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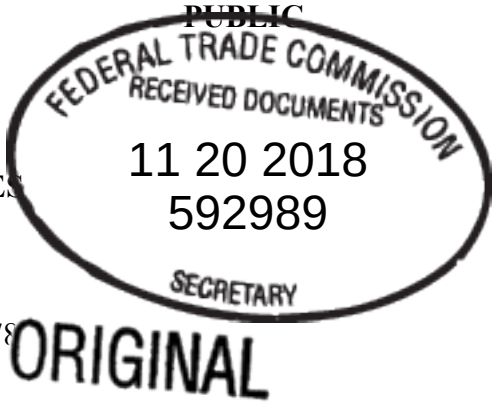

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

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

ORIGINAL

RESPONDENT'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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Dated: November 20, 2018

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RESPONDENT'S PROPOSED FINDINGS OF FACT

I. BACKGROUND

A. Parties

1. Ottobock

1. Otto Bock HealthCare North America, Inc. ("Ottobock") is a pioneering prosthetics and orthotics company and is a subsidiary of Otto Bock Healthcare SE & Co. KGaA headquartered in Germany ("Ottobock Germany"). (Kannenberg Tr. 1932-1933, Schneider Tr. 4277-4279, 4337-4342, 4281-4284, Carkhuff Tr. 710-711; (PX05155 (Ehrich (Ottobock), Dep. at 60)). Ottobock Germany provides upper and lower limb prosthetics, orthotics, mobility solutions, and medical-related services to customers in various countries throughout the world. (RX-0964).

2. Ottobock Germany is named after its founder, Otto Bock, a certified prosthetist and orthotist who founded the company in 1919 in Berlin, Germany. (RX-0964; Schneider, Tr. 4277). Otto Bock is regarded as the Henry Ford of prosthetics. (Schneider, Tr. 4277). The current majority owner of Ottobock Germany is Otto Bock's grandson, Professor Hans Georg Näder. (Schneider, Tr. 4279).

3. Ottobock Germany opened its first foreign branch, Ottobock, in 1958 in Minneapolis, Minnesota. (Schneider, Tr. 4279). Ottobock moved its American headquarters from Minneapolis to Austin, Texas in 2014, and the Austin headquarters employs about 100 individuals. (Schneider, Tr. 4284, 4285). Ottobock also has manufacturing and R&D facilities in Salt Lake City, Utah that employ between 220 and 250 employees, as well as logistics facilities in Louisville, Kentucky where another 25 people work. (Schneider, Tr. 4285). Ottobock also employs between 75 and 100 people in the field that work as sales representatives, clinical specialists, or reimbursement specialists. (Schneider, Tr. 4285).

4. Ottobock sells all of these products in the United States. (Schneider, Tr. 4304).

2. Freedom

5. FIH Group Holdings, LLC ("Freedom") was founded in 2002. (RX-0947; Carkhuff, Tr. 293). Freedom sells over twenty different brands of prosthetic feet and two prosthetic knees, the Liberty and the Plié, in the United States. (RX-0949). Freedom has facilities in Utah and California and employs approximately 150 people. (Carkhuff, Tr. 321, 329). Prior to the acquisition by Ottobock, Freedom had been privately held, and the majority shareholder had been Health Evolution Partners Fund I (AIVI), LP ("HEP"), a private equity firm. (PX05113 (Chung, Dep. at 119); Lee, Tr. 2542).

6. 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. (RX-0947). Freedom has a portfolio of lower limb prosthetic solutions and support services focusing

mostly on prosthetic feet and ankles. (RX-0947). In particular, Freedom markets 23 brands of carbon fiber feet that can be customized to fit any lifestyle from everyday walking to extreme sports. (RX-0949). The vast majority of Freedom's revenue is derived from the sale of prosthetic feet and ankles, and *not* prosthetic knees.

7. For the first five years of Freedom's existence, it sold exclusively carbon fiber foot products. (Carkhuff, Tr. 293). Since 2007, Freedom has only manufactured one prosthetic knee, the Plié. (Carkhuff, Tr. 294). 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. (Carkhuff, Tr. 335-336; [redacted] 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. [redacted]

8. At the time of the Acquisition, Freedom expected [redacted] Freedom has claimed to be developing a new MPK known as the "Quattro Project." (Prince, Tr. 2673). [redacted]

9. 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. (Carkhuff, Tr. 587). 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. (Carkhuff, Tr. 304-305). 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. (Carkhuff, Tr. 305).

10. 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. (Carkhuff, Tr. 587-588). Flex-Foot then entered into a joint venture with MIT to develop an MPK. (Carkhuff, Tr. 588).

11. In February 2000, before Flex-Foot could commercialize the MPK, Flex-Foot was sold to Össur. (Carkhuff, Tr. 588). After that acquisition, Carkhuff worked for Össur as the President and CEO of Össur Prosthetics, and Flex-Foot was merged into Össur's business. (Carkhuff, Tr. 588-589). Össur continued to manufacture Flex-Foot carbon fiber foot products in the ACT manufacturing plant owned by Dr. Christensen. (Carkhuff, Tr. 306).

12. 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." (Carkhuff, Tr. 589). Before Össur purchased Flex-Foot, Össur was primarily a liner company. [redacted] Össur has grown significantly since it purchased Flex-Foot in 2000, and it is now a publicly traded company. (Carkhuff, Tr. 588-589).

13. In August of 2001, Össur terminated Mr. Carkhuff's employment. (Carkhuff, Tr. 590). Össur then moved the carbon fiber manufacturing from ACT's plant in Gunnison, Utah to Össur's headquarters in Reykjavik, Iceland. (Carkhuff, Tr. 306). That left Dr. Christensen with an empty plant, a large number of employees, and knowledge about carbon foot products. (Carkhuff, Tr. 306). 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. (Carkhuff, Tr. 306). Following a contractual non-competition period, Carkhuff because the President of Freedom in 2005. (Carkhuff, Tr. 590-591).

14. 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). [redacted]

15. In 2007, Freedom launched the Plié prosthetic knee. (Carkhuff, Tr. 294). The Plié 2 was released in 2010, and the Plié 3 was released in 2014. (Carkhuff, Tr. 294). Freedom markets the Plié 3 as an MPK. (Carkhuff, Tr. 323). In 2017, [redacted]

16. At the time of the acquisition, Freedom owed Bank of Montreal and Madison Capital approximately $27.5 million with a debt maturity date in September 2017, was running out of funds to operate and make payroll, had cut R&D projects, and had retained investment bankers to shop Freedom for sale. (Smith Tr. 6485-6486; PX05007 (Carkhuff, IH at 26); Hammock, Tr. 6065, 6125).

B. The Acquisition

17. Ottobock acquired Freedom on September 22, 2017 pursuant to an Agreement and Plan of Merger (the "Acquisition"). (RX-0548; RX-0820 at 001). Ottobock acquired Freedom for [redacted] A substantial piece of the consideration for the Acquisition was used to pay off Freedom's debt. [redacted]

C. Witness Backgrounds

1. Ottobock Witnesses

a. Scott Schneider, Ottobock

18. Scott Schneider is Vice President of Government, Medical Affairs, and Future Development at Ottobock. (Schneider, Tr. 4260). Mr. Schneider remains involved in patient care in his role at Ottobock, and he is familiar with how prosthetic devices are manufactured by Ottobock and reimbursed by insurance providers. (Schneider, Tr. 4267-4268, 4272). Mr. Schneider also analyzes new technologies, new business models, and strategic opportunities. (Schneider, Tr. 4272).

19. Mr. Schneider has worked in the prosthetics industry for 30 years. (Schneider, Tr. 4260). Schneider worked as a prosthetist from 1988 to 1995 in St. Cloud, Minnesota at a clinic called Northwestern Artificial Limb and Brace. (Schneider, Tr. 4261). As a prosthetist and an orthotist, Mr. Schneider fitted patients with prosthetic devices, including prosthetic knees. (Schneider, Tr. 4261, 4264).

20. Mr. Schneider was also co-owner of TEC Interface, a business that specialized in prosthetic socket technology. (Schneider, Tr. 5262-6263). After significantly growing the company and developing nearly twenty patents, Mr. Schneider sold the business to Ottobock in 2003. (Schneider, Tr. 4262-4263).

21. Mr. Schneider has worked in various product development, operations, research and development, sales, marketing, and executive positions both at Ottobock and Ottobock Germany. (Schneider, Tr. 4264-4266). From 2011 until the end of 2013, Mr. Schneider was the Regional Vice President of Ottobock, which was equivalent to a CEO position. (Schneider, Tr. 4269-4271). During that time, the executive team also included Brad Ruhl, who was the President of the healthcare prosthetics division and who is today the Managing Director of Ottobock. (Schneider, Tr. 4271, 4274).

b. Dr. Andreas Kannenberg, Ottobock

22. Dr. Andreas Kannenberg is the Executive Medical Director for Ottobock. (Kannenberg, Tr. 1819). He has held that position since the summer of 2013. (Kannenberg, Tr. 1819). As the Director of Medical Affairs, Dr. Kannenberg established Otto Bock's clinical research department. (Kannenberg, Tr. 1821). The department is responsible for gathering new evidence and developing existing evidence regarding Ottobock's products to assist payers for reimbursement purposes. (Kannenberg, Tr. 1821, 1823). The department is also responsible for providing education and training to prosthetists, orthotists, physical therapists, physicians, and payers around the world. (Kannenberg, Tr. 1822).

23. Dr. Kannenberg received his M.D. in 1989 and a Ph.D. in 1992 from Humboldt University of Berlin. (Kannenberg, Tr. 1820). He joined Otto Bock in 2003 as the Director of Medical

Affairs, and held that position until he became the Executive Medical Director. (Kannenberg, Tr. 1821). As Director of Medical Affairs, he learned how the clinical team works to select products for patients and the criteria used for reevaluating reimbursement claims for prosthetists. (Kannenberg, Tr. 1822-1823). In 2014, he also assumed responsibility for the Reimbursement Department. (Kannenberg, Tr. 1823).

c. Cali Solorio, Ottobock

24. Cali Solorio is the senior prosthetics marketing manager at Ottobock. (Solorio, Tr. 1575). Ms. Solorio assumed her current position in March 2017. (Solorio, Tr. 1575). In her previous position as marketing manager for microprocessor knees at Ottobock, Ms. Solorio's responsibilities included managing Otto Bock's microprocessor knee products in North America. (Solorio, Tr. 1575). Ms. Solorio has assisted in creating the marketing strategy for microprocessor knees and had responsibility for Otto Bock's pricing and promotions on microprocessor knees. (Solorio, Tr. 1576-1577). Ms. Solorio joined Otto Bock in December 2014 as a marketing manager generalist. (Solorio, Tr. 1573).

2. Freedom Witnesses

a. Maynard Carkhuff, Freedom

25. Maynard Carkhuff is currently the Chairman of Freedom, which is a senior strategic position and a position he has held since October 2017. (Carkhuff, Tr. 290, 292). Mr. Carkhuff has worked in the healthcare industry for over thirty years. (PX05007 (Carkhuff IH, at 20)).

26. Mr. Carkhuff joined Freedom in 2005 as the President, and in 2012 became CEO and President of Freedom. (Carkhuff, Tr. 291-292). In 2014, Mr. Carkhuff became the Chairman of Freedom's Board of Directors. (Carkhuff, Tr. 291). In April of 2016, Mr. Carkhuff became Vice Chairman and Chief Innovation Officer. (Carkhuff, Tr. 292). During 2014 through 2016, Mr. Carkhuff was a board member of AOPA. (Carkhuff, Tr. 301).

27. Prior to joining Freedom, Mr. Carkhuff co-founded Flex-Foot in 1985, which was a prosthetics company and the predecessor company to Freedom. (PX05007 (Carkhuff IH, at 20). Flex-Foot was sold in 2000 to Össur, and Mr. Carkhuff was named President and CEO of Össur Prosthetics. (PX05007 (Carkhuff IH, at 20). Mr. Carkhuff left Össur after a year and a half, and then joined Freedom in 2005. (PX05007 (Carkhuff IH, at 21).

b. Mark Testerman, Freedom

28. Mark Testerman is the Vice President of National and Key Accounts for Freedom. (Testerman, Tr. 1072-1073). He has served in that position since February 2014. (Testerman, Tr. 1073). National and Key Accounts are Freedom Innovation's top fifty accounts. (Testerman, Tr. 1073). Mr. Testerman reports to Jeremy Matthews, the Senior

Vice President of Sales and Marketing. (Testerman, Tr. 1074-1075). Testerman works with the decision makers at prosthetic clinics, which could be prosthetists, chief operating officers, or CEOs. (Testerman, Tr. 1080). Testerman contacts each of Freedom's key accounts every quarter. (Testerman, Tr. 1081). Testerman has authority to approve certain discounts for particular customers. (Testerman, Tr. 1082-1083). Testerman is responsible for negotiation of prices and setting prices for Freedom's key accounts, including SPS. (Testerman, Tr. 1085; 1085).

29. Prior to serving as the vice president of national and key accounts, Mr. Testerman was the Vice President of domestic sales. (Testerman, Tr. 1073). Mr. Testerman joined Freedom in 2010. (Testerman, Tr. 1072). As Vice President of Domestic Sales, Testerman directed the daily activities of the sales team, spent time in the field working with the sales team, helped the sales team with problem solving, and worked with Freedom's customers. (Testerman, Tr. 1075).

c. Eric Ferris, Freedom

30. Eric Ferris is the Vice President of Marketing, Customer Service, and Client Development for Freedom. (Ferris, Tr. 2299, 2304). Mr. Ferris is a member of Freedom's Operating Committee, Executive Committee, Product Approval Committee, and Intellectual Property Committee. (Ferris, Tr. 2299-2300).

31. Mr. Ferris joined Freedom in 2015 as the Director of Marketing and Customer Service. (Ferris, Tr. 2298). He held that role until February 2018, when he assumed his current role. (Ferris, Tr. 2298-2299). As the Director of Marketing for Freedom, Mr. Ferris' responsibility was to promote, market, and message Freedom's products, as well as to perform competitive assessments and analyze pricing for Freedom, and educate customers about Freedom's products. (Ferris, Tr. 2303). Prior to working at Freedom, Mr. Ferris had multiple positions in product development and marketing. (Ferris, Tr. 2301).

d. Lee Kim, Freedom

32. Lee Kim is currently the Chief Financial Officer (CFO) of Freedom, a position he has held since joining Freedom in February 2008. (Kim, Tr. 2492). As CFO, Mr. Kim is responsible for preparing Freedom's financial statements. (Kim, Tr. 2493). Mr. Kim is also responsible for developing Freedom's financial forecasts and reporting those forecasts to Freedom's board of directors. (Kim, Tr. 2494). Mr. Kim was responsible for providing Freedom's lenders with compliance reports that were required under credit agreements. (Kim, Tr. 2495). Mr. Kim was responsible for engaging outside accountants to conduct the audit of Freedom's annual financial statements. (Kim, Tr. 2497).

e. Dr. Stephen Prince, Freedom

33. Dr. Stephen Prince is a project manager for Freedom. (Prince, Tr. 2672). Prince has worked at Freedom since June 2012 when he joined as an engineer. (Prince, Tr. 2673). Dr. Prince

is currently the project manager and technical leader for Freedom's Quattro R&D project. (Prince, Tr. 2673). Dr. Prince was previously one of two mechanical engineers in charge of developing the Kinnex microprocessor ankle. (Prince, Tr. 2674).

3. Manufacturer Witnesses

a. Össur hf. ("Össur")

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

b. Kim Peter Viviane De Roy, Össur

35. Kim Peter Viviane De Roy is the Executive Vice President of Research and Development at Össur. (De Roy, Tr. 3525-3527). Mr. De Roy is responsible for overseeing all research and development projects at Össur, including those related to prosthetic knees and feet. (De Roy, Tr. 3527). Mr. De Roy has been in his current role since November 2017. (De Roy, Tr. 3527).

36. Prior to his current role, Mr. De Roy was Össur's Vice President of Sales, Prosthetics from 2013 to 2017. (De Roy, Tr. 3528). He also simultaneously served as the vice president of global marketing prosthetics from 2012 to 2017. (De Roy, Tr. 3528-3529). As Vice President of Sales, Prosthetics, Mr. De Roy oversaw all sales-created activities for prosthetics in the Americas market, including prosthetic knees (which also included both microprocessor knees and K-3 Non-MPKs). (De Roy, Tr. 3529). Mr. De Roy also served as Vice President of Global Marketing, Prosthetics, and he oversaw the global activities in marketing for prosthetics, including the Americas, Europe, and Asia Pacific. (De Roy, Tr. 3529).

c. Charles A. Blatchford & Sons Limited d/b/a Endolite (Blatchford or Endolite)

37. Blatchford is a family-owned business which manufactures lower limb prosthetic devices and provides patient care services in a number of locations in the United Kingdom and Norway. (Blatchford, Tr. 2089-2090). Blatchford was founded in 1890 by Mr. Blatchford's great grandfather. (Blatchford, Tr. 2090).

38. Blatchford products are sold under the trade name Endolite throughout the world, including the United States. (Blatchford, Tr. 2099). Endolite sells a wide range of prosthetics products in the United States, including energy-storing feet, hydraulic ankles,

microprocessor-controlled feet, non-MPKs, and MPKs, among other products. (2099-2100). Endolite employs roughly 80 people in the United States, including 60 at its Miamisburg, Ohio headquarters and 15 sales reps and 5 clinical support specialists that operate throughout the United States. (Blatchford, Tr. 2100-2101).

39. [redacted]

d. Brian Stephen Blatchford, Endolite

40. Stephen Blatchford is employed by Blatchford in the United Kingdom. (Blatchford, Tr. 2089). Mr. Blatchford is also executive chairman of Blatchford. (Blatchford, Tr. 2091). His main responsibilities include looking at the strategic direction of the company and managing the board. (Blatchford, Tr. 2091). Mr. Blatchford is particularly interested in product development, and retains responsibility for the strategic direction of the products developed by Blatchford. (Blatchford, Tr. 2091). Mr. Blatchford spends a lot of his time looking at what Blatchford's competitors are doing, trying to understand what the market is doing, and what Blatchford should be doing. (Blatchford, Tr. 2092). [redacted]

e. Proteor, Inc. d/b/a Nabtesco Proteor USA (Nabtesco Proteor)

41. Nabtesco Proteor is a subsidiary of Proteor, France. (Mattear, Tr. 5516-5517). Nabtesco Proteor was established in 2016. (Mattear, Tr. 5518). Nabtesco Proteor sells prosthetics products manufactured by Proteor France, based in Dijon, France, and Nabtesco Corporation, based in Kobe, Japan, directly to prosthetics and orthotics clinics in the United States. (Mattear, Tr. 5516-5517, 5519-5522).

42. In 2018, Nabtesco Proteor acquired Ability Dynamics, the manufacturer of the RUSH Foot, and Ability Dynamics' sales force and clinical team. (Mattear, Tr. 5518-5520; 5527-5528, 5555-5561). Nabtesco Proteor now has seven sales representatives, a certified prosthetist clinician, and a business development manager. (Mattear, Tr. 5527-5528; 5555-5559; 5563-5564).

f. Brad Mattear, Nabtesco Proteor

43. Bradley Mattear has been the Managing Director of Nabtesco Proteor since 2016. (Mattear, Tr. 5510, 5523). Mr. Mattear is a certified prosthetic assistant, and he has the ability to evaluate, fit, adjust, and modify prosthetics. (Mattear, Tr. 5511). Mr. Mattear has worked in the prosthetics industry for over fifteen years. (Mattear, Tr. 5510). Mr. Mattear went into orthopedics and sports medicine after graduate school, and transitioned into orthotics and prosthetics with a company called Restorative Care of America. (Mattear, Tr. 5510). From 2003 to 2011, Mr. Mattear worked for a company named Orthotics and Prosthetics

1, a custom fabrication manufacturer of prosthetics and orthotics, sockets for amputees, and assistive devices. (Mattear, Tr. 5510-5511, 5514). From 2011 to 2016, Mr. Mattear was a business development manager in charge of the Midwest region for Cascade, a distributor of prosthetic products. (Mattear, Tr. 5514). In that position, Mr. Mattear created business relationships with practitioners on staff at various facilities so that they would buy their necessary prosthetic components from Cascade. (Mattear, Tr. 5515).

g. Ohio Willow Wood Company (Willow Wood)

44. Willow Wood was founded in 1907, and it manufactures and sells prosthetic products in the United States. (Arbogast, Tr. 4932). Willow Wood is a multi-national business, which sells its product offerings in over 30 markets. (Arbogast, Tr. 4933). Willow Wood is one of the leading liner manufacturers in the United States. (Matera, Tr. 5226; Schneider, Tr. 4304). They also manufacture knees, ankles, feet, sockets, and the LimbLogic vacuum pump. (Matera, Tr. 5226).

45. Willow Wood also sells software services, including a scan system which allows prosthetists to scan a limb of the amputee so that Willow Wood can make a socket for the residual limb. (Matera, Tr. 5226). Willow Wood also creates products and technologies for prosthetics, including a recent CAD/CAM software technology which modernizes the shape capture and fabrication processes for amputees, a LimbLogic system comprised of a microprocessor-controlled vacuum or suspension system that holds the prosthesis onto the limb, and a Myoliner liner with electrodes and circuitry integrated to allow an amputee to more intuitively use a powered or a myoprocessor-controlled device. (Arbogast, Tr. 4933-4934).

h. Ryan Arbogast

46. Ryan Arbogast is majority owner and CEO of Willow Wood. (Arbogast, Tr. 4929). Mr. Arbogast owns 67 percent of Willow Wood, and each of his three sisters own 11 percent. (Arbogast, Tr. 4930). In addition to his role at Willow Wood, Mr. Arbogast previously served on the Ohio level orthotics and prosthetics board and as advisor to the national-level AOPA board. (Arbogast, Tr. 4930).

i. John Matera

47. John Matera is the Chief Operating Officer at Willow Wood. (Matera, Tr. 5224-5225). He has served in that position for the last five years. (Matera, Tr. 5225). Mr. Matera reports to Mr. Arbogast, President and CEO of Willow Wood. (Matera, Tr. 5229). Prior to joining Willow Wood, Mr. Matera worked for General Electric Company in operations positions, with Tosoh SMD as the operations manager and purchasing manager, and at Diamond. (Matera, Tr. 5225).

j. College Park Industries (College Park) and William Carver, III

48. College Park is a prosthetic manufacturer that sells prosthetic feet, knees, liners, endo components, and upper limb products in the United States. (Carver, Tr. 2003). [redacted]

49. William James Carver, III is president and chief operating officer of College Park. (Carver, Tr. 2003). Mr. Carver began working at College Park in 2009 as College Park's operations manager. (Carver, Tr. 2003-2004). Mr. Carver was next promoted to the director of operations position, where his responsibilities included receiving, returns, manufacturing, some of the manufacturing and engineering department, and the toolmakers and machining department. (Carver, Tr. 2004). Mr. Carver became chief operating officer in 2011. (Carver, Tr. 2005). As COO, the executive management team reports to Mr. Carver, and Mr. Carver assists in developing the strategy and business plan of the company. (Carver, Tr. 2005).

4. Clinic Witnesses

a. Hanger, Inc. (Hanger) and Southern Prosthetic Supply (SPS)

50. Hanger provides healthcare services for through a large network of orthotic and prosthetic patients in forty-four states and Washington, D.C. (Asar, Tr. 1307; Testerman, Tr. 1259). Hanger has two business segments: (1) its patient care segment, which fits prosthetic knees, and (2) its products and services segment, which has a distribution business and a therapeutic solutions business that calls on skilled nursing facilities. (Asar, Tr. 1307-1309). Hanger's total revenues are approximately one billion dollars. (Asar, Tr. 1307). Over eighty percent of its revenues, or about $850 million, comes from its patient care segment. (Asar, Tr. 1307-1308). Hanger has 800 clinics across the country, and there are about 3,400 to 3,500 total clinics in the United States. (Asar, Tr. 1379). Hanger employs about 1500 clinicians, and there are about 6,000 clinicians in the United States. (Asar, Tr. 1313, 1380).

51. Hanger is the largest U.S. customer of virtually every seller of prosthetics in the United States, including Freedom, [redacted] (Carkhuff, Tr. 298, Testerman, Tr. 1098; [redacted]).

52. SPS, owned by Hanger, is the largest distributor in the country. (Schneider, Tr. 4402; Mattear, Tr. 5515). Stephen Blatchford testified that 60% of Endolite's sales are through SPS, with 60% of that going to Hanger itself, and 40% going to independent clinics. (Blatchford, Tr. 2103).

b. Vinit Asar, Hanger and SPS

53. Mr. Vinit Asar is the President and Chief Executive Officer of Hanger. (Asar, Tr. 1308). Mr. Asar is also a board member on Hanger's board. (Asar, Tr. 1308). Vinit Asar is not a prosthetist, has never fit a device, and is not involved in patient care. [redacted]

c. Scheck & Siress Prosthetics, Inc. (Scheck & Siress) and Michael Oros

54. Scheck & Siress is an orthotic and prosthetic provider in the Chicago metro area. (Oros Tr., 4771). Scheck & Siress is one of the largest private clinic organizations in the United States. (Oros Tr., 4773). Sheck & Siress currently has fifteen locations. (Oros Tr., 4771). Its locations are spread between the State of Illinois and Northwest Indiana. (Oros Tr., 4771). Scheck & Siress employs a little less than 200 people. (Oros Tr., 4771). Scheck & Siress employs thirty-two certified prosthetists and orthotists. (Oros, Tr. 4772).

55. Mr. Oros is a certified prosthetist and orthotist and is the president and CEO of Scheck & Siress. (Oros Tr., 4774, 4771). Mr. Oros has been president of Scheck & Siress for 13 years and CEO for the past four years. (Oros, Tr. 4773). He has worked at Scheck & Siress for twenty-two years. (Oros, Tr. 4773). Before he became president of Scheck & Siress, Mr. Oros was a clinical lab manager of one of its facilities for approximately six or seven years. (Oros, Tr. 4773). Mr. Oros is the immediate past president of the American Orthotic and Prosthetic Association ("AOPA"). (Oros, Tr. 4780).

d. Scott Sabolich and Scott Sabolich Prosthetic & Research (SSPR)

56. SSPR is headquartered in Oklahoma City, Oklahoma. (Sabolich, Tr. 5788). Sabolich is a prosthetics-only facility which was founded in 1947 by Mr. Sabolich's grandfather. (Sabolich, Tr. 5790). Sabolich employs fifty people, twelve of whom are certified prosthetists and two of whom are prosthetic assistants. (Sabolich, Tr. 5793). Sabolich's main office is in Oklahoma City, and its secondary office is in Dallas, Texas. (Sabolich, Tr. 5788). SSPR has two locations, one in Oklahoma City and one in Dallas, Texas. (Sabolich, Tr. 5788). SSPR considers itself to be a destination facility (Sabolich, Tr. 5800). SSPR's Dallas facility is 12,000 square feet, which they believe to be the largest prosthetics-only privately owned facility in Texas. (Sabolich, Tr. 5803). SSPR frequently sees patients that have been fit at other facilities that are having issues (Sabolich, Tr. 5804-05). SSPR has a running track and golf course so that they can service patients who have goals like running or playing golf. (Sabolich, Tr. 5811-13).

57. Scott Alan Sabolich is a prosthetist and the owner and clinical director of SSPR. (Sabolich, Tr. 5788). Mr. Sabolich has been the owner of SSPR since May 1999. (Sabolich, Tr. 5790). Scott Sabolich has been involved in the U.S. Paralympics since 1996. (Sabolich, Tr. 5812).

e. Keith Senn and Center for Orthotic and Prosthetic Care (COPC)

58. COPC is an orthotic and prosthetic company which orthotic and prosthetic devices and services to patients. (Senn, Tr. 149). COPC operates 25 offices. (Senn, Tr. 151; 156-157). COPC employs approximately 120 people. (Senn, T. 157). Approximately fifteen prosthetists work at the clinics located in Kentucky and Indiana. (Senn, Tr. 158). COPC does not offer patient care support. (Senn, Tr. 182).

59. Keith Senn is president of the Kentucky and Indiana operations at COPC. (Senn, Tr. 149). Mr. Senn is not a prosthetist, does not work directly with any prosthetists, does not provide any patient care, cannot write or fill prescriptions, and does not directly fit any prosthetics. (Senn, Tr. 152-154). Mr. Senn has never observed COPC patients with MPKs navigating terrain such as hills or stairs. (Senn, Tr. 173). Mr. Senn has been employed at the COPC since January 1997, when the center first began operating. (Senn, Tr. 149-150). Mr. Senn's current responsibilities at the COPC involve setting up policy and procedural manuals so that the COPC clinics in Indiana and Kentucky are all following the same procedures. (Senn, Tr. 152).

f. Mark Ford and Prosthetic and Orthotic Associates (POA)

60. POA is an orthotic and prosthetic clinic. (Ford, Tr. 902). Mark William Ford is the President and Managing Partner at POA. (Ford, Tr. 902). Mark Ford is not a prosthetist, has never been a prosthetist, and is not personally involved in providing patient care. (Ford, Tr. 918-19). Mr. Ford has been President and Managing Partner since June 2016. (Ford, Tr. 902). As the President of POA, Mr. Ford oversees the business operations, manages the partner team, and he oversees operations at POA facilities. (Ford, Tr. 902). Mr. Ford works with POA's top key suppliers to create plans with them regarding their relationships, including negotiations on price. (Ford, Tr. 904).

g. Mid-Missouri Orthotics and Prosthetic (Mid-Missouri) and Tracy Ell

61. Mid-Missouri provides orthotics and prosthetics, artificial limbs, and braces. (Ell, Tr. 1659). Mid-Missouri fits a variety of levels of prosthetics of all different extremities, as well as bracing. (Ell, Tr. 1559-1660). Tracy Duncan Ell is the owner and chief prosthetist at Mid-Missouri. (Ell, Tr. 1659). Mr. Ell has been the owner of Mid-Missouri for 18 years. (Ell, Tr. 1659).

h. Ability Prosthetics and Orthotics (Ability P&O) and Jeff Brandt

62. Ability P&O provides patient care to both amputee and brace wearers in ten facilities across three states. (Brandt, Tr. 3742). Ability employs certified prosthetists and orthotists to provide that care. (Brandt, Tr. 3742). Once a patient is referred to Ability P&O for its

services, Ability P&O evaluates, designs, and fits the prescribed device, and then provides ongoing follow-up care and maintenance for that patient over the course of the lifetime of the device. (Brandt, Tr. 3742).

63. Jeffrey M. Brandt is the CEO of Ability P&O. (Brandt, Tr. 3742). [redacted] Mr. Brandt founded Ability P&O in 2004, and has worked there for about fourteen and a half years. (Brandt, Tr. 3742, 3744).

5. Cascade Orthopedic Supply (Cascade) and Jeffrey Collins

64. Cascade is a wholesale distributor of medical supplies and equipment, specifically serving certified, independently owned, *i.e.*, non-Hanger-owned, orthotic and prosthetic clinics in the United States. (Collins, Tr. 3271-3272). In addition to private clinics, Cascade has national contracts with large institutions like the Shriners Hospitals and other university hospitals, as well as a number of governmental agencies including the DOD and the VA. (Collins, Tr. 3272).

65. Jeffrey James Collins is the president of Cascade. He also serves as the president of a Canadian subsidiary, OrthoPed ULC. (Collins, Tr. 3270). Mr. Collins leads a team of directors, and oversees day-to-day management of his team. He provides strategic planning efforts for the business, and performs other administrative tasks. (Collins, Tr. 3271). Mr. Collins speaks with Cascade's customers at least weekly, and discusses industry-related matters with customers. (Collins, Tr. 3272. Mr. Collins also discusses specific commercial questions and topics that are relevant to his commercial activities. (Collins, Tr. 3273). Mr. Collins is on the board of the American Orthotic and Prosthetic Association, and in that capacity is aware of reimbursement trends and matters, policy issues, regulatory matters, and industry-related matters. (Collins, Tr. 3272-3273). Mr. Collins joined Cascade in 2002 as the controller of the firm. (Collins, Tr. 3271). He was promoted to vice president of finance two years later. (Collins, Tr. 3271). Mr. Collins became president of Cascade in 2006. (Collins, Tr. 3271).

6. Payer Witnesses

a. United HealthCare (United or UHC) and Jack Sanders

66. United is a national health insurance company. (Sanders, Tr. 5370-5371). It is one of the largest insurers of prosthetics in the United States. (DeRoy, Tr. 3631; Sanders, Tr. 5371). United Healthcare is a subsidiary of United Health Group and is sometimes referred to as UHC. (Sanders, Tr. 5371).

67. Jack Sanders is a senior clinical program consultant at United, a national health insurance company. (Sanders, Tr. 5370-5371). Mr. Sanders has been in that role for five years. (Sanders, Tr. 5371). Mr. Sanders' responsibilities as a senior clinical program consultant include the areas of durable medical equipment, prosthetics, orthotics, and supplies.

(Sanders, Tr. 5371). Mr. Sanders handles all aspects of those areas, including training nurses and doctors who perform prior authorization and predetermination insurance reviews, research, and net promoter scores. (Sanders, Tr. 5372, 5374). Mr. Sanders has handled the prosthetic category for health plans for the last eighteen to nineteen years. (Sanders, Tr. 5372). Jack Sanders is not and has never been a certified prosthetist. (Sanders, Tr. 5377).

7. Doctor Witnesses

a. Dr. Potter

68. Benjamin Kyle Potter, M.D., is the Chief of the Department of Orthopedics at Walter Reed National Military Medical Center, a tertiary medical treatment facility in Bethesda, Maryland. (Potter, Tr. 744). Dr. Potter performs the majority of the amputation surgery at Walter Reed National Military Medical Center. (Potter, Tr. 747). Dr. Potter performs surgeries from initial wounding (in the case of a trauma or combat-related amputation, including definitive revision and closure, and additional surgeries for amputees, including reoperations or revision procedures. (Potter, Tr. 747).

