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AL TRADE COMMISSION

UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSIO OFFICE OF ADMINISTRATIVE LAW JUDGE

In the Matter of

SECRETARY ORIGINAL

ERAL

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

Docket No. 9378

Respondent.

COMPLAINT COUNSEL'S CORRECTED POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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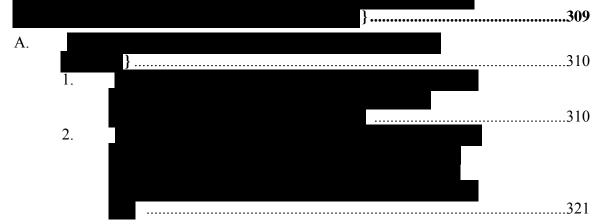
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Complaint Counsel's Proposed Conclusions of Law

Witness Index

Exhibit Index

I. THE PARTIES TO THE ACQUISITION

A. THE ACQUIRING COMPANY

1. Otto Bock HealthCare North America

- Otto Bock is a "Minnesota corporation, with its U.S. headquarters in Austin, Texas." (PX07049 at 008 (¶ 14) (Otto Bock Amended Answer); JX001 at 001 (¶5); PX05010 (Schneider (Otto Bock) IHT at 36)). Otto Bock moved its U.S. headquarters in 2014 from Minneapolis, Minnesota to Austin, Texas. (PX05010 (Schneider (Otto Bock) IHT at 36)).
- 2. Otto Bock has locations in Austin, Texas; Salt Lake City, Utah; Louisville, Kentucky; Sacramento, California; and Southern California. (PX05010 (Schneider (Otto Bock) IHT at 31-32)).
- 3. Otto Bock has approximately 600 employees in the United States. (PX05010 (Schneider (Otto Bock) IHT at 35-36)).
- 4. Otto Bock provides "upper and lower limb prosthetics, orthotics, mobility solutions, and medical-related services to customers" in the United States and around the world. (PX07049 at 008 (¶ 14) (Otto Bock Amended Answer)). Its lower-limb prosthetics include mechanical knees and MPKs. (Solorio (Otto Bock) Tr. 1632, 1637).
- 5. } (Asar (Hanger) Tr. 1385-1387 (*in*

camera)).

- 6. Otto Bock launched its C-Leg 4 MPK in the United States in 2015. (JX001 at 003 (¶ 36)). Today, Otto Bock sells the C-Leg 4 in the United States. (JX001 at 003 (¶ 34)).
- 7. Otto Bock is the leading manufacturer and supplier of microprocessor prosthetic knees in the United States.

See CCFF ¶ 964, below (*in camera*) (U.S. MPK market share estimated by Complaint Counsel's expert economist, Dr. Fiona Scott Morton); *see also* CCFF ¶¶ 967-980, below (*in camera*) (Respondent's ordinary course share estimates)).

- 8. In 2016, Matthew Swiggum became regional president and CEO of Otto Bock. (Swiggum (Otto Bock) Tr. 3310).
- 9. Mr. Swiggum served as regional president and CEO of Otto Bock at the time of the Merger and was personally involved in meetings regarding the integration of Freedom after it was acquired by Otto Bock. (Swiggum (Otto Bock) Tr. 3309-10).

10. After Matthew Swiggum left the company, Brad Ruhl "was elevated to the top position" of Otto Bock. (Schneider (Otto Bock) Tr. 4762). Today, Brad Ruhl is the managing director of Otto Bock North America. (Kannenberg (Otto Bock) Tr. 1925).

