 (S.D.N.Y. 1969) (rejecting as “speculation” the government’s contention that a divestiture may not occur.”).

Here, the likely effect of the divestiture to [REDACTED]

[REDACTED] is

that the MPK Divestiture buyer will likely succeed in selling Freedom’s MPK products [REDACTED]

[REDACTED]

[REDACTED] In the case of [REDACTED]

[REDACTED]

B. An MPK Divestiture To [REDACTED] Will Keep The Assets In The Alleged Relevant Market And Contradicts Any Harm To Competition Alleged By Complaint Counsel.

1.

[REDACTED]

[REDACTED]

2.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3. [REDACTED]

4. [REDACTED]

Because Complaint Counsel alleges anticompetitive effects in a market that consists solely of MPKs, complete divestiture of Freedom’s MPK business through the APA immediately eliminates any such alleged anticompetitive effects.

5. [REDACTED]

[REDACTED]

C. The Court May Find Partial Divestiture As An Appropriate Remedy.

Combining the Acquisition with an MPK Divestiture eliminates any adverse effect on competition. Moreover, as to issues of any remedy for any possible violation, “[t]he key to the whole question of an antitrust remedy is of course the discovery of measures effective measures to restore competition. Courts are not authorized in civil proceedings to punish antitrust violators, and relief must not be punitive.” *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 326 (1961); *see also Gilbertville Trucking Co. v. United States*, 371 U.S. 115, 129-30 (1962).

Over two thirds of Freedom's business relates to prosthetic feet. Complaint Counsel has neither alleged nor proven adverse effects on competition in any market that includes prosthetic feet. Thus, any adverse effects on competition alleged in the Complaint would be completely restored by an MPK Divestiture remedy. Because a proposed divestiture is adequate to restore any lost competitive intensity, unwinding the entire Acquisition, or ordering a divestiture of all assets acquired in the Acquisition, is not supportable as a remedy.

Courts frequently approve settlements involving a remedy of less than total divestment. *See, e.g., United States v. US Airways Group*, 38 F. Supp. 3d 69 (D.D.C. 2014) (approving a proposed consent decree resolving a civil antitrust suit against two merging airlines requiring the divestiture of slots, gates, and ground facilities at seven airports); *United States v. SBC Communications, Inc.*, 489 F. Supp. 2d 1, 7 (D.D.C. 2007), (approving proposed settlements of civil antitrust cases against telecommunications companies with fiber optic connections to commercial buildings requiring the defendants to divest indefeasible rights of use for last-mile connections to certain buildings in certain metropolitan areas, along with transport facilities to use them); *United States v. Abitibi-Consolidated, Inc.*, 584 F. Supp. 2d 162, 164 (D.D.C. 2008) (approving a consent decree resolving an antitrust action involving merging newsprint producers required the merged firm to divest a particular newsprint mill); *United States v. Newpage Holdings, Inc.*, No. 14-cv-2216, 2015 U.S. Dist. LEXIS 175650, at *7 (D.D.C. Dec. 11, 2015) (approving a settlement of a civil enforcement action against two merging producers of certain paper products requiring the divestment of two mills); *United States v. Sinclair Broadcast Group, Inc.*, 74 F. Supp. 3d 468, 473-74 (D.D.C. 2014) (approving settlement of a civil action against two broadcasting corporations requiring divestiture of assets required to operate a particular TV station).

Because the MPK Divestiture would cure any harm claimed by Complaint Counsel, any broader remedy would be punitive and wholly unnecessary to achieve Complaint Counsel's only legitimate objective of restoring competition. Thus, this Court's remedy, if any, should be limited to an MPK Divestiture to [REDACTED]

V THE FAILING FIRM DEFENSE APPLIES TO THE ACQUISITION AS A COMPLETE DEFENSE TO COMPLAINT COUNSEL'S CLAIMS.