69. Dr. Potter treats amputees of all ages. (Potter, Tr. 748). Dr. Potter treats patients who require amputations due to cancer, trauma, combat-related injuries, and diabetic and dysvacular-type injuries. (Potter, Tr. 748). He started performing transfemoral amputations in 2003, and has performed over one hundred transfemoral amputations since then. (Potter, Tr. 754).

b. Dr. Douglas Smith

70. Dr. Douglas George Smith is an orthopedic surgeon who is board-certified in orthopedic surgery. (Smith, Tr. 5961, 5968). Dr. Smith is a professor emeritus in the Department of Orthopedic Surgery at the University of Washington in Seattle. (Smith, Tr. 5961). He also has a part-time job with the military through the Henry Jackson Foundation for the Advancement of Military Medicine as a professor in the Department of Physical Medicine and Rehabilitation at the Uniformed Services University of Health Sciences. (Smith, Tr. 5961-5962). Dr. Smith was asked for apply for, and received privileges at Walter Reed, where he performed some surgeries and worked with younger surgeons to try to pass along insight, see patients, and help with decision-making. (Smith, Tr. 5971).

71. Dr. Smith attended medical school at the University of Chicago, performed his residency in orthopedic surgery and rehabilitation at Loyola University, and performed a one-year advanced clinical training in Seattle, Washington with the former chair of orthopedic surgery at the University of Washington. (Smith, Tr. 5961-5963). Dr. Smith then worked at Harborview Hospital, where he ran the Level 1 trauma call, performing amputation services including surgeries and working in an amputee clinic. (Smith, Tr. 5965, 5968). Harborview is the only Level 1 trauma center for Washington, Alaska, Montana, Idaho, and part of Wyoming. (Smith, Tr. 5964-5965).

72. Dr. Doug Smith estimates that throughout the course of his career, he performed 150 amputation surgeries per year for 28 years, about 80 to 85 percent of which were lower-limb amputations. (Doug Smith, Tr. 5979). Dr. Doug Smith began learning about prosthetic components when he was a resident at Loyola in Chicago, and decided to do a one-year fellowship in Seattle at an amputee clinic, and continued to be heavily involved in prosthetics throughout his career. (Doug Smith, Tr. 5977, 5979). Dr. Smith also was involved with the beginning of military amputee care programs in the United States. (Smith, Tr. 5970). He also gave a series of lectures on amputation surgeries, including different levels and decision-making, and rehabilitation and care of amputees, including insight into prosthetics. (Smith, Tr. 5970).

c. David Smith

73. David Smith was the Chairman and CEO of Freedom from April 1, 2016 through September 2017. (Smith, Tr. 6408). David Smith's tenure as Chairman and CEO of Freedom ended the Friday before the Acquisition. (PX05122, Tr. 7). Prior to the Acquisition, Mr. Smith had been involved in approximately 130 to 150 merger and acquisition transactions. (Smith, Tr. 6412).

74. Prior to joining Freedom, Mr. Smith was a CPA with PriceWaterhouseCoopers, and he later joined PSS World Medical, where he served in such positions as CFO, Chairman and CEO. (Smith, Tr. 6409). After working for PSS World Medical, Mr. Smith joined Health Evolution Partners ("HEP"), and worked in a variety of roles. (Smith, Tr. 6409). Mr. Smith was an operating partner of HEP and was the CEO of one of HEP's portfolio companies. (Smith, Tr. 6409). Mr. Smith left HEP in the spring of 2016. (Smith, Tr. 6409). Mr. Smith was not a partner of HEP after he became CEO and Chairman of Freedom. (Smith, Tr. 6410). Prior to joining Freedom, Mr. Smith had no experience in the prosthetic industry, nor did Mr. Smith have any knowledge concerning prosthetics products, prosthetics manufacturers, prosthetics customers or prosthetics regulations. (Smith, Tr. 6411).

d. Dr. Kenton Kauffman

75. Kenton Richard Kaufman, Ph.D. is employed by the Mayo Clinic in Rochester, Minnesota. (Kenton, Tr. 807). Dr. Kaufman is the W. Wendell Hall, Jr. Musculoskeletal Research Professor, a professor of biomechanical engineering, and the director of the Motion Analysis Laboratory. He is also on staff in the departments of orthopedic surgery, physiology, and biomechanical engineering at the Mayo Clinic. (Kenton, Tr. 808). Dr. Kaufman occasionally works with clinicians who are fitting prosthetics on patients by providing objective data on a patient's gait to provide information on things that cannot be seen, like forces, moments, muscle activity, and asymmetry. (Kenton, Tr. 814).

76. Dr. Kaufman is not qualified to select which knee is appropriate for a particular patient, does not fit patients with prosthetic devices, and does not determine the K-level of any particular amputee. (Kenton, Tr. 872-873). Dr. Kaufman is also not involved with reimbursements on microprocessor-controlled knees, nor does he generally know the

relative costs to prosthetic clinics for fitting different types of knees. (Kenton, Tr. 875-876).

8. Moelis & Company (Moelis) and Jon Hammack

77. Jon Hammack is currently the Managing Director at Moelis, an independent investment bank. (Hammack, Tr. 6062–6063). Mr. Hammack's industry focus is within the medical device industry. (Hammack, Tr. 6063-6064). Mr. Hammack was the lead representative from Moelis in charge of its formal engagement with Freedom, which began in May of 2017. (Hammack, Tr. 6063). Mr. Hammack has worked at Moelis for five years, and has sixteen years' of experience in the investment bank industry. (Hammack, Tr. 6063). Mr. Hammack has been involved in between forty and fifty merger and acquisition transactions in his career, with more than twenty of those involved a company that was sold through a bidding process. (Hammack, Tr. 6063). Prior to joining Moelis, Mr. Hammack was the managing director and head of the medical technology group at Morgan Stanley for just under eight years, and also worked in the healthcare investment banking groups at Credit Suisse and Bank of America Securities. (PX05110 (Hammack Dep, at 11).

9. Expert Witnesses

a. Dr. David Argue

78. Dr. David Argue is currently a Corporate Vice President and Principal at Economists Incorporated. (Argue, Tr. 6132). Dr. Argue's area of specialization is in industrial organization, and, specifically, in competition and antitrust issues. (Argue, Tr. 6134). For the last twenty-five years, Dr. Argue's practice has been heavily devoted to economic and competition issues within the healthcare industry. (Argue, Tr. 6134). Dr. Argue has worked on roughly seventy mergers; and, of those seventy, more than sixty have involved the healthcare industry. (Argue, Tr. 6135-6136). Dr. Argue has worked on forty to fifty private litigation matters involving the healthcare industry. (Argue, Tr. 6136). Prior to this matter, Dr. Argue has previously been retained as an expert by the FTC. (Argue, Tr. 6137). Dr. Argue has previously been retained by the Utah state legislature to evaluate the competitiveness of the markets for healthcare services in Utah. (Argue, Tr. 6137).

79. Economists Incorporated provides economic consulting, with a special focus on antitrust matters. (Argue, Tr. 6132). Dr. Argue has worked at Economists Incorporated for twenty-eight years. (Argue, Tr. 6132). Dr. Argue began working at Economists Incorporated in 1990, immediately after he graduated from the University of Virginia with a Ph.D. in Economics and a specialty in industrial organization. (Argue, Tr. 6133). Before Dr. Argue received his Ph.D., he received his Master's Degree in Economics from the University of Virginia and his undergraduate degree in Economics from American University. (Argue, Tr. 6133).

80. Dr. Argue was retained by Respondent to consider the prosthetic knee businesses of Ottobock and Freedom, and to evaluate in properly defined antitrust markets whether there

would be any adverse competitive effects likely as a result of Ottobock acquiring Freedom. (Argue, Tr. 6141).

b. James Peterson

81. James Peterson is currently a principal at Deloitte, within Deloitte's Transaction and Business Analytics division. (Peterson, Tr. 6594–95). Mr. Peterson is the head of Deloitte's Life Sciences and Healthcare Mergers and Acquisitions practice group ("LSHMA"). (Peterson, Tr. 6595). Mr. Peterson has operational responsibilities within the LSHMA group for the corporate finance practice, valuation practice, financial practice, corporate turnaround practice, and the due diligence practice. (Peterson, Tr. 6595). Prior to joining Deloitte in July 2002, Mr. Peterson worked in Arthur Andersen's economic financial consulting practice group for five to six years. (Peterson, Tr. 6595).

82. For the last twenty-two years, during his time at Deloitte and Arthur Andersen, Mr. Peterson has focused solely on healthcare merger and acquisition transactions. (Peterson, Tr. 6594-6595). Mr. Peterson has expertise from the concept stage of a transaction all the way to planning for integration and then actually executing on post-merger integration. (Peterson, Tr. 6596). Mr. Peterson has worked on hundreds of merger and acquisition transactions. (Peterson, Tr. 6596). Mr. Peterson has also worked on hundreds of transactions where he performed analyses to determine whether the companies will be able to meet their financial obligations in the near future. (Peterson, Tr. 6597). Mr. Peterson has also been involved in dozens of transactions where companies were analyzing whether they would be able to successfully reorganize under Chapter 11 of the bankruptcy laws. (Peterson, Tr. 6597-6598). In those transactions, Mr. Peterson also performed liquidation valuations and sensitivity analyses. (Peterson, Tr. 6597).

83. Mr. Peterson has been involved in the sale bidding process for dozens of merger and acquisition transactions. (Peterson, Tr. 6598). Mr. Peterson has been named an expert in the past, but has never, until the trial in this matter, testified as an expert witness in court. (Peterson, Tr. 6599). Mr. Peterson has, however, served as an expert witness during public hearings. (Peterson, Tr. 6601). Mr. Peterson has previously made a presentation to the Federal Trade Commission to assist a client with a failing firm analysis in a hospital analysis. This presentation was made before the merger was consummated, and, after the presentation of the failing firm primary defense, the government ultimately permitted the sale. (Peterson, Tr. 6603-6604).

c. Fiona Scott Morton

84. Fiona Scott Morton is a professor at Yale University and a senior consultant at Charles River Associates. (Morton, Tr. 3847). Ms. Morton has worked at Yale since 1999, with the exception of a nineteen-month leave that she took from May 2011 to December 2012 to serve as the deputy assistant attorney general for economic analysis at the Department of Justice Antitrust Division. (Morton, Tr. 3849-3850). Ms. Morton is being paid $945 an hour to work on this case. (Morton, Tr. 3963). While Ms. Morton did not know how many hours she had spent on this case, she knows it is less than one hundred hours, but not much

less. (Morton, Tr. 3963). She does not know how much time her firm, Charles River Associates, has spent on this case. (Morton, Tr. 3964). Between two-thirds and three-quarters of her annual income is derived from her expert testimony work. (Morton, Tr. 3965-3966).

d. Christine Hammer

85. Christine Hammer has been self-employed since 1981 at Hammer & Associates, which currently only employs Ms. Hammer. (Hammer, Tr. 2868). Ms. Hammer was engaged as an expert witness by Complaint Counsel in January 2018. (Hammer, Tr. 3000). Ms. Hammer is being compensated for her work in this case at a rate of $800 per hour. (Hammer, Tr. 3001). As of June 11, 2018, Ms. Hammer had earned about $300,000 working on this case. (Hammer, Tr. 3001). Ms. Hammer was assisted in this case by Cornerstone Research, an economic consulting firm. (Hammer, Tr. 3001). Ms. Hammer receives an additional financial benefit, on top of the $800 per hour, from Cornerstone Research's work; although, Ms. Hammer only knows that she receives somewhere between seven and fifteen percent of Cornerstone Research's staff billings. (Hammer, Tr. 3002). As on August 17, 2018, Cornerstone Research had been paid roughly one million dollars ($1,000,000.00) by the Federal Trade Commission for their work on this case. (Hammer, Tr. 3008). During Ms. Hammer's forty-five year career, she has worked in some capacity on about eight to ten merger and acquisition transactions. (Hammer, Tr. 3017). Only in four of those transactions was Ms. Hammer involved before the transaction was consummated. (Hammer, Tr. 3018). Ms. Hammer has only worked on two pre-consummation transactions on behalf of a target company, and, during those two transactions, Ms. Hammer did not focus on any bidding process. (Hammer, Tr. 3019). One of those transactions occurred in the late 1970's, and the other transaction took place in the early 1980's. (Hammer, Tr. 3020). Neither transaction involved the healthcare industry. (Hammer, Tr. 3020). Ms. Hammer has served as a proposed expert witness about 100 times. (Hammer, Tr. 3023). Ms. Hammer has testified as an expert witness thirty-five times. (Hammer, Tr. 3023). In recent years, Ms. Hammer has focused much more on litigation than on consulting. (Hammer, Tr. 3022). In 2017, 90-100% of Ms. Hammer's work was litigation-related. (Hammer, Tr. 3022). Other than this case, Ms. Hammer has had no experience in the prosthetics industry. (Hammer, Tr. 3027).

10. Other Witnesses

a. Matt Swiggum

86. Mr. Swiggum was terminated as regional president and CEO of Ottobock after less than two years in the role. (Swiggum, Tr. 3313, 3316). Mr. Swiggum joined Otto Bock in 1997 as a sales representative. (Swiggum, Tr. 3315). He was subsequently promoted to a district sales manager position, and in 2004 became the regional sales manager of the central region. (Swiggum, Tr. 3315). In 2005, Mr. Swiggum became the director of sales for technical orthopedics for Otto Bock U.S., and in 2010 he became the business unit director of mobility solutions for Otto Bock North America. (Swiggum, Tr. 3316).

II. INDUSTRY BACKGROUND

A. Lower Limb Prostheses

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

88. A lower-limb prosthesis for an above-the-knee amputee consists of either a suspension or a liner, a socket, which is a rigid or semi-rigid negative of the residual limb, a knee, a pylon connecting the knee to a foot, and a foot shell and any other cosmesis covering. (Schneider, Tr. 4303-4304; Senn, Tr. 171).

89. Prosthetic clinics purchase most components from prosthetic manufacturers or distributors, but may fabricate certain components themselves, such as sockets. Typically, clinics do not stock prosthetic components, but purchase them individually for each particular patient. (Oros, Tr. 4778-4779).

90. A socket is a device that is typically custom-manufactured by a prosthetist from commodity products, such as plastics, polypropylene or carbon fiber. (Carkhuff, Tr. 600). The socket is custom-made by the prosthetist to fit the patient's residual limb. 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. (Carkhuff, Tr. 600). And then 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. (Carkhuff, Tr. 600).

91. Patients desiring a lower-limb prosthesis have varying degrees of potential mobility. (Schneider, Tr. 4287-4288). The "K-Level" rating system was developed by Medicare and is generally accepted in the prosthetics industry in the United States to classify patients into five ascending mobility levels, K-0 to K-4. (JX01, ¶ ¶ 16-18; PX08003 at 002; Schneider, Tr. 4287-4288).

92. The following table reflects Medicare's description of each K-Level and describes in general terms the type of prosthetic knee that Medicare will cover for each K-Level. (PX08003 at 002).

K-Level	Description	Medicare Reimbursed Prosthetic Knee
K-0	Non-ambulatory: "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

93. Prosthetic knees available for sale to prosthetics 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 . . . K-3 or K-4 level ambulatory, so they have swing and stance control, stumble recovery." (Solorio Tr. 1637).

94. 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 K-3/K-4 patients. (Mattear, Tr. 5558; Schneider, Tr. 4305; Arbogast, Tr. 4960-4961).

B. The Prosthetic Fitting Process

1. Amputation Surgery

95. About 75 percent of leg amputations occur because of vascular disease like diabetes. (Schneider, Tr. 4287). Other causes include trauma, cancer, and flesh-eating bacteria. (Schneider, Tr. 4287; Senn, Tr. 163; Doug Smith, Tr. 5982-83). The surgeon's goal in performing a lower-limb amputation is usually to amputate only as much of a limb as is necessary. (Doug Smith, Tr. 5988).

96. When a patient undergoes amputation surgery, that procedure is typically performed by an orthopedic or vascular surgeon, who determines where on the limb to do the amputation. (Doug Smith, Tr. 5988). 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. (Doug Smith, Tr. 5988; 5999-6000).

97. An above-the-knee amputation is also referred to as a transfemoral amputation. (Doug Smith, Tr. 5988). In a typical transfemoral amputation, after a patient is under anesthesia, the surgeon makes a skin incision generally just above the knee level. (Potter, Tr. 756). 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. (Potter, Tr. 756). Then the surgeon isolates the femur and transects the femur with a saw. (Potter, Tr. 756). Then, he or she must divide the muscles of the posterior leg, get control of the bigger blood vessels which require isolation, and tie those off. (Potter, Tr. 756-757). 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. (Potter, Tr. 757).

98. 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. (Potter, Tr. 757). 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. (Potter, Tr. 757). The surgeon anchors the muscle groups into the bone for function and for additional padding. (Potter, Tr. 757). 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. (Potter, Tr. 757-58).

2. Initial Prosthesis

99. Following surgery, patients typically stay overnight at an inpatient facility from at least three days to a more than a week. (Potter, Tr. 758-59). 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. (Potter, Tr. 760-61). After three weeks, a patient is typically ready to have sutures removed, and after six weeks, to be fit with an initial prosthesis. (Potter, Tr. 762).

100. 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. (Sabolich, Tr. 5841).

101. Prosthetists typically fit a basic K-1/K-2 level knee as the initial prosthesis that is stable in design. (Sabolich, Tr. 5841). 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. (Sabolich, Tr. 5841-5842).

3. Definitive Prosthesis

102. After a patient has been wearing a temporary prosthesis for about six months to a year, the patient is ready to receive a definitive prosthesis, or more permanent prosthetic device. (Sabolich, Tr. 5842).

103. Typically, to begin their evaluation for a definitive prosthesis, prosthetists receive a vague referring prescription which does not specific a type of knee to be fit on a patient, but may indicate the physician's assessment of mobility level. (Sabolich, Tr. 5838; Oros, Tr. 4783; Potter, Tr. 774-775).

104. 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. (Sabolich, Tr. 5833, 5844).

105. Important decision criteria for selecting a definitive prosthesis include activities of daily living, health, insurance coverage, vocation. (Schneider, Tr. 4306-4307). The decision of which prosthetic knee to fit depends collaboration between the patient, the prosthetist, the payer, and the physician. (Schneider, Tr. 4306).

a. Patients

106. Patients have a significant amount of input into the type of prosthetic components that make up their final prosthetic device. (Doug Smith, Tr. 6010-11).

107. Patients have discretion to choose between different prosthetic knees that are medically appropriate for them based on financial considerations as well as the fit and features of the prosthetic knee. (Doug Smith, Tr. 6010-11; Sabolich, Tr. 5845; Ell, Tr. 1690; Oros, Tr. 4787).

108. Patients that want to use a prosthetic device typically are responsible for a portion of the reimbursement allowable or fee set by their insurance provider or payer. [redacted] Schneider, Tr. 4300). Medicare and private insurance reimbursement typically requires that the patient cover twenty percent of the reimbursement amount unless the insured has secondary coverage. (Senn, Tr. 260). Patients insured by DOD, VA, or WC do not usually have any out-of-pocket costs. (Sabolich, Tr. 5826).

109. However, patients almost never cover the entire cost of the prosthetic device out of pocket. (Sabolich, Tr. 5821; Schneider, Tr. 4298).

110. A patient's financial obligation, or out-of-pocket cost, for a prosthetic device is not related to the prices that manufacturers charge to clinics for prosthetic components. (Schneider, Tr. 4300). If prosthetic device manufacturers raised prices, it would not impact the amount that amputees pay for prosthetic devices because patients pay a portion of the reimbursement allowable, not a portion of the product's cost. (Carkhuff, Tr. 596-597).

111. Choosing between non-MPKs and MPKs for K-3 and K-4 users is very "patient-specific" and is usually determined during product trials where users will try out both non-MPKs and MPKs before choosing. (De Roy, Tr. 3554).

112. Most users' insurance providers only provide reimbursement for one prosthetic knee at a time. (Senn, Tr. 182). Patients typically use a prosthetic knee until its needs to be replaced or until the user can receive reimbursement for a new prosthetic knee. (Senn, Tr. 181).

b. Prosthetists

113. Manufacturers of prosthetic devices consider prosthetic clinics to be their primary customers. (De Roy, Tr. 3538). Manufacturers of prosthetic components typically sell their products to prosthetic clinics, who then fit prosthetic devices on amputee patients. (Blatchford, Tr. 2128; Schneider, Tr. 4308; Oros, Tr. 4782). Amputee patients do not purchase prosthetic components directly from manufacturers. (Schneider, Tr. 4308). Prosthetic clinics can be independent entities, networks of clinics, or may be affiliated with a hospital. There are approximately 3,400 prosthetic clinics in the United States. [redacted]

114. Prosthetic clinics employ prosthetists, who can be certified by the American Board for Certification in Orthotics, Prosthetics, and Pedorthics to make and fit prostheses and manage comprehensive patient care of amputees. (Senn, Tr. 178). There are approximately 6,500 certified prosthetists in the United States. (PX05153A (Asar, Dep. at 77-78)).

115. The prosthetist begins the consultation by talking with the patient, understanding their goals, activities of daily living, and history. (Sabolich, Tr. 5833; Oros, Tr. 4785). During the initial evaluation, the prosthetist also does functional level testing in order to determine the patient's K-Level. (Sabolich, Tr. 5833; Oros, Tr. 4785). The treating physician must corroborate the prosthetist's K-Level assessment. [redacted] Oros, Tr. 4784-85; (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 21)).

116. Prosthetists are educated and trained to evaluate patients to determine their potential mobility level, or K-Level classification, and fit them with a prosthesis. (Sabolich, Tr. 5838). Prosthetists can be certified if they have passed a national examination. (PX05149 (Brandt, Dep. at 97-98)). Some states require that prosthetists be licensed. (PX05149 (Brandt, Dep. at 97-98)).

117. After prosthetists determine a patient's K-Level, prosthetists have discretion to choose between different prosthetic knees that are appropriate for that 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, vocation, among other things. (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) (Oros, Tr. 4785)).

118. Medicare and private insurance providers require documentation of the patient's mobility level in order to reimburse the prosthetic clinic for prosthetic components. (Senn, Tr. 160).

119. It takes prosthetists several weeks to fit a patient with a prosthetic device, and can take several visits. (Senn, Tr. 170-171). Patients frequently make follow-up visits with their prosthetists after they receive their prosthetic device.

120. 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. (Sabolich, Tr. 5837; [redacted] The treating physician must sign off on the Detailed Written Order. [redacted]

c. Payers

121. Insurance providers play a key role in determining and limiting eligibility for and access to prosthetics products. [redacted]

122. The reimbursement amount for prosthetic devices and related services is capped by Medicare. (Schneider, Tr. 4300-4301). Besides Medicare and private insurance, DOD, VA, and WC are the next most common providers of reimbursement for prosthetic devices. (Schneider, Tr. 4296).

123. The "Big 5" insurance providers for prosthetic devices in the United States are Medicare, United HealthCare, Kaiser, Cigna, and Aetna. (De Roy, Tr. 3631-3632). Insurers offer hundreds and hundreds of different insurance plans with different coverage criteria for prosthetics devices. (Schneider, Tr. 4307).

124. Payers reimburse for the provision of prosthetic devices based on "L-Codes" which is a system developed by The Centers for Medicare and Medicaid Services ("CMS") but used by private payers as well. (Schneider, Tr. 4291). The prosthetic codes are traditionally L codes, and then it has a four-digit number after it representing a function in the prosthesis. (Schneider, Tr. 4291). A prosthetic component could have multiple functions and therefore use multiple L codes. (Schneider, Tr. 4291).

125. A pricing committee sets the fee or allowable for each one of the L-Codes. (Schneider, Tr. 4292). Manufacturers apply for L-Codes and CMS determines whether or not to grant a new L-Code. (Schneider, Tr. 4292). CMS reviews the fee for each L-Code and can decrease or increase the fee associated with L-Codes. (Schneider, Tr. 4292). CMS can

also eliminate L-Codes. (Schneider, Tr. 4292). New L-Codes are becoming rare. (Schneider, Tr. 4292**).**

126. Public and private insurance payers use this established reimbursement amount to determine how much they will agree to reimburse for a particular L-Code, with the CMS-established rate representing the high-end of the possible reimbursement. (PX05010, (Schneider (Ottobock) IH, at 64-65); PX05002, (Asar (Hanger) IH Tr. at 13); PX05134, Oros (Scheck) Dep. Tr., at 183-184; PX05149, (Brandt (Ability P&O), Dep. at 181).

d. Physicians

127. In addition to a prosthetist, the medical team caring for a patient that wants a prosthetic device generally includes a surgeon who performs the amputation surgery and a physiatrist who is a physician with a specialty in rehabilitation. (Doug Smith, Tr. 6003-6004).

128. Sometimes, the treating physician is also involved in the evaluation for a definitive prosthesis, if it is a physician familiar with prosthetic components. (Oros, Tr. 4782-83). In this case, the prescription for a prosthetic knee is more detailed, and may specify the category of knee to be fit on the patient. (Doug Smith, Tr. 6006-6007).

129. The physician does not prescribe a category of knee to be fit on a patient before speaking with the patient about his or her vocation, activities of daily living, or preferences. (Doug Smith, Tr. 6006, 6007, 6010).

130. In order for a prosthetic clinic to begin seeing a patient, a physician (either a surgeon or a physiatrist) must write a referring prescription, which is typically very vague, allows a prosthetist to begin evaluating a patient for a prosthetic device. (Oros, Tr. 4783-4784). Physicians do not prescribe a specific type of knee before the prosthetist has had an initial consultation with the patient. (Oros, Tr. 4786).

III. PRODUCT MARKET

A. <u>Prosthetic Knees Generally</u>

1. Basic Functionality

131. Prosthetic knees attempt to provide users with normal gait function. (Schneider, Tr. 4309).

132. A gait cycle consists of two phases: (i) when a lower-limb prosthesis is in contact with the ground, the prosthetic knee is considered to be in the stance phase of the gait cycle; (ii) when a lower-limb prosthesis is in the air, the prosthetic knee is considered to be in the swing phase of the gait cycle. (Schneider, Tr. 4309; Carkhuff, Tr. 342-343).

133. In normal ambulation, individuals spend sixty percent of the time in the stance phase of the gait cycle and forty percent in the swing phase. (Schneider, Tr. 4309).

134. A prosthetic knee tries to replicate those two phases, swing and stance, and provide the user with as close to normal gait function as possible. (Schneider, Tr. 4309).

2. Constant-Friction Knees For K-1 And K-2 Patients

135. A constant friction knee provides a uniform resistance level in both the swing and stance phases of the gait cycle. (Ell, Tr. 1771-1772).

136. An example of a constant-friction knee for K-1 and/or K-2 users is the Ottobock 3R49, which was submitted at trial as RDX-004. (Schneider, Tr. 4289). The 3R49 is a single-axis, constant friction mechanical knee for K-1-and K-2 patients. (Schneider, Tr. 4289-4290). It has settings for extension and flexion that must be manually adjusted with an Allen wrench. (Schneider, Tr. 4289-4290).

137. K-1 and K-2 knees are often used on new amputees as an initial prosthesis. (Carver, Tr. 2027-28; Sabolich, Tr. 5841).

138. Freedom recently began selling a constant-friction knee for K-1 and K-2 patients in the United States called the Liberty Knee, which, according to Freedom's marketing and sales executives, does not compete with knees for K-3 and K-4 patients. [redacted]; Testerman, Tr. 1250)

3. Fluid-Controlled Knees For K-3 And K-4 Patients

139. Fluid-controlled knees use pneumatic, hydraulic, or magnetorheological fluid to provide pre-set or variable resistance levels in the swing and stance phases of the gait cycle, respectively. (Kannenberg, Tr. 1941-1942; 1966-1968; Blatchford, Tr. 2148-2150).

a. Fluid-Controlled Non-MPKs

140. Fluid-controlled knees that do not have microprocessor-control of the swing or stance phases of the knee offer different, pre-set resistance levels for the swing and stance phases of the gait cycle, respectively. (Kannenberg, Tr. 1951).

141. Non-MPKs appropriate for K-3 and K-4 patients are different than the knees that are appropriate for K-1 and K-2 patients. (Oros, Tr. 4790).

142. Prosthetists can change the resistance levels of the swing and stance phases of sophisticated non-MPKs using tools, such as an Allen wrench or an air pump. (Kannenberg, Tr. 1951; Schneider, Tr. 4327-28).

143. There are many sophisticated non-MPKs sold in the United States. Some examples include the Össur Mauch, Össur Total Knee, Ottobock 3R80, Ottobock 3R60, Endolite Mercury, Endolite KX06, and Nabtesco Symphony. (Kannenberg, Tr. 1950; Schneider, Tr. 4327; Mattear, Tr. 5542-5543). There are close to 50 different types of sophisticated non-MPKs on the U.S. market for K-3 and K-4 patients. (Schneider, Tr. 4370). Ottobock's Scott

Schneider described the 3R60, introduced at trial as RDX-009, as a "super cool knee" with "lots of sophistication." (Schneider, Tr. 4335).

i. Ottobock Non-MPKs

144. Ottobock makes several Non-MPKs that it recommends for K-3 and K-4 patients, including the 3R106, 3R60, and 3R80. (Solorio, Tr. 1637; De Roy, Tr. 3542).

145. The Ottobock 3R80 was introduced at trial as RDX-003. (Schneider, Tr. 4326).

146. In the 3R80, the resistances or friction that the knee produces for the stance and swing phase, respectively, can be adjusted manually with turntables and Allen wrenches. (Kannenberg, Tr. 1951; Schneider, Tr. 4327-28). The 3R80 does offer swing and stance control, *i.e.*, it can switch between the pre-set swing and stance resistance levels. (Schneider, Tr. 4326-4327). The 3R80 switches from stance to swing phase without a microprocessor, it uses a mechanical mechanism that is triggered by the position of the knee and weight of the patient. (Schneider, Tr. 4371). The 3R80 does not require the use of an air pump to set the swing phase of the knee. (Schneider, Tr. 4327-4328).

147. The 3R80 offers a stumble recovery feature for K-3 and K-4 patients. (Schneider, Tr. 4337). The 3R80 has a manual locking feature which can lock the knee in one position to perform a specific exercise. (Solorio, Tr. 1637-38). The 3R80 has adjustment bumpers on the knee to adjust for swing and stance resistance. (Solorio, Tr. 1637-1638). The 3R80 is completely waterproof and corrosion resistant. (Solorio, Tr. 1637-38, 41).

148. RDX-009 is an Ottobock 3R60. (Schneider, Tr. 4335). It is designed for K-3 and K-4 users in the United States. (Schneider, Tr. 4335). It is a polycentric, five-bar knee that uses hydraulics to provide swing control. It is also adjusted with a small Allen wrench, like the Plié and 3R80. (Schneider, Tr. 4335). The 3R60 is a "super cool knee" with lots of sophistication. (Schneider, Tr. 4335). The mechanics behind the five-bar hydraulic system make the knee "super, super safe." (Schneider, Tr. 4335-4336).

149. The average selling price for the 3R60 is $4,000, and it is reimbursed at $11,000 for a gross margin of $7,000 to the clinic. (Schneider, Tr. 4336-4337).

ii. Össur Non-MPKs

150. Össur offers a variety of non-MPKs that have pneumatic and hydraulic control for K-3 and K-4 users. (De Roy, Tr. 3541-3542). Those knees include the Mauch Knee and Total Knee. (De Roy, Tr. 3541-3542). The Mauch Knee Plus and Total Knee 2100 are "beefed up" versions that are more suitable for K-4 patients that need more durable knees. (De Roy, Tr. 3549-3550).

151. Össur offers non-MPKs for K-3 and K-4 users for two reasons: (i) because some patients cannot afford an MPK, and (ii) because some patients prefer the fit and comfort of non-MPKs to MPKs. (De Roy, Tr. 3553-3554).

iii. Endolite Non-MPKs

152. Endolite offers an extensive range of K-3 and K-4 non-MPKs, including the Mercury and the KX06. (De Roy, Tr. 3542). All of the non-MPKs sold by Endolite in the United States are fluid-controlled and suitable for K-3 and K-4 amputees. (Blatchford, Tr. 2213).

153. The Mercury is a high-quality hydraulic knee offers swing and stance control without a microprocessor. (RX-0814; Blatchford, Tr. 2237-2238).

154. The KX06 uses the same the same hydraulic cylinder as the Mercury, but it utilizes a very robust, four-bar linkage for more active K-3 and K-4 patients. (RX-0814; Blatchford, Tr. 2238-2239). The KX06, due to its four-bar technology, is also more appropriate than Endolite's Orion 3 for K-3 or K-4 amputees with a longer residual limb. (Blatchford, Tr. 2238-2239; 2246).

155. [redacted]

156. Both the Mercury and KX06 knees have a lever on the back of the hydraulic cylinder to put the knee in free swing mode for certain activities, including cycling. (Blatchford, Tr. 2239). Endolite's MPKs, on the other hand, use a microprocessor to change the way the knee reacts during the gait cycle, rather than a switch. (Blatchford, Tr. 2240). Generally, if you are a runner or a cycler, you would want the Mercury or KX06 and not an MPK. (Blatchford, Tr. 2241; 2249-2250).

157. Endolite's ESK variable knee control offers swing control both, and has an option to come either with or without a microprocessor. (RX-0814; Blatchford, Tr. 2242-2243). The PSPC version utilizes pneumatic swing control without a microprocessor, and the Smart IP version utilizes a microprocessor for swing control. (RX-0814; Blatchford, Tr. 2242-2243). The stance phase in all versions of the ESK Variable Knee is not fluid controlled. (Blatchford, Tr. 2243).

158. Endolite's non-MPKs have a position sensor that monitor when load is applied to the knee to switch between swing and stance phase. (Blatchford, Tr. 2113-2114).

159. If a K-3 or K-4 patient exceeds 275 pounds in body weight, Endolite would recommend an Endolite non-MPK over an Endolite MPK for that patient. (Blatchford, Tr. 2216-2217).

160. Endolite does not recommend any of its knees for K-1 or K-2 patients, because of reimbursement issues in the United States and because the hydraulic cylinder in Endolite's knees require amputees to walk at a reasonable speed to properly function. (Blatchford, Tr. 2248-2249; [redacted]

iv. Nabtesco's Non-MPKs

161. Nabtesco manufactures Symphony non-MPK for K-3 and K-4 patients. (Mattear, Tr. 5568, 5577; RX-0345).

162. They Symphony knee utilizes six-bar technology, is considered very sophisticated, and took a lot of engineering to develop. (Mattear, Tr. 5573-5574).