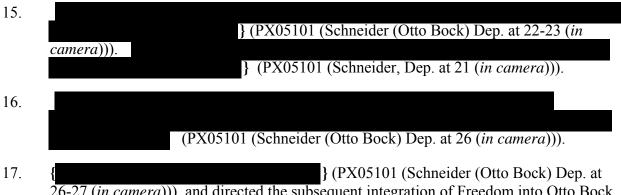
2. The Parent Company of Otto Bock HealthCare North America

- a) <u>Otto Bock HealthCare GmbH</u>
- Otto Bock's parent company, Otto Bock HealthCare GmbH, was founded in 1919. (PX07049 at 008 (¶ 14) (Otto Bock Amended Answer)). It is headquartered in Duderstadt, Germany. (PX07049 at 008 (¶ 14) (Otto Bock Amended Answer)).
- 12. Otto Bock HealthCare GmbH has over 7,000 employees worldwide and operates in 50 countries. (PX07049 at 008 (¶ 14) (Otto Bock Amended Answer)).
- 13. Otto Bock GmbH has overarching managerial responsibility over Otto Bock. (PX05101 (Schneider (Otto Bock) Dep. at 13-14, 20-21)).

(PX05101 (Schneider (Otto Bock) Dep. at 33-34 (in

camera))).

14. Otto Bock employees report to executives at Otto Bock HealthCare GmbH. For example, Matthew Swiggum, former head of Otto Bock HealthCare North America, reported to Ralf Stuch, head of Global Sales and Marketing at Otto Bock HealthCare GmbH. (PX05101 (Schneider (Otto Bock) Dep. at 108)). Likewise, the CFO of Otto Bock HealthCare North America reports to the CFO of Otto Bock HealthCare GmbH. (PX05101 (Schneider (Otto Bock) Dep. at 108)).



- 26-27 (*in camera*))), and directed the subsequent integration of Freedom into Otto Bock. (PX05104 (Rössing (Otto Bock) Dep. at 92-93); PX01084 (Otto Bock) at 009).
 - b) <u>Otto Bock SE & Co. KGaA</u>
- Post-Merger, Otto Bock HealthCare GmbH underwent a restructuring. (PX05101 (Schneider (Otto Bock) Dep. at 86)). Dr. Oliver Scheel became the new CEO of Otto Bock HealthCare GmbH. (PX05101 (Schneider (Otto Bock) Dep. at 87)). He reduced the number of executives that report to him and restructured the top management. He

also integrated global sales and marketing under one head. (PX05101 (Schneider (Otto Bock) Dep. at 87-88)).

19. Otto Bock HealthCare GmbH also changed its legal designation and name to Otto Bock "SE & Co. KGaA." (PX05155 (Ehrich (Otto Bock) Dep. at 60)).

B. THE ACQUIRED COMPANY

1. Freedom

- FIH Group Holdings, LLC ("Freedom") was founded in 2002. (Carkhuff (Freedom) Tr. 293; PX07049 at 008 (¶ 15) (Otto Bock Amended Answer); PX05103 (Kim (Freedom) Dep. at 17)). Freedom was founded by Roland Christensen and Rick Meyers. (Carkhuff (Freedom) Tr. 304). It is headquartered in Irvine, California. (Carkhuff (Freedom) Tr. 330).
- 21. Freedom began by selling carbon fiber foot products. (Carkhuff (Freedom) Tr. 293).
- 22. "Freedom has a history of innovation," so after its founding "there were new products introduced at least every year." (Carkhuff (Freedom) Tr. 293-294).
- 23. Freedom introduced its first MPK, the Plié, in 2007. (Carkhuff (Freedom) Tr. 293-294). Its next generation MPK, the Plié 2, was introduced in 2010, and its Plié 3 was introduced in 2014. (Carkhuff (Freedom) Tr. 294). The Plié 3 is manufactured in Gunnison Utah, and "is the only American-made [MPK] product." (Carkhuff (Freedom) Tr. 328-329).
- 24. Today, Freedom "manufactures and sells lower limb prosthetics, including the Plié 3 microprocessor prosthetic knee and the Kinnex microprocessor prosthetic foot." (PX07049 at 008 (¶ 15) (Otto Bock Amended Answer); JX001 at 002 (¶ 11)). These prosthetic products are designed and manufactured at facilities in California and Utah. (PX07049 at 008 (¶ 15) (Otto Bock Amended Answer)).
- 25. Prior to the Merger, Freedom was "privately owned and headquartered in Irvine, California." (PX07049 at 008 (¶15) (Otto Bock Amended Answer); JX-001 at 002 (¶ 10)). {
 (PX05007 (Carkhuff (Freedom) IHT at 26 (*in camera*))). Freedom employed approximately 150 people. (PX07049 at 008 (¶ 15) (Otto Bock Amended Answer)).