The "failing firm" defense has existed as a defense to a Section 7 monopolization action since the Supreme Court's decision in *International Shoe Co. v. FTC*, 280 U.S. 291, 299-303 (1930); *see also, e.g., United States v. Black & Decker Mfg. Co.*, 430 F. Supp. 729, 776 (D. Md. 1976) (citing *International Shoe*). The defense "was preserved by explicit references in the legislative history of the modern amendments to § 7." *General Dynamics*, 415 U.S. at 506; *see also California v. Sutter Health Sys.*, 84 F. Supp. 2d 1057, 1081-83 (N.D. Cal. 2000). Thus, it is a complete defense to a Section 7 claim that the acquired entity is "a corporation with resources so depleted and the prospect of rehabilitation so remote that it faced the grave probability of a business failure." *International Shoe*, 280 U.S. at 777. Numerous courts have held that acquired firms were "failing" under the failing firm defense. *See, e.g., Reilly v. Hearst Corp.*, 107 F. Supp. 2d 1192, 1203-05 (N.D. Cal. 2000); *California v. Sutter Health Sys.*, 84 F. Supp. 2d 1057, 1081-83 (N.D. Cal. 2000); *FTC v. Great Lakes Chem. Corp.*, 528 F. Supp. 84, 96-98 (N.D. Ill. 1981); *United States v. Black & Decker Mfg. Co.*, 430 F. Supp. 729, 778-81 (D. Md. 1976); *In re SKF Indus.*, 94 F.T.C. 6, 1979 F.T.C. LEXIS 292, at *77-85 (F.T.C. 1976); *United States v. M.P.M. Inc.*, 397 F. Supp. 78, 98-101 (D. Colo. 1975); *United States v. Maryland & Virginia Milk Producers Ass'n*, 167 F. Supp. 799, 808 (D.D.C. 1958).

The failing firm defense is also recognized in the most recent version of Section 11 of the Merger Guidelines, which state that the failing firm defense applies in cases where Respondent

establishes that: “(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.” *See also Dr. Pepper / Seven-Up Cos. v. FTC*, 991 F.2d 859, 864-65 (D.C. Cir. 1993).

Respondent easily satisfies each of these requirements elements. Prior to the Acquisition, Freedom was experiencing catastrophic financial problems. FOF ¶¶ 1312-1314. Chief among Freedom’s problems was its lack of capital, which Freedom attempted to solve through onerous debt that would ultimately cause Freedom to become insolvent. FOF ¶¶ 1305, 1313. The debt aside, Freedom’s business was grossly mismanaged for many years leading up to the Acquisition. FOF ¶ 1300. Freedom had a long history of overstating and failing to achieve financial projections that was so egregious that Freedom’s own CEO, David Smith, believed prior management had been [REDACTED] for many years. FOF ¶¶ 1315-1316. [REDACTED]

[REDACTED] Not only is the Acquisition entitled to the benefit of the failing firm defense on the elements, but the circumstances of Freedom presents one of the strongest failing firm defenses when compared to available failing firm precedent.

A. Freedom Was Unable to Meet Its Financial Obligations In The Near Future Prior To The Acquisition.

[REDACTED]

[REDACTED]

1. Freedom Suffered From Poor Performance And Gross Mismanagement.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Further, Freedom suffered from gross mismanagement. FOF ¶ 1330, 1338, 1339, 1354. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

a. Freedom was failing by virtually every financial measure.

[REDACTED]

EBITDA is also an important metric in measuring the financial health of a company because “it’s an approximation of the operating cash flow generated by the business of the company.” FOF ¶ 1301. Negative or close to breakeven EBITDA indicates poor financial health because: “EBITDA needs to be high enough to cover things like 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.” FOF ¶ 1302. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In addition, in 2017, Freedom presented a projected loss at the EBITDA level before consideration of additional cash requirements of the business including

taxes, debt service and capital spending in its pitch book to potential investors. FOF ¶ 1308.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

b. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁵

	2014	2015	2016
2012 Projected Revenue	\$69,282	\$87,713	\$106,476
Actual Revenue	\$40,215	[REDACTED]	[REDACTED]
Shortfall	(\$29,067)	[REDACTED]	[REDACTED]

⁵The information is compiled from RX0005-00050 and RX00006. Dollar figures represent thousands of dollars.

[REDACTED]

[REDACTED]⁶

	2014	2015	2016
2012 Projected EBITDA	\$25,055	\$34,054	\$42,991
Actual EBITDA	\$3,414	[REDACTED]	[REDACTED]
Shortfall	(\$21,641)	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Among many other reasons,

Freedom failed to achieve its financial projections because it [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁶The information is compiled from RX0005-00050 and RX00006. Dollar figures represent thousands of dollars.

[REDACTED]

c. David Smith’s attempted turnaround failed.