163. The Symphony utilizes p-MRS technology that uses geometrics and proprietary technology to detect different gait phases of the knee and adapt the stability accordingly. (Mattear, Tr. 5574; RX-0897; Mattear, Tr. 5580-5582). It has a hydraulic cylinder and allows for manually-adjusted extension and flexion adjustments. (Mattear, Tr. 5576). It has excellent flexion of 170 degrees offering greater range of motion than other K-3 and K-4 knees on the market. (Mattear, Tr. 5577).

b. Fluid-controlled knees with a microprocessor that controls only the switch between swing and stance phase

164. A fluid-controlled knee with a microprocessor-controlled switch ("MP-Switch") uses sensors and a microprocessor to switch the prosthetic knee between stance and swing phase. (Kannenberg, Tr. 1954). The stance and swing phases otherwise offer a predetermined resistance level set by the prosthetist or the patient. (Kannenberg, Tr. 1955).

165. There is no L-Code that describes the MP-Switch function. (Schneider, Tr. 4324).

166. Ottobock sells a MP-Switch knee the 3E80, in markets outside of the United States. (Kannenberg, Tr. 1954; Solorio, Tr. 1638).

167. The only MP-Switch knee sold in the United States is the Freedom Plié. (Kannenberg, Tr. 1954).

i. Freedom's Plié

168. The microprocessor in the Plié 3 switches the knee from a fixed stance phase resistance and a fixed swing phase resistance, but it cannot vary the resistance throughout the gait cycle. (Carkhuff, Tr. 335; Schneider, Tr. 4310, 4320).

169. A Plié 3 was introduced as a demonstrative exhibit at trial, identified by PXD0001. (Schneider, Tr. 4311).

170. The resistance levels in swing and stance are not variable and not modified by a microprocessor; they are pre-set. (Schneider, Tr. 4310).

171. [redacted]

[redacted]

172. The stance flexion of the on the Plié 3 is set by use of a four-millimeter Allen wrench, very similar to the way the resistance is set on the Ottobock 3R80. (Schneider, Tr. 4311, Kannenberg, Tr. 1953). The microprocessor in the Plié 3 cannot vary the stance resistance. (Schneider, Tr. 4311).

173. There are two adjustments on the Plié 3 for the swing phase of the knee. (Schneider, Tr. 4313). One of them is the hydraulic unit with is preset with an Allen wrench. (Schneider, Tr. 4313). The other adjustment is made on the pneumatic cylinder, by inserting a pump that comes with the Plié 3, which is similar to a bicycle pump. (Schneider, Tr. 4313). The bicycle pump that comes with the Plié 3 was introduced as a demonstrative at trial at RDX-008. (Schneider, Tr. 4311).

c. Fluid-controlled knees with a microprocessor that controls and moderates the resistance in the swing phase only

174. A fluid-controlled knee with a microprocessor-controlled swing phase only ("MP-Swing") uses sensors and a microprocessor to switch the prosthetic knee between stance and swing phase and to provide variable resistance control in the swing phase of the knee. (Kannenberg, Tr. 1955).

175. The resistance in the swing phase of the knee is set to a predetermined level by the prosthetist. (Kannenberg, Tr. 1955).

176. The SmartIP sold by Endolite in the United States is an example of a MP-Swing knee. (Blatchford, Tr. 2142). The SmartIP was developed in the late 1980's-early 1990's with microprocessor-controlled swing technology licensed from Nabtesco. (Blatchford, Tr. 2141-2142).

177. The SmartIP uses a microprocessor to control the resistance in the swing phase but not the stance phase. (Blatchford, Tr. 2142). "It means that an amputee would – that the swing side of his gait would be controlled very nicely by the knee, but the stance side is not microprocessor-controlled, so you don't get the benefit of improved stumble control, reduced falls, and so on. (Blatchford, Tr. 2143). MP-swing only knees are typically fit on patients that are very physically active. (Kannenberg, Tr. 1956).

178. Nabtesco manufactures the Hybrid, an MP-Swing-Only and hydraulic stance control knee for K-3 and K-4 patients. (Mattear, Tr. 5568; 5594-5597; RX-0345 at 003).

179. The Hybrid knee offers a unique battery that can last for a year without requiring recharge, which is one reason users chose the Hybrid knee. (Mattear, Tr. 5596-5597).

180. The Endolite SmartIP and Hybrid knee are reimbursed with code L5857 for swing-only microprocessor control, not L5856 for swing and stance microprocessor control. (Schneider, Tr. 4351; Mattear, Tr. 5595).

d. Fluid-controlled knees with a microprocessor that controls and moderates the resistance in the stance phase only

181. The Compact and Kenevo sold by Ottobock in the United States are examples of MP-Stance knees. (Schneider, Tr. 4324). Ottobock's Kenevo and Compact use a microprocessor to control the stance phase of the knee, but the swing phase is set manually. (Schneider, Tr. 4324; [redacted]).

182. The Kenevo was launched in 2015. (Schneider, Tr. 4344; Solorio, Tr. 1634). Its design targets K-1 and K-2 users, but Medicare and most private payers do not reimburse the MPKs for K-1 and K-2 patients. (Schneider, Tr. 4344-4345; Solorio, Tr. 1634).

183. The Kenevo was designed for a patient who does not vary their cadence and take small shuffly steps. (Solorio, Tr. 1634). The Kenevo can recognize if a patient is walking with a cane or walker, and can adjust accordingly. (Solorio, Tr. 1634). The Kenevo has special functions to help with essential movements like sitting and standing and can be programmed for a different range of stance stability based on what a particular low-mobility patient needs. (Solorio, Tr. 1634).

184. Ottobock does not consider the pricing of any other knees when setting the price of the Kenevo. (Schneider, Tr. 4346).

185. The functionality of the Kenevo is "far superior" to the Plié (Schneider, Tr. 4346).

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

187. The Compact is the predicate device for L5858. (Schneider, Tr. 4350). The Compact cannot be billed under L5856. (Kannenberg, Tr. 1999).

188. MP-Stance knees, such as the Kenevo and Compact, are reimbursed under the base L-Code L5858 for stance-only microprocessor control, not L5856 for swing and stance microprocessor control. (Schneider, Tr. 4350).

e. Fluid-controlled knees with a microprocessor that controls and moderates the resistance in both the swing and stance phases

189. The applicable base L-Code for a fluid-controlled knee with a microprocessor-controlled swing and stance phase control ("MP-Swing-and-Stance") knee is L5856, which covers "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type." (JX01, ¶ 24; Schneider, Tr. 4350).

190. Examples of MP-Swing-and-Stance knees sold in the United States include Ottobock's C-Leg, Össur's Rheo, Endolite's Orion, Nabtesco's Allux, and DAW's Stealth Knee. (Kannenberg, Tr. 1961-1962; Schneider, Tr. 4322, 4367; [redacted]

i. Ottobock's MP-Swing-and-Stance Knees

191. The C-Leg is the predicate device for L-Code L5856, and that code did not exist when Ottobock developed the C-Leg. (Schneider, Tr. 4294, 4299-4300).

192. Ottobock released the C-Leg 4 in 2015. (Schneider, Tr. 4342). Ottobock's C-Leg 4 meets the definition of MPK as defined by Complaint Counsel in the Complaint. (Schneider, Tr. 4309-4310). It monitors the entire gait cycle and adjusts the valves for resistance in order to provide real-time adjustability in all phases of the gait, swing and stance. (Schneider, Tr. 4310, 4342-4343).

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

194. The C-Leg's microprocessor is able to process rule sets that take environmental conditions and put the leg in the right place to enable people to ambulate in a more safe manner. (Schneider, Tr. 4321-4322).

195. The C-Leg's microprocessor can adjust the resistances in the hydraulic unit from step to step and also within once step, if necessary. (Kannenberg, Tr. 1846-47; 1963). It is continually adjusting the variability of resistance in both stance and in swing phase. (Schneider, Tr. 4320). The C-Leg 4 does not have screws or bezels to adjust resistance manually; instead the prosthetist adjusts settings via software. (Kannenberg, Tr. 1963)

196. The C-Leg 4 is designed for a user that varies their cadence, navigates different terrains, and navigates stairs and ramps. (Solorio, Tr. 1634-35). It allows a patient to walk backwards, and has a feature called intuitive stance that provides relief for the rest of a patient's body if they have to stand for long periods of time. (Solorio, Tr. 1635). The C-Leg 4 has programmable additional modes that allow for particular activities, such as pushups. (Solorio, Tr. 1635).

197. The C-Leg 4 has an IP-67 rating which means that it can be submerged up to a meter for 30 minutes. (Solorio, Tr. 1641). Prosthetic knees with an IP-67 rating are not designed to be repeatedly submerged or be in corrosive environments like chlorinated water or salt water. (Solorio, Tr. 1641).

ii. Össur's MP-Swing-and-Stance Knees

198. Össur recommends its Rheo for all K-3 patients and some K-4 patients. (De Roy, Tr. 3579-3580).

199. Össur's Rheo uses MR technology. (De Roy, Tr. 3577; Schneider, Tr. 4398-4399). Magnetic particles in an oil are kept in a cylinder between blades. The knee creates a magnetic field that aligns the magnetic particles within that fluid between the blades building bridges and providing variable resistance to the swing and stance phases of the knee. (De Roy, Tr. 3577).

200. MR technology in the Rheo offers variable resistance control in both the swing and stance phases of the knee. (De Roy, Tr. 3639). Users of the Rheo do not need to use Allen wrenches and/or air pumps to control the swing and stance phase resistance of thee knees. (De Roy, Tr. 3639).

201. Össur's Rheo is technologically sophisticated and uses a microprocessor and sensors to adjust magnetorheological fluid to control the way the knee swings and locks during stance phase. (Blatchford, Tr. 2148-2149).

202. The Rheo knee transitions between functions and all different modes automatically through the intelligence of the knee, *i.e.*, there is no need to switch the modes manually. (De Roy, Tr. 3579).

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

iii. Endolite's MP-Swing-and-Stance Knees

204. The original Orion knee was launched in 2010, and the Orion 2 was launched in 2014. (Blatchford, Tr. 2109-2110). Endolite launched the Orion 3 in the United States in September 2016. (Blatchford, Tr. 2109). The Orion 3 is a new model of MPK, not just an upgrade of the Orion 2. (Blatchford, Tr. 2110).

205. Orion 3 is an MPK that offers MPK control of both the swing and stance phases of the gait cycle. (PX03176-09; Blatchford, Tr. 2215-2216). Orion 3 is able to make adjustments to the friction level of the knee while the knee is either in swing or stance phase. (PX03176-09; Blatchford, Tr. 2215-2216). The microprocessor in the Orion 3 is directing and controlling those adjustments to the swing and stance phase of the knee. (PX03176-09; Blatchford, Tr. 2215-2216). The friction levels in the swing and stance phases, respectively, of the knee are not set manually; they are variable based on sensors in the microprocessor. (PX03176-09; Blatchford, Tr. 2215-2216).

206. Orion 3 uses a hybrid cylinder that has two chambers. (Blatchford, Tr. 2134). The pneumatic chamber controls the resistance level in the swing phase of the knee whereas the hydraulic chamber controls the resistance level in the stance phase of the knee. (Blatchford, Tr. 2134-2135). The hydraulic cylinder is the part that would lock under load to make it safe, and the pneumatic cylinder is the part that varies the resistances as it swings to make it react to the user as he or she walks. (Blatchford, Tr. 2108-2109). The pneumatic chamber does not need to be refilled like Freedom's Plié with the use of an air pump. (Blatchford, Tr. 2135).

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

208. The sensors in the Orion 3 are able to analyze changes "virtually instantaneously" at about one fiftieth of a second. (Blatchford, Tr. 2112). What is important to the performance of the knee is not so much how fast the processor is but how fast the mechanism can react to it. (Blatchford, Tr. 2112). "Analyzing the sensor information is a lot quicker than the mechanism reacting to it once you tell the mechanism to do something." (Blatchford, Tr. 2112).

iv. Nabtesco's MP-Swing-and-Stance Knee

209. The Allux is the only four-bar, MP-Swing-and-Stance Knee on the market in the United States. (Mattear, Tr. 5601; Schneider, Tr. 4352). The final version of the Allux was launched on June 1, 2017. (RX-0346; Mattear, Tr. 5598-5599; 5775). On June 1, 2017, Nabtesco launched the full-release model of the Allux in the United States; before June 1, 2017 Allux was just a beta model. (Mattear, Tr. 5598-5599; 5775-5776).

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

211. According to Freedom's Chairman, "Nabtesco positions [Allux] as the ultimate safety knee as it uses a very safe mechanical geometry and MPC controlled hydraulic swing and stance control." (RX-0268; Carkhuff, Tr. 127). The four-bar technology offers the user greater toe clearance and lowers the tendency that the user will stumble or fall. (Mattear, Tr. 5602-5603; Ferris, Tr. 2357).

212. The Allux's battery length is four days, which is longer than its primary competitors. (Mattear, Tr. 5603). [redacted] The Allux has an internal battery that only takes 3 hours to charge, and it also offers a backup battery for emergencies. (Mattear, Tr. 5621-5622).

213. The Allux also comes with a remote control that allows the user to toggle between different preset modes. (Mattear, Tr. 5604-5605).

214. Nabtesco recommends and markets the Allux for K-3 and K-4 users. (Mattear, Tr. 5607-5608; [redacted]

v. DAW's MP-Swing-and-Stance Knee

215. [redacted]

216. [redacted]

vi. High-End MP-Swing-and-Stance knees

217. The most technologically and functionally advanced MP-Swing-and-Stance knees are considered to be very high-end MPKs ("High-End MPKs"). (Senn, Tr. 200-202). They are characterized by enhanced technological features and functionality, such as being IP68 rated for dustproofness and waterpoofness, walk to run, and advanced rule sets. (Schneider, Tr. 4297-4298; [redacted] Solorio, Tr. 1635; Oros, Tr. 4794).

218. The Genium and X3 are "High-end" MPKs sold by Ottobock. (Solorio, Tr. 1635-36).

219. The Genium has a different rule set than the C-Leg and is designed for a higher activity K-3 patient into the K-4 level. (Solorio, Tr. 1635). The Genium has a feature called optimized physiological gait which is a different rule set for controlling swing and stance and allows for the most natural walking experience. (Solorio, Tr. 1635). The Genium has a walk-to-run feature. (Solorio, Tr. 1635-36).

220. The X3 has all of the features of the Genium, but it is fully corrosion and water resistant, and has a dedicated running mode. (Solorio, Tr. 1636). The X3 has an IP-68 rating. (Solorio, Tr. 1642)

221. High-End MPKs are also significantly more costly than other MP-Swing-and-Stance knees. High-End MPKs are typically two to three times the cost of other MP-Swing-and-Stance knees. (Senn, Tr. 200-202).

222. Össur characterizes its Rheo XC as a "step up" from the Rheo. (De Roy, Tr. 3532). The Rheo XC offers greater functionality than the Rheo. Rheo XC offers additional features like walk to run, greater efficiency on stairs. (De Roy, Tr. 3578-3579). The features are automatic, i.e., no switch is involved. (De Roy, Tr. 3579). Rheo XC also offers ability to ride a bike. (De Roy, Tr. 3579).

223. Össur targets first-time users with the Rheo XC. (De Roy, Tr. 3583). Medicare and most private payers do not provide additional reimbursement for the Rheo XC relative to the Rheo. (De Roy, Tr. 3583-3584). WC and VA provide additional reimbursement for the Rheo XC relative to the Rheo. (De Roy, Tr. 3583-3584).

224. The Genium and X3 are the Rheo XC's main competitors. (De Roy, Tr. 3584). The Rheo XC is $9,000 to $10,000 more expensive than the Rheo. (De Roy, Tr. 3584).

225. [redacted]

226. Ottobock does not consider the prices of any other products when setting the price of the X3, because "it's in a league of its own." (Schneider, Tr. 4339).

227. According to Ottobock, the only product that competes with the Genium is the X3, and Ottobock does not consider the prices of other knees when setting the price of the Genium. (Schneider, Tr. 4341-4342).

228. High-End MPKs are not reimbursed by Medicare and are typically not reimbursed by private insurers for their enhanced technological features. (Senn, Tr. 201-204; [redacted] DOD, VA, and WC have historically been more likely to reimburse High-End MPKs for their enhanced technological features. (Senn, Tr. 201-204; [redacted]

vii. Powered MPKs

229. The Power Knee is a powered microprocessor-controlled device. (De Roy, Tr. 3576). It is motorized and lifts a user's knee for them. (De Roy, Tr. 3584-3585). Both MPKs and non-MPKs have swing and stance control that is triggered by the position of the knee, whereas, the Power Knee can actually generate the swing phase automatically, which decreases the energy expenditure required by the patient. (De Roy, Tr. 3585).

230. Össur recommends the Power Knee for K-3 patients (De Roy, Tr. 3585). The Power Knee has received PDAC verification from Medicare, so there have been instances where Medicare has reimbursed the Power Knee. (De Roy, Tr. 3585). Private insurers reimburse for the Power Knee on a case-by-case basis. (De Roy, Tr. 3585). The DOD and VA have provided reimbursement for the Power Knee. (De Roy, Tr. 3586).

231. No other prosthetic knee competes with the Power Knee. (De Roy, Tr. 3586). According to Össur's former head of prosthetics in the United States, "[t]here's no real comparable technology on the market today [to the Power Knee]." (De Roy, Tr. 3586).

232. [redacted]

233. The Össur Power Knee is leading prosthetic knee innovation, because it is the only powered knee on the market in the United States. (Doug Smith, Tr. 5995).

234. Endolite's Chairman does not believe that Endolite sells any product that competes with the Power Knee because it is unique in that it is the only knee to provide power during the swing phase to assist the amputee. (Blatchford, Tr. 2151-2152).

f. Integrated microprocessor-controlled leg systems

235. A fluid-controlled knee and foot integrated together and controlled by microprocessors ("Integrated Leg System") combine a MP-Swing-and-Stance knee with a microprocessor-controlled ankle. (Blatchford, Tr. 2110). The sensors and microprocessor in the knee is able to communicate with the sensors and microprocessor in the ankle. Endolite's Linx and Össur's Symbionic are Integrated Leg Systems. (Blatchford, Tr. 2110; [redacted]

236. The Linx has better situational awareness than the Orion 3 because it has a control system that integrates data from the microprocessor control in the foot as well. (Blatchford, Tr. 2138). The Linx won the Gold Medal Award in Rehab and Assistive Technology Products at the 2017 Medical Design Excellence Awards. (RX-01069).

237. [redacted]

238. Össur also sells the Symbionic Leg. (De Roy, Tr. 3576). It is a combination of the Rheo and a Proprio ankle. (De Roy, Tr. 3576).

239. [redacted]

B. Reimbursement

1. Reimbursement For Prosthetic Knees In The United States Is Dictated By Patient's K-Level Classification

a. Reimbursement generally

240. CMS coverage determinations are based on K-Level classification. (Schneider, Tr. 4287); (Ell, Tr. 1684).

241. Mark Ford testified that the prosthetics market is an insurance-dictated market, and the most important person in the equation is the insurance company. (Ford Tr. 920).

242. Prosthetic manufacturers classify and market their products by the K-Level patients they are appropriate, and reimbursable, for. [redacted]

243. The reimbursement system, and the K-Level classification system, affects what products are available to patients; for instances, there are instances in which a patient would benefit from an MPK, but it is not covered by insurance. (Ell, Tr. 1788)

244. Some clinicians believe that [redacted]

245. K-Level O is described by CMS as Nonambulatory: "Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility." (JX01, ¶ 19).

246. K-Level 1 is described by CMS as a Household Ambulator: "Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence." (JX01, ¶ 20).

247. K-Level 2 is described by CMS as a Limited Community Ambulator: "Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces." (JX01, ¶ 21).

248. K-Level 3 is described by CMS as an Unlimited Community Ambulator: "Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion." (JX01, ¶ 22).

249. K-Level 4 is described by CMS as Very Active: "Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete." (JX01, ¶ 23)

b. K-0 patients cannot receive reimbursement for a prosthetic knee

250. If the prosthetist and physician conclude that a patient is classified as a K-0 patient, Medicare and private insurers in the United States will not provide reimbursement to a prosthetic clinic for a prosthetic knee for that patient. (Schneider, Tr. 4287).

c. K-1 and K-2 patients can receive reimbursement for a constant friction knee but not a fluid-controlled knee

251. If the prosthetist and physician classify a patient as either K-1 or K-2, that patient will be eligible for a constant friction knee to be reimbursed by Medicare and/or private insurance. (Senn, Tr. 253). A patient classified as K-1 or K-2 is not eligible for reimbursement by Medicare and most private insurance for a sophisticated non-MPK. (Schneider, Tr. 4288).

252. Freedom's Chairman and former CEO testified that although K-2 patients may benefit medically from using a prosthetic knee that contains a microprocessor, due to reimbursement constraints dictated by insurance providers, K-2 patients are not fit with MPKs in the United States. (Carkhuff, Tr. 614-615).

253. Ottobock is working to expand coverage for MPKs to K-2 patients since 2006; however, Ottobock's Vice President of Government, Medical Affairs, and Future Development does not expect that to happen for at least five to ten years. (Schneider, Tr. 4308, 4532; Kannenberg, Tr. 1995-1996). Ottobock's head of reimbursement, Dr. Kannenberg, also

believes that it will take at least five to ten years for K-2 patients to receive reimbursement for MPKs. (Kannenberg, Tr. 1995-1996).

d. K-3 and K-4 patients can receive reimbursement for a fluid-controlled knee

254. A prosthetist and physician must classify a patient as either K-3 or K-4 in order for the patient to be eligible to receive reimbursement from Medicare and/or private insurance for a sophisticated non-MPK. (Senn, Tr. 253-254).

255. A prosthetist and physician must classify a patient as either K-3 or K-4 in order for the patient to be eligible to receive reimbursement from Medicare and/or private insurance for an MPK; Medicare will not pay for an MPK for K-1 or K-2 patient. (Senn, Tr. 176, 179).

256. Medicare reimburses MPKs for only K-3 and K-4 level patients. (Schneider, Tr. 4307). Private insurers will typically reimburse MPKs for only K-3 and K-4 level patients as well. (Schneider, Tr. 4308).

257. A patient must be classified as either K-3 or K-4 to be eligible for an MPK. U.S. reimbursement requires that a patient be K-3 or K-4 to receive an MPK. (De Roy, Tr. 3630).

258. Blatchford believes that the Orion 3 is suitable for all K-3 amputees. (Blatchford, Tr. 2139-2140). Endolite does not recommend the Orion 3 for K-1 or K-2 patients because the reimbursement for those products is not there yet in the United States. (Blatchford, Tr. 2140)

2. Reimbursement Is Limited By L-Codes

259. The amount of reimbursement that a particular prosthetic device is eligible for under Medicare depends upon whether it has certain characteristics, which correspond with "L-Codes" established by CMS, and L-Codes determine the maximum amount that will be reimbursed to a prosthetic clinic for a prosthetic component. [redacted]

260. An L-Code is an alphanumeric code system that was set up by Medicare. (Schneider, Tr. 4291). The prosthetic codes are traditionally L codes, and then it has a four-digit number after it representing a function in the prosthesis. (Schneider, Tr. 4291). A prosthesis could have multiple functions and therefore use multiple L codes. (Schneider, Tr. 4291).

261. CMS sets the L-Codes and has another committee that sets the fee or allowable for each one of the L-Codes. (Schneider, Tr. 4292). Manufacturers apply for L-Codes and CMS determines whether or not to grant a new L-Code. (Schneider, Tr. 4292). Medicare reviews the fee for each L-Code and can decrease or increase the fee associated with L-Codes. (Schneider, Tr. 4292). CMS can also eliminate L-Codes. (Schneider, Tr. 4292). There are very few L-Codes added anymore. (Schneider, Tr. 4292**).**

262. Most insurers have adopted Medicare's L-Code-based reimbursement system. (Senn, Tr. 202). Reimbursement rates are set by stacking L-Codes based on product functionality. (De Roy, Tr. 3558).

263. Prosthetists works with a physician to determine the best prosthetic device for the user and will code the prosthetic device with L-Codes and seek reimbursement for those L-Codes. (Schneider, Tr. 4290-4291). Tracy Ell stated that after a prescription is provided to the clinic, then his clinic assigns L-Codes to the devices that they intend to provide, and create a Detailed Written Order with L-Codes that the physician must sign off on. (Ell, Tr. 1695).

264. L-Codes are based on manufacturer recommendations. (Kannenberg, Tr. 1970). There is no obligation for manufacturers to have L-Codes independently verified. (Kannenberg, Tr. 1970).

265. Over the last ten years, Medicare reimbursement for prosthetic products has actually gone down. (Schneider, Tr. 4298). There have only been six new L-Codes issued in the last ten years. (Schneider, Tr. 4298). It is very difficult to get new codes and increased fees from CMS. (Schneider, Tr. 4298-4299).

266. [redacted]

3. Reimbursement Is Intended To Cover All Costs Associated With Product Acquisition, Fitting, And Servicing

267. CMS intends for the L-Code fee to cover the clinic's cost in acquiring the prosthetic device as well as all services and costs related to fitting and servicing that device. (Schneider, Tr. 4295).

268. L-Codes cover all costs, including acquisition cost and all fitting and servicing costs. (De Roy, Tr. 3559). "So the L code is supposed to cover the device they purchase, the efforts required to put the device in place and the basic teaching of the user on how to utilize the device and then some service aspects as well following, following that procedure." (De Roy, Tr. 3559). CMS intends for the L-Code fee to cover the clinic's cost in acquiring the prosthetic device as well as all services and costs related to fitting and servicing that device. (Schneider, Tr. 4295).

269. Reimbursement for a particular prosthetic device is intended to cover not only the cost of acquiring the prosthesis but also the prosthetist's labor and overhead. (Senn, Tr. 200-201). The L-Code system reimburses for the entire patient care episode. (Ford, Tr. 977-978) [redacted]

270. Costs that are not separately reimbursed include the cost of marketing, administrative costs, costs associated with the work performed by a clinic's certified prosthetists, costs associated with the technical staff building the leg, overhead costs, human resources, payroll, facility costs, and other operational costs. (Senn, Tr. 257).

271. Clinics incur significant costs, in addition to the cost of a prosthesis, that are not separately reimbursable. (Senn, Tr. 256).

272. Clinics have significant overhead costs that reduce profitability, including [redacted]

i. Costs related to fitting and serving MPKs are greater than costs related to fitting and servicing non-MPKs

273. The additional costs (besides the cost of the prosthesis) of fitting a patient with an MPK are significantly more than the additional costs of fitting a patient with a non-MPK. (Senn, Tr. 258). Those costs include programming of the knee and the follow-up and potential follow-up programming costs. (Senn, Tr. 258). In addition, it is more difficult and time-consuming to fit an MPK on a patient than a non-MPK. (Senn, Tr. 258).

274. Patients require several follow-up visits after being fitted with an MPK. (Oros, Tr. 4787-4788). A patient will typically require at least three follow up visits in the first year, and as many as 24 visits. (Oros, Tr. 4787).

275. Accounting for these additional costs, which are greater for an MPK than a non-MPK, and which are not separately reimbursed, it is possible that fitting an MPK on a patient would cause the clinic to break even and not make a profit. [redacted]

ii. Private insurers provide reimbursement at or below the fees set by CMS

276. "Private insurers definitely reimburse below Medicare." (Schneider, Tr. 4295). Freedom's former CEO testified that whereas in much of healthcare, Medicare is the lowest standard of reimbursement, in the O&P industry, it is the highest level of reimbursement and private carriers will negotiate off Medicare rates for discounts of 20 to 40 percent. (Carkhuff, Tr. 594).

277. Typically, private insures discount off of Medicare by 20 to 40 percent. (Schneider, Tr. 4296). Private insurers will many times actually discount their reimbursement off of Medicare's fees by 20 or 30 percent, or maybe more. (Testerman, Tr. 1260-1261).

278. Many private insurance providers reimburse at amounts discounted off of the amount set by the CMS L-Code. The discounted rate ranges from around 67% up to 96% of the Medicare allowance. [redacted] (Sabolich, Tr. 5827) (testifying that United Healthcare is the lowest reimburser for prosthetics in the United States.); (Senn, Tr. 261-262) (testifying that Anthem, a large insurer, only reimburses COPC at 75% of Medicare, or $15,000);

((PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 30-31)(Commercial health plans' allowable amounts are generally 10% to 40% below Medicare's.).

279. [redacted]

280. [redacted]

281. The percentage of patients on Medicare varies by clinic. (Sabolich, Tr. 5822) (testifying that 68 percent of SSPR's patients are Medicare patients); (Schneider, Tr. 4290) (testifying that Medicare represents about 30 percent of the payer mix, and most all users of prosthetic devices have some type of insurance); [redacted] (Senn, Tr. 259-260) (Private insurance reimbursement is the biggest percentage of COPC's clinics' reimbursement at more than 30 percent).

282. [redacted]

283. [redacted]

284. The discounted fees paid by private insurers are also intended to cover the cost of the prosthetic device and all costs related to fitting and servicing the device. (Schneider, Tr. 4296).

285. Freedom's Vice President of National and Key Accounts noted: "There's so much going on right now as it relates to reimbursement that they're discussing whether it's these private payers and the discounts associated with that. It puts pressure on them, puts pressure on their patients. The patients are feeling the struggles through their practitioners associated with large deductibles, with a lot of out-of-pocket costs, and that puts pressure on the decision-making process sometimes of a prosthetist or the key accounts that I'm calling on." (Testerman, Tr. 1261).

286. Because of the lower reimbursement rate, margins on a prosthesis reimbursed by private insurance are far less than margins on prostheses reimbursed through Medicare. (Schneider, Tr. 4302).

287. [redacted]

4. Costs Related To Reimbursement Audits

288. A RAC audit is a Recovery Audit Contractor audit, commissioned by CMS. (Ford Tr. 973). A RAC audit is a look back at claims to audit whether Medicare compliance was met for that patient care episode. (Brandt, Tr. 3764; Ford Tr. 973; Asar, Tr. 1545).

289. If a prosthetic device is subjected to a RAC audit and the claim is denied, Medicare recoups the full reimbursement amount from the prosthetic clinic. (Senn, Tr. 258-259; Ford, Tr. 973-974; Sabolich, Tr. 5828). During RAC audit, Medicare immediately claws back the reimbursement amount, and that is a cost to the clinic. (Brandt, Tr. 3764-3765; Schneider, Tr. 4381; Ford, Tr. 973-974).

290. The various types of audits, including preauthorization and RAC audits, are important factors in a prosthetist's knee selection. (Blatchford, Tr. 2259).

291. If an MPK is audited, Medicare will recoup its payment to the clinic pending appeal, which can take years. (Senn, Tr. 258; Schneider, Tr. 4381). The prosthetic clinic may appeal the denial of the claim, [redacted], but the appeals process typically takes several years and has several levels of appellate review. (Senn, Tr. 258; [redacted] The prosthetic clinic cannot receive reimbursement until the claim is approved. (Senn, Tr. 258). During the appeals process, the clinic has to front the money for the MPK, which is another potentially significant cost of prescribing an MPK over a non-MPK. (Senn, Tr. 258-259).

292. During the time that an appeal is pending, many times the amputee goes without a knee. (Brandt, Tr. 3754).

293. [redacted]

294. RAC audits are a frequent occurrence. (Senn, Tr. 210-211) At COPC, RAC audits occur monthly. (Senn, Tr. 210-211).

295. [redacted]

296. [redacted] Ferris, Tr. 2309-2310)

297. Scott Sabolich believes that RAC audits came about because "prosthetists started improperly billing Medicare and never getting caught, and Medicare had to crack down" but that caused a "horrible effect for all prosthetists," in that "through 2010 to 2016, Medicare introduced RAC auditing and post-payment audits to where [the clinic] would build the prosthesis, [the clinic would] do it properly, [the clinic would] then get audited two years later when the trail has gone cold, and if every I wasn't dotted and T crossed, [the clinic would] be committing, quote-unquote, fraud." (Sabolich, Tr. 5829).

298. Scott Sabolich believes that RAC audits make Medicare unfriendly to prosthetists to work with because they can claw back reimbursement in such a way that would cripple a prosthetist's facility to go in two years later and have to pay back 20 C-Legs all at once. (Sabolich, Tr. 5831)

299. Third party payers also have stringent documentation requirements to obtain reimbursement. [redacted]

300. The risk of RAC audits causes clinics to take measures to make sure that they will pass such audits. (Senn, Tr. 211) (testifying that COPC provides guidance to its clinics for how to handle RAC audits).

301. For instance, SSPR changed the way it does business based on RAC audits, and retooled and redid its structures so that SSPR is more audit proof than it was before. (Sabolich, Tr. 5830-31).

302. The risk of audit impacts the prosthetists selection of prosthetic devices for patients, and, in particular, it makes prosthetists less likely to provide MPKs. (Sabolich, Tr. 5851-52) (testifying that he believes that the threat of RAC audits scare a lot of prosthetists away from MPKs); (Senn, Tr., 232) (testifying that he spends more of his time focused on managing costs related to prosthetic knees than feet because of "[t]he cost factor and the risk of audit.")

303. There is a much higher risk of a RAC audit with an MPK than a non-MPK, which is an additional cost unique to MPKs. (Senn, Tr. 258). [redacted]

304. Some clinicians believe that payers often try to deny reimbursement for MPKs. (Ell, Tr. 1786).

305. Defects in documentation can result in denial of payment. Sabolich's clinic had issues with the MPKs that were audited, because of timing issues between the creation and sign off by the physician on a Detailed Written Order. (Sabolich, Tr. 5830). If there were any L-Code changes on the Detailed Written Order, the physician would have to approve it before the patient receives the device, or else that was considered fraud. (Sabolich, Tr. 5830).

306. Audits may occur even after a prosthesis is delivered to the patient. In 2014, SSPR's Dallas facility got hit with a RAC audit, where 20 MPKs that had already been delivered to patients were audited. (Sabolich, Tr. 5829).

5. PDAC Verification Is Important To Clinics Concerned With The Risk Of Audits

307. [redacted]

308. [redacted]

309. The C-Leg 4 and Össur Rheo are PDAC verified for L5856, *i.e.*, CMS has confirmed their functionality conforms to the L-Code for microprocessor-controlled swing and stance. (Schneider, Tr. 4381-4382, 4294; Kannenberg, Tr. 2000).

310. The Plié 3 has not been submitted for PDAC verification. (Schneider, Tr. 4381-82). Ottobock's C-Leg is PDAC verified. (De Roy, Tr. 3646-3648).

311. [redacted]

6. Reimbursement Constrains Pricing of Prosthetics Devices

312. Freedom, Ottobock, Össur, and Endolite all set prices based primarily on the available reimbursement amount dictated by the recommended L-Codes. (Carkhuff, Tr. 594; [redacted] Schneider, Tr. 4302-4303; Blatchford, Tr. 2124; De Roy, Tr. 3557-3558).