26.	{ (PX05007
	(Carkhuff (Freedom) IHT at 25 (in camera)); PX05103 (Kim (Freedom) Dep. at 17-18)).
	} (PX05103 (Kim (Freedom) Dep. at 17-
	18 (in camera); Carkhuff (Freedom) Tr. 304).
	(PX05103
	(Kim (Freedom) Dep. at 18-19 (in camera); Carkhuff (Freedom) Tr. 310)).

- 27. At the time of the Merger, HEP was the majority shareholder of Freedom, and Parker Hannifin was the minority shareholder. (Carkhuff (Freedom) Tr. 311).
- 28. At the time of the Merger, Freedom's only prosthetic knee on the market was the Plié 3. (Carkhuff (Freedom) Tr. 323). Freedom had no mechanical knees. (Carkhuff (Freedom) Tr. 323).
- 29. (PX01623 (Otto Bock) at 010 (*in camera*); PX01003 (Otto Bock) at 009 (*in camera*)).
- 30. Freedom's next-generation MPK, the Quattro, was in development at the time of the Merger. (PX05111 (Prince (Freedom) Dep. at 58); PX07049 at 005 (Otto Bock Amended Answer)). {

} (*See* CCFF ¶¶ 1207-1209, below). Freedom planned to manufacture the Quattro MPK in Irvine, California. (Carkhuff (Freedom) Tr. 330).

31. (PX01318 (Freedom) at 060 (*in camera*)){ } (PX05114 (Ferris (Freedom) Dep.

at 96-97 (in camera))).

- 32.
 - 2. Freedom's Shareholders
 - a) <u>Health Evolution Partners</u>
- 33. {
 33. {
 (Carkhuff (Freedom) IHT at 25 (*in camera*)); PX05103 (Kim (Freedom) Dep. at 17-18 (*in camera*))). {
 (PX05103 (Kim (Freedom) Tr. 304).
 (PX05103 (Kim (Freedom) Dep. at 18-19 (*in camera*);

Carkhuff (Freedom) Tr. 310)).

- 34. At the time of the Merger, HEP was the majority shareholder of Freedom, and Parker Hannifin was the minority shareholder. (Carkhuff (Freedom) Tr. 311).
- 35. At the time of the Merger, HEP employees Braden Kelly and Ned Brown were on the board of directors of Freedom. (PX05113 (Chung (HEP) Dep. at 32-33)).

- b) <u>Parker Hannifin</u>
- 36. At the time of the Merger, HEP was the majority shareholder of Freedom, and Parker Hannifin was the minority shareholder. (Carkhuff (Freedom) Tr. 311).
- 37. At the time of the Merger, Parker Hannifin employee Achilleas Dorotheou was on the board of directors of Freedom. (PX05103 (Kim (Freedom) Dep. at 113-114)). Mr. Dorotheou's position at Parker Hannifin is Vice President of the Human Motion Control Business Unit. (PX05103 (Kim (Freedom) Dep. at 113-114)).