Because Freedom’s financial condition was so poor in 2016, Freedom replaced Carkhuff as CEO with David Smith, effective April 1, 2016. FOF ¶ 1330. Before joining Freedom, Smith was a partner in HEP. FOF ¶ 1331. Smith surrendered his partnership with HEP after becoming the CEO of Freedom in order to avoid any potential conflict of interest. FOF ¶ 1332. Smith had no experience in the prosthetics industry before he joined Freedom. FOF ¶ 1333. As a result, Smith persuaded the board to retain Carkhuff in an executive role as Vice Chairman so he could advise Smith about the industry. FOF ¶ 1334.

Around the time he became CEO, Smith learned that Freedom was in terrible financial condition and that prior management had been [REDACTED]

[REDACTED]

[REDACTED] However, he soon realized that the company needed to “survive” by increasing revenue without spending more money: “So my goal was to increase revenues without spending money so I have more on the bottom so that I could pay debt and maybe hit my covenants or have money to fix the problems that I could see.” FOF ¶ 1337.

[REDACTED]

Smith simply did not have sufficient time before Freedom's outstanding debt was due to implement a turnaround plan. FOF ¶ 1355. Smith believes that he needed at least an additional 18 months to implement the plan, assuming he could have obtained sufficient financing of \$27.5 million to pay off the debt, and \$10 million to \$15 million of capital to improve the business. FOF

By way of comparison, Össur's YTD gross margin for the same time period was [REDACTED] approximately [REDACTED] basis points higher than Freedom's. FOF ¶ 1366. If Freedom increased its prices to achieve a gross margin consistent with Össur, Freedom's YTD 2017 EBITDA would have been [REDACTED] higher than the company's actual performance. FOF ¶ 1366. This level of EBITDA would imply an EBITDA margin for Freedom of [REDACTED] which is much higher than actual performance, but still well below that of Össur's EBITDA margin, as of June 30, 2017, of [REDACTED] FOF ¶ 1366. From 2012 to 2015, total operating expenses increased from \$14.2 million or 48.0% of revenue to \$27.0 million or 63.1% of revenue, driven by increases in sales and marketing, research and development, and general and administrative spending that outpaced the pricing strategy of Freedom FOF ¶ 1367.

For these reasons, Peterson opined: "Freedom's low margins are not sustainable. In order to operate in the prosthetics industry and compete effectively, significant R&D is required. Further, absent market level EBITDA, lenders are unlikely to provide capital necessary to fund growth." FOF ¶ 1368. Peterson also testified: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. Freedom's Debt Was Insurmountable.

In addition to disastrous financial performance, Freedom was burdened by insurmountable debt that it could not pay other than through the Acquisition. FOF ¶ 1369. Indicia of a failing firm include that a firm's "assets were pledged as collateral for debt, the company was seriously in default of its Bank obligations, its trade debts were severely past due, and new sources of capital were non-existent." *United States v. Black & Decker Mfg. Co.*, 430 F. Supp. 729, 781 (D. Md.

1976). The evidence introduced at trial was clear that Freedom was beyond serious default on its debt obligations; its lenders, Bank of Montreal (“BMO”) and Madison Capital Funding, LLC (together, the “Lenders”), intended to force Freedom into liquidation if they were not paid in the very near future through an acquisition. FOF ¶¶ 1371, 1381, 1527.

Freedom entered into a Credit Agreement, dated as of February 16, 2012 (the “Credit Agreement”) that provided Freedom with, among other things, a \$40 million term loan. FOF ¶ 1369. [REDACTED]

[REDACTED]

Throughout the life of the Credit Agreement, Freedom routinely breached certain covenants and required various amendments in order to become compliant with the terms of the Credit Agreement. FOF ¶ 1374. [REDACTED]

[REDACTED] The first through sixth amendments were executed on March 31, 2013, June 7, 2013, November 24, 2014, June 30, 2016, August 15, 2016, and August 22, 2016, respectively. FOF ¶ 1376. [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

| | |

[REDACTED]

| | |

[REDACTED]

[REDACTED]

| | |

[REDACTED]

3. Freedom's Auditors Had Substantial Doubt That Freedom Could Continue As A Going Concern In April 2017.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