313. Reimbursement rates constrain Össur's MPK pricing, affect Össur's product development plans, and influence Össur's product positioning strategy. (De Roy, Tr. 3557-3558).

314. [redacted]

315. Ottobock relies on the product coding and reimbursement allowable associated with those codes when it sets prices for prosthetic products in the United States. (Schneider, Tr. 4302-4303). Ottobock sets its prices according to the fee schedule set by Medicare and private insurers. (Schneider, Tr. 4303).

316. Endolite pays keen attention to reimbursement rates and customer margins when setting prices. (Blatchford, Tr. 2124).

317. Endolite looks at three factors when considering price points for its MPKs. (Blatchford, Tr. 2122). First, it considers what margin Endolite needs to make in order to be profitable. (Blatchford, Tr. 2122). Next, it tries to "understand how the price of our products compares with the reimbursement that our customers would get, so whether they would make money if they use our products." (Blatchford, Tr. 2122). Third, Endolite compares the pricing and positioning of its MPKs against other competitors' prices and positions. (Blatchford, Tr. 2122).

318. The reimbursement system constrains prices because the manufacturer knows how much Medicare pays for a device, and their prices are based on what the L Code is going to pay the clinic for the device, and is not based on what it costs them to build the knee or foot or liner. The acquisition price of a device reflects a profit margin that the manufacturer and prosthetist can both live with. (Sabolich, Tr. 5831); [redacted]

319. Likewise, the L-Code system affects products that manufacturers bring to market. [redacted] De Roy, Tr. 3557-3558).

320. [redacted]

321. There have only been six new L-Codes issued in the last ten years. (Schneider, Tr. 4298). It is very difficult to get new codes and increased fees from CMS. (Schneider, Tr. 4298-4299).

322. [redacted]

323. Manufacturers are cognizant of the restraints of the reimbursement system. [redacted]

7. Reimbursement For Prosthetic Knees Has Been Declining Over The Last Decade

324. Maynard Carkhuff testified that Medicare reimbursement for prosthetic devices has stayed relatively flat and has not kept up with the Consumer Price Index. (Carkhuff, Tr. 596).

325. Reimbursement amounts for MPKs from insurance and Medicare have gone down over the last several years while clinic costs have gone up. (Senn, Tr. 259).

326. Over the last ten years, Medicare reimbursement for prosthetic products has actually gone down. (Schneider, Tr. 4298). Medicare has not increased its reimbursement schedule to keep up with inflation. (Senn, Tr. 260).

327. [redacted]

328. While reimbursement amounts are staying flat or decreasing, clinics are facing significant reimbursement pressure from smaller allowables, audits, and preauthorizations and the costs associated with those things. (Schneider, Tr. 4301)

329. The terms of reimbursement are dictated by the insurers, and clinicians have little leverage to demand higher reimbursement. [redacted]

330. [redacted] COPC has contracts with over 200 different payers. (Senn, Tr. 199).

8. Reimbursement Is Manufacturer And Brand Agnostic

331. Medicare's reimbursement is based entirely on the L-Codes that a prosthesis is eligible for. In other words, prosthesis with the same L-Codes will be reimbursed the same, even if they are from different manufacturers, and even if the manufacturer's price to the clinic was different. (Senn, Tr. 203; 204; Schneider, Tr. 4352).

332. Indeed, clinics may not even specify the brand of MPK it is fitting on a patent when it applies for reimbursement from Medicare, since it is not required by Medicare. (Senn, Tr. 202; Kannenberg, Tr. 1871-1872, 1933-1934).

333. [redacted]

334. Because reimbursement is based entirely on L-Code, a prosthetist benefits financially by selecting the MPK that costs the clinic the least amount of money to obtain from the manufacturer. (Senn, Tr. 204). "And since, generally, Medicare gives [COPC] the same amount of money for an L code regardless of the price or regardless of the brand or manufacturer, financially, it's a benefit to [COPC] to provide to the patient the MPK that costs [COPC] the least amount of money." (Senn, Tr. 204).

C. Any Relevant Product Market Is Broader Than Only MPKs

1. Sophisticated K-3 And K-4 Knees Are Functionally Interchangeable With MPKs And The Plié 3 In Particular

335. The hydraulic controls 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 K-3 and K-4 amputee. (Oros, Tr. 4791; [redacted]

336. There is overlap in the technology of non-MPKs and MPKs that are appropriate for K-3 patients; many MPKs and non-MPKs hydraulically controlled cylinder, and in an MPK the microprocessor aspect is controlling that hydraulically controlled cylinder, so the microprocessor is an enhancement to existing hydraulic technology. (Oros, Tr. 4791-4793; Doug Smith, Tr. 5991-5992, 5994 (the microprocessor just "adds one more little level of control."); [redacted] Ford Tr. 1052; [redacted]**.}**

337. Prosthetists and physicians do not divide the world up into non-MPKs and MPKs. They 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. (Doug Smith, Tr. 6007-6008; PX05166 (Watson (Fourroux) Dep. at 148-149)).

338. Össur's Mauch Knee and the Freedom Plié require similar manual adjustments for swing and stance control. (De Roy, Tr. 3652). Maynard Carkhuff testified that the Mauch knee controls swing and stance of the knee in a similar way to the Plié. (Carkhuff, Tr. 619-20).

339. Össur recommends using a non-MPK to K-3 and K-4 patients that want to run a marathon. (De Roy, Tr. 3580).

340. Maynard Carkhuff testified that there are some pretty sophisticated non-microprocessor fluid-controlled knees, such as the Mauch knee, and other knees that have unique geometric designs that would benefit K-3 and K-4 patients. (Carkhuff, Tr. 618-619).

341. Maynard Carkhuff testified that the primary difference between the Plié and sophisticated non-MPK hydraulic knees is that the Plié uses a microprocessor to control and trigger the switch between swing and stance phase. (Carkhuff, Tr. 620).

342. Maynard Carkhuff testified that many more K-3 and K-4 patients are fit with non-MPKs than are fit with MPKs. (Carkhuff, Tr. 621).

343. Sophisticated non-MPKs compete with MPKs for K-3 and K-4 users in the United States, as both are medically appropriate for K-3 and K-4 users. (Schneider, Tr. 4329; Blatchford, Tr. 2254).

344. Clinicians have reported that non-MPKs have become increasingly safe, stable and functional. (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 24)).

345. The number of K-3 and K-4 users fit with a non-MPK is about equal to the number fit with an MPK each year in the United States. (Schneider, Tr. 4329; Oros, Tr. 4792; [redacted]

346. For K-3 and K-4 patients in the United States, about 55% of Endolite's sales are attributable to non-MPKs and 45% are attributable to MPKs. (Blatchford, Tr. 2254-2256).

347. Manufacturers recognize that non-MPKs have certain technical advantages over MPKs, including durability in multiple environments, less required maintenance, and lack of a need to charge the Knee. (Solorio, Tr. 1640; Blatchford, Tr. 2260-2261; Kannenberg, Tr. 1985; Schneider, Tr. 4332-4333).

348. In fact, the majority of knees offered by Endolite for moderately active to more active users are sophisticated knees that are user-controlled, rather than microprocessor-controlled. (Blatchford, Tr. 2254)

349. Prosthetists recognize that non-MPKs have certain technical advantages over MPKs, including less service failures, lighter weight, greater flexion, greater water resistance, and lack of necessity to charge the knee. (Ell, Tr. 1723, 1783, 1785; Sabolich, Tr. 5848-49 ("I can give you a C-Leg 4 and give you stability at heal strike that you can't get in your mechanical knee, but I am going to . . . give you a lot more weight than you want. Or I can give you a lightweight knee that has a manual lock, that's stable, but doesn't have the stumble recovery like the C-Leg, so everything is a little different.")).

a. **No clinical studies show any benefits of the Plié 3 relative to Sophisticated Non-MPKs.**

350. There is no evidence that the Freedom Plié 3 provides K-3 or K-4 patients with significant health, safety, and quality-of-life benefits over Sophisticated non-MPKs. (Schneider, Tr. 4361).

351. There is no evidence that the Plié 3 allows amputees to maneuver through obstacles and over uneven terrain better than non-MPK, fluid-controlled knees. (Schneider, Tr. 4361-4362).

352. There is no evidence that the Plié 3 reduces falls relative to Sophisticated non-MPKs. (Schneider, Tr. 4362).

353. Freedom's Plié 3 does not use an internal computer to monitor each phase of the amputee's walking pattern and change the resistance therein. (Schneider, Tr. 4362).

354. The Freedom Plié 3 does not use a series of sensors which help patients walk with a much more stable and efficient gait that more loosely resembles natural walking pattern. (Schneider, Tr. 4362).

355. There is no evidence that the Freedom Plié 3 enables patients to easily navigate ramps, stairs and nearly every type of challenging surface even walking backwards. (Schneider, Tr. 4362).

356. PX01548 reflects Ottobock's evidence-based conclusion that the Plié 3 lacks microprocessor-controlled swing and stance variable control; therefore, Freedom should not recommend L5856 for the Plié. (Schneider, Tr. 4373). Ottobock did not create documents like PX01548 for Össur and Endolite because the Rheo and Orion 3 are properly recommended as L5856. (Schneider, Tr. 4373-4374).

357. "Results of a more recent study of the Plié 3 presented at the ISPO World Congress revealed that these differences still exist between the current versions of Plié and the C-Leg." (PX01548; Schneider, Tr. 4375).

358. Dr. Doug Smith testified that his clinical study on the benefits of C-Leg, PX00855, cannot support the conclusion that the Plié 3 provides clinical benefits to K-3 patients, and it would be misleading or fraudulent to say that it could. (Doug Smith, Tr. 6032).

359. [redacted]

360. [redacted]

361. [redacted]

362. One hundred percent of clinical trials that showed benefits of microprocessor knees over non-microprocessor knees were done with Ottobock MPKs. (Kannenberg, Tr. 1843-44).

363. Dr. Kannenberg is not aware of a single study that shows the benefit of microprocessor knees made by manufacturers other than Ottobock. (Kannenberg, Tr. 1843-44).

i. The Rand Study

364. PX08004 is a study referred to throughout the record as the RAND Study. [redacted]

365. [redacted]

366. [redacted]

367. [redacted] Kauffman, Tr. 877)}

368. The RAND study is not a clinical study because it does not rely on new clinical data, it relies on previously published data. [redacted]; Kauffman, Tr. 877; Kannenberg, Tr. 1935).

369. The RAND study does not study Plié or any studies that study Plié (Kauffman, Tr. 878: 8-12; Kannenberg, Tr. 1937; [redacted]).

370. [redacted]

371. Vinit Asar's knowledge of the benefits of MPKs comes only from the RAND study. (Asar, Tr. 1339)

ii. Dr. Kauffman has never published a study showing the Plié 3 to be safer or more beneficial for K-3 and K-4 patients than Sophisticated Non-MPKs

372. PX08010, PX08011, PX08029 are studies authored by Dr. Kenton Kauffman, and all three were conducted on the same set of 15 patients. (Kauffman Tr. 879-885).

373. PX08010 does not study the Plié. (Kauffman Tr. 879-885).

374. PX08011 does not study the Plié. (Kauffman Tr. 879-885).

375. PX08029 does not study the Plié. (Kauffman Tr. 879-885).

376. PX08016 is a study authored by Dr. Kenton Kauffman, and is a literature review of 18 studies. (Kauffman Tr. 879-885).

377. All 18 studies reviewed by PX08016 study the C-Leg, and do not study the Plié, and the conclusions can only apply to the C-Leg. (Kauffman Tr. 885:10-886:15).

378. PX00849-22 is a study titled Gait and Balance of Transfemoral Amputees using passive mechanical and microprocessor controlled prosthetic knees, and is a secondary analysis of a study done with the C-Leg, and the conclusions can only apply to the C-Leg. (Kannenberg, Tr. 1852-53).

379. PX00849-27 is a study titled Gait Asymmetry of Transfemoral Amputees using Mechanical and Microprocessor-Controlled knees and is a secondary analysis of a C-Leg study, and the conclusions can only apply to the C-Leg. (Kannenberg, Tr. 1854).

iii. The FastK2 Study is immaterial given the current reimbursement system

380. One study cited by Complaint Counsel compares the Freedom Plié 3 to K-2 mechanical knees like the Ottobock 3R49, and not Sophisticated Non-MPKs like the Ottobock 3R80 (the FastK2 Study). (Kauffman, Tr. 889; [redacted]}).

381. The FastK2 Study does not show that the Freedom Plié 3 has any clinical benefits relative to Sophisticated, Non-MPKs. [redacted]

b. Industry Participants Do Not Consider Freedom Plié 3 To Be An MP-Swing-and-Stance Knee

382. Freedom's Plié 3 does not meet Complaint Counsel's definition of microprocessor knee as alleged in the Complaint. (Schneider, Tr. 4310).

383. Competitor knee manufacturers consider the Plié 3 to be a hybrid knee which functions more like a non-MPK and is "a knee that utilizes some of the mechanical characteristics, such as hydraulics or pneumatics, in combination with a microprocessor, where some of the tasks are microprocessor-controlled, some of the tasks are hydraulic or pneumatic-controlled." (DeRoy, Tr. 3665; Schneider, Tr. 4324).

384. Össur distinguishes the Plié and other hybrid knees from "a device that is fully microprocessor-controlled like the Rheo Knee." (DeRoy, Tr. 3665).

385. Keith Senn of COPC's definition of an MPK as "a knee with a computer chip that monitors the patient's gait and analyzes their gait to assist them in walking and stumble recovery" excludes the Plié 3. (Senn, Tr. 172; Carkhuff, Tr. 335; [redacted]).

386. Orthotics and Prosthetics Center's owner describes Plié 3 as having a mechanical stance feature that is "not electronically reading the space in time where the knee is." (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 64, 66)).

387. Tracy Ell's definition of an MPK as "generally any knee that utilizes a computer to control the resistances throughout swing or stance or both that increases the inherent stability of the bending of the knee" excludes the Plié 3 (Ell, Tr. 1678; Carkhuff, Tr. 335; [redacted]).

388. William Carver described a mechanical knee as something that can be tuned to one set of setting that match what the patient needs most of the time, versus a microprocessor knee that can vary those fixed settings, but the Plié 3 offers fixed settings. (Carver, Tr. 2019; Carkhuff, Tr. 335; [redacted]).

389. Blatchford defines an MPK as having "a microprocessor control system, and the control system will, generally speaking, control valves that affect the resistance the knee has to motion and the resistance the knee has to – well, and also enables the knee to lock under load. And because its controlled by a computer system, it means – and has a number of sensors in the knee, it means that it has a good understanding of what the amputee is doing at the time and therefore can react in real time as the amputee walks or as he stands." (Blatchford, Tr. 2104-2109). Blatchford noted that his definition of an MPK only applies to Endolite's MPKs. (Blatchford, Tr. 2109).

390. [redacted]

391. [redacted]

2. Users Substitute Between All Fluid-Controlled Knees Based On Functionality And Cost

392. The patient has significant input into which knee they get. (Sabolich, Tr. 5845; Doug Smith, Tr. 6010). Even if an MPK would clinically benefit a patient, the patient absolutely has a choice not to get one, based on their lifestyle. (Doug Smith, Tr. 6010; Senn, Tr. 263).

393. Patients, physicians, and prosthetists frequently weigh the pros and cons with a of a microprocessor knee versus a non-microprocessor knee. (Doug Smith, Tr. 6007; Ford, Tr. 1055).

394. Prosthetists narrow down the available knees to the patient to the ones that are appropriate for their functional level classification, and weigh the pros and cons with the patient. (Sabolich, Tr. 5845-46; Ford, Tr. 992-995).

395. Prosthetists allow patients to trial various knees, including both non-MPKs and MPKs. (Ell, Tr. 1690; Oros, Tr. 4786)

396. When selecting between an MPK and non-MPK, where there is simply no clear right or wrong choice, it comes down to the preference of the patient or the prosthetist. (Sabolich, Tr. 5851; Oros, Tr. 4787; Senn, Tr. 263).

397. [redacted]

398. 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. (Sabolich, Tr. 5849-5850; Oros, Tr. 4793).

399. Some K-3 and K-4 amputees prefer the voluntary control of a non-MPK to the computerized control of an MPK. (Schneider, Tr. 4406).

400. Patients who value the robustness that a mechanical knee can provide might choose the Ottobock 3R80 over the Ottobock C-Leg 4. (Solorio, Tr. 1640; Sabolich, Tr. 5850).

401. Sophisticated non-MPKs cost a patient less out of pocket than MPKs, which influences patient choice. (Ell, Tr. 1784; [redacted]

402. Dr. Doug Smith testified that if a patient told him that they did not want to have to charge their knee, he would not prescribe them an MPK even if the patient would benefit clinically from an MPK. (Doug Smith, Tr. 6010).

403. If a physician prescribes a particular knee, the physician only does so after discussing with the patient about their preferences and what their life is like. (Doug Smith, Tr. 6006-6007, 6010 (testifying that if a patient told him they did not want to have to charge their knee, he would not prescribe them an MPK even if the patient would benefit clinically from an MPK).

404. Even if a patient is a good candidate for an MPK, sometimes they do not chose an MPK because of their lifestyle. (Doug Smith, Tr. 6007-6008).

405. Many patients have less frustration with a mechanical knee than an MPK. (Doug Smith, Tr. 6010-11).

406. Össur's Sophisticated Non-MPKs are medically appropriate for K-3 patients and can support their activities for daily living. (De Roy, Tr. 3644).

3. Prosthetists Substitute Among All Sophisticated Knees Appropriate For K-3 And K-4 Patients Based On Margin Between Reimbursement And Costs

407. Prosthetists consider margins more than price to determine profitability. (Schneider, Tr. 4356).

408. Many factors impact a prosthetist's knee selection. (Blatchford, Tr. 2258). Insurance coverage is a really important factor. (Blatchford, Tr. 2258). The various types of audits, including preauthorization and RAC audits, is another important factor in a prosthetist's knee selection. (Blatchford, Tr. 2259). Prosthetists also consider their margins when selecting a knee for a K-3 or K-4 patient. (Blatchford, Tr. 2259-2260). Durability, environmental considerations, and vocation also impact prosthetists' knee selection. (Blatchford, Tr. 2260-2261).

409. The gross margin is the allowable reimbursement for a prosthetic less costs like the acquisition cost, staff involved in delivery of care, and technical services. [redacted]

410. Because of factors such as patients not paying their copay to insurers not paying reimbursement, clinics often fail to collect the full reimbursable amount for prosthetics. [redacted]

411. Patients sometimes fail to satisfy their portion of the cost for a prosthesis. [redacted]; (Senn, Tr. 260) (testifying that there is a pretty good risk that COPC is not going to be able to collect the full Medicare copay associated with MPKs; in fact, more often than not COPC does not collect he Medicare copay in full).

412. [redacted] The amount that Medicare reimburses for a particular prosthetic varies by state. [redacted]

413. The same risk exists with private insurance because patient copays are often not collected in full for MPKs. (Senn, Tr. 261)

414. [redacted]

415. Because the additional costs for fitting an MPK are higher than a non-MPK, providing an MPK results in a lower margin and lower profitability. [redacted]

[redacted]

416. The costs associated with fitting MPKs are higher than the costs associated with fitting Sophisticated non-MPKs. (Ford, Tr. 1062-1063; Doug Smith, Tr. 6011; PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 108-109); (PX05151 (Patton (Prosthetic Solutions), Dep. at 75, 93). Patients return to the prosthetist less for follow-up visits with a mechanical knee than with a microprocessor knee. (Doug Smith, Tr. 6011). There are higher costs associated with higher-technology products like MPKs. (Schneider, Tr. 4356-57).

417. Maynard Carkhuff testified that while prosthetists only fit what they consider to be appropriate technology, they may fit a non-MPK even if an MPK may be more appropriate, if the reimbursement may be questionable, so price becomes an issue between products that are both medically appropriate. (Carkhuff, Tr. 625-26)

418. Prosthetic clinics have slim margins and tight operating conditions. [redacted] Senn, Tr. 262; [redacted] PX05140 (Weott (Orthotic Prosthetic Center), Dep. at 26-27)).

419. With some low-paying private insurance contracts, Prosthetic clinics sometimes lose money or break even on certain fittings. (PX05140 (Weott (Orthotic Prosthetic Center), Dep. at 31)).

a. Margins on other lower-limb prosthetic components besides the knee cannot overcome lost margin on the knee.

420. Margins on lower-limb prosthetic components besides the knee are usually the same regardless of whether an MPK or non-MPK is selected. (De Roy, Tr. 3560-3561). "I would say that it's the same difference as just looking at the individual components because typically a K-3 knee will be used with a K-3 foot will be used with a socket, components, and a liner, and those are going to be identical in most cases between a mechanical or a microprocessor-controlled knee, so I would say that the margin difference is going to be the same between a microprocessor leg and a mechanical leg for that matter." (De Roy, Tr. 3561).

421. With the reimbursement that clinics receive from third-party payers, clinics must cover their costs, including labor, materials, and G&A. (Ell, Tr. 1795-96; [redacted] PX05135 (Weber (Prosthetic & Orthotic Care), Dep. at 44)).

422. [redacted] Roughly half of the overall reimbursement amount from a lower-limb prosthesis comes from the MPK. (Senn, Tr. 200).

423. Because of those additional costs, a clinic needs a margin of at least $10,000 between the cost of the knee and the reimbursement amount to cover all of the other costs associated with fitting a prosthetic knee; otherwise it will not be profitable. (Senn, Tr. 257-258). The

difference between the reimbursement and the cost of the knee, in order for COPC to operate profitably, needs to be about $10,000 to cover all of those other costs. (Senn, Tr. 257-258).

424. If the knee costs $10,000 and COPC needs a $10,000 margin to cover its other costs, then COPC is not going to be able to profitably provide a $10,000 knee to an Anthem-insured patient. (Senn, Tr. 261-263). The same is true for other private insurers and even Medicare. (Senn, Tr. 262).

425. Prosthetists and clinic management admit that if they were losing money on an MPK, they would consider selling non-MPKs to patients because the clinic needs to make a profit in order to stay in business. (Senn, Tr. 263, [redacted] Ford, Tr. 933; PX05151 (Patton (Prosthetic Solutions), Dep. at 76-78)).

426. Prosthetists admit that fitting products at a loss is not sustainable. (Ell, Tr. 1790).

427. Individual prosthetists are also sensitive to the overall profitability of Prosthetic clinics, because their individual compensation is tied to clinic profitability. (Ford, Tr. 928; Senn, Tr. 215, 219; [redacted])

428. [redacted]

429. Some clinics must follow particular internal procedures before fitting MPKs to make sure the clinic is compliant with reimbursement requirements, and that the patient's eligibility for an MPK as a K-3 users is documented in case Medicare audits the claim, which Medicare regularly does. (Senn, Tr. 170).

430. At least one Clinic has admitted that it fits a lower percentage of patients with private insurance with MPK than their overall population. (Ford, Tr. 1059-1060).

431. Vinit Asar testified that if private insurance stopped reimbursing for MPKs, then they would consider fitting MPKs on only Medicare patients, and not on private insurance patients. (Asar, Tr. 1548).

432. Carkhuff also confirmed that prosthetists are "[v]ery much" concerned about their margins, because "[p]atient care facilities operate on relatively thin margins, and there is a lot of time that's spent on fabricating and aligning these products and doing a lot of follow-up and programming of the products. … [T]here's always a lot of questions about whether they will get reimbursed and how many months it will take." (Carkhuff Tr. 623).

433. 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. (Argue, Tr. 6174).

434. Dr. Argue used the following inputs in his "Model of Clinic Profitability": 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 then the resulting profit. (Argue, Tr. 6174).

435. 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. (Argue, Tr. 6174).

436. Based on the economic reality confirmed by prosthetists that they would not fit MPKs if they lost money on those fittings, Dr. Argue concluded that based on his model and based on the small critical loss number applicable in this case, about 6%, that clinicians would switch patients in sufficient numbers to non-MPKs defeat a SSNIP in the proposed MPK market. (Argue, Tr. 6177).

437. In fact, Dr. Argue concluded, based on his review of the evidence, and application of his Model of Clinic Profitability, clinics can earn little to no margin on MPKs fit on patients with private insurance. (Argue, Tr. 6163-6171). Conversely, Dr. Argue concluded that Sophisticated Non-MPKs almost always earn the clinic some margin. (Argue, Tr. 6163-6171).

b. RAC audits encourage clinics to substitute Sophisticated Non-MPKs for MPKS

438. Medicare auditors tend to target high-cost items like MPKs for audit even though the financial risk to the clinic is not just the payment received for the MPK but for the entire prosthetic limb. (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 85, 103-105)).

439. RAC audits change how clinics do business, in terms of their documentation and approach to fitting process. (Ford, Tr. 972, Brandt, Tr. 3767; Asar, Tr. [redacted]; PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 39, 106-107); PX05135 (Weber (Prosthetic & Orthotic Care), Dep. at 30, 38)).

440. [redacted]

441. When RAC audits are more frequent, customers have tendency to select more non-MPKs to avoid the potential big repayment associated with a RAC audit. (De Roy, Tr. 3567). If a RAC audit disallows a payment, the clinic takes the loss, not the manufacturer. (De Roy, Tr. 3567).

442. [redacted]

443. Hanger identifies reimbursement issues and RAC audits as risk factors it faces in the prosthetics industry within its 10-K. (Asar, Tr. 1543).

444. In 2014, Hanger had $82 million in disallowed revenue as a result of audits. (Asar, Tr. 1552). In 2016, despite improving the paperwork process for reimbursement, Hanger had $49 million in disallowed revenue as a result of audits. (Asar, Tr. 1552).

445. If a doctor determines that a patient is eligible for an MPK, the patient could still receive a less sophisticated knee if that was their choice. (Kannenberg, Tr. 1944).

c. There is no evidence that all users of MPKs wear MPKs out of medical necessity

446. "Medical necessity justification" are criteria that have been established by insurance companies to determine eligibility for an MPK. (Kannenberg, Tr. 1833).

447. Dr. Kannenberg testified that his understanding of the term "medical necessity" from a physician standpoint is different than is used in the prosthetics field relating to insurance coverage eligibility. (Kannenberg, Tr. 1939).

448. Medical necessity refers to eligibility for a particular device. For example, CMS deems MPKs to be "medically necessary" for K-3 and K-4 patients. This means that MPKs are available to that patient population, but does not mean that every eligible patient must get an MPK. (Schneider, Tr. 4405; Kannenberg, Tr. 1944).

449. There are instances where a non-MPK and an MPK are both medically appropriate for the same patient. [redacted]

450. A patient could be clinically indicated for an MPK but an insurance company may nevertheless deny coverage. (Brandt, Tr. 3752).

451. Both MPKs and sophisticated non-MPKs are medically appropriate for patients with K-3 or K-4 mobility levels. (Sabolich, Tr. 5855).

452. Letters of medical necessity are about coverage determinations and eligibility; they are not about clinical determinations. (Doug Smith, Tr. 6016-17).

453. Most patients' providers do not require a letter of medical necessity to justify their prosthetic device. (Doug Smith, Tr. 6014-6015). Dr. Smith testified that most of the time he does not have to write a letter of medical necessity for either an MPK or a non-MPK. (Doug Smith, Tr. 6014-6015).

454. When selecting prosthetic components for patients, no one thing is perfect or absolute, and there advantages and disadvantages to each option, and is not the same as a life-and-death situation. (Doug Smith, Tr. 6004-05).

455. Dr. Doug Smith testified that he has prescribed an MPK for a patient and had a prosthetist refuse to fit that patient with an MPK. (Doug Smith, Tr. 6012).

456. Medical necessity is a spectrum, and does not mean the same in all medical scenarios. (Doug Smith, Tr. 6012). On one end of the medical necessity spectrum is an urgent and emergent medical condition, like if a patient's appendix is about to burst. In this scenario, the physician does not ask for permission from an insurance carrier, because it is clear the patient needs to go to the OR and have his or her appendix taken out. (Doug Smith, Tr. 6012-13). The next level on the medical necessity spectrum, according to Dr. Doug Smith, is a medical condition that is not emergent, and the physician decides on a treatment plan that the insurance carrier questions. In that scenario, the physician might have a conversation with the insurance carrier to explain his or her reasoning of the wisdom of that treatment plan. (Doug Smith, Tr. 6013). When it gets to the level of part A versus part B, they can manage with either of them, but one might be a benefit to the person in that they might be able to do a little better on uneven surfaces, they might be able to do better on stairs, so in that sense the term medical necessity is still used, even though it's very different than a life-and-death situation. (Doug Smith, Tr. 6016).

457. If a patient is classified as K-3, then medical necessity can be established for either an MPK or non-MPK. (Sabolich, Tr. 5855; [redacted]

458. Clinicians at times obtain "medical necessity" documentation after the prosthetist and patient have already decided on the type of knee the patient will receive. [redacted]

459. If insurance determines that an MPK is "medically necessary" for that patient as defined by that plan, the prosthetist, physician, or patient can still decide to use a non-MPK. (Schneider, Tr. 4405). This happens often. "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." (Schneider, Tr. 4405).

460. Dr. Doug Smith has had patients that are fit with an MPK, wear an MPK for a while, and later decide that they prefer a mechanical knee. (Doug Smith, Tr. 6011).

4. Manufacturers develop, manufacture, and sell non-MPKs and MPKs in the same fashion

461. Blatchford has been personally involved in the development of Endolite's MPKs and non-MPKs. (Blatchford, Tr. 2105). Blatchford uses the same formal five-stage process to develop its MPKs and non-MPKs. Blatchford, Tr. (2105-2107).

462. Freedom has a Product Approval Committee that is involved in the development and approval of Freedom's R&D projects; there is no committee specifically designated for the development of MPKs. (Carkhuff, Tr. 298; [redacted] Prince, Tr. 2680).

463. Endolite's sales force sell Endolite's whole product line. (Blatchford, Tr. 2129). Endolite utilizes a sales force and clinical team to promote its products in the United States. (Blatchford, Tr. 2130-2131).

464. Össur's total U.S. sales force is roughly fifty people, including representatives and clinicians. (De Roy, Tr. 3539; 3568). Össur's direct sales force sells both MPKs and non-MPKs. (De Roy, Tr. 3570).

465. Each of Ottobock's prosthetic sales reps sells Ottobock's full suite of prosthetic components. (Solorio, Tr. 1639).

466. Freedom's sales reps sell Freedom's feet, knees, and ankles. (Testerman, Tr. 1118). The job of Freedom's sales reps is to talk about features and benefits of Freedom's products and sell how Freedom's products are differentiated versus the competition. (Testerman, Tr. 1117-1118).

467. Freedom's sales reps help with the fitting process for all of Freedom's products, including the Plié 3. (Testerman, Tr. 1118-1119). Freedom's sales representatives assist clinics and patients with troubleshooting issues with Freedom products. (Testerman, Tr. 1119). Freedom's sales reps try to convert any competitive product, not just MPKs, to Plié sales. (Testerman, Tr. 1132).

468. It is important for Freedom's sales reps to understand what competitive knees, whether MPKs or non-MPKs, are being used at Freedom's key accounts so Freedom can develop a strategy to switch those customers to Plié 3. (Testerman, Tr. 1132-1133 ("There's multiple factors that go into the decision-making process in an office, is my understanding. And if you've seen one facility, you've seen one facility in the way in which they make a decision as far as what MPK they're going to put on a particular patient. If you're a large key account – I'll give you an example – COPC, they have a nice procedure that they go through to determine what prosthetic they're going to put on that particular patient. If you went to one that was less sophisticated like, say, a Yankee Bionics, then it's going to be a completely different process to try to determine what, call it, an MPK or an ankle is going to be put on that particular patient. So I just go back to what I said, that there's no real just A or B. There's A through Z as far as the decision-making process for what prosthesis is going to go on a patient, in my opinion.")).

5. Market Participants Recognize Competition By K-Level Classification

a. Competition defined by K-Level classification

469. [redacted]

470. Ottobock considers C-Leg 4 to compete with all K-3 and K-4 non-MPKs and MPKs that are available to most K-3 and K-4 patients. (Schneider, Tr. 4343).

471. According to Schneider, Sophisticated, Non-MPKs compete with MPKs for K-3 and K-4 users in the United States. (Schneider, Tr. 4329).

472. Maynard Carkhuff testified that Freedom competes for sales to clinics with all prosthetic knees that are suitable for K-3 and K-4 patients, and there are hundreds of brands of such knees on the market. (Carkhuff, Tr. 618).

473. Maynard Carkhuff testified that many more K-3 and K-4 patients are fit with non-MPKs than are fit with MPKs. (Carkhuff, Tr. 621).

474. Maynard Carkhuff testified that in Freedom's view they compete with every knee manufacturer, because there are so many different knees and a wide variety of patient and prosthetist preferences, so the sales reps have to be aware of what different offices are using to customize the sales pitch. (Carkhuff, Tr. 621).

475. Blatchford considers its three different non-MPKs sold by Endolite in the United States to all be appropriate for K-3 patients. (Blatchford, Tr. 2254).

476. [redacted]

477. The purpose of PAVET form at Hanger is to verify K-Level to determine eligibility for an MPK or a mechanical knee. (Asar, Tr. 1340).

478. The same patient could be a target patient for the Ottobock 3R80 non-microprocessor knee and the C-Leg 4 microprocessor knee. (Solorio, Tr. 1639). The same patient would not be a target patient for both the Ottobock C-Leg 4 and the Ottobock Kenevo, because those knees are designed for different K-Levels. (Solorio, Tr. 1639).

b. Evidence provided by sellers of MPKs highlight competition with non-MPKs

479. MPK manufacturers recognize that MPKs compete with non-MPKs. (Testerman, Tr. 1264; Schneider, Tr. 4404; [redacted]

480. [redacted]

[redacted]

481. [redacted]

482. Maynard Carkhuff testified that in Freedom's view they compete with every knee manufacturer, because there are so many different knees and a wide variety of patient and prosthetist preferences, so the sales reps have to be aware of what different offices are using to customize the sales pitch. (Carkhuff, Tr. 621).

483. [redacted]

484. [redacted]

485. [redacted]

486. [redacted]

487. [redacted]

488. Endolite's marketing material groups its non-MPKs and MPKs together under one "Knees" category. (RX-0814; [redacted]).