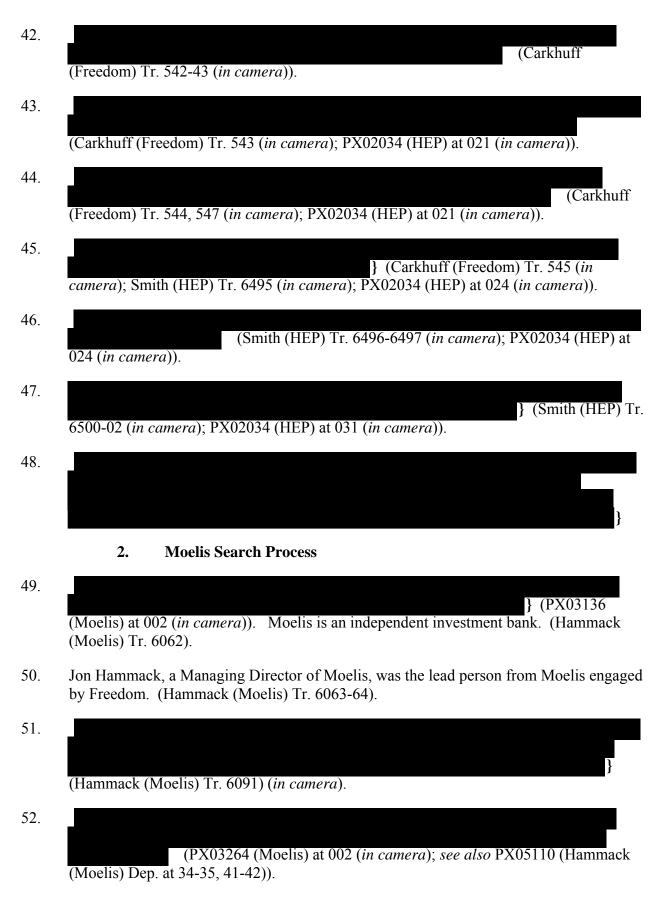
II. THE SALES PROCESS, ACQUISITION, AND POST-TRANSACTION PROCEDURAL HISTORY

A. FREEDOM SALES PROCESS

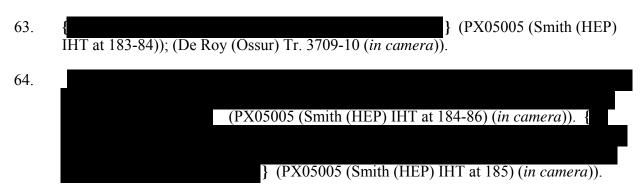
1. Freedom's Early Discussions with Otto Bock about an Acquisition

38.	} (Carkhuff (Freedom) Tr. 649 (<i>in camera</i>)).
39.	
	(Carkhuff (Freedom) Tr. 519, 522, 525-26, 649 (<i>in camera</i>)). { (Carkhuff (Freedom) Tr. 520-21 (<i>in camera</i>); PX01068 (Freedom) (<i>in camera</i>)).
40.	
	}
	b) <u>March 2017 Meeting in Berlin</u>
41.	(Carkhuff (Freedom) Tr. 541-42 (<i>in camera</i>); Smith (HEP) Tr. 6491-92 (<i>in camera</i>); PX02034 (HEP) at 001 (<i>in camera</i>)).

a) October 2016 Meetings in Berlin and New York



53.	(PX03264 (Moelis) at 001 (<i>in camera</i>); <i>see also</i> PX05110 (Hammack (Moelis) Dep. at 34-35, 41-42)).
54.	} (PX05110 (Hammack (Moelis) Dep. at 41-42); PX03264 (Moelis) at 001 (<i>in camera</i>)).
55.	Jon Hammack testified that only Össur and Permobil were told that Freedom was the name of the potential target company. (PX05110 (Hammack (Moelis) Dep. at 57)).
56.	No prosthetics companies were contacted other than Össur and Otto Bock. (PX07051 (Otto Bock) at 003 (¶ 2) (Respondent's Answers to Complaint Counsel's First Set of Interrogatories); <i>see also</i> CCFF ¶¶ 2098, 2102-2104, 2121-2162, below).
57.	(PX03056 (Moelis) at 003 (<i>in camera</i>); PX05110 (Hammack (Moelis) Dep. at 79)). No other companies received a process letter to submit an indication of interest. (PX05110 (Hammack (Moelis) Dep. at 79)).
58.	(PX03057 (Moelis) at 002 (<i>in camera</i>); PX05110 (Hammack (Moelis) Dep. at 48-49); PX02033 (HEP) at 021; Smith (HEP) Tr. 6550-51 (<i>in camera</i>)).
59.	
	3. Initial Bids for Freedom
60.	} (Carkhuff (Freedom) Tr. 660-61 (<i>in camera</i>)).
61.	} (Carkhuff (Freedom) Tr. 660 (<i>in camera</i>)).
62.	<pre>{</pre>