B. Freedom Would Not Have Been Able To Successfully Reorganize Under Chapter 11 Of The Bankruptcy Act.

Section 11 of the Merger Guidelines articulate the second prong of the failing firm defense as requiring that the allegedly failing firm “would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act.” However, “[t]he weight of authority suggests that dim prospects for bankruptcy reorganization are not essential to successful assertion of the failing company defense.” *United States v. Black & Decker Mfg. Co.*, 430 F. Supp. 729, 778 (D. Md. 1976). Whether required or not, the evidence introduced at trial was undisputed that Freedom would not have been able to successfully reorganize under Chapter 11. FOF ¶¶ 1521, 1523.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

For similar reasons, Peterson reviewed the record and opined that “[t]o the extent Freedom had filed for protection under Chapter 11 of the U.S. Bankruptcy Code . . . it is unlikely that a reorganization would have been successful.” FOF ¶ 1528. Peterson identified factors that would have been significant obstacles for Freedom as Freedom’s declining available cash and margins. FOF ¶¶ 1524, 1525. In addition, Peterson recognized that, in order to reorganize under Chapter 11, Freedom would have needed to obtain financing in order to operate as a stand-alone business. FOF ¶ 1525. However, given the position of the existing Lenders and Freedom’s inability to secure additional financing, there was no reasonable prospect for Freedom to obtain the financing necessary to survive Chapter 11. FOF ¶ 1525. Indeed, Freedom’s YTD 2017 Leverage Ratio far exceeded lender risk profile. FOF ¶ 1525.

Freedom was simply out of options to avoid liquidation. Freedom’s management consistently testified at trial that, if Freedom had not been sold to Ottobock in 2017, Freedom would have been liquidated. FOF ¶ 1528. [REDACTED]

[REDACTED]

[REDACTED]

C. Freedom Exhausted Good Faith Efforts To Obtain Reasonable Alternatives To The Acquisition.

The third element of the failing firm defense, according to Section 11 of the Merger Guidelines, is that the firm “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.” However, this prong does not impose an obligation to contact every possible financing partner or strategic alternative; only good faith efforts to obtain *reasonable alternative* offers are required. “The failing firm should not be required to do more than make a canvass sufficient to indicate that further efforts would be unlikely to bear fruit.” IV Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 954d (4th ed. 2016); *see also* RX-1048-00038 (“In my experience, sale processes do not involve direct contact with every conceivable potential financial or strategic buyer, including every participant within a relevant industry.”).

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Freedom's search for

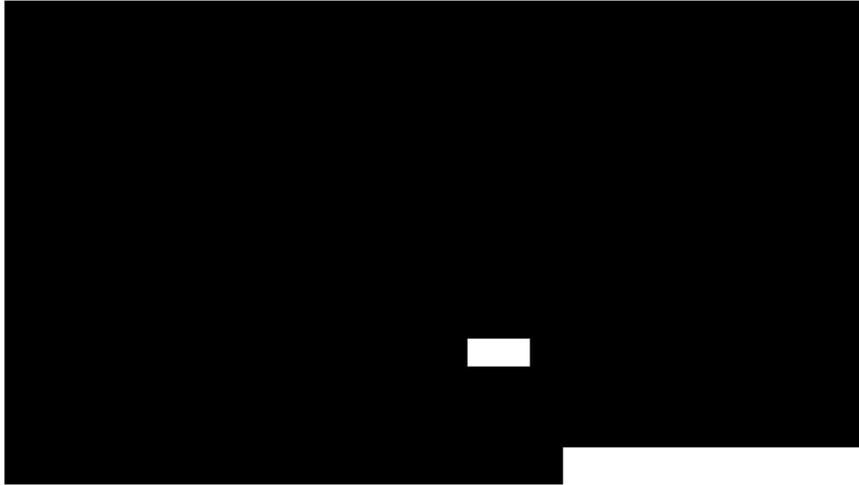
potential alternatives was robust, exhaustive, and consistent with typical sale and refinancing processes employed by similar companies. FOF ¶ 1452.