489. [redacted]

490. RX-0906 is marketing material from Össur that highlights MPKs and non-MPKs for K-3 and K-4 patients. (De Roy, Tr. 3634-3637). Össur markets the OP5, Total Knee, Rheo, Power Knee, Mauch Knee, and Rheo XC for K-3 and K-4 patients in the United States. (De Roy, Tr. 3634-3637). Össur distributes RX-0906 to clinics and patients so they have a clear overview of all of the available knee solutions for their activity level. (De Roy, Tr. 3637-3638).

491. Endolite's sales team in the United States meet with prosthetists and tout the benefits of its MPKs versus its non-MPKs because, "speaking economically, if we sell a microprocessor knee, we get more money that if we sell a non-microprocessor knee." (Blatchford, Tr. 2253).

492. Blatchford encourages Endolite's sales and marketing groups to highlight the differences between its MPKs and non-MPKs to encourage sales of MPKs. (2117-2121). "Because we think it's important that our customers are aware of those clinical benefits, because we think it will help promote the sale of our microprocessor knee products." (Blatchford, Tr. 2120).

493. Össur attempts to upgrade K-3 and K-4 users from non-MPKs to MPKs. (De Roy, Tr. 3662).

494. [redacted]

495. Dr. Kauffman testified that clinical studies that are cited by MPK manufacturers in advertising are intended to enable MPKs to better compete against non-MPKs. (Kauffman, Tr. 825; 892-893).

6. High-End MPKs Are In A Separate Product Market

496. Keith Senn testified that "Otto bock has a couple other knees that are considered higher end and I don't have by memory all the codes for those knees, but they have a couple above the C-Leg 4 that are for specific patients." (Senn, Tr. 204:15).

497. Mark Testerman believes that the Ottobock X3 and Genium do not compete with the Plié 3. (Testerman, Tr. 1263:11-16).

498. Vinit Asar, CEO of Hanger, referred to Genium and X3 as different and "high-end." (PX05153A (Asar, Dep. at 49); PX05153B (Asar, Dep. at 79); [redacted]

499. Össur considers Rheo XC, X3, Genium, Kenevo, Compact, and Sophisticated, No-MPKs to be in a different segment than the Rheo. (De Roy, Tr. 3602-3603).

500. [redacted]

501. The Rheo XC is not reimbursed by Medicare. (De Roy, Tr. 3639).

502. Össur considers Rheo XC's closest competitor to be Ottobock Genium. (De Roy, Tr. 3640).

503. Cali Solorio testified that generally the type of patient who has insurance coverage for the C-Leg 4 would not have the insurance coverage to qualify them for a Genium or X3. (Solorio, Tr. 1636)

504. Genium and X3 are usually sold through WC, VA, or DOD. (Solorio, Tr. 1636-37).

505. The X3 is Ottobock's most sophisticated MPK. (Schneider, Tr. 4337-4338). It was released on the U.S. market in 2015 as part of a development project with the U.S. Army and Department of Defense. (Schneider, Tr. 4338). The X3 is the only waterproof MPK sold in the United States. (Schneider, Tr. 4338).

506. Ottobock does not consider the prices of any other products when setting the price of the X3, it's in a league of its own. (Schneider, Tr. 4339).

507. Genium is the next most advanced MPK. (Schneider, Tr. 4339-4341). The original Genium was released in 2012, but it had a facelift within the last two years. (Schneider, Tr. 4340). It offers five different modes and a vast array of rule sets that increase performance. (Schneider, Tr. 4340). The only product that competes with the Genium is the X3, but Ottobock does not consider the prices of other knees when setting the price of the Genium. (Schneider, Tr. 4341-4342).

508. [redacted]

509. [redacted]

D. Dr. Argue's Conclusions Regarding Market Definition

510. Dr. Argue concluded that the properly defined market for this analysis should be the market involving all fluid-controlled knees, excluding the very high-end and integrated products. (Argue, Tr. 6144).

511. Dr. Argue concluded that very high-end MPKs are more expensive than base-level MPKs and they are not adequately reimbursed by Medicare. (Argue, Tr. 6146). Össur's Power Knee is not in the relevant market defined by Dr. Argue because it is priced much higher than other knees and serves a different purpose. (Argue, Tr. 6156).

512. Reimbursement is particular important to the economic analysis of this Acquisition according to Dr. Argue. (Argue, Tr. 6152, 6229-6231). Medicare has created a capitated reimbursement program that is followed by the private insurers as well. (Argue, Tr. 6152, 6229-6231). Dr. Argue considered the fact that suppliers of prosthetic knees have testified that they take reimbursement into account when they are setting prices for prosthetic knees. (Argue, Tr. 6152-6153, 6229-6231).

513. According to Dr. Argue, there is significant evidence in the record regarding the functional interchangeability of MPKs and Sophisticated, Non-MPKs. (Argue, Tr. 6162-6163).

514. Dr. Argue also performed a Hypothetical Monopolist Test. (Argue, Tr. 6163-6171). According to the Hypothetical Monopolist Test, if each clinic switched one MPK to a non-MPK every four years in response to a five percent increase by a hypothetical monopolist of MPKs, then the market would Sophisticated, Non-MPKs. (Argue, Tr. 6170). In reviewing the record, Dr. Argue found sufficient customer testimony to support a willingness to switch from an MPK to a Sophisticated non-MPK in the event of a price increase of five to ten percent. (Argue, Tr. 6172-6192).

515. Dr. Argue calculated market shares based on units rather than revenues because differentiated products with different price points that are one-for-one substitutes should be measured in units and not revenues under § 5.2 of the *Merger Guidelines*. (Argue, Tr. 6194).

516. Dr. Argue concluded that clinics and suppliers all consider all base MPKs to be alternatives to one another and the marketplace is characterized by repeated and consistent interbrand switching. [redacted]

517. Dr. Argue concluded that the properly defined market for this analysis should be the market involving all fluid-controlled knees, excluding the very high-end and integrated products. (6144).

518. Dr. Argued concluded that there is essentially no likelihood of adverse competitive effects as a result of the acquisition. (Argue, Tr. 6144).

519. Dr. Argue concluded that very high-end MPKs are more expensive than base-level MPKs and they are not adequately reimbursed by Medicare. (Argue, Tr. 6146).

520. Dr. Argue found that Ottobock had a share of 48.6 and Freedom had a share of 6.2 percent in the relevant market. (Argue, Tr. 6147). The combined share was 54.8 percent. (Argue, Tr. 6147).

521. Dr. Argue concluded that there would be little likelihood of competitive harm arising, in either the market defined by Professor Scott Morton or in the market defined by Dr. Argue as a result of the acquisition because prosthetics clinics have sufficient alternatives to prevent the combined entity from raising prices above competitive levels or producing quality that's below competitive levels. (Argue, Tr. 6148).

522. Dr. Argue testified that he has no doubt that Plié is not the closest competitor to the C-Leg 4, and he contends that Plié 3 is probably one of the most distant MPK competitors to the C-Leg 4. (Argue, Tr. 6150).

523. Buyers in this case are prosthetic and orthotic clinics who purchase prosthetic knees. (6150). Hanger is the largest buyer of prosthetic knees in the United States, and it has the ability on its own to negotiate lower prices from prosthetic knee suppliers because it has sufficient leverage. (Argue, Tr. 6151-6152, [redacted] Hanger is also

uniquely positioned to thwart any attempts to raise price because it can and has diverted volume between various suppliers. (Argue, Tr. 6152, [redacted]

524. Reimbursement is particular important to the economic analysis of this Acquisition. (6152, 6229-6231). Medicare has created a capitated reimbursement program that is followed by the private insurers as well. (Argue, Tr. 6152, 6229-6231). All suppliers of prosthetic knees have testified that they take reimbursement into account when they are setting prices for prosthetic knees. (Argue, Tr. 6152-6153, 6229-6231).

525. Dr. Argue concluded that the proposed divestiture to [redacted] would ameliorate any competitive concerns that might arise from the overlap in products between Ottobock and Freedom. (Argue, Tr. 6153).

526. Össur's Power Knee is not in the relevant market defined by Dr. Argue because it is priced much higher than other knees and serves a different purpose. (Argue, Tr. 6156).

527. Economic theory and economic formulae can be "nice shortcuts," but they cannot substitute for analysis of the real world evidence in the record. (Argue, Tr. 6157).

528. According to Dr. Argue, there is significant evidence in the record regarding the functional interchangeability of MPKs and Sophisticated, Non-MPKs. (Argue, Tr. 6162-6163).

529. Dr. Argue also performed a Hypothetical Monopolist Test. (Argue, Tr. 6163-6171). According to the Hypothetical Monopolist Test, if each clinic switched one MPK to a non-MPK every four years in response to a five percent increase by a hypothetical monopolist of MPKs, then the market would Sophisticated, Non-MPKs. (Argue, Tr. 6170). In reviewing the record, Dr. Argue found sufficient customer testimony to support a willingness to switch from an MPK to a Sophisticated non-MPK in the event of a price increase of five to ten percent. (Argue, Tr. 6172-6192).

530. Dr. Argue calculated market shares based on units rather than revenues because differentiated products with different price points that are one-for-one substitutes should be measured in units and not revenues under § 5.2 of the *Merger Guidelines*. (Argue, Tr. 6194).

531. Dr. Argue concluded that clinics and suppliers all consider all base MPKs to be alternatives to one another and the marketplace is characterized by repeated and consistent interbrand switching. (Argue, Tr. 6209-6217).

532. The closeness of competition between the products of the merging parties is critical to anticompetitive effects analysis under the *Merger Guidelines*. (Argue, Tr. 6217-6219).

533. Dr. Argue concluded that Ottobock and Freedom are not close competitors. (Argue, Tr. 6220). The Plié is functionally inferior to the C-Leg and at the end of its product lifecycle. (Argue, Tr. 6220-6223). There are many other products that have been introduced to the market since the Plié 3 in 2014, including the Össur Rheo, Endolite Orion 3, and Nabtesco Allux that function more similarly to the C-Leg 4 than the Plié 3 does. (Argue, Tr. 6220-6223). Dr. Argue stated that Freedom markets and prices its Plié differently than Ottobock

markets and prices the C-Leg. (Argue, Tr. 6224-6226). Clinics and MPK suppliers also consider the Plié 3 and C-Leg to be not particularly close competitors. (Argue, Tr. 6226-6228).

534. [redacted]

535. [redacted]

536. [redacted]

537. [redacted] For instance, the C-Leg 4's battery can last up to 48 hours, but it can take a few hours to charge. (Solorio Tr. 1645-1646.)

E. Criticisms Of Fiona Scott Morton

538. [redacted]

539. [redacted]

540. [redacted]

541. [redacted]

[redacted]

542. [redacted]

543. [redacted]

544. [redacted]

545. [redacted]

546. [redacted]

547. [redacted]

548. [redacted]

549. [redacted]

550. [redacted]

551. [redacted]

[redacted]

552. [redacted]

553. [redacted]

554. [redacted]

555. [redacted]

556. [redacted]

557. [redacted]

558. [redacted]

559. [redacted]

560. [redacted]

561. [redacted]

562. [redacted]

[redacted]

563. [redacted]

564. [redacted]

IV. COMPETITIVE EFFECTS

A. The Alleged MPK-Only Market Was Very Competitive And Marked By Constant Innovation Before The Acquisition

565. Complaint Counsel acknowledge that manufacturers in their alleged market competed on the price and features of their MPKs to secure the business of prosthetic clinics, even though they also claimed that Ottobock had a leading market share pre-Acquisition. (Compl., ¶¶ 9, 26).

566. Industry participants describe the MPK segment as very competitive (Testerman, Tr. 1183 ("And it's a very competitive marketplace. So we are taking some business from C-Leg 4. We're taking some business from Rheo 3. We're taking business from the Orion 3, the Allux. We don't discriminate who we try to take market share from."; 1147 ("It's a very competitive market, and we have to find ways to differentiate ourselves as we discussed so far here today, and this is just another program that we implemented in order to stay competitive in order to try to take share from all microprocessor knees.")).

567. With respect to the MPK segment, industry participants recognize that "there's always so much going on with different products that are being launched" and the technology is rapidly changing. (Testerman, Tr. 1103; Doug Smith Tr. 5994).

568. [redacted]

569. Patients are actually open to different makes of MPK when they replace their MPK, evidently because "technology changes so fast in three to five years." (PX05151, Patton (Prosthetic Solutions), Dep. at 105)).

570. All MPK manufacturers view every other base-level MPK on the United States market to be its competition in the MPK segment. (Blatchford, Tr. 2144; Testerman, Tr. 1262-1263). Blatchford testified that the Orion 3 competes against all other MPKs on the U.S. market, including the Ottobock C-Leg, Össur Rheo, Freedom Plié, Nabtesco Allux, and the MPK from DAW. (Blatchford, Tr. 2144).

571. Maynard Carkhuff testified that Ottobock, Össur, Endolite, DAW, and Nabtesco all sell microprocessor knees in the United States, and Freedom competes with all of those manufacturers. (Carkhuff, Tr. 617)

572. The direction of the technology now is going towards powered prosthetics, and right now the Össur Power Knee is leading that innovation, because it is the only powered knee on the market in the United States. (Doug Smith, Tr. 5995).

573. Clinicians have observed that competition from both Össur and Endolite has compelled Ottobock and Freedom to improve their products. (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 109)).

574. Dr. Doug Smith testified that all MPK manufacturers are trying to improve the durability of their products and their software, and all are trying to innovate. (Doug Smith, Tr. 5997-98).

575. Mark Ford believes that four MPK manufacturers are "actively trying to get POA's business" even though he sells less than seven MPKs per year (Ford, Tr. 945-946).

576. Since Freedom launched the Plié 3 in 2014, the following products have been released in the United States: The Orion 3, the Allux, the Rheo 3, the current Rheo, the Rheo XC, the Symbionic, the Linx, the C-Leg 4, and the Genium facelift. (Schneider, Tr. 4398).

B. Freedom's Plié 3 And Ottobock's C-Leg 4 Are Not Close Competitors

1. Freedom's Plié 3 Technology And Functionality Is Inferior And Outdated Relative To Other MPKs Sold In The United States

577. Among prothetic knees that contain a microprocessor, the Plié 3 is most functionally distant from the C-Leg 4. (Schneider, Tr. 4351; [redacted] Kannenberg, Tr. 1881; Solorio, Tr. 1646-1647; Sabolich, Tr. 5859-5860).

578. [redacted]

579. [redacted]

580. The Plié 3's pneumatic cylinder leaks air over time and must be pumped up manually, in fact, the knee leaks air often enough that users of the Plié 3 are supposed to carry their bicycle pumps around with them. (Kannenberg, Tr. 1953; Schneider, Tr. 4314-4319, [redacted]

581. The patient has to adjust the air pressure constantly because pressure in the Plié 3 is always changing either due to leakage or temperature or atmospheric changes. Changes to the air pressure in the Plié 3 can materially affect the swing phase of the knee increasing the chances that the user will stumble and fall. (Schneider, Tr. 4314-4319).

582. The pneumatic bladder in the Plié provides pressure to the hydraulic cylinder and because it is pressurized, it tends to leak, which is why it needs to be recharged with an air pump. (Blatchford, Tr. 2136).

583. Maynard 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." [redacted]

584. Maynard Carkhuff stated that Plié is at the very end of its product life cycle. (Carkhuff, Tr. 616).

585. Maynard Carkhuff testified that Freedom's engineers believe that Plié is an old design, and having been redesigned a number of times, that there are very few improvements that they can make to the product based on its current technology platform. (Carkhuff, Tr. 616).

586. Prior to the Acquisition, Freedom considered whether it could release the changes as a new iteration of the Plié, the Plié 4, but market intelligence concluded that the improvements were not significant enough for Freedom to "credibly call it a Plié 4." (Ferris, Tr. 2324; [redacted]

587. [redacted]

588. The microprocessor in the Plié works differently than all of those products. (Schneider, Tr. 4322-4323). The difference between all of the former MPKs and the Plié 3 is important to K-3 and K-4 amputees. (Schneider, Tr. 4323). The variable resistance is what's important because it can adjust and vary the resistance to make the gait of the knee more natural, safe gait. (Schneider, Tr. 4323).

589. If a user has a Plié 3 and wants to change the resistance level for the stance phase of his or her Plié 3, to, for example, go for a bike ride, they have to make an appointment with the prosthetist for an adjustment. (Schneider, Tr. 4312).

590. Prosthetists do not like the fact that Plié 3 users must pump the pneumatic cylinder with air using a bike pump. (Sabolich, Tr. 5861). Sabolich testified, "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." (Sabolich, Tr. 5861).

591. [redacted]

592. [redacted]

593. [redacted]

594. Scott Schneider strongly disagrees with the allegation that when the Plié 3 was launched, it offered similar or better functions than the C-Leg at a discounted price. (Schneider, Tr. 4359). Plié 3 had very little advancements over the Plié 2. (Schneider, Tr. 4359-4360). The only thing it offered was IP67 rating. (Schneider, Tr. 4360).

595. The Plié 3 has had very minor updates since its launch in 2014. (Testerman, Tr. 1172-1173).

596. The Plié 3 is more similar to a non-MPK than it is to the C-Leg 4, and is not a particularly close competitor to the C-Leg 4 given its difference in functionality, quality, and price. (Doug Smith, Tr. 6020; Sabolich, Tr. 5859-5860; Solorio, Tr. 1646; Kannenberg, Tr. 1981-82; [redacted] Carkhuff, Tr. 619-620 (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.").

597. Prosthetists must make manual adjustments to set up the Plié. (Ell, Tr. 1709).

598. Freedom believes that the Plié 3 is really at the end of its design cycle and Freedom feels that there is very little more that we can do to improve that product," [redacted]

599. [redacted]

600. [redacted]

601. The issues with the Plié 3's pneumatic air chamber changing pressure and requiring pumping will increase the user's chance of stumbling. (Schneider, Tr. 4394). The swing phase of the Plié 3 is erratic and not controlled by the microprocessor. (Schneider, Tr. 4397).

602. If you have a Plié 3, you need to carry around a pump with you when you leave home. (Schneider, Tr. 4397).

2. Freedom's Recommendation That Plié 3 Is An L5856 Knee Is Improper

603. Maynard Carkhuff testified regarding the difference between Plié 3 and other MPKs: "our 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." (Carkhuff, Tr. 335).

604. The Plié 3's coding recommendation for L5856 swing and stance microprocessor control is not proper and is costing the U.S. taxpayer money. (Schneider, Tr. 4383). Its coding should be downgraded and reimbursement should be less by two to six thousand dollars per knee. (Schneider, Tr. 4384). [redacted]

605. The Plié is really more of a hybrid knee, which is basically just a mechanical swing and stance controlled knee with an MP-switch. (Schneider, Tr. 4351; Kannenberg, Tr. 1881).

606. [redacted]

3. There Is Very Little Evidence Of Head-To-Head Competition Between The C-Leg And The Plie

607. Prosthetic industry participants consider Ottobock's C-Leg 4 to be the gold standard and market-leader in the industry, including distributors, prosthetists, physicians, and other manufacturers. [redacted] Oros, Tr. 4794-95; Blatchford, Tr. 2144-2145; [redacted] Ell, Tr. 1797-98; De Roy, Tr. 3591 (Össur believes that C-Leg is the market leader because they were first, and "because it's a really good knee)).

608. Maynard Carkhuff testified that Ottobock introduced the first swing and stance MPK to the US Market in 1998 and there was a period of time when Ottobock sold the only available swing and stance MPK in the United States, the C-Leg. (Carkhuff, Tr. 616).

609. The launch materials for the C-Leg 4 focused more on Össur and Endolite, than on the Plie. (Schneider, Tr. 4344, 4434-4436). The only functionality that the C-Leg has incorporated in response to the Plié is its IP67 rating. (Solorio, Tr. 1642-6643). Ottobock markets the C-Leg 4 as weatherproof. (Solorio, Tr. 1641).Freedom markets the Plié 3 as waterproof. (Solorio, Tr. 1641-42).

610. Freedom admits that the Plié 3 should not contact salt or chlorinated water. (Ferris, Tr. 2330). Freedom's use of the word waterproof to describe an IP-67 rated product confuses practitioners. (Solorio, Tr. 1642). The "rule sets" in Ottobock MPKs are the brains in the computer which tells the valves to open and close to control the variance and the resistance of the valves. (Schneider, Tr. 4347).

611. The Ottobock C-Leg 4 is the market leader in the United States because "it is a very good product." (Blatchford, Tr. 2144). The C-Leg is considered a very reliable knee. (Blatchford, Tr. 2145). The launch of the C-Leg 4 had an immediate impact on the sales of Össur. (De Roy, Tr. 3679-3680).

612. The entire prosthetics industry benefits from the clinical studies that Ottobock does. (Kannenberg, Tr. 1933).

613. Over the years, Ottobock's MPKs have been subjected to various clinical studies, over sixty. (Schneider, Tr. 4360).

614. Those clinical studies reveal that some of Ottobock's MPKs are safer and require less energy than non-MPKs. (Schneider, Tr. 4360-4361).

615. PX01499 was created in response to the misleading and false advertising claims being made by Freedom related to the functionality of the Plié 3. (Schneider, Tr. 4376-77).

616. Össur and Endolite have not made misleading and false advertising claims about the functionality of the Rheo and Orion, respectively, therefore Ottobock has not created similar PowerPoints targeting their products. (Schneider, Tr. 4377).

4. [redacted]

617. [redacted]

618. Blatchford considers the Orion 3 to be the closest competitor to the C-Leg 4. (Blatchford, Tr. 2213:25-2214:2). Blatchford considers the Orion 3 to be functionally and qualitatively as good as the C-Leg 4. (Blatchford, Tr. 2214).

619. Blatchford considers the Orion 3 to be functionally superior to Freedom's Plié 3. (Blatchford, Tr. 2214). "Because the stance control mechanism on the Plié is basically a simple – the stance control mechanism on the Plié is a simple on/off lock, it will either lock

or it will be free to move, whereas the stance control on the Orion 3 can vary the resistance from a low resistance to a high resistance to a lock, hence you have more control. And also the swing phase on the Orion 3, there is greater control in the way it works than on the Plié." (Blatchford, Tr. 2214).

620. A transfemoral amputee would find the Orion 3 an easier knee to work with, it adapts better to the terrain, and it is just generally overall nice. (Blatchford, Tr. 2214-2215).

621. Endolite's Orion 3 does not have a large opening in the back of the knee like Freedom's Plié 3. (Blatchford, Tr. 2219).

622. One of the design criteria for both the Endolite Orion 3 and Linx was to increase the stability of the knee because Endolite felt, from feedback from its customers, that the previous versions weren't as stable as Endolite's main competitor, the C-Leg 4. (Blatchford, Tr. 2219). So Orion 3 includes something which is called stance support mode so that when the amputee is not walking, the limb will effectively lockup and be stable. (Blatchford, Tr. 2219-2220).

623. The sensors in the Orion 3 and Linx have also been upgraded. (PX03176 at 10; Blatchford, Tr. 2220-2221). Previously, the Orion 2 just had a sensor which registered the weight going through the knee and a sensor which registered how much the knee had flexed, whereas in the Orion 3 it's been replaced by what we call an IMU, which will actually – will tell the knee the position in space the knee is at, where it is, whether it's flexed, and so on, and that gives the control unit more information about what the knee is doing. (PX03176 at 10; Blatchford, Tr. 22202220-2221).

624. The hybrid cylinder in the Orion 3 and Linx was also improved. (PX03176 at 10; 2221). "And the improvement is that we've spent quite a lot of time on the seals so that the unit is more reliable, it leaks less, and can actually deal with higher pressures within the hydraulic element of it." (Blatchford, Tr. 2221). The Orion 3, nor its predecessor versions, does not require an external pump to set the resistance level in the swing phase of the knee. (Blatchford, Tr. 2221).

625. Orion 3 also added weatherproofing. (PX03176 at 10; 2221). The Orion 3 can now work outside in the rain or if it gets splashed with water. (PX0376-10; 2221-2222). There is no particularly consistent set of definitions surrounding the terms weatherproof and waterproof; what Endolite means is that the Orion 3 can be worn in adverse weather conditions but you cannot swim with it. (Blatchford, Tr. 2223-2224). The Orion 3 is also dustproof. (Blatchford, Tr. 2225).

626. The Orion 3 also offers intuitive software, which is software that is easy to use. (PX03176 at 10; Blatchford, Tr. 2226). Endolite has recently launched some apps so users can manipulate the programming of the Orion 3 with their smart phone. (Blatchford, Tr. 2226).

627. Endolite significantly upgraded the battery in the Orion 3 and Linx. (Blatchford, Tr. 2226). While the Orion 2's battery could only last for a day and a half, the Orion 3's battery life is three days. (Blatchford, Tr. 2226). The Orion 2 offered a nickel metal hydride battery, whereas the Orion 3 offers a lithium ion battery. (Blatchford, Tr. 2226).

628. Endolite's Orion 3 uses a combination of hydraulics and pneumatics to modify the resistance in the swing and stance phases of the knee. (Schneider, Tr. 4399)

629. Ottobock does not consider Endolite's Orion 3 to be inferior to Freedom's Plié 3 because it is a full MP-Swing-and-Stance knee. (Schneider, Tr. 4399-4400).

630. [redacted]

631. Freedom uses the Ideal Combo to compete against all competitor knees, including the C-Leg 4, Orion 3, or the Rheo 3, and it was not developed to combat the C-Leg 4 launch. (Testerman, Tr. 1146, 1201; Ferris, Tr. 2314, 2316).

632. There is nothing special about the Ideal Combo as a sales promotion; Freedom's Sales team could use other discounting programs besides the Ideal Combo to make sales. (Testerman, Tr. 1149-1150).

633. Freedom had used the demo knees program in key accounts prior to 2015 when Ottobock launched the C-Leg 4, and the demo knee program has been effective versus C-Leg 4, Orion 3, Rheo, and other MPKs. (Testerman, Tr. 1193).

634. PX01166 was an email from February 2016 from Freedom's senior product manager who manages the marketing of the Plié 3 to the highest executives at Freedom. (Testerman, Tr. 1268:25-1270:2). Freedom's product manager for the Plié 3 was concerned about an advertisement from Össur regarding the Rheo 3. (Testerman, Tr. 1270). The claims raised by Össur regarding the Rheo 3 were discussed by Freedom's SMC. (Testerman, Tr. 1270:14-21). Pages 4 and 5 reflect "a competitor update that again is designed to go to the field force to give them messaging and understanding and learning of what they need to do and say to compete in this case versus Össur's microprocessor knee." (PX01166; 1271:1-16). Freedom's use this document to sell Plié 3 to Freedom's key accounts. (Testerman, Tr. 1271-1272).

635. PX01167 is an email from Plié 3's product manager to the highest-level executives at Freedom regarding Endolite's launch of the Orion 3 in late December 2016. (Testerman, Tr. 1272). It is important for the SMC and executives at Freedom to have an understanding of all competitive threats to the Plié 3, including the launch of Endolite's Orion 3. (Testerman, Tr. 1272-127). PX01167 was designed to combat the competitive threat from Orion 3. (Testerman, Tr. 1273).

636. Page 4 of PX01167 is "an example of a competitor info document, similar to what we've seen, the Plié 3 versus the Orion 3. It's the goal of our marketing and clinical teams to provide our sales force with the correct selling points, messaging points, to be able to compete versus our competitors." (Testerman, Tr. 1273-1273).

637. In December 2015, Testerman was hearing from Freedom's national and key accounts about the release of the Orion 3 in the United States. (Testerman, Tr. 1273). PX01167 helps Freedom's sales team drive revenue and profitability for Freedom related to the Plié 3. (Testerman, Tr. 1274).

638. RX-0268 is an email from Maynard Carkhuff, Freedom's Chairman and former CEO, in August 2016. (Testerman, Tr. 1274). Carkhuff was warning Freedom executives about the launch of Nabtesco's new four-bar MPK, the Allux. (RX-0268; 1274). Freedom was seriously concerned about the competitive impact of Nabtesco's Allux even before it was fully launched in the United States. (RX-0268; Testerman, Tr. 1274).

639. "Nabtesco positions it as the ultimate safety knee as it uses a very safe mechanical geometry and MPC controlled hydraulic swing and stance control." (RX-0268; 1275:1-6). The list price of the Nabtesco Allux in 2016 was $17,485, roughly eight percent less than the Plié 3. (RX-0268; Testerman, Tr. 1275).

640. Plié 3's product manager responded: "We have had our eye on this product as well. We have provided the product info into the Quattro team a while ago to ensure we are up-to-date and aware of the continued changing market and product introductions." (RX-0268; Testerman, Tr. 1275).

641. Plié 3's product manager shared the Nabtesco Allux information with the Quattro R&D team because Freedom wanted to make sure that when new technology like Nabtesco's Allux is launched into the United Sates that Freedom understands that technology and can potentially incorporate that technology into the development of the Quattro. (RX-0268; Testerman, Tr. 1276).

642. Nabtesco's competitive significance in the United States has changed recently due to its acquisition of Ability Dynamics and the RUSH Foot. (Testerman, Tr. 1276).

643. RX-0277 is an email from September 2016 from Testerman to Matthews and Presswood. (Testerman, Tr. 1296). Freedom's VP of Sales (Matthews) asked Testerman to provide him with reasons why Plié 3 sales were declining in 2016. (Testerman, Tr. 1296). Testerman identified the top 5 reasons for the Plié 3's decline in 2016 as follows: (i) quality issues; (ii) loaner issues; (iii) introduction of the Allux by Nabtesco; (iv) aggressive pricing at $11,000 from Endolite with the Orion 3; and accounts switching from the Plié 3 to Non-MPKs based on reimbursement and audit pressures. (RX-0277; Testerman, Tr. 1296-1298). These five issues were raised by the SMC team regarding decline in Plié 3 sales. (RX-1299 at 1-4).

644. Testerman did not include competition from Ottobock's C-Leg 4 in his e-mail (RX-0277) because "it wasn't a top five issue" causing Plié 3 sales decline. (Testerman, Tr. 1299).

645. [redacted]

5. Ottobock's C-Leg Competes Most Closely With [redacted] With Respect To Functionality, Quality And Reliability

646. Other MPKs that offer functionality similar to the C-Leg include Össur Rheo and Össur Rheo XC, the Endolite Orion 3 and Linx, the Nabtesco Allux, and DAW Stealth. (Schneider, Tr. 4322).

647. Össur considers the C-Leg 4 is functionally superior to the Plié 3. (De Roy, Tr. 3593). The Orion is functionally more comparable to the Plié according to Össur. (De Roy, Tr. 3594).

648. [redacted]

649. [redacted]

650. C-Leg 4's closest competitor is Össur's Rheo, because it is most similar to the C-Leg 4 in terms of functionality, quality, and price. [redacted] Doug Smith, Tr. 6020; Sabolich, Tr. 5858).

651. Maynard Carkhuff testified that Ottobock and Össur are the leading manufacturers of prosthetic knees for active and former military. (Carkhuff, Tr. 595).

652. Ottobock considers Össur's Rheo to be C-Leg 4's closest competitor. (Solorio, Tr. 1646; Kannenberg, Tr. 1981).

653. Össur's Rheo MPKs use magnetorheological ("MR") fluid to modify the resistance of the knee in swing and stance phase, but Ottobock does not consider Össur's Rheo to be inferior to Plié 3 because of the different types of technology platforms. (Schneider, Tr. 4398-4399).

654. Rheo competes with the following MPKs: C-Leg, Orion, Plié, Allux, Genium and X3. (De Roy, Tr. 3582).

655. Whether an insurer covers the Rheo depends on the patient's plan. (De Roy, Tr. 3582).

656. A former perceived disadvantage of the Rheo was that if it lost power, the knee would become free swinging; however, the latest version of the Össur Rheo does have a manual knee lock to mitigate this disadvantage. (Blatchford, Tr. 2149-2150). If the Rheo loses power, the knee enters free swing mode, so it can no longer provide variable cadence control, but it does offer a mechanical lock that can be engaged to stiffen the knee. (De Roy, Tr. 3581). Freedom learned that Össur had developed a new, manual safety lock for the Rheo 3 knee for circumstances where the knee lost power. (Ferris, Tr. 2333-2334; PX01176-003). There are also warning signals that prevent users from forgetting to recharge the Rheo. (De Roy, Tr. 3581).

657. Össur's Rheo is a very good knee that has been successfully marketed in the United States according to Blatchford. (Blatchford, Tr. 2235-2236).

658. Dr. Potter testified that the only knees he was familiar with are Ottobock and Össur knees, and that he had never heard of Freedom prior to the government calling him and telling him about the acquisition. (Potter, Tr. 787-788, 791-792).

659. After the Rheo, the next closest competitor to C-Leg 4 is the Endolite Orion 3, given its similar functionality. (Sabolich, Tr. 5859 (testifying that if the C-Leg and Rheo were not available, he would look to Endolite Orion 3 because it is the third-best option); Kannenberg, Tr. 1981).

660. [redacted]

6. Freedom's Plié 3 Targets Price-Sensitive Prosthetists And Patients

661. Freedom's Plié 3 tends to be less expensive than all other MPKs sold in the United States. (Blatchford, Tr. 2148).

662. [redacted]

663. Maynard Carkhuff testified that the Plié 3 is priced below C-Leg 4 because the Rheo and the Orion3 are more recent designs based on technology platforms that offer more features and benefits, and the Plié 3 has limited functions and capabilities relative to those products. (Carkhuff, Tr. 622-23).

664. [redacted]

665. [redacted]

666. C-Leg 4 does not compete with Plié 3 on price. [redacted] Ford, Tr. 1044 (POA clinicians believe that C-Leg is simply a better product than the Plié due to quality of their product and service; [redacted]

667. Össur considers the C-Leg 4 to be functionally superior to the Plié 3. (De Roy, Tr. 3593). The Orion is functionally more comparable to the Plié according to Össur. (De Roy, Tr. 3594). The two lowest priced MPKs are the Plié and the Orion. (De Roy, Tr. 3596). They are lower priced than the Össur Rheo and Ottobock C-Leg. (De Roy, Tr. 3597).

668. Even Tracy Ell, who was called to testify by Complaint Counsel testified that Mid-Missouri purchased 10 to 12 C-Leg 4s in 2017 and "not very many" Plié 3s. (Ell, Tr. 1740-41).

669. [redacted]

670. Plié 3 is COPC's preferred knee according to its guidelines for K-3 amputees is Freedom's Plié 3 because of the discount arrangement between Freedom and COPC. (Senn, Tr. 180).