- 65. Freedom subsequently assigned Moelis to continue acting as the go-between with both Otto Bock and Össur to try to "get valuation up." (PX05005 (Smith (HEP) IHT) at 186-87).
 - 4. Due Diligence by Otto Bock and Össur
 - a) <u>Due Diligence by Otto Bock</u>
 - (1) Initiation of Otto Bock Due Diligence
- 66. Tr. 4578 (*in camera*)).
- 67. The due diligence process began after Moelis informed Otto Bock that Freedom would be sold (rather than refinanced) and formally solicited initial bids in June 2017. (PX05131 (Gück (Otto Bock) Dep. at 61)).
- 68. { (Swiggum (Otto Bock) Tr. 3322 (*in camera*)).
- 69. Dr. Sönke Rössing, Chief Strategy and Human Resource Officer for Otto Bock HealthCare GmbH, led Project Roosevelt. (Swiggum (Otto Bock) Tr. 3322-23). Other Otto Bock executives who worked on Project Roosevelt included Matthew Swiggum, Otto Bock North America's CEO at the time of the Merger; Dr. Falk Berster, Head of Business Unit, Prosthetics, Lower Limb; Ralf Stuch, Global Vice President of Sales; Andreas Eichler, Head of Business Unit, Prosthetics, Lower Limb Mechatronic Systems; Dr. Helmut Pfuhl, Head of Strategic Business Unit, Prosthetics; and Alexander Gück, Director of Strategy and M&A. (Swiggum (Otto Bock) Tr. 3322-26).
- 70. Matthew Swiggum, Otto Bock's CEO at the time of the Merger, and others on his team were responsible for reviewing Freedom's sales and marketing activities relating to North America. (Swiggum (Otto Bock) Tr. 3326). Mr. Swiggum was also involved in discussions about Freedom's Plié 3 and Quattro, should they be acquired by Otto Bock. (Swiggum (Otto Bock) Tr. 3327-28).

71. Scott Schneider, Vice President of Government, Medical Affairs and Future Development, led Otto Bock's U.S. due diligence team looking at the commercial market and reimbursement for Freedom's products, reporting to Mr. Swiggum. (Schneider (Otto Bock) Tr. 4407-4408). This team included Andreas Kannenberg, Executive Medical Director; Scott Weber, North America Market Manager; Walter Governor, Senior Director of Sales and Clinical Services, Prosthetics; Sebastian Kuch, Business Analyst, Sales and Marketing; and Kimberly Hanson, Director of Reimbursement. (Schneider (Otto Bock) Tr. 4409).

(PX01091

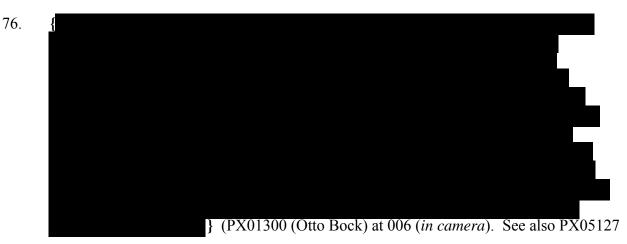
(Otto Bock) (in camera); Schneider (Otto Bock) Tr. 4450-52 (in camera)).

- Alexander Gück, Director of Strategy and M&A, and Linus Cremer, Manager, Corporate Strategy and M&A, drafted a memo to Otto Bock owner Professor N\u00e4der on July 25, 2017 to update N\u00e4der on the status of the Freedom due diligence and sales process. (PX01017 (Otto Bock); PX05131 (G\u00f4ck (Otto Bock) Dep. at 62)).
- 73. Due diligence activities included reviewing materials provided by Freedom in a digital data room, including "[i]nformation about the functions of Freedom, customers, products, and their market views." (PX05127 (Rössing (Otto Bock) Dep. at 42-43). Review of these materials was overseen by Mr. Rössing, Chief Strategy and Human Resource Officer, but was conducted by individuals within Otto Bock as well as its consultants, Rodl & Partners. (PX05127 (Rössing (Otto Bock) Dep. at 43-44).
 - (2) Otto Bock's August 2017 Due Diligence on Freedom