1. Freedom Engaged In Extensive Efforts To Attract Refinancing Partners.

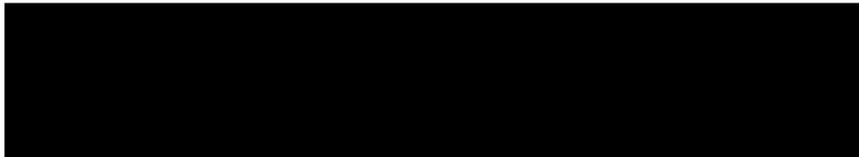
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED]



| | |



[REDACTED]

[REDACTED] The decision not to contact certain companies proved appropriate because the evidence suggests they would not have even attempted to bid. FOF ¶ 1484. For example, both Hanger and [REDACTED] [REDACTED] knew that Freedom was going through a sale process before the Acquisition closed in September 2017 and chose not to make an offer. FOF ¶ 1484. If a [REDACTED] representative had expressed interest in purchasing Freedom, Smith would have invited them to submit an offer. FOF ¶ 1485.

[REDACTED]

3. **Össur's [REDACTED] Does Not Constitute A "Reasonable Alternative Offer."**

Össur's [REDACTED] in Freedom does not qualify as a "reasonable alternative offer" as that phrase applies to the failing firm defense for at least four reasons: (i) Össur's [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

a. **Össur's proposal was not an "offer."**

[REDACTED]

A mere expression of interest does not constitute an "offer." *See, e.g., United States v. Culbro Corp.*, 504 F. Supp. 661, 669 (S.D.N.Y. 1981); *California v. Sutter Health Sys.*, 130 F. Supp. 2d

1109, 1136-37 (N.D. Cal. 2001). For this reason alone, Össur’s proposal does not qualify as a “reasonable alternative offer” because it was no offer at all.

b. Össur’s proposal was not serious.

[REDACTED]

[REDACTED]

1 [REDACTED]

1 [REDACTED]

1 [REDACTED]

1 [REDACTED]

1 [REDACTED]

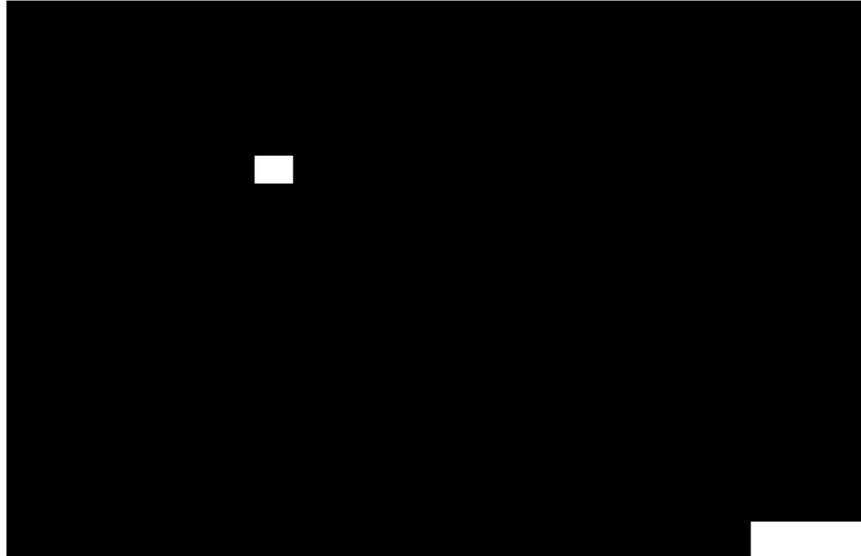
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



Össur's apparent lack of sincerity in the sale process also indicates that its proposal was not a real "offer" and thus not a "reasonable alternative offer" for purposes of the failing firm defense.

c. Össur's proposed purchase price was unreasonably low.

Össur's proposed purchase price of \$ [REDACTED] was too unreasonably low to qualify as a "reasonable alternative offer." "[T]he law has some obligation to waive its preference for an alternative purchaser where necessary to protect the failing firm against 'unreasonably' low offers." Areeda & Hovenkamp ¶ 954d. An offer that is too low is deemed unreasonable not just to protect the failing firm, but also because it raises questions about whether the acquirer intends to keep the purchased assets in the market. For that reason, in the context of determining whether a divestiture is an appropriate remedy, the government "will not approve a purchaser if the purchase price clearly indicates that the purchaser is unable or unwilling to compete in the relevant market. A purchase price that is 'too low' may suggest that the purchaser does not intend to keep the assets in the market." U.S. Dep't of Justice, *Antitrust Division Policy Guide to Merger Remedies* at 30-31 (June 2011).