671. [redacted]

672. [redacted]

673. [redacted] COPC also received a rebate on each Plié 3 that COPC bought over a certain amount, and that rebate is still in effect post-acquisition. (1237-1238).

674. [redacted]

675. [redacted]

676. [redacted]

677. The Orion 3, Nabtesco Allux, and Ottobock Compact are priced most closely to the Plié 3. (Schneider, Tr. 4355).

678. [redacted]

679. Freedom's Vice President for National and Key Accounts was aware of clinics that were paying around $11,000 for the Orion 3. (RX-0277; Testerman, Tr. 1296-1299).

7. Össur's Rheo And Ottobock's C-Leg Compete Most Closely On Price

680. [redacted]

681. [redacted]

682. [redacted]

683. The two lowest priced MPKs are the Plié and the Orion. (De Roy, Tr. 3596). They are lower priced than the Össur Rheo and Ottobock C-Leg. (De Roy, Tr. 3597).

684. Ottobock considers the price of the Rheo and Rheo XC when setting the price of the C-Leg 4. (Schneider, Tr. 4343-4344). It does not consider the price of the Plié. (Schneider, Tr. 4344). [redacted]

685. [redacted]

686. Össur characterizes its Rheo as a "mainstream" MPK with a list price of $19,500. (De Roy, Tr. 3532). Össur characterizes its Rheo XC as a "step up" from the Rheo with a list price between $26,000 and $27,000. (De Roy, Tr. 3532).

687. [redacted]

8. [redacted]

688. [redacted]

689. [redacted]

690. [redacted]

b. [redacted]

691. [redacted]

692. [redacted]

693. [redacted]

694. [redacted]

695. [redacted]

696. [redacted]

697. [redacted]

698. [redacted]

699. [redacted]

700. [redacted]

701. [redacted]

702. [redacted]

703. Kinnex's durability issues have "absolutely" impacted Freedom's overall revenue. (Testerman, Tr. 1251). "[W]hen you have a product that is rocking and rolling, like that product was, and you have revenue that's exceed or exceeding a million dollars and then that product is removed, it can have a – it can have a dramatic effect." (Testerman, Tr. 1251).

704. Freedom has not provided a date certain for when the Kinnex is going to be returned to the United States market. (Testerman, Tr. 1252).

c. [redacted]

705. [redacted]

706. [redacted]

707. [redacted]

708. [redacted]

709. [redacted]

710. [redacted]

d. [redacted]

711. The Quattro is not a close competitor to C-Leg 4 because no one knows when Quattro will launch, what features it will have, how it will be priced, or if it will be a reliable product. (Testerman, Tr. 1252:11-14; [redacted]

712. [redacted]

713. [redacted]

714. [redacted]

715. [redacted]

716. [redacted]

717. [redacted]

718. [redacted]

719. [redacted]

720. [redacted]

721. [redacted]

722. [redacted]

723. [redacted]

724. [redacted]

725. [redacted]

726. "The Quattro project is a – another microprocessor knee that Freedom is looking to bring to market some day." (Testerman, Tr. 1252). There has been frustration from Freedom's sales team on the delayed development of the Quattro project. (Testerman, Tr. 1252).

727. [redacted]

728. [redacted]

729. [redacted]

730. [redacted]

731. [redacted]

732. [redacted]

733. [redacted]

734. [redacted]

735. [redacted]

736. [redacted]

737. [redacted]

738. [redacted]

739. [redacted]

740. [redacted]

741. [redacted]

e. [redacted]

742. [redacted]

743. [redacted]

744. [redacted]

745. [redacted]

746. [redacted]

C. Customers Of MPKs Repeatedly And Consistently Engage In Inter-brand Switching

747. Prosthetists regularly substitute between various types of MPKs for K-3 and K-4 patients. (Schneider, Tr. 4403).

748. [redacted]

749. [redacted]

750. "Prosthetists substitute based off of a patient's specific and individual needs. They could also make a decision based off of the history of the patient, if they have a high rate of falls, for example, or if they have a particular profession, surgeons, for example, short steps. They also, depending upon the payer and the contract that the prosthetist has or from a margin perspective could also play an important role in that decision on which microprocessor knee to use." (Schneider, Tr. 4403).

751. Prosthetists also switch depending on quality. (Schneider, Tr. 4403-4404). "The market is extremely fickle. The margins .. are getting smaller and smaller and the transactional costs are higher and higher. If a company falters on its commitment to quality or has quality issues, it is damaged quickly, and prosthetists will make an immediate change." (Schneider, Tr. 4404).

752. Prosthetists also make immediate changes to other MPKs based on price. (Schneider, Tr. 4404).

1. Prosthetics Clinics Are Price Sensitive And Will Switch Between MPKs Due To Price

753. COPC purchased more Pliés than Össur MPKs because Freedom "gave very aggressive pricing based on the volume of knees that we purchased from Freedom." (Senn, Tr. 192).

754. [redacted]

755. If the price of the Plié went up, one prosthetist testified that "I just wouldn't use it. I would use the Orion 3." (PX05151 (Patton (Prosthetic Solutions), Dep. at 123)).

756. [redacted]

757. [redacted]

758. [redacted]

[redacted]

759. [redacted]

760. [redacted]

761. [redacted]

2. Price Discounts In The Prosthetics Industry Are Often Based On Volume Discounts, So It Is Beneficial To Clinics To Drive Volume Toward A Few Suppliers

762. The price offered by Endolite to COPC for the Orion 3 is without negotiating any volume discounts. (Senn, Tr. 254). If COPC negotiated volume discounts with Endolite and COPC moved volume to COPC, the price paid by COPC for the Orion 3 would go down even further. (Senn, Tr. 254-255).

763. Some prosthetics clinics require their prosthetists to follow purchasing guidelines related to the selection of MPKs and non-MPKs for K-3 and K-4 users of prosthetic knees. (Senn, Tr. 154-155, 179, 230). Those guidelines provide the clinics' prosthetists with preferred products to which the clinics would like to drive volume because of contracts and discounts with manufacturers of those products. (Senn, Tr. 179).

764. COPC's negotiations with manufacturers of MPKs focus primarily on volume discount arrangements. (Senn, Tr. 195). COPC negotiates pricing with MPK manufacturers annually. (Senn, Tr. 195).

765. Though COPC has not yet had a need to do so, COPC could switch enough MPK volume to Össur that would give COPC a discount that would be comparable to Freedom. (Senn, Tr. 193).

766. The prosthetist makes the decision of which knee will be ordered for a particular patient. (Senn, Tr. 205-206). COPC publishes a preferred guideline to its practitioners, but practitioners are "not required to completely follow [the guideline] in every case." (Senn, Tr. 205-206). COPC's guideline specifies that Freedom's Plié 3 is its preferred MPK due to the costing o the knee. (Senn, Tr. 205, 208). The Plié 3 is COPC's preferred MPK because of its low cost and the higher margin it affords COPC. (Senn, Tr. 208). If a prosthetist at COPC wants to choose an MPK besides Plié 3, the prosthetist needs to justify that decision by sending a request to the general manager explaining why, and the general manager must approve the request. (Senn, Tr. 209-210).

767. All MPKs are available to every prosthetic clinic, even if it is not a product that the clinic typically purchases. (Ell, Tr. 1731). A prosthetist from Mid-Missouri testified that MPKs

from Ottobock, Freedom, Össur, Endolite, and DAW are available for purchase). (Ell, Tr. 1731)

768. Mark Ford testified that even though POA has not purchased an Össur Rheo in the last three years, POA still makes the Rheo available for "test driving." (Ford, Tr. 955).

769. Clinics can negotiate for better prices on a volume basis. (Senn, Tr. 195). Price sensitive clinics want to "drive volume as much as they can." (Senn, Tr. 207).

770. Keith Senn is not familiar with the Nabtesco Allux at this time, but he believes that COPC could switch purchases of MPKs from Freedom to Nabtesco if COPC got educated on Nabtesco's MPKs. (Senn, Tr. 194).

771. All MPK manufacturers market to all prosthetics clinics and try to win their business, even if it has not historically been a large customer. (Ell, Tr. 1732 (Testifying that he does not buy MPKs from Össur, but that the Össur sales reps still come out and demonstrate the knee to his clinic; Ell, Tr. 1736-1737 (Ottobock, Freedom, Össur, and Endolite have all provided demonstrations on MPK knees and training coursework to Mid-Missouri)

772. Clinics describe pricing negotiations as being based on driving volume, do not describe them as based on playing one manufacturer against another. [redacted] Ford, Tr. 904, 935-937; [redacted]

a. Reimbursement encourages switching

773. The amount of reimbursement that COPC receives from Medicare and private insurance does not vary depending on the brand of MPK, and brand is not indicated on reimbursement submission. (Senn, Tr. 200).

774. The reimbursement is paid according to L-Codes and is manufacturer agnostic. (Schneider, Tr. 4352; Kannenberg, Tr. 1934).

775. Mark Ford believes that the most important person in knee provided is the insurance company, and they do not have a preference as between MPKs manufacturers, as long as the L-Codes are the same. (Ford Tr. 920).

776. All MPK manufacturers use clinical studies that study Ottobock knees to market their MPKs and encourage switching (Kauffman, Tr. 892-893).

D. Expansion Into The Alleged MPK Market Would Be Timely, Likely, And Sufficient

777. There is minimal investment in hiring and training additional sales representatives (Schneider, Tr. 4286; Testerman, Tr. 1255-1256). Freedom's regional sales managers are paid somewhere in the mid-$70,000 range. (Testerman, Tr. 1257-1258). New prosthetics

sales representatives can be trained to sell MPKs and other products in three months or less. (Schneider, Tr. 4286; Testerman, Tr. 1255-1256).

778. None of Freedom's regional sales managers sell only the Plié 3 in the United States, they sell all of Freedom's products. (Testerman, Tr. 1258).

779. Prior to joining Freedom, Testerman had no experience selling MPKs. (Testerman, Tr. 1248:17-20). Testerman was able to start effectively selling Plié 3 within a month or two. (Testerman, Tr. 1248-1249).

780. [redacted]

781. POA sells a little less than seven MPKs per year on average. (Ford, Tr. 945-946)

1. Freedom Was Not Ottobock's Only Competitive Constraint In The MPK-Only Market

782. For clinics who primarily buy Freedom and Ottobock MPKs, this is not borne out of necessity, and other firms can constrain prices at those clinics. [redacted]

783. [redacted]

784. If any prosthetics supplier in the U.S. acquired Freedom's MPK assets, they would acquire an immediate presence in the MPK segment in the United States. (De Roy, Tr. 3726).

785. Pricing of the Plié 3 has had only a "limited effect" on Össur's and Ottobock's pricing. (De Roy, Tr. 3676).

786. [redacted]

787. [redacted]

788. [redacted]

2. Össur Is A Significant Competitive Constraint

789. Össur sells the Rheo, Rheo XC, and Power Knee in the United States. (De Roy, Tr. 3576). The Power Knee is a powered microprocessor-controlled device. (De Roy, Tr. 3576).

790. [redacted]

791. [redacted]

792. Össur offers the full range of lower-limb prosthetic products to restore mobility. (De Roy, Tr. 3537).

793. [redacted]

794. Össur is constantly innovating its MPKs. (De Roy, Tr. 3545). "I think it's fair to say that we always have projects ongoing for MPKs. Since we developed the Rheo Knee, there's been continuous improvements and updates and upgrades to the product, so we are always working on a project of that type, yes." (De Roy, Tr. 3545).

795. The 2017 upgrade version of the Rheo was the fourth generation Rheo, but Össur dropped the numbering system and called it simply the Rheo. (De Roy, Tr. 3545).

796. Össur is constantly innovating its MPKs "because it is a competitive field and we want to make sure that we have the ability to compete with other products that are on the market as well." (De Roy, Tr. 3546).

797. Over the last few years, the time frames of product launches have gotten shorter and new generations of MPKs are being launched more frequently. (De Roy, Tr. 3546).

798. Össur uses clinical studies to market its MPKs against non-MPKs. (De Roy, Tr. 3549).

799. Össur does not sell any MPKs or non-MPKs that require an external air pump. (De Roy, Tr. 3551-3552).

800. [redacted]

[redacted]

801. [redacted]

802. [redacted]

803. [redacted]

804. [redacted]

805. [redacted]

806. [redacted]

807. [redacted]

3. Endolite Is A Significant Competitive Constraint [redacted]

808. Blatchford is a global company employing about 900 people worldwide. (Blatchford, Tr. 2208).

809. Adrian Stenson has been Endolite's global CEO since April 1, 2015. (Blatchford, Tr. 2208).

810. Stenson manages the day-to-day operations of Endolite while Stephen Blatchford handles strategic initiatives and product development. (Blatchford, Tr. 2208-2209).

811. Stenson is also tasked with achieving Endolite's ambitious growth plant to increase its revenues from $60 million pounds per year to 125 million by 2020 and 250 million by 2025. (Blatchford, Tr. 2209).

812. Professor Saeed Zahedi is Endolite's Director of Technology and also sits on Endolite's management team. (Blatchford, Tr. 2210). He has a background in prosthetic and orthotic technology and a Ph.D. from Strathclyde University. (Blatchford, Tr. 2211). He is a knight. (Blatchford, Tr. 2211).

813. [redacted]

814. Endolite has a significant U.S. presence with about eighty total employees, sixty of whom are located at Endolite's U.S. headquarters in Miamisburg, Ohio. (Blatchford, Tr. 2211; 2213). Endolite's Ohio headquarters manages marketing, finance, and administrative functions and also manufactures hydraulic cylinders for Endolite's fluid-controlled, non-MPKs. (Blatchford, Tr. 2213). John Braddock is the U.S. sales manager, and John Hawke is financial controller for the U.S. business. (Blatchford, Tr. 2211-2212).

815. Endolite's U.S. sales force reports to John Braddock and consists of two regional sales managers for the east and the west, respectively, and fifteen sales representatives

816. [redacted]

817. [redacted]

818. [redacted]

819. [redacted]

820. After a slow start the Orion 3 has done very well in the U.S. market and has been stealing market share. (Schneider, Tr. 4400).

821. [redacted]

822. [redacted]

[redacted]

823. [redacted]

824. [redacted]

825. [redacted]

826. [redacted]

827. [redacted]

828. [redacted]

829. [redacted]

830. [redacted]

831. [redacted]

832. "Endolite was taking a very aggressive approach in the pricing of their [Orion 3]. In particular, I can think of an account outside of Memphis, Tennessee, Human Technologies,

where we were losing share because they were offering in some cases buy more than one knee, you receive a price of $11,000 per knee. And that was costing us business." (Testerman, Tr. 1297-1298).

833. Mark Ford believes that competition from Endolite has caused improvements in innovation in MPKs. (Ford, Tr. 1050-1052; PX05145 (Ford, Dep. at 144)).

834. There have been increasing amounts of head-to-head trial battles between Orion 3 and C-Leg 4. (Solorio, Tr. 1647). Endolite's Orion 3 is a good product and is an improvement over the Orion 2. (Solorio, Tr. 1647). Endolite is becoming a stronger competitor to Ottobock as a result of the improved quality of Orion 3. (Solorio, Tr. 1647).

835. Prosthetic clinics believe that the Orion is becoming more interchangeable as a result of the improved quality of that product. (PX05128 (Senn, Dep. at 107)).

836. If the Plié stopped being available or increased in price, COPC would consider buying more Orions. (Senn, Tr. 256). At COPC, Orion, C-Leg, and Plié are on the OK to provide list on the product selection guide, and Orion and Plié received the same rating on that guide selection system. [redacted]

837. The only complaints voiced by customers regarding Endolite have to do with its size, and not the quality of its products. (Ford, Tr. 967; [redacted]

838. [redacted]

839. [redacted]

840. [redacted]

841. [redacted]

842. [redacted]

843. [redacted]

844. [redacted]

[redacted]

845. [redacted]

846. [redacted]

847. [redacted]

848. [redacted]

849. [redacted]

850. [redacted]

851. [redacted]

852. [redacted]

853. [redacted]

854. [redacted]

855. [redacted]

856. [redacted]

857. [redacted]

858. [redacted]

859. Freedom executives routinely shared competitive information regarding Endolite's Orion 3. (Ferris, Tr. 2338; PX01176-005). Freedom had noted that the Orion 3 offered three days of battery life versus the one day of battery life with the Plié 3. (Ferris, Tr. 2340 (PX01176-005).

4. Nabtesco Proteor Is A Market Participant [redacted]

860. Nabtesco Proteor was started in 2016 and is relatively new to the marketplace. (Mattear, Tr. 5518).

861. Nabtesco manufactures the Allux and other Sophisticated, Non-MPKs. (Mattear, Tr. 5541-5542). Nabtesco manufactures the Hybrid and Symphony knees. (Mattear, Tr. 5568; RX-0345). The Symphony knee utilizes six-bar technology, is considered very sophisticated and took a lot of engineering to develop. (Mattear, Tr. 5573-5574). It utilizes p-MRS technology that uses geometrics and proprietary technology to detect different gait phases of the knee and adapt the stability accordingly. (Mattear, Tr. 5574; RX-0897; Mattear, Tr. 5580-5582). It has a hydraulic cylinder and allows for manually-adjusted extension and flexion adjustments. (Mattear, Tr. 5576). It has excellent flexion of 170 degrees offering greater range of motion than other K-3 and K-4 knees on the market. (Mattear, Tr. 5577).

862. The Hybrid Knee has MP-Swing control and hydraulic stance control. (Mattear, Tr. 5594-5597; RX-0345-003). It is billed as a swing-only knee with L-Code L5857, not L5856, which has negatively impacted sales. (Mattear, Tr. 5595). It does offer a unique battery that can last for a year without requiring recharge, which is one reason users chose the Hybrid knee. (Mattear, Tr. 5596-5597).

863. The Allux's four-bar technology allows for greater toe clearance which lowers the tendency that a user will stumble or fall. (Mattear, Tr. 5616-5617; RX-0894 at 008).

864. The Allux offers greater range of motion than its primary MPK rivals. (Mattear, Tr. 5617). It offers 155 degrees of flexion, more than MPKs on the market. (Mattear, Tr. 5617). The Allux also allows users to bike. (Mattear, Tr. 5618).

865. The Allux can also accumulate up to two years of user data that can be shared with a prosthetist to assist with performance and reimbursement. (Mattear, Tr. 5619-5620; RX-0894-015).

866. The Allux has an internal battery that only takes 3 hours to charge, and it also offers a backup battery for emergencies. (Mattear, Tr. 5621-5622).

867. RX-0898 shows the benefits of the Allux versus the C-Leg 4, Össur Rheo, Endolite Orion 3, and Freedom Plié 3, including greater flexion angle and longer battery life. (Mattear, Tr. 5622-5626). The Allux is also the lowest price option. (Mattear, Tr. 5630-5632; RX-0898). A clinician would earn the highest margin on an Allux relative to the C-Leg, Rheo, Orion, and Plié. (Mattear, Tr. 5632; RX-0898).

868. [redacted]

869. [redacted]

870. [redacted]

871. The introduction and penetration of the Allux in the United States was causing Freedom some "heartbreak" in 2016, even while the Allux was still in beta release. (Testerman, Tr. 1297). Nabtesco also has an ex-Freedom certified prosthetist working for it and their national sales director came from SPS and had over 20 years' experience in the prosthetics industry; according to Testerman, she "had great relationships and knew the industry inside and out." (Testerman, Tr. 1297).

872. [redacted]

873. [redacted]

874. [redacted]

875. [redacted]

876. Össur is familiar with Nabtesco and its MPK, the Allux. (De Roy, Tr. 3594-3595). The Allux offers multiaxial, polycentric design. (De Roy, Tr. 3595). To De Roy's knowledge, Nabtesco did not have direct sales force in the United States. (De Roy, Tr. 3595).

877. [redacted]

878. [redacted]

879. [redacted]

880. [redacted]

881. Blatchford is familiar with Nabtesco, and the MPK it sells in the United States, the Allux. (Blatchford, Tr. 2150).

882. Endolite's Chairman, Stephon Blatchford, considers Nabtesco's Allux to be "quite a nice functioning knee." (Blatchford, Tr. 2227). Blatchford had not yet heard about Nabtesco's distribution arrangement with Proteor in the United States. (Blatchford, Tr. 2227). Blatchford is familiar with Proteor, a French prosthetics company owned by the Pierron family that has been in business for about 90 years. (Blatchford, Tr. 2227).

883. Blatchford is aware of the fact that Proteor acquired Ability Dynamics. (Blatchford, Tr. 2228). Ability Dynamics makes the Rush Foot which competes with Endolite's line of prosthetic feet in the United States. (Blatchford, Tr. 2228).

884. Blatchford believed that Nabtesco lacked an adequate U.S. sales force. (Blatchford, Tr. 2229) Nonetheless, he believed that it would only take Nabtesco six months to a year to hire the necessary sales force and another six months to train the sales force to effectively compete in the United States. (Blatchford, Tr. 2229).

885. Nabtesco is part of Kobe Steel, a very large Japanese manufacturer. (Blatchford, Tr. 2229).

886. Blatchford agreed to execute an affidavit in this case to avoid coming to the United States of an investigational hearing. (Blatchford, Tr. 2230) Blatchford modified the draft affidavit that was prepared by Complaint Counsel in this case to add the word "currently" to the following sentence: "Nabtesco is not currently a meaningful competitor for microprocessor knees." (Blatchford, Tr. 2231-2234; [redacted] RX-0707). "I was concerned that the original version didn't reflect the functionality of the knee, and therefore I was concerned that if the sales support structure around that sold the product was better, then it could become a competitor, a meaningful competitor, because there is nothing wrong functionally with the knee they sell." (Blatchford, Tr. 2234). "If they would add a sales force, it would mean that we would – and if they did a good job, we would worry about it, yes." (Blatchford, Tr. 2234-2235).

887. The Allux as a "relatively new product" and as a "new entrant" into the market, that has started to show recurring interest in the field. (Collins, Tr. 3280-81, 3305).

888. Jeff Collins testified that Nabtesco's Allux is starting to show recurring interest in the field. (Collins, Tr. 3305).

889. Jeff Collins testified that with the right investment of resources, there are some things that Cascade could do that would increase the sales of the Allux, such as the addition of salespeople, clinical staff, and a reimbursement support team, and the creation of a loaner pool. (Collins, Tr. 3305-3306).

890. Jeff Collins testified that an exclusive distribution arrangement would allow a distributor to invest in a product and be rewarded for making that investment. (Collins, Tr. 3307).

891. Jeff Collins believes that an exclusive distribution arrangement incentives a distributor to dedicate more resources to a product than it otherwise would. (Collins, Tr. 3307).

a. Nabtesco Proteor has repositioned [redacted] Allux's market share

892. Proteor France wants to significantly grow its U.S. business, and that is why it has acquired Ability Dynamics and entered into an exclusive distribution agreement with Nabtesco Corporation in 2018. (Mattear, Tr. 5562).

893. [redacted]

894. [redacted]

895. [redacted]

896. [redacted]

897. [redacted] One of Nabtesco's engineers developed the technology currently used in the C-Leg. (Mattear, Tr. 5534). Nabtesco also developed the technology that was used in the first MP-Swing knee sold by Endolite, the IP knee. (Blatchford, Tr. 2141-2142). Nabtesco has a very good reputation for quality and innovation. (Mattear, Tr. 5534-55357).

898. Nabtesco Proteor had a very small operation in Wisconsin until it acquired Ability Dynamics in 2018 and its large sales and clinical team. (Mattear, Tr. 5518-5520; 5527-5528). Nabtesco Proteor now has seven sales representatives, a certified prosthetist clinician, and a business development manager. (Mattear, Tr. 5527-5528; 5555-5559; 5563-5564). Ability Dynamics also makes the Rush Foot, which is a sophisticated fiberglass foot. (Mattear, Tr. 5555-5561).

899. Ability Dynamics was a start-up that developed a fiberglass foot technology. (Testerman, Tr. 1278). That technology, combined with a strong combination of experienced, former Freedom sales reps, marketing, and clinical allowed Ability to do a very nice job in taking share from Freedom and other foot manufacturers. (Testerman, Tr. 1278).

900. Prior to being acquired, Ability Dynamics had 27 or 28 employees. (PX05158 (Swain (Ability Dynamics), Dep. at 9)). Ability Dynamics had multiple consulting certified prosthetists who assist in product development, continuing education, and attendance at trade shows. (PX05158 (Swain (Ability Dynamics), Dep. at 14)). Dynamics has a sales team in the US selling to prosthetists and international distribution. (PX05158 (Swain (Ability Dynamics), Dep. at 16-17)).

901. Ability Dynamics sells six types of mechanical prosthetic feet. (PX05158 (Swain (Ability Dynamics), Dep. at 19)). Ability Dynamics has tested feet from Ottobock, Össur, Freedom, Endolite, Fillauer, and College Park. (PX05158 (Swain (Ability Dynamics), Dep. at 23)).

902. Freedom launched the Maverick glass composite foot to compete directly with Ability Dynamics. (PX05158 (Swain (Ability Dynamics), Dep. at 23-24)). Although Freedom's product is similar and identical in color, it is an inferior product. (PX05158 (Swain (Ability Dynamics), Dep. at 24-26)).

903. Ability Dynamics sells feet to the VA and Hanger/SPS. (PX05158 (Swain (Ability Dynamics), Dep. at 43-44)). An advertising arrangement between SPS and Ability Dynamics allows it to reach more customers. (PX05158 (Swain (Ability Dynamics), Dep. at 60)).

904. Ability Dynamics considers its foot products differentiated from others in the market and puts product quality at a premium. (PX05158 (Swain (Ability Dynamics), Dep. at 62-63)).

905. Ability Dynamics has different types of mechanical feet in its R&D product pipeline. (PX05158 (Swain (Ability Dynamics), Dep. at 90)).

906. According to a study under peer review for publication by Dr. Kaufman of the Mayo Clinic, patients have significantly higher satisfaction with glass composite feet than carbon fiber feet. (PX05158 (Swain (Ability Dynamics), Dep. at 109-110)).

907. Unique glass composite construction makes Rush foot the best performing prosthetic foot on the market. (PX05158 (Swain (Ability Dynamics), Dep. at 126-127)). This is based on patient feedback about their quality of life and ability to do things. (PX05158 (Swain (Ability Dynamics), Dep. at 126-127)). Prosthetists enjoy a margin of two to three times above list price on Rush products. (PX05158 (Swain (Ability Dynamics), Dep. at 128)).

908. Industry trends support increasing domestic and international demand for Rush Foot products. (PX05158 (Swain (Ability Dynamics), Dep. at 128)).

909. Prior to Nabtesco/Proteor's acquisition of Ability, it had one sales rep; it now has eight sales reps to sell the Allux in the United States. (Testerman, Tr. 1278-1279).

910. Nabtesco Proteor's certified prosthetist is Craig Armstrong, a former employee of Freedom. (Mattear, Tr. 5564-5565). He has been at Nabtesco Proteor for about a year. (Mattear, Tr. 5566).

911. Four or five of the sales reps that Nabtesco Proteor acquired with the Ability Dynamics acquisition used to work at Freedom and have experience selling the Plié 3. (Mattear, Tr. 5566-5567).

912. Nabtesco Proteor presented the Allux at the 2018 Hanger Education Fair, a significant opportunity for Nabtesco Proteor to educate prosthetists from around the United States on the features and benefits of the Allux. (Mattear, Tr. 5608; RX-0894). Craig Armstrong and Akio Sakata, certified prosthetists, demonstrated the Allux and its various benefits and features at the Hanger Education Fair. (Mattear, Tr. 5608; RX-0894).

913. Nabtesco Proteor started to exclusively distribute Nabtesco Corporation's products in September 2018 and has the exclusive right to supply the Nabtesco Allux in the United States through its direct sales force. (Mattear, Tr. 5521; 5525-5526; RX-0896; RX-0167; Mattear, Tr. 5546-5547). Nabtesco believes this new business structure will be more advantageous than the previous structure. (Mattear, Tr. 5554).

914. [redacted]

915. [redacted]

916. [redacted]

917. [redacted]

918. Competitors are taking note of Nabtesco's recent growth. Freedom's Vice President of National and Key Accounts noted that Nabtesco's exclusive distribution arrangement with Proteor, Inc. give him "a lot heartburn." (Testerman, Tr. 1276).

919. As part of the Ability Dynamics acquisition, Nabtesco Proteor acquired Ability Dynamics' seven sales reps, five of whom used to work at Freedom and four of whom reported to Testerman when he was Vice President of Domestic Sales. (Testerman, Tr. 1277). Those four sales reps have "extensive knowledge of microprocessor knees and the Plié," of large microprocessor knee customers, and relationships based on their tenure at Freedom. (Testerman, Tr. 1277). The fifth former Freedom sales person is the Freedom's former National Sales Director. (Testerman, Tr. 1277). Nabtesco Proteor's current manager is a certified prosthetist and also an ex-Freedom clinical specialist. (Testerman, Tr. 1277-1278).

920. According to Testerman, "this recent acquisition and the change with Proteor and Nabtesco I believe is dramatic and that – it keeps me up at night." (Testerman, Tr. 1278).

921. "The Allux product is very intriguing." (Schneider, Tr. 4400). The addition of Ability's aggressive and dedicated sales force and the RUSH foot product line will increase Allux's competitiveness in the U.S. (Schneider, Tr. 4400-4401).

922. The four-bar technology in the Allux actually shortens when the knee swings making it easier to clear the toe and avoid stumbling. (Ferris, Tr. 2357).

b. Allux is the ideal MPK for knee disarticulation patients, who are currently underserved by MPKs in the marketplace

923. A knee disarticulation is a subset of amputations, where the part of the leg is removed by dividing between the knee joint surfaces; separating the joint. (Doug Smith, Tr. 5981,

5985). Knee disarticulation patients require a knee joint as part of their prosthetic device. (Doug Smith, Tr. 5981-82).

924. Knee disarticulation has some advantages, such as allowing more weight-bearing on the residual limb, and more balanced thigh muscles. (Doug Smith, Tr. 5981, 5986). Dr. Doug Smith testified that if he could choose between knee disarticulation and transfemoral amputation, he would choose knee disarticulation, but a prosthetist finds it difficult to fit a prosthetic knee onto a knee disarticulation patient because the residual limb is long and the knees end up at different levels. (Doug Smith, Tr. 5987).

925. In Doug Smith's view, for a knee disarticulation patient, the most clinically appropriate knee is a four-bar linkage knee, and that patient should receive a four-bar knee, regardless of whether or not that knee has a microprocessor or not. (Doug Smith, Tr. 6017-6019).

926. The fact that a knee has four-bar linkage is a more important feature for knee disarticulation patients than the presence of a microprocessor. (Doug Smith, Tr. 6019).

5. DAW Is A Market Participant

927. DAW sells MPKs in the United States that are manufactured by Teh Lin in Taiwan. (PX05147 (Belzidsky (DAW), Dep. at 16, 23-24)). DAW sold 48 MPKs in the United States in 2016, and as of December 15, 2017, DAW had sold 44 MPKs. (PX05146, (Marquette, Dep. at 34-35)). DAW has been selling MPKs in the United States for a little over fifteen years. (PX05147 (Belzidsky (DAW), Dep. at 36)).

928. DAW also sells prosthetic feet, ankles, liners, skins, foam, and titanium components along with the prosthetic knees. (PX05146 (Marquette (DAW) Dep. at 23)).

929. It employs six or seven sales and customer service representatives. (PX05146 (Marquette (DAW) Dep. at 25)).DAW uses sales representatives to sell MPKs and non-MPKs and offers a full range of prosthetic products. (PX05147 (Belzidsky (DAW), Dep. at 34-35)).

930. DAW sets is prices for MPKs according to reimbursement amounts. (PX05147, Belzidsky, Dep. 50).

931. Dr. Doug Smith testified that Teh Lin markets in the United States through DAW industries, has driven advances in microprocessor knees, and has great knees. (Doug Smith, Tr. 5996).

932. Blatchford is familiar with DAW "to a limited extent." (Blatchford, Tr. 2151). Blatchford does not know the name of the DAW MPK and believes it had very little presence in the United States. (Blatchford, Tr. 2151).

933. [redacted]

934. [redacted]

935. [redacted]

936. [redacted]

937. [redacted]

938. DAW's Taiwanese manufacturer, Teh Lin could easily meet an increase in demand for MPKs. (PX05147, Belzidsky, Dep. 97-98).

939. DAW has plans to expand the sale of MPKs in the United States. (PX05147, Belzidsky, Dep. at 23).

940. Even DAW, which lacks the resources of the other MPK manufacturers, launched a new MPK, the Multi-Matrix Self-Learning Knee ("MTX"), in 2017. (RX-0734 (Declaration of Stuart Marquette (DAW Industries) Dec. 15, 2017) at ¶ 4).

E. Ottobock's Rationale For The Acquisition Was The Acquisition Of Freedom's Foot Products.

941. The primary strategic rationale for Ottobock's acquisition of Freedom was to [redacted]

942. [redacted]

943. Maynard Carkhuff testified that Freedom is most well-known for its carbon fiber foot products, it sells 18 foot products with 27 models, and roughly 75% of its annual revenue is derived from foot sales. (RX-0439; Carkhuff, Tr. 603-04).

944. [redacted]

945. Freedom has a great line of prosthetic feet. (Testerman, Tr. 1150). Freedom sells twenty-plus brands of feet in the United States. (Testerman, Tr. 1249:16-19). Freedom offers a large portfolio of feet, and prosthetists like them. (Ferris, Tr. 2316). Freedom offers feet that can fit any stage of the amputee experience. (Ferris, Tr. 2317-2318).

946. The market thinks very highly of Freedom's feet. (Ferris, Tr. 2316 ("We have done some studies and some, you know, qualitative, quantitative studies, and our feedback from that from our customer base says that they value them greatly); [redacted]

947. The market has a low perception of Ottobock's feet. ((PX05158 (Swain (Ability Dynamics), Dep. at 65, 83). Ability P&O noted that Ottobock has the worst prosthetic feet on the market, Össur and Freedom feet are higher quality. ((PX05158 (Swain (Ability Dynamics), Dep. at 65, 83).

948. Ottobock acquired Freedom to obtain its very desirable foot portfolio, where Ottobock has a gap. (Schneider, Tr. 4410).

949. [redacted]

950. [redacted]

951. [redacted]

952. [redacted]

953. [redacted]

954. Scott Schneider led the U.S. due diligence team related to the Acquisition. (Schneider, Tr. 4407). He analyzed the U.S. commercial market and reimbursement issues. (Schneider, Tr. 4407). Schneider analyzed Freedom's product portfolio and how to code Freedom's products. (Schneider, Tr. 4407).

955. Schneider's team did not look at potential pricing decisions for the Plié 3 or Freedom's foot portfolio. (Schneider, Tr. 4407).

956. Matt Swiggum played "very little" role in the due diligence and decision to acquire Freedom. (Schneider, Tr. 4408). He had only two or three comments during due diligence, and Schneider authored the diligence report and Swiggum just put his name on it. (Schneider, Tr. 4408).

957. Swiggum did not participate in any commercial due diligence meetings related to the Acquisition. (Schneider, Tr. 4411).

958. Swiggum did not analyze Freedom's product portfolio and how that would fit in with Ottobock's product portfolio. (Schneider, Tr. 4408).

959. The North American commercial due diligence team consisted of Schneider, Dr. Andreas Kannenberg, Scott Weber, Walter Governor, Sebastian Kuch, and Kimberly Hanson. Swiggum did not participate in the commercial due diligence efforts. (Schneider, Tr. 4409).

960. [redacted]

961. [redacted]

F. There Are Numerous Structural Competitive Constraints With Respect To Prosthetic Knees

962. Actual sales prices to clinics are determined by bilateral negotiations between prosthetic clinic and prosthetic manufacturer. (Brandt, Tr. 3770 (testifying that every year he has a negotiation with each manufacturer to negotiate price for the next year based on volume; PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 33))

963. [redacted]

964. [redacted] (Sabolich, Tr. 5866 (testifying that Sabolich testified that because Medicare "sets the price," that makes him "want to sort of stand up and scream why are we all here.")

965. Reimbursement rates constrain Össur's MPK pricing. (De Roy, Tr. 3557-3558). Reimbursement affects Össur's development plans and product line plans. (De Roy, Tr. 3557). Reimbursement is important for Össur to position its MPKs and how to price its MPKs. (De Roy, Tr. 3557-3558).

966. The price offered by Endolite to COPC for the Orion 3 is without negotiating any volume discounts. (Senn, Tr. 254). If COPC negotiated volume discounts with Endolite and COPC moved volume to COPC, the price paid by COPC for the Orion 3 would go down even further. (Senn, Tr. 254-255).

G. Hanger Is A Power Buyer That Constrains Manufacturers

1. Hanger Is A Large Organization That Plays A Big Role In The Prosthetics Industry In The United States

967. Hanger is a nationwide network of prosthetics and orthotics clinics. (Schneider, Tr. 4401). Hanger does business in 44 states and Washington, D.C. (Asar, Tr. 1307:14-19) Hanger is a publicly traded company, but was delisted from the New York Stock Exchange in 2016 and is currently traded on the OTC pink market. (Asar, Tr. 1530).

968. Hanger is composed of two business segments: Patient Care, and Products & Services. Products & Services has a distribution business (SPS) and therapeutic solutions business that calls on skilled nursing facilities (Asar, Tr. 1307-1308).

969. Hanger's total yearly revenue is $1 billion, with $850 million in the patient care segment. (Asar, Tr. 1307-1308).

970. Southern Prosthetic Supply ("SPS") is the distribution business of Hanger. (Asar, Tr. 1318-1319; Schneider, Tr. 4402). It has independent O&P clinics as its customers. (Asar, Tr. 1318-1319). The O&P clinics use SPS as a one-stop shop, rather than having to deal with numerous manufacturers. (Asar, Tr. 1318-1319).

971. Hanger represents a large portion of the Prosthetic Clinics in the United States. Hanger has 800 clinics across the country. It employs about 1,500 clinicians. By comparison, there are about 6,500 total clinicians in the US, and there are about 3,400 clinics. (Asar, Tr. 1312, 1313, 1316, 1317, [redacted] *see also* [redacted] (Carkhuff, Tr. 298:17-21) (testifying that Hanger is virtually every manufacturer's biggest customer in the United States); (Sanders, Tr. 5379) (testifying that Hanger is the largest O&P network that has a contract with United Healthcare in the United States)

972. Hanger owns its contract provider, Linkia, which helps non-Hanger clinics make reimbursement claims. (Schneider, Tr. 4401-4402).

973. Hanger is Ottobock's largest U.S. customer. (Schneider, Tr. 4401).

974. [redacted]

975. [redacted]

2. Hanger Exerts Significant Bargaining Power Over Manufacturers

976. [redacted]

977. [redacted]

978. [redacted]

979. [redacted]

980. Hanger is keenly aware of its significant leverage over manufacturers, given its size and ability to get better pricing and discounts. (Asar, Tr. 1554). Hanger lists as a "competitive strength" on their 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. (Asar, Tr. 1555).

981. [redacted]

982. [redacted]

983. [redacted]

984. [redacted]

3. Hanger Has Tools To Constrain Ottobock's Pricing Going Forward

985. One of Hanger's most important tools to shift volume to other manufacturers is Hanger's ability to control the prices that Hanger clinicians pay for prosthetic components. [redacted]

986. [redacted]

987. [redacted]

988. Hanger's past experience indicates that its clinicians will select MPKs based on price. [redacted]

989. One of Hanger's tools to constrain Ottobock's pricing is the opportunity that it has to provide centralized education to all of its clinicians and educate its clinicians about competitor or alternative products. The Hanger education fair is hosted in February, where Hanger has 1,000 of its employees come together, together with manufacturers, with a focus on providing education courses to the clinicians. (Asar, Tr. 1325; 1326; 1328 -1329).

990. [redacted]

4. [redacted]

991. [redacted]

992. [redacted]

993. [redacted]

994. [redacted]

995. [redacted]

996. [redacted]

997. [redacted]

998. [redacted]

999. [redacted]

1000. [redacted]

1001. [redacted]

1002. [redacted]

1003. [redacted]

H. The Acquisition Has Not Had Anticompetitive Effects In The Alleged MPK-Only Market

1. Freedom's Pricing And Promotions Have Remained Autonomous

1004. Since the acquisition, Ottobock never had any involvement in any of the day-to-day operations of Freedom. (1304:1-3). Since the acquisition, Ottobock has not given any directives to Testerman about negotiation prices with Freedom's key accounts. (1304). Since the acquisition, Testerman never had any conversations with anyone from Ottobock regarding pricing and promotions for the Plié 3. (1304). Since the acquisition, Freedom has continued to promote the Plié 3 to its key accounts and to try to take share from all of its competitors, including Ottobock. (1304).

1005. [redacted]

1006. [redacted]

1007. Michael Oros testified that as a major customer for prosthetic knees in the United States, he has no concerns about Ottobock's acquisition of Freedom, and he has no objection to the acquisition. (Oros, Tr. 4795-4796).

1008. Dr. Kauffman testified that he has observed no effects. (Kauffman, Tr. 893-894).

1009. [redacted]

1010. [redacted]

1011. [redacted]

1012. Tracy Ell testified that Mid-Missouri has not lost any sales or business opportunities as a result of the Acquisition, the Acquisition has not had any impact on Mid-Missouri's business, he is not aware of any clinics that have been impacted by the Acquisition, and he is not aware of any patients that have been impacted by the Acquisition. (Ell, Tr. 1799-1800).

1013. Tracy Ell testified that Mid-Missouri has not changed its ordering practices, and has not seen any changes in product prices since the Acquisition. (Ell, Tr. 1800).

1014. Freedom has continued to add sales representatives as needed after the acquisition; Freedom has 14 sales reps, including one that was added within the last 60 to 90 days. (Testerman, Tr. 1114-1115).

1015. [redacted]

1016. [redacted]

1017. [redacted]

1018. Freedom has continued to hire new, necessary personnel. Freedom has recently hired a senior director of quality, and she is on the Product Approval Committee ("PAC"). (Prince, Tr. 2680-2681).

1019. [redacted]

1020. [redacted]

1021. [redacted]

1022. [redacted]

2. [redacted]

1023. The Quattro was being designed to compete against all other microprocessor knees. (Testerman, Tr. 1208-1209).

1024. [redacted]

1025. [redacted]

1026. [redacted]

1027. [redacted]

1028. [redacted]

1029. [redacted]

1030. [redacted]

1031. [redacted]

1032. [redacted]

1033. [redacted]

1034. [redacted]

1035. [redacted]

1036. [redacted]

1037. [redacted]

1038. [redacted]

I. The Acquisition Will Promote Competition

1. Dual Brand Strategy

1039. [redacted]

1040. [redacted]

1041. [redacted]

1042. [redacted]

1043. [redacted]

1044. Maynard Carkhuff testified that since the acquisition, Freedom has required financial assistance from Ottobock and Ottobock has provided that assistance. (Carkhuff, Tr. 710)

1045. Maynard Carkhuff testified that as a person who cares about where Freedom's business is going, he believes that Freedom is better off as a result of the Acquisition by Ottobock. (Carkhuff, Tr. 710)

1046. Maynard Carkhuff believes that Freedom is better off as part of Ottobock, because "Otto Bock has long been admired as the best orthotic and prosthetic company in the U.S. and in the world. They're the most innovative. They have high integrity. They have the very highest quality. And certainly they have the resources to fund our projects, and to me, they've demonstrated the intent to do that, and they continue to support the company." (Carkhuff, Tr. 710-711).

1047. Maynard Carkhuff testified that Ottobock is "the ideal partner" and personally feels "very honored that they would respect Freedom and acquire Freedom, enable it to operate as an independent business and to enable us to maintain our own heritage." (Carkhuff, Tr. 711)

1048. [redacted]

1049. [redacted]

1050. [redacted]

1051. Testerman was a shareholder of Freedom when it was acquired by Ottobock in September 2017. (Testerman, Tr. 1299). As a shareholder, Testerman voted to approve the acquisition. (Testerman, Tr. 1299). Ottobock had a plan in place at the time of the acquisition to move forward as two separate entities under the one umbrella and that the entities would operate under a dual brand strategy. (Testerman, Tr. 1299-1300). The plan was communicated to Freedom's key accounts immediately after the acquisition that pricing and sales would remain completely separate in the United States. (Testerman, Tr. 1299-1300). On the Sunday before the acquisition, Carkhuff called Testerman to tell him about the separate entity strategy. (Testerman, Tr. 1300). "Within the next 48 hours, phone calls were had that confirmed that this was going to be the strategy moving forward: separate entities, dual-brand strategy, status quo, let's go take share from all microprocessor knees and all competitors." (Testerman, Tr. 1300).

1052. PX00824 is an email from Matthews to Hanger's highest-level field executives after the acquisition in October 2017. (PX00824; Testerman, Tr. 1300). It was a follow-up to a conference call regarding the dual brand strategy. (PX00824; Testerman, Tr. 1301-1302). PX00824 reflects Freedom's official corporate message to key accounts after the acquisition. (Testerman, Tr. 1302).

1053. [redacted] (Testerman, Tr. 1302). National O&P was a diamond status Ottobock account that had bought five C-Legs in the last three months and another patient ready to fit with a C-Leg. (Testerman, Tr. 1302-1303). Testerman did not ask anyone from Ottobock if he could go after a diamond status C-Leg account because Freedom was continue to operate aggressively against Ottobock pursuant to the dual brand strategy. (Testerman, Tr. 1303).

1054. Freedom's decision not to go forward with a sales strategy with Empire that it had discussed in May 2017 in no way related to Ottobock's acquisition of Freedom. (Testerman, Tr. 1303).

1055. As an executive that has been with Freedom since 2010, Testerman cares about what happens to Freedom. (Testerman, Tr. 1304). "There's no doubt in my mind that [Freedom is better after the acquisition]. Ottobock is a strong company, an innovative company. I love the idea of being able to move forward with this dual-brand strategy, coupled with the resources from Ottobock, and if Ottobock had not stepped in, who knows what it would be." (Testerman, Tr. 1305).

1056. Since the acquisition, Ottobock never had any involvement in any of the day-to-day operations of Freedom. (Testerman, Tr. 1304). Since the acquisition, Ottobock has not given any directives to Testerman about negotiation prices with Freedom's key accounts. (Testerman, Tr. 1304). Since the acquisition, Testerman never had any conversations with anyone from Ottobock regarding pricing and promotions for the Plié 3. (Testerman, Tr. 1304). Since the acquisition, Freedom has continued to promote the Plié 3 to its key accounts and to try to take share from all of its competitors, including Ottobock. (Testerman, Tr. 1304).

1057. As an executive that has been with Freedom since 2010, Testerman cares about what happens to Freedom. (Testerman, Tr. 1304). "There's no doubt in my mind that [Freedom is better after the acquisition]. Ottobock is a strong company, an innovative company. I love the idea of being able to move forward with this dual-brand strategy, coupled with the resources from Ottobock, and if Ottobock had not stepped in, who knows what it would be." (Testerman, Tr. 1305).

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1062. Prosthetic Clinics recognize that "if Freedom product line was managed under a stronger financial entity, it could help with product development." (PX05135 (Weber (Prosthetic & Orthotic Care), Dep. at 125)).

1063. After Ottobock acquired Freedom, there were no plans to lower the R&D budget for Ottobock. (Schneider, Tr. 4380).

1064. Since Acquisition in September 2017, Ottobock has not any involvement in the day-to-day operations of Freedom. (Schneider, Tr. 4413). Ottobock has not given any directives to Freedom on how to set prices. (Schneider, Tr. 4414). Ottobock has had no communications with Freedom regarding pricing or promotions. (Schneider, Tr. 4414).

1065. A dual brand strategy is when a single company will have two different brands and brand promises in the same market. (Schneider, Tr. 4414).

1066. Ottobock utilizes a dual brand strategy in markets outside the United States. (Schneider, Tr. 4414-4415). Ottobock utilizes the Polior brand in Brazil, Russia, India, and China. (Schneider, Tr. 4415). Ottobock uses the Polior brand to target price-sensitive customers and Ottobock as a more premium brand in those markets. (Schneider, Tr. 4415). The dual brand strategy has been successful for Ottobock in those markets. (Schneider, Tr. 4415).

1067. Since the date of the Acquisition, Schneider is not aware of anyone from Ottobock directing anyone from Freedom to change how Freedom markets its products. (Schneider, Tr. 4416).

1068. Schneider is not aware of anyone from Ottobock directing anyone at freedom to change how freedom is developing its next-generation MPK since the Acquisition. (Schneider, Tr. 4416).

1069. Schneider disagrees with the allegation that the Acquisition has already harmed consumers because neither company has done anything differently post-acquisition. (Schneider, Tr. 4416-4417). There has been no change in Freedom's operations except that Ottobock is now providing financial funding to Freedom so it can stay viable. Otherwise, Freedom would have gone out of business. (Schneider, Tr. 4417).

1070. Schneider disagrees with the allegation that Ottobock and Freedom sales personnel no longer have an incentive to compete against each other for sales because the plan is to keep the sales forces separate, therefore they are still competing in the marketplace against each other. (Schneider, Tr. 4417).

1071. [redacted]

1072. [redacted]

1073. Despite decreasing reimbursement rates and a lack of approval for new L-Codes, Ottobock has continued to innovate. (Schneider, Tr. 4299). The Compact is the predicate device for L-5858 and C-Leg is predicate for L-5856, and those codes did not exist when Ottobock developed those products. (Schneider, Tr. 4299-4300).

2. Ottobock Has Continued To Innovate Post-Acquisition

1074. The C-Leg 5 has been in development since February 2017. (Schneider, Tr. 4354). [redacted]

1075. [redacted]

3. Customers Have Not And Will Not Be Harmed By The Acquisition

1076. Ottobock's acquisition of Freedom has not impacted COPC's business at all. (Senn, Tr. 264). COPC is still receiving the exact same pricing it received before the acquisition. (Senn, Tr. 264-265). COPC has not lost any sales and its patients have not been impacted by the acquisition. (Senn, Tr. 265). Post-acquisition, COPC is still able to buy Freedom's Plié 3 at discounted prices offered pre-acquisition. (Senn, Tr. 265).

1077. Scott Sabolich testified that he understands why Ottobock bought Freedom, because Ottobock's foot portfolio is not very strong, and he thinks that Ottobock bought Freedom for the feet, not for the Plié. (Sabolich, Tr. 5866).

1078. Scott Sabolich testified that as a major customer for prosthetic knees in the United States, he does not have any concern that Ottobock's acquisition of Freedom would harm competition in the United States with respect to MPKs. (Sabolich, Tr. 5866-5867).

1079. Scott Sabolich testified that he believes that the Acquisition could benefit clinics, because Ottobock could improve the quality of the Plié. (Sabolich, Tr. 5867).

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2. The Acquisition Is Not Likely To Have A Substantially Adverse Effect On Competition In Any Relevant Market

a. Since the Acquisition, Ottobock has maintained the independence of Freedom and financially stabilized Freedom and competition has not been adversely affected

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e. Transition services

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V. FREEDOM WAS A FAILING FIRM

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

1. Freedom Was Failing By Virtually Every Financial Measure

1291. [redacted]

1292. Freedom's audited financial data for the years 2012 through 2016 is reflected in its audited financial statements, which are contained in RX-0822, [redacted] and RX-0824. Freedom's unaudited financial data for the first months of 2017 is contained in [redacted]

1293. [redacted]

1294. [redacted]

1295. Freedom's EBITDA was $6,347,000 in 2012; $4,180,000 in 2013; $3,414,000 in 2014; [redacted]

1296. Freedom's operating income was ($836,000) in 2012; ($4,061,000) in 2013; ($4,815,000) in 2014; [redacted]

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1308. 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. (RX-0451, at 11).

1309. [redacted]

1310. [redacted]

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1313. [redacted]

1314. Likewise, in early 2017, Freedom's financial condition was so dire that Smith believed that "we weren't going to make payroll" so Freedom "put . . . money in the trust account" that "could only be used for payroll and payroll taxes." (Smith, Tr. 6429-31). Freedom did the same thing later in the summer "during the bank negotiations." (Smith, Tr. 6431-32).

2. Freedom's Financial Projections Were Terrible

1315. [redacted]

1316. Smith believed that Freedom's projections were "cooked" and "misleading." (Smith, Tr. 6414-6417).

1317. The following chart compares Freedom's annual revenue projections prepared in 2012 for the years 2014, 2015, and 2016 to Freedom's actual annual revenue in the same years:[1]

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

1318. The following chart compares Freedom's annual EBITDA projections prepared in 2012 for the years 2014, 2015, and 2016 to Freedom's actual EBITDA in the same years:[2]

	2014	2015	2016
2012 Projected EBITDA	$25,055	$34,054	$42,991

[1] The information is compiled from RX-0005 at 00050 and RDX-06. Dollar figures represent thousands of dollars.

[2] The information is compiled from RX-0005 at 00050 and RDX-006. Dollar figures represent thousands of dollars.

Actual EBITDA	$3,414	[redacted]	[redacted]
Shortfall	($21,641)	[redacted]	[redacted]

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3. David Smith's Attempted Turnaround Failed

1330. Because Freedom's financial condition was so poor in 2016, Freedom replaced Carkhuff as CEO with David Smith, effective April 1, 2016. (Smith, Tr. 6413-6415).

1331. Before joining Freedom, Smith was a partner in HEP. (Smith, Tr. 6410).

1332. Smith surrendered his partnership with HEP after becoming the CEO of Freedom in order to avoid any potential conflict of interest. (Smith, Tr. 6410).

1333. Smith had no experience in the prosthetics industry before he joined Freedom. (Smith, Tr. 6411; *see also* Smith, Tr. 6411 (Smith confirming that he learned everything he knows about the prosthetics industry in the year and a half he served as CEO of Freedom.)).

1334. 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. (Smith, Tr. 6411-6412).

1335. Around the time he became CEO, Smith learned about Freedom's financial condition and concluded that prior management had "cook[ed]" the books and "misleading the board for a long time." (Smith, Tr. 6414-6415).

1336. Smith's initial objectives as CEO were to try to "improve product portfolio, improve, you know, customer satisfaction, improve profitability, improve innovation." (Smith, Tr. 6422).

1337. However, Smith 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." (Smith, Tr. 6422-6423).

1338. Smith attempted to implement a turnaround plan, but he identified significant obstacles that prevented him from doing so. For example, Freedom's products did not match the company's warranty and marketing claims. (Smith, Tr. 6423).

1339. In addition, Freedom's "team wasn't as competent as they needed to be to execute the strategy to be successful." (Smith, Tr. 6423).

1340. [redacted]

1341. [redacted] Smith, Tr. 6426; 6429).

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1346. The improvement in top line revenue in 2017 did not solve Freedom's financial problems because Freedom "needed capital." (Smith, Tr. 6429).

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1355. Smith did not have sufficient time before Freedom's outstanding debt was due to implement a turnaround plan. (Smith, Tr. 6424-6425).

1356. Smith believed 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. (Smith, Tr. 6424-6425).

1357. At the same time, it would have been difficult to raise capital because "until [Freedom] started getting some operational results, bringing in capital was going to be a difficult process because anybody that brings in capital is going to be intelligent and they're going to want to do due diligence, and [Freedom] never would have passed due diligence at that time." (Smith, Tr. 6423-24).

1358. [redacted]

4. Freedom's Pricing Strategy Was Not Sustainable

1359. [redacted]

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1364. From 2012 to YTD17, Freedom's gross margin was more than [redacted] basis points lower than guideline public companies ("GPCs") with operations similar to Freedom, according to Peterson. (RX-1048-0011 ¶ 22). GPC data are typically used to benchmark private companies against publicly traded companies. (RX-1048-0012 ¶ 23).

1365. Those margins indicate that [redacted] (RX-1048-0012 ¶ 24). Given the observed below-market margins, Freedom would likely need to raise its prices in order to achieve industry level margins. (RX-1048-0013 ¶ 24.b).

1366. Össur's YTD gross margin for the same time period was [redacted], approximately [redacted] basis points higher than Freedom's. (RX-1048-0012 ¶ 24.a) If Freedom increased its prices to achieve a gross margin consistent with Össur, Freedom's YTD17 EBITDA would have been [redacted] higher than the company's actual performance. (RX-1048-0012 ¶ 24.a). 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] (RX-1048-0012 ¶ 24.a, [redacted]

1367. 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. (RX-1048-0013 ¶ 25, [redacted] RX-822-6, RX-824-6).

1368. "Freedom's low margins [were] 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." (RX-1048 ¶ 27; [redacted]

B. Freedom's Debt Was Insurmountable

1369. Freedom was burdened by significant debt. 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. (RX-826 at 00001; RX-826 at 00028).

1370. [redacted]

1371. [redacted]

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1373. [redacted]

1374. 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. (PX-5113, (Chung, Dep. at 135)).

1375. [redacted]

1376. 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. RX-831 (First Amendment); RX-832 (Second Amendment); RX-829 (Third Amendment); RX-827 (Fourth Amendment); RX-830 (Fifth Amendment); RX-828 (Sixth Amendment).

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

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

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1451. [redacted]

1452. Freedom's search for potential alternatives was robust, exhaustive, and consistent with typical sale and refinancing processes employed by similar companies. (RX-1048-0031 ¶ 75-76).

1. Freedom Engaged In Extensive Efforts To Attract Refinancing Partners

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1469. "[G]iven Freedom's small size and financial condition, . . . the outcome of the Moelis process, bids from strategic players, was the most reasonable, expected and obvious outcome." (RX1048-0038 ¶ 94).

2. Freedom's Formal Sale Process Was Robust And Far-Reaching

1470. [redacted]

1471. Moelis conducted a formal sale bidding process for Freedom that began in May 2017 and continued until the Acquisition closed in September 2017. (Hammack, Tr. 6063-65).

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1479. [redacted] illow Wood was aware that Freedom was for sale in 2017, but declined to submit a bid to acquire Freedom. (Arbogast (Willow Wood), Tr. 4979).

1480. [redacted] is a small competitor with revenues of approximately [redacted] in 2017. (PX-5105 (Fillauer, Dep. at 25). However, a company would need at least $100 million in annual revenue to finance a purchase of Freedom. (Hammack, Tr. 6091; RX-1048-0037 ¶ 93.a).

1481. Hanger: [redacted] In addition, it could have had "really damaging consequences" for Freedom to alert Hanger, an important customer, of its precarious financial condition and that it was for sale. (PX-5110 (Hammack Dep., Tr. 182)).

1482. Nabtesco: On September 7, 2017, Carkhuff emailed Smith stating that "I was just approached by Nabtesco regarding their interest in acquiring Freedom." (PX-1288-002). [redacted]

[redacted]

1483. [redacted]

1484. The decision not to contact certain companies also proved appropriate because the evidence suggests they would not have even attempted to bid. For example, [redacted] Willow Wood knew that Freedom was going through a sale process before the Acquisition closed in September 2017 and chose not to make an offer. (Arbogast (Willow Wood), Tr. 4979; [redacted]

1485. [redacted]

1486. [redacted]

1487. "[S]ale processes do not involve direct contact with every conceivable potential financial or strategic buyer, including every participant within a relevant industry." (RX-1048-00038 ¶ 94).

1488. [redacted]

1489. [redacted]

1490. [redacted]

1491. [redacted]

1492. However, Freedom's management had significant concerns regarding Össur's sincerity and willingness to actually close an acquisition for the following reasons:

- [redacted]

[redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

1493. [redacted]

1494. [redacted]

1495. [redacted]

1496. [redacted]

1497. [redacted]

1498. [redacted]

1499. Even if Össur had made a real offer to purchase Freedom, an acquisition of Freedom by Össur at any price would have posed a greater danger to competition, if any, than the Acquisition by Ottobock. (RX-1049-0081 ¶ 176).

1500. [redacted]

1501. [redacted]

1502. [redacted]

1503. [redacted]

1504. [redacted]

1505. Accordingly, if Össur were to have acquired Freedom, it would likely have created a more significant threat of harm to competition than the Ottobock-Freedom transaction. (RX-1049-0083 ¶ 176).

3. The Ottobock Acquisition Was A Last Resort For Freedom

1506. [redacted]

1507. [redacted]

1508. [redacted]

1509. [redacted]

1510. [redacted]

1511. [redacted]

1512. Smith would have presented a refinancing option to the board even if it would have been harmful to existing investors. (Smith, Tr. 6467).

1513. [redacted]

1514. [redacted]

1515. [redacted]

1516. Moelis also performed third-party valuations of Freedom that estimated value on a discounted cash flow ("DCF") basis. The February 2017 Management Case valued Freedom as between $100 million to $130 million without synergies and between $280 million and $355 million with synergies. (PX-3002-2; PX-3060-003) The March 2017 Upside Case valued Freedom as between $135 million and $170 million without synergies and as between $300 million and $370 million with synergies. (PX-3060-003). The valuation with synergies is the amount that Moelis would have expected a strategic buyer, like Ottobock, to pay for the company based on Freedom's projected financial performance. (PX-3060-003).

1517. [redacted]

1518. [redacted]

1519. [redacted]

1520. [redacted]

1521. [redacted]

1522. [redacted]

1523. [redacted]

1524. [redacted]

1525. In order to reorganize under Chapter 11, Freedom would have needed to obtain financing in order to operate as a stand-alone business. (RX1048-0042). 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. (RX1048-0042; [redacted] Indeed, Freedom's YTD17 Leverage Ratio far exceeded the risk profile of lenders. (RX1048-0042 ¶ 103).

1526. [redacted]

1527. [redacted]

1528. Therefore, "[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."

(RX1048-00039 ¶ 99). Thus, liquidation would have been the most likely outcome for Freedom absent an acquisition. (RX1048-0040 ¶ 99; [redacted]

1529. [redacted]

1530. [redacted]

1531. [redacted]

VI. EFFICIENCIES

1532. Ottobock began its integration planning process, identifying synergy and efficiency opportunities, prior to its acquisition of Freedom. [redacted] PX05170 (Schneider Dep. at 16-18)).

1533. [redacted]

1534. One week after the Merger, Ottobock engaged AT Kearney to assist in merger integration planning activities. (RX-0616).

1535. AT Kearney's responsibilities included, but was not limited to: (1) establishing an integration program; and (2) defining and identifying synergy opportunities, targets, and capture plans. (RX-0616 –00004).

1536. Ottobock and AT Kearney identified numerous efficiencies to be gained from the Merger, including cost reductions in back office, distribution, and sales and marketing functions. (PX05170 (Schneider Dep. at 90-92, 168)).

1537. Ottobock analyzed the efficiencies from the Merger and determined that the [redacted] for both Ottobock and Freedom. (PX05170 (Schneider Dep at 91)).

1538. [redacted] (PX05138 (Reissfelder Dep. at 129)).

1539. After the Merger, and before the Hold Separate Agreement, Ottobock and Freedom collaborated to identify additional synergies, such as the consolidation of manufacturing

and distribution, and leveraging its increased purchasing power to obtain lower supply costs. (PX05138 (Reissfelder Dep. at 132-133)).

1540. [redacted] Kim, Tr. 2668).

1541. If Össur acquired Freedom, it would have shut down Freedom's operations, and the Plié would likely no longer be available to amputees. (Smith, Tr. 6481; PX05122 (Smith Dep. at 179)).

1542. [redacted]

1543. [redacted]

1544. [redacted]

1545. [redacted] (RX-0724; RX-0616; PX01011; PX03185).

1546. [redacted]

1547. [redacted]

1548. [redacted] (RX-0724; RX-0616; PX01011; PX03185).

1549. [redacted] (RX-0724).

1550. Ottobock has not realized any efficiencies because it has complied with the terms of the hold-separate agreement. (Schneider, Tr. 4413).

1551. [redacted]

[redacted]
(PX05138 (Reissfelder Dep. at 147-149)).

1552. [redacted]

1553. [redacted]

1554. The merger-specific efficiencies would result in New Freedom's and Ottobock's gross margin improvements allowing both companies to: (1) improve the quality of their products through increased spending on research and development; (2) maintain and/or lower the prices of their current prosthetic products, including their MPKs; and (3) develop new technology for future prosthetic devices, which it can then afford to sell at affordable prices. [redacted] PX05170 (Schneider Dep. at 52-53, 91, 123)).

1555. Expert James Peterson also analyzed the cognizable, merger-specific efficiencies resulting from an Ottobock-Freedom Merger. (RX-1048 – 0045-0053).

1556. Peterson's expert opinion is that Ottobock management and AT Kearney performed significant work to attempt to quantify the efficiencies of the Transaction and economic benefits of the Dual Brand Strategy; and through the process identified a number of efficiencies. (RX-1048 –0048).

1557. [redacted]

1558. Peterson's expert opinion is that only Ottobock had the ability to achieve and fully implement certain synergies such as gross margin improvements, reduction of European sales force, and quality improvements. (RX-1048 at 0051-0052).

1559. Freedom was operating well below the guideline public companies ("GPCs") with operations similar to Freedom in terms of gross margin and SG&A as a percentage of revenue. (RX-1048 at 0049).

1560. [redacted]

1561. [redacted]

1562. Peterson concluded that the Ottobock merger-specific efficiencies included gross margin improvements, [redacted] and quality improvements. (RX-1048 –0051 & 0052).

1563. Peterson calculated that the merger-specific efficiencies [redacted] (RX-1048 at 0050).

1564. Peterson performed an Efficiencies Sensitive Analysis ("Sensitivity Analysis") for the efficiency benefits expected from the Merger. (RX-1048 –0052-0053).

1565. To be conservative, for his Sensitivity Analysis, Peterson discounted the potential merger-specific efficiencies for [redacted] (RX-1048 at 0052-0053).

1566. [redacted]

1567. [redacted]

1568. Peterson also concluded that, 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. (RX-1048 at 0053).

1569. Based on Peterson's analysis, his expert opinion is that the Transaction offered material and achievable efficiencies. (RX-1048 at 0054).

1570. [redacted]

1571. [INTENTIONALLY LEFT BLANK]

VII. REMEDIES

A. [redacted]

1572. [redacted]

1573. [redacted]

1574. [redacted]

1575. [redacted]

1576. [redacted]

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B. [redacted]

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1599. [redacted]

C. [redacted]

1600. [redacted]

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1611. [redacted]

1612. [redacted]

1613. **[INTENTIONALLY LEFT BLANK]**

D. [redacted]

1614. [redacted]

1615. [redacted]

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1618. [redacted]

1619. [redacted]

1620. [redacted]

1621. [redacted]

1622. [redacted]

1623. [redacted]

1624. [redacted]

E. [redacted]

1625. [redacted]

1626. [redacted]

1627. [redacted]

1628. [redacted]

1629. [redacted]

1630. [redacted]

1631. [redacted]

1632. [redacted]

1633. [redacted]

1634. [redacted]

RESPONDENT'S PROPOSED CONCLUSIONS OF LAW

I. APPLICABLE LEGAL STANDARD AND BURDEN OF PROOF

1635. Section 7 of the Clayton Act, 15 U.S.C. § 18, prohibits acquisitions where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, prohibits "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce" and provides for proceedings by the FTC. The same legal standards apply to evaluate a claim under Section 7 of the Clayton Act and Section 5 of the FTC Act. *See In re Polypore Int'l,* 149 F.T.C. 486, 798 (F.T.C. March 1, 2010) (Chappell, A.L.J.).

1636. The "analytical approach to Section 7 cases . . . has traditionally consisted of a burden shifting exercise with three parts." *Polypore,* 149 F.T.C. at 798 (citing *United States v. Baker Hughes, Inc.,* 908 F.2d 981, 982-83 (D.C. Cir. 1990)).

1637. "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)).

1638. 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)).

1639. "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)).

1640. "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)).

1641. "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. *See Polypore,* 149 F.T.C. at 798.

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

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

1642. "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).

1643. "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)).

1644. "Complaint Counsel bears 'the burden of proving a relevant market within which anticompetitive effects are likely as a result of the acquisition.'" *Id.* at 799-800 (quoting *In re R.R. Donnelley & Sons,* 1995 FTC LEXIS 450, at *38); *see also 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").

B. Courts Consider The Reasonable Interchangeability Of Use Or The Cross-Elasticity Of Demand In Defining A Product Market

1645. "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)).

1646. "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).

1647. 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)).

1648. "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).

1649. "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)).

1650. "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).

1651. A product market may "be determined by examining such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Polypore*, 149 F.T.C. at 809 (quoting *Brown Shoe,* 370 U.S. at 325).

1652. 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.*

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

1653. Complaint Counsel has failed to prove that the relevant product market is no broader than the manufacture and sale of microprocessor prosthetic knees to prosthetic clinics in the United States.

1654. Complaint Counsel's proffered market definition is contradictory to 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. (FOF ¶¶ 335-509).