Here, Össur's proposed of \$ [REDACTED] was so far outside the range of reasonable corporate valuations that it should not be credited as a reasonable alternative. Moelis also performed third-party valuations of Freedom that estimated value on a discounted cash flow ("DCF") basis as between \$135 and \$170 million without synergies and between \$300 and \$370 million with synergies. FOF ¶ 1516. The valuation with synergies is the amount that Moelis would have expected a strategic buyer, like Ottobock or Össur, to pay for the company based on Freedom's projected financial performance. FOF ¶ 1516. A \$ [REDACTED] purchase price would have been many orders of magnitude outside the range of expected purchase prices for financial or strategic buyers. [REDACTED]

[REDACTED]

[REDACTED]

Because the purpose of the failing firm defense is not served by allowing unreasonable offers to defeat an otherwise valid defense, Össur's proposal should not be considered a "reasonable alternative offer."

d. An Össur acquisition did not pose a less severe danger to competition.

An acquisition of Freedom by Össur at any price would have not have posed a less severe danger to competition, if any, than the Acquisition by Ottobock. FOF ¶ 11499. "A 'preferred purchaser' is an acquirer (1) who would remain in the market; and (2) whose acquisition would be lawful a) even if the acquired firm were not failing, or b) simply on proof that [failure was impending]." The policy underlying the failing firm defense clearly does not intend to deny the defense because an anticompetitive alternative may have been available:

A 'preferred purchaser' should be significantly more attractive from a competitive standpoint than the proposed acquirer. Slight differences would not justify intervention even if the offers seemed comparable and private interests are equally well served;

determining comparability would raise difficult judgmental questions that should be avoided if at all possible.”

Areeda & Hovenkamp ¶ 954c (emphasis added). “As a basic premise, [an] alternative acquirer should be deemed preferable only when its market share is substantially less than that of other acquirers, including the proposed acquirer.” *Id.* ¶ 954c3.

As stated above in Section II, *supra*, Complaint Counsel has failed to meet its burden to establish a relevant antitrust market that is no broader than all MPKs sold in the United States. However, applying Complaint Counsel’s alleged market definition to an Össur acquisition of Freedom would lead to the obvious conclusion that such an acquisition would yield a presumption of harm to competition. FOF ¶ 1505. [REDACTED]

[REDACTED] Thus, in either market, an Össur acquisition would have been “presumed to be likely to enhance market power” under the Merger Guidelines. FOF ¶ 1505.

[REDACTED]

[REDACTED]

Moelis' DCF valuations of between \$135 and \$170 million without synergies and between \$300 and \$370 million with synergies further support this point. FOF ¶ 1516. [REDACTED]

[REDACTED]

[REDACTED] He further opined that “given Freedom’s small size and financial condition, that the outcome of the Moelis process, bids from strategic players, was the most reasonable, expected and obvious outcome.” FOF ¶ 1469.

CONCLUSION

For the reasons set forth above and explained at length during 12 weeks of trial, the Court should reject Complaint Counsel’s Claims because the Acquisition is not likely to lessen competition. Complaint Counsel has failed to prove any harm in this case, first failing to establish a clearly defined relevant market and then adducing no evidence of anticompetitive effects even within the deeply flawed alleged market.

In contrast, Respondent proved at trial that (i) Ottobock and Freedom are not close competitors in MPKs; (ii) several existing MPK manufacturers are increasing output in the near

future in numbers greater than Freedom’s annual output; and (iii) powerful buyers and the third-party reimbursement system in the United States discipline and severely constrain the ability of manufacturers to raise prices on MPKs. Respondent also established that the Acquisition should be upheld under the “failing firm” defense because Freedom was on the verge of liquidation for, among other reasons, its inability to pay its \$27.5 million debt when due. At a minimum, Freedom was a “flailing firm” at the time of the Acquisition that posed no competitive threat in the alleged market.

Lastly, Complaint Counsel’s entire case theory ignores the critical fact that Respondent has agreed to divest 100% of Freedom’s assets in the alleged market to [REDACTED]

[REDACTED]

[REDACTED]

An MPK Divestiture would eliminate any perceived harm to competition from the Acquisition because, [REDACTED]

[REDACTED]

It would be unjust, unnecessary, and legally insupportable to require any remedy broader than an MPK Divestiture in light of these facts and the evidence introduced at the trial.

Dated: November 20, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 20, 2018, I caused a true and correct copy of the foregoing Respondent's Post-Trial Brief to be served via the FTC E-Filing System and e-mail upon the following:

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Notice of Electronic Service

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