1655. Complaint Counsel's proffered market definition also incorrectly includes High-End MPKs that are only available to a very small patient population. (FOF ¶¶ 496-509).

1656. All MPKs are not functionally or reasonably interchangeable. (FOF ¶¶ 350-391).

1657. At the same time, some MPKs are functionally and reasonably interchangeable with Non-MPKs, particularly Sophisticated Non-MPKs. (FOF ¶¶ 392-468).

1658. Complaint Counsel's product market definition includes practical indicia establishing that any relevant market must be broader than Complaint Counsel suggests, including evidence of financial incentives; patient and provider preferences; and classification of product within the industry.

1659. The hypothetical monopolist test confirms that the relevant product market is broader than an MPK-only market. (FOF ¶¶ 514, 1661-1665).

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

1660. "The second step in analyzing a Section 7 case is to determine whether the effect of the acquisition 'may be substantially to lessen competition, or to tend to create a monopoly.'" *Polypore*, 149 F.T.C. at 800 (quoting 15 U.S.C. § 18).

1661. "After determining the relevant product and geographic markets, an analysis of the likely competitive effects of an acquisition requires a determination of the transaction's probable effects on competition in those markets." *Id*. at 849 (citing *CCC Holdings*, 605 F. Supp. 2d at 37 (citing *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 618-23 (1974); *Gen'l Dynamics*, 415 U.S. at 510-11)).

1662. "[T]o satisfy section 7, the government must show a reasonable probability that the proposed transaction would substantially lessen competition in the future." *Id*. (quoting *FTC v. University Health*, 938 F.2d 1206, 1218 (11th Cir. 1991); *FTC v. Warner Communs. Inc.*, 742 F.2d 1156, 1160 (9th Cir. 1984)).

1663. Complaint Counsel has the burden of proving a "reasonable probability" of substantial competitive harm; a mere possibility will not suffice. *United States v. Marine Bancorporation, Inc*., 418 U.S. 602, 622-23 (1974); *United States v. Sungard Sys. Inc*., 172 F. Supp. 2d 172, 180 (D.D.C. 2001); *New York v. Kraft General Foods, Inc*., 926 F. Supp. 321, 358-59 (S.D.N.Y. 1995).

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

1664. 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."

1665. However, calculating market shares and market concentration is "not an end in itself," but rather "one useful indicator of likely anticompetitive effects." 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. *Id.* § 5.3. Market "shares may not fully reflect the competitive significance of firms in the market or the impact of a merger." *Id.*

1666. "[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 Weyerhauser Co.,* 1985 FTC LEXIS 26, at *215 (F.T.C. Sept. 26, 1985)) (substitutions and omission in original).

1667. 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.")

1668. Complaint Counsel bases its case entirely on alleged unilateral effects on competition.

1669. However, the evidence at trial established 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. (FOF ¶¶ 565-1290). *See*, *e.g.*, *General Dynamics*, 415 U.S. 486.

1670. Complaint Counsel has failed to establish a presumption that Ottobock could exercise market power post-Acquisition.

B. Strong Evidence Rebuts Complaint Counsel's *Prima Facie* Case

1671. In addition, a respondent may rebut a prima facie case of anticompetitive effects. "Factors which may be considered to rebut a prima facie case include 'ease of entry into the market, the trend of the market either toward or away from concentration, and the continuation of active price competition.'" *Polypore*, 149 F.T.C. at 801 (quoting *Kaiser Aluminum*, 652 F.2d at 1341).

1672. "The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral effects." *ProMedica*, 749 F.3d, at 569; *see also 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; *Merger Guidelines* § 6.1.

1673. "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." *Merger Guidelines* § 6.1.

1674. 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.

1675. "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).

1676. The existence of a powerful buyer may mitigate the anticompetitive effects of a merger. In particular, "[t]he '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." *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.

1677. 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).

1678. The "weakened competitor" defense may be satisfied even where an element of failing firm defense is technically lacking in some respect. *See Arch Coal*, 329 F. Supp. at 157.

1679. "[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.")

1680. The evidence established the following facts, which are sufficient to rebut any *prima facie* case of anticompetitive effects and to demonstrate that the Acquisition is actually beneficial to competition:

a. 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 Plie. (FOF ¶¶ 577-746).

b. Ottobock's closest competitor, Össur, and other manufacturers selling MPKs, are willing and able to expand to compete for share of MPK sales. (FOF ¶¶ 777-940).

c. Hanger and other sophisticated customers have significant buying power and have promoted expansion and innovation. These buyers have to discipline and constrain manufacturers from raising the prices of MPKs and to prevent any reasonably likely anticompetitive effects. (FOF ¶¶ 967-1003).

d. The third-party payer reimbursement system in the United States severely constrains the ability of prosthetic knee manufacturers to raise prices. (FOF ¶¶ 962-66).

e. 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).

f. 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 ¶¶ 1039-1073).

g. The Acquisition will generate substantial cognizable, merger-specific efficiencies that will benefit consumers. (FOF ¶¶ 1532-1570).

IV. THE ACQUISITION SUBJECT TO THE MPK DIVESTITURE WILL HAVE NO ADVERSE EFFECT ON COMPETITION AND ANY REMEDY OUTSIDE THE ALLEGED MARKET WOULD BE PUNITIVE

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

1681. As established in *FTC v. Arch Coal, Inc.*, No. 1:04-cv-00534, ECF No. 67 at 7 (D.D.C. July 7, 2004) (attached as Exhibit D), 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.*

1682. 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, 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).

1683. "In rebuttal, a defendant may introduce evidence that a proposed divestiture would 'restore the competition' lost by the merger counteracting the anticompetitive effects of the merger." *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)).

1684. This is consistent with 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"). Although the Commission 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.

1685. The 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.

1686. Ottobock entered into a Hold Separate Agreement. Complaint Counsel has introduced no evidence of anticompetitive effects from the Acqisition either before or after the Hold Separate Agreement was entered. To the contrary, the evidence shows that Freedom has

continued to operate independently. (FOF ¶¶ 1155-1166). As such, despite the FTC's refusal to characterize the divestiture as an "affirmative defense" – a distinction that was appropriate before trial – at this point, it is clear that to the extent that the divestiture would restore any competition lost by the merger, it is a complete defense to the complaint.

1687. "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 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)).

1688. "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.").

1689. The evidence establishes that [redacted] will be a more successful competitor than Freedom. As a result, with [redacted]

1690. The divestiture to [redacted] would restore any alleged lost competition in the alleged market.

1691. [redacted] As such, the divestiture would cause no harm to competition. To the contrary, because [redacted] is likely to be a more effective competitor than Freedom, the divestiture will likely promote competition. (FOF ¶¶ 1238).

1692. Likewise, [redacted] will allow it to innovate more effectively than Freedom. This will also have the effect of enhancing competition. (FOF ¶¶ 1239-1248).

1693. The APA provides [redacted] (FOF ¶¶ 1249-1282).

1694. It is not necessary that the divestiture have been consummated for a court to consider it as part of a transaction. In this case, the evidence shows that the parties will consummate the divestiture if they are permitted to do so. (FOF ¶¶ 1081, 1167-1248).

1695. The Acquisition, considered with a divestiture to [redacted] will cause no harm to competition.

1696. [redacted]

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

1697. As to issues of 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).

1698. Because a proposed divestiture is adequate to restore any alleged lost competitive intensity, unwinding the entire Acquisition, or ordering a divestiture of all assets acquired in the Acquisition, is not supportable as a remedy.

1699. 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.

1700. 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).

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

1701. 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).

1702. 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.

1703. 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).

1704. 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." S*ee also Dr. Pepper / Seven-Up Cos. v. FTC*, 991 F.2d 859, 864-65 (D.C. Cir. 1993).

1705. The Acquisition satisfies each element of the failing firm defense as articulated in the Merger Guidelines and applicable law.

1706. **First**, the evidence establishes that, but for the Acquisition, Freedom would have been unable to meet its financial obligations in the near future. Freedom had long suffered serious management and financial difficulties and new management was unable to turn it around. (FOF ¶¶ 1291-1448).

1707. Freedom had significant and rapidly maturing debt with no way to repay it. (FOF ¶¶ 1369-1413); *United States v. Black & Decker Mfg. Co.,* 430 F. Supp. 729, 781 (D. Md. 1976) (indicia of a failing firm include that its "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.").

1708. **Second**, Freedom would not have been able to successfully reorganize under Chapter 11 of the Bankruptcy Act because it lacked the resources to successfully emerge from that process. (FOF ¶¶ 1521-1528).

1709. Further, "[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).

1710. **Third**, Freedom exhausted good faith efforts to obtain reasonable alternatives to the Acquisition. (FOF ¶¶ 1449-1505).

1711. The third prong of the failing firm defense 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).

1712. In addition, "the 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 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).

1713. "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]." Areeda & Hovenkamp ¶ 954c (emphasis added). "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." *Id.* "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.

1714. Freedom's efforts to attract refinancing partners and its formal sale process were appropriate and robust. (FOF ¶¶ 1449-1505)

1715. Össur's non-binding indication of interest was not a reasonable alternative offer because (i) Össur's indication of interest does not qualify as an "offer"; (ii) Össur was not serious about closing an acquisition of Freedom; (iii) [redacted] and (iv) an Ossur acquisition does not pose a less severe danger to competition than the Acquisition by Ottobock, because an Össur acquisition would have been presumed to be likely to enhance market power not only in a market for MPKs, but also in a market for feet. (FOF ¶¶ 1490-1505).

Dated: November 20, 2018

Respectfully submitted,

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Counsel for Respondent
Otto Bock HealthCare North America, Inc.

CERTIFICATE OF SERVICE

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

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

Donald S. Clark
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Washington, DC 20580

Meghan Iorianni
Jonathan Ripa
Steven Lavender
William Cooke
Yan Gao
Lynda Lao
Stephen Mohr
Michael Moiseyev
James Weiss
Daniel Zach
Lisa De Marchi Sleigh
Catherine Sanchez
Sarah Wohl
Joseph Neely
Dylan Brown
Betty McNeil
Stephen Rodger
Jordan Andrew

Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC, 20580

/s/ Sean P. McConnell
Sean P. McConnell

EXHIBIT A

REDACTED IN ENTIRETY

EXHIBIT B

In the Matter of Otto Bock HealthCare North America, Inc.
Docket No. 9378

RESPONDENT'S WITNESS INDEX

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Keith Senn	President	Center for Orthotics & Prosthetics Care	*Public* Tr. 148:6-219:20 Tr. 229:3-232:25 Tr. 250:3-266:3 Tr. 280:3-4 *In Camera* Tr. 220:3-228:7 Tr. 234:8-249:16 Tr. 269:4-279:6	7/18/2018
Maynard Carkhuff	Chairman	Freedom	*Public* Tr. 287:6-378:23 Tr. 586:5-630:2 Tr. 710:1-718:11 Tr. 736:3-736:8 *In Camera* Tr. 381:13-435:5 Tr. 438:5-499:5 Tr. 502:11-556:12 Tr. 564:5-585:6 Tr. 631:4-708:7 Tr. 719:5-735:2	7/19/2018 – 7/20/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Benjamin Kyle Potter	Chief of Department of Orthopedics	Department of Orthopedics – Walter Reed Medical Center	*Public* Tr. 743:23-796:6	7/20/2018
Kenton Richard Kaufman	Musculoskeletal Research Professor, a Professor of Biomechanical Engineering, and the Director of the Motion Analysis Laboratory; Orthopedic Surgeon	Mayo Clinic	*Public* Tr. 806:12-838:22 Tr. 854:21-894:17 *In Camera* Tr. 839:9-853:4	7/24/2018
Mark William Ford	President & Managing Partner	Prosthetic & Orthotic Associates, Inc	*Public* Tr. 901:14-1021:2 Tr. 1037:9-1067:5 *In Camera* Tr. 1022:12-1035:23	8/1/2018
Mark Donald Testerman	VP of National and Key Accounts	Freedom	*Public* Tr. 1070:5-16 Tr. 1071:17-1163:20 Tr. 1168:9-1210:7 Tr. 1248:8-1279:10 Tr. 1296:6-1305:17 *In Camera* Tr. 1211:8-1246:11 Tr. 1280:4-1295:2	8/1/2018 – 8/2/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Vinit Asar	President and Chief Executive Officer	Hanger, Inc.	*Public* Tr. 1306:23-1350:8 Tr. 1528:15-1558:4 Tr. 1570:4-1571:5 *In Camera* Tr. 1351:8-1377:8 Tr. 1379:12-1424:5 Tr. 1431:13-1527:22 Tr. 1559:17-1569:3	8/2/2018 – 8/3/2018
Cali Solorio	Senior Prosthetics Marketing Manager	Ottobock	*Public* Tr. 1572:15-1598:18 Tr. 1632:11-1652:10 *In Camera* Tr. 1599:4-1631:20	8/3/2018
Tracy Duncan Ell	Owner & Chief Prosthetist	Mid-Missouri O&P	*Public* Tr. 1658:17-1743:4 Tr. 1749:9-1801:3 Tr. 1814:4-1816:9 *In Camera* Tr. 1744:7-1748:2 Tr. 1802:6-1813:20	8/8/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Andreas Kannenberg	Executive Medical Director	Ottobock	*Public* Tr. 1818:4-1886:18 Tr. 1923:16-2001:21 *In Camera* Tr. 1887:6-1916:4	8/8/2018 – 8/9/2018
William James Carver III	President & Chief Operating Officer	College Park Industries	*Public* Tr. 2002:13-2031:21 Tr. 2087:3-5 *In Camera* Tr. 2032:8-2086:17	8/9/2018
Brian Stephen Blatchford	Executive Chairman	Chas A. Blatchford & Sons Ltd.	*Public* Tr. 2089:2-2152:23 Tr. 2207:16-2261:21 Tr. 2294:4-2295:24 *In Camera* Tr. 2153:5-2199:20 Tr. 2262:11-2293:5	8/9/2018 – 8/10/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Eric Ferris	VP of Marketing, Customer Service, and Client Development	Freedom	*Public* Tr. 2297:2-2298:6 Tr. 2299:5-2364:18 Tr. 2457:10-2480:12 *In Camera* Tr. 2365:7-2388:8 Tr. 2391:7-2456:24 Tr. 2481:6-2484:8	8/10/2018
Lee Kim	Chief Financial Officer	Freedom	*Public* Tr. 2491:16-2550:14 Tr. 2671:3-4 *In Camera* Tr. 2551:6-2596:4 Tr. 2599:16-2670:24	8/15/2018
Stephen William Prince	Project Manager	Freedom	*Public* Tr. 2671:20-2682:9 Tr. 2866:3-4 *In Camera* Tr. 2683:7-2725:3 Tr. 2737:10-2834:10 Tr. 2837:8-2865:3	8/15/2018 – 8/16/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Christine Hammer	CPA/Independent Consultant & Sr. Advisor	Hammer & Associates	*Public* Tr. 2866:15-2905:5 Tr. 2999:16-3047:15 Tr. 3257:9-3259:10 *In Camera* Tr. 2906:7-2947:20 Tr. 2949:8-2991:10 Tr. 3048:6-3095:4 Tr. 3097:7-3158:5 Tr. 3161:8-3226:22 Tr. 3228:6-3256:9	8/16/2018 – 8/17/2018
Jeffrey James Collins	President	Cascade Orthopedic Supply, Inc.	*Public* Tr. 3269:12-3287:2 Tr. 3302:14-3308:21 *In Camera* Tr. 3288:10-3301:13	8/22/2018
Matt Swiggum	Former Regional President & CEO	Ottobock	*Public* Tr. 3309:7-3332:1 Tr. 3426:16-3439:17 Tr. 3519:3-5 *In Camera* Tr. 3333:6-3363:24 Tr. 3365:7-3424:13 Tr. 3440:7-3494:15 Tr. 3497:11-3518:2	8/22/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Kim Peter Viviane DeRoy	Executive VP of Research & Development	Össur	*Public* Tr. 3524:22-3600:23 Tr. 3628:16-3654:21 Tr: 3732:3-5 *In Camera* Tr. 3601:3-3615:13 Tr. 3617:9-3627:5 Tr. 3655:6-3693:14 Tr. 3696:6-3731:21	8/24/2018
Jeffrey M. Brandt	CEO	Ability Prosthetics & Orthotics, Inc.	*Public* Tr. 3741:3-3769:9 Tr. 3830:11-3840:4 Tr. 3846:3-4 *In Camera* Tr. 3770:6-3829:21 Tr. 3841:3-3845:9	8/29/2019

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Fiona Margaret Scott Morton	Professor of Economics	Yale School of Management	*Public* Tr. 3846:20-3881:6 Tr. 3959:10-4023:13 Tr. 4028:10-4059:23 Tr. 4250:3-4251:23 *In Camera* Tr. 3882:6-3906:18 Tr. 3911:8-3958:21 Tr. 4060:6-4116:24 Tr. 4118:7-4180:5 Tr. 4183:6-4249:13	8/29/2018 – 8/30/2018
Scott Schneider	Vice President of Government, Medical Affairs and Future Development	Ottobock	*Public* Tr. 4259:15-4412:2 Tr. 4413:6-4418:6 Tr. 4727:8-4740:19 Tr. 4742:11-4755:8 Tr. 4760:8-4763:5 *In Camera* Tr. 4420:3-4471:8 Tr. 4473:6-4520:6 Tr. 4527:7-4601:10 Tr. 4603:7-4665:10 Tr. 4671:11-4715:15 Tr. 4717:11-4726:6 Tr. 4756:10-4759:23	9/5/2018 – 9/6/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Michael Oros	President & CEO	Scheck & Siress	*Public* Tr. 4770:24-4796:8 Tr. 4848:5-4903:6 Tr. 4908:6-4920:20 *In Camera* Tr. 4797:6-4846:11 Tr. 4904:7-4907:23	9/7/2018
Ryan Arbogast	CEO & President	Ohio Willow Wood Company	*Public* Tr. 4929:13-4940:11 Tr. 4942:3-4980:1 Tr. 5068:6-5079:9 Tr. 5224:4-7 *In Camera* Tr. 4981:7-5012:22 Tr. 5014:7-5065:16 Tr. 5080:4-5197:1 Tr: 5206:12-5223:16	9/12/2018 – 9/13/2018
John Matera	Chief Operations Officer	Ohio Willow Wood Company	*Public* Tr: 5224:14-5244:1 Tr. 5293:4-5300:12 Tr. 5364:4-6 *In Camera* Tr. 5245:19-5291:5 Tr. 5301:7-5351:16 Tr. 5352:5-5363:6	9/13/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Jack Sanders	Sr. Clinical Program Consultant	United Healthcare Services, Inc.	*Public* Tr. 5369:23-5398:9 Tr. 5399:3-5431:2 Tr. 5463:11-5475:3 *In Camera* Tr. 5432:7-5462:3 Tr. 5476:7-5507:20	9/19/2018
Bradley Douglas Mattear	Managing Director	Nabtesco/Proteor	*Public* Tr. 5509:7-5634:22 Tr. 5709:23-5719:10 Tr. 5786:3-4 *In Camera* Tr. 5640:8-5708:11 Tr. 5720:6-5785:12	9/19/2018 – 9/19/2018
Scott Alan Sabolich	Prosthetist, Owner & Clinical Director	Scott Sabolich Prosthetics & Research, LLC	*Public* Tr. 5787:10-5867:14 Tr. 5881:3-5916:16 Tr. 5922:5-5960:15 *In Camera* Tr. 5868:6-5880:24	9/20/2018 – 9/21/2018
Douglas George Smith	Orthopedic Surgeon; Professor Emeritus	University of Washington; Uniformed Services University of the Health Sciences	*Public* Tr. 5960:22-6057:12	9/21/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
Jon Hammack	Managing Director	Moelis & Company	*Public* Tr. 6062:9-6067:10 Tr. 6077:9-6097:11 Tr. 6131:3-4 *In Camera* Tr. 6068:9-6076:24 Tr. 6098:14-6130:3	9/26/2018
David Argue	Corporate Vice President & Principal	Economists Incorporated	*Public* Tr. 6131:11-6192:19 Tr. 6193:24-6211:1 Tr. 6211:18-6213:18 Tr. 6213:20-6223:12 Tr. 6224:6-6226:9 Tr. 6226:12-6231:23 Tr. 6254:1-6262:5 Tr. 6264:3-6289:13 Tr. 6399:3-4 *In Camera* Tr. 6211:2-17 Tr. 6213:19 Tr. 6226:10-11 Tr. 6232:6-6251:16 Tr. 6263:3-11 Tr. 6290:10-6338:3 Tr. 6345:10-6398:22	9/26/2018 – 9/27/2018

Witness Name	**Title**	**Company**	**Transcript Cite**	**Date**
David Anthony Smith	Former CEO & Chairman	Freedom	*Public* Tr. 6406:13-6437:7 Tr. 6586:3-5 *In Camera* Tr. 6438:8-6562:17 Tr. 6565:16-6585:24	9/28/2018
James Peterson	Principal – Transaction and Business Analytics Division	Deloitte	*Public* Tr. 6593:10-6612:10 Tr. 6680:22-6709:22 Tr. 6887:3-4 *In Camera* Tr. 6613:6-6679:2 Tr. 6710:6-6740:22 Tr. 6745:4-6794:16 Tr. 6796:5-6850:10 Tr. 6857:8-6886:4	10/3/2018 – 10/4/2018

EXHIBIT C

Otto Bock HealthCare North America, Inc.

Docket No. 9378

RESPONDENT'S DEMONSTRATIVE INDEX

Exhibit No.	Description	BegBates	EndBates	Date Introduced	Trial Transcript Citation
RDX-001	Drawing of a Transfemoral Prosthetic Device	RDX-001.001	RDX-001.001	7/20/2018	599:10 - 603:1
RDX-002	Ottobock C-Leg 4	RDX-002.001	RDX-002.001	8/9/2018	1962:10 - 1963:2 4946:13 - 4947:7
RDX-003	Ottobock 3R80 Hydraulic Swing and Stance Control Mechanical Knee	RDX-003.001	RDX-003.001	8/9/2018	1951:1 - 1952:8 2048:22 - 2050:23 3468:16 - 3469:3 4015:17 - 4016:17 4326:4 - 4328:8 4337:13-18 4760:9-25 5077:1-16 5194:20 - 5195:19
RDX-004	Ottobock 3R49	RDX-004.001	RDX-004.001	8/9/2018	1993:20 - 1995:13 2021:20 - 2022:21 2025:1-7 4289:2 - 4290:7 4760:9-25 5076:8-25
RDX-005	Chart/Sampling of Prosthetic Knees Available to K-3 & K-4 Patients in the US	RDX-005.001	RDX-005.001	8/9/2018	1974:14 - 1975:6 1982:17 - 1983:18 1998:7 - 1999:5 4363:10 - 4372:3
RDX-006	Table 1 from James Peterson's Expert Report	RDX-006.001	RDX-006.001	8/15/2018	2579:1 - 2584:25 2618:1 - 2625:13 2627:19 - 2629:3 2634:25 - 2637:9 2641:20-24 3153:24 - 3154:19 6614:9 - 6618:8
RDX-007	Table 3 from James Peterson's Expert Report	RDX-007.001	RDX-007.001	8/15/2018	2585:1 - 2587:13 2588:5-20 2625:14 - 2627:18
RDX-008	Plié pump - vacuum pump gauge	RDX-008.001	RDX-008.002	8/29/2018	3832:11 - 3834:17 4314:24 - 4315:25 5409:18 - 5410:10
RDX-009	Ottobock 3R60	RDX-009.001	RDX-009.002	9/6/2018	4334:16 - 4337:8

EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, **Plaintiff,** **v.** **ARCH COAL, INC., et al.,** **Defendants.**	**Civil Action No. 04-0534 (JDB)**
STATE OF MISSOURI, et al., **Plaintiffs,** **v.** **ARCH COAL, INC., et al.,** **Defendants.**	**Civil Action No. 04-0535 (JDB)** **(Consolidated Cases)**

MEMORANDUM OPINION

On May 29, 2003, defendant Arch Coal, Inc. ("Arch") entered a Merger and Purchase Agreement to acquire defendant Triton Coal Co. ("Triton") -- including two mines, the Buckskin mine and the North Rochelle mine -- from Triton's parent, defendant New Vulcan Coal Holdings, LLC ("Vulcan"). Arch and Triton filed pre-merger notification forms on July 11, 2003, with the Department of Justice and the Federal Trade Commission ("FTC" or "Commission") under the Hart Scott Rodino ("HSR") Act, 15 U.S.C. § 18a. In August 2003, the FTC sent Arch and Triton Requests for Additional Information ("Second Requests") to aid in its investigation of the

proposed acquisition. Arch informed the FTC in early December 2003 that it was contemplating the sale of the Buckskin mine to Peter Kiewit Sons, Inc. ("Kiewit"). Arch notified the FTC in late January 2004 that an agreement to sell Buckskin to Kiewit had been signed ("Kiewit transaction"). The FTC considered the Arch-Triton merger in light of the additional information concerning the proposed Kiewit transaction, but nevertheless issued an administrative complaint challenging the merger.

On April 8, 2004, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), the FTC filed a motion for preliminary injunction to enjoin Arch from acquiring, directly or indirectly, any stock, assets, or other interests in Triton. That same day, plaintiffs States of Arkansas, Illinois, Iowa, Kansas, Missouri, and Texas ("States") filed a similar motion for a preliminary injunction pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.[1] Presently before the Court is the motion in limine filed by the FTC to exclude, for the purposes of the preliminary injunction proceeding, all evidence and argument on the issue of Arch's proposed sale of the Buckskin mine to Kiewit. In effect, the FTC asks this Court to assess the proposed merger as if Arch would retain both the North Rochelle and Buckskin mines.

DISCUSSION

The FTC characterizes the proposed post-merger divestiture of Buckskin to Kiewit as a "self-help permanent remedy" that is not properly before this Court. FTC Mot. at 3. The FTC argues that the Court should exclude consideration of the Kiewit transaction because, as a question of "remedy," it cannot be considered by this Court in a Section 13(b) action for

[1] By minute entry order issued on April 21, 2004, this Court consolidated the FTC and States cases for purposes of the preliminary injunction hearing and all discovery and pre-hearing proceedings related thereto.

preliminary relief, and because the proposed Kiewit transaction is not a sufficiently binding commitment in any event. In their responses to plaintiffs' complaints and requests for a preliminary injunction, defendants have explained that the proposed acquisition challenged by the FTC is properly seen as a set of two transactions involving, first, the acquisition of Triton's North Rochelle and Buckskin mines by Arch, and then the "concurrent divestiture" of the Buckskin mine to Kiewit. Arch Answer at 1. Defendants argue that ignoring the second transaction would be tantamount to the Court assessing "a purely hypothetical transaction of the Commission's making -- that none of the parties are proposing." Defs.Opp. at 2.

The Court's analysis centers initially on the task of defining the transaction that is being challenged by the FTC. The FTC argues that the Kiewit transaction is merely a proposed remedy to the Arch-Triton merger, while defendants argue that it is a central component of what they are proposing to do and hence what the FTC is challenging. The case most directly on point is Federal Trade Comm'n v. Libbey, 211 F.Supp.2d 34 (D.D.C. 2002). In Libbey, the FTC brought a Section 13(b) preliminary injunction proceeding to enjoin the acquisition of one glassware manufacturer by another. About a month after the FTC had voted to seek a preliminary injunction, and a week after the FTC had filed its complaint in district court, the parties to the merger amended their agreement to allow one party to acquire only a part of the other's manufacturing plants and glassware business, while the rest of the assets would be transferred to another entity. Id. at 38. The court in Libbey, noting that the parties had made a good-faith effort to address the FTC's concerns regarding the original merger agreement in amending that agreement, concluded that

> . . . parties to a merger agreement that is being challenged by the government can abandon that agreement and propose a new one in

> an effort to address the government's concerns. And when they do so under circumstances as occurred in this case, it becomes the new agreement that the Court must evaluate in deciding whether an injunction should be issued.

Id. at 46.

The FTC makes much of the fact that here defendants Arch and Triton, unlike the defendants in Libbey, have not amended their merger agreement to include the sale of Buckskin to Kiewit. The Commission notes that the Kiewit transaction is separate and distinct from the Arch-Triton merger agreement, that the Arch-Kiewit contract is contingent upon the successful acquisition of Triton by Arch and contains provisions that allow one or both parties to walk away from the deal, and that the deal might be renegotiated. The Commission therefore argues that the only transaction squarely in issue before this Court is the Arch-Triton merger.

While it cannot be denied that Arch, Triton, and Kiewit have chosen to structure the proposal as two separate transactions rather than one three-way agreement, the Court does not find this structural choice to be dispositive on the issue whether the Kiewit transaction should be considered in the preliminary injunction proceeding. In Libbey, the court noted that even after the parties had amended their merger agreement, the FTC remained capable of vetting the amended agreement and had in fact voted to enjoin the amended merger agreement. The court therefore concluded that it was the amended merger agreement that the FTC was challenging and that was properly before the court for review on the FTC's motion for preliminary injunction. Libbey, 211 F.Supp.2d at 46. Here as well, Arch informed the Commission in late January 2004 that it had signed an agreement with Kiewit and the FTC then issued its administrative complaint challenging the merger after "determin[ing] that the competitive concerns posed by Arch's acquisition of Triton were not remedied by Arch's offer to sell the Buckskin mine to Kiewit."

FTC Mot. at 4. Thus, the FTC has assessed and is in reality challenging the merger agreement imcluding the Buckskin divestiture.

The fact that the Kiewit transaction is contingent on the successful acquisition of Triton by Arch is not only a logical matter of course, but also reinforces, rather than casts doubt on, the representation the parties have made that the sale of the Buckskin mine will in fact take place after the Arch-Triton merger. The uncontroverted facts, as presented to the Court by both parties, reveal that the Kiewit transaction was proposed as a good faith response to the Commission's investigation and concerns regarding the competitive effects of the Arch-Triton merger. Arch and Kiewit, through senior officers, have testified unequivocally that each is fully committed to the transaction if the Arch-Triton merger is allowed, and that the Buckskin sale will definitely occur. The contract termination provisions referenced by the FTC do state that either Arch or Kiewit may terminate the agreement after a certain set "expiration date," if the closing on the Kiewit transaction, as determined by the closing of the Arch-Triton transaction, has not occurred by that date. But that is little more than a restatement of the obvious fact that the Arch-Kiewit contract is contingent upon the successful acquisition of Triton by Arch. Although theoretically the parties could renegotiate the Kiewit deal, senior officers have affirmed their intent to consummate all aspects of the transaction if not enjoined by this Court. The Court therefore concludes that the transaction that is the subject of the FTC's challenge is properly viewed as the set of two transactions involving the acquisition of Triton by Arch and the immediate divestiture of the Buckskin mine to Kiewit.

The FTC also argues that consideration of the Kiewit transaction is beyond the purview of this Court in a Section 13(b) preliminary injunction hearing and would impinge on the authority of

the FTC . The FTC contends that, absent a preliminary injunction from this Court, if Arch were permitted to acquire Triton and then sell Buckskin to Kiewit, the Commission would be unable to order Triton's current operations to be reconstituted in the hands of a new competitor if the Commission were to permanently enjoin the challenged transactions.[2] Therefore, the argument goes, the Commission would be irreparably prejudiced in its ability to fashion a complete and effective permanent remedy at the end of the administrative proceedings. The Court notes again, however, that the FTC, in bringing its administrative complaint against defendants in this Court, first determined that the Kiewit transaction did not resolve its concerns about the transaction. Consistent with the review structure created by Section 13(b), the burden is on the FTC to convince this Court that its judgment is correct that the Arch-Triton merger including the Kiewit transaction raises questions so serious, substantial, difficult and doubtful as to make the challenged transactions fair ground for permanent injunction proceedings before the Commission.

The role of the district court, according to the FTC, is not to sit as the ultimate fact-finder. See Federal Trade Comm'n v. Food Town Stores, Inc., 539 F.2d 1339, 1342 (4th Cir. 1976) ("The district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in FTC in the first instance. The only purpose of a proceeding under § 13 is to preserve the status quo until FTC can perform its function."). Rather, this Court's role is simply to determine whether the FTC has established a likelihood of success on the merits of its case by "raising questions going to the merits so serious, substantial, difficult and

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[2] This argument is not much different from the competing problems presented in considering whether to allow any merger. If not enjoined preliminarily but later found to violate the law, can pre-merger competition really be recreated; and if enjoined preliminarily, would the merger be abandoned and thus no longer possible even if ultimately found lawful? See Federal Trade Comm'n v. Heinz, 246 F.3d 708, 726 (D.C. Cir. 2000).

doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance and ultimately by the Court of Appeals." Federal Trade Comm'n v. Heinz, 246 F.3d 708, 714-15 (D.C. Cir. 2000) (citations omitted). The FTC therefore argues that the DOJ antitrust cases cited by defendants are not applicable because in those cases the district court does sit as the finder of fact. This distinction, however, does not affect the applicability of the observation in United States v. Franklin Electric Co., Civ. A. No. 00-c-0334-c (W.D.Wisc. July 19, 2000) (order denying plaintiff's motion in limine), that a proposed transaction to resolve government antitrust concerns regarding a proposed merger or acquisition should be considered by the district court as "relevant to the determination whether, considered as a whole, defendants' transaction will lessen future competition substantially." Even under Section 13(b), this Court's task in determining the likelihood of the FTC's success in showing that the challenged transaction may substantially lessen competition in violation of Section 7 of the Clayton Act requires the Court to review the entire transaction in question. Given this Court's conclusion, based on all circumstances including the evidence presented at the preliminary injunction hearing, that the Arch-Kiewit transaction will in fact occur as agreed if the Arch-Triton merger goes forward, the Court is unwilling simply to ignore the fact of the divestiture of Buckskin to Kiewit.

CONCLUSION

Because this Court regards the challenged transaction as consisting of both the acquisition of Triton by Arch and the divestiture of the Buckskin mine to Kiewit, and because its role under Section 13(b) requires it to give the challenged transaction a thorough, good-faith review, the Court concludes that excluding evidence and argument regarding the Kiewit transaction would be

tantamount to turning a blind eye to the elephant in the room. The FTC's motion in limine will therefore be denied. A separate order accompanies this memorandum opinion.

/s/ John D. Bates
JOHN D. BATES
United States District Judge

Dated: July 7, 2004

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Notice of Electronic Service

I hereby certify that on November 20, 2018, I filed an electronic copy of the foregoing Public - Respondent's Proposed Findings of Fact and Conclusions of Law, with:

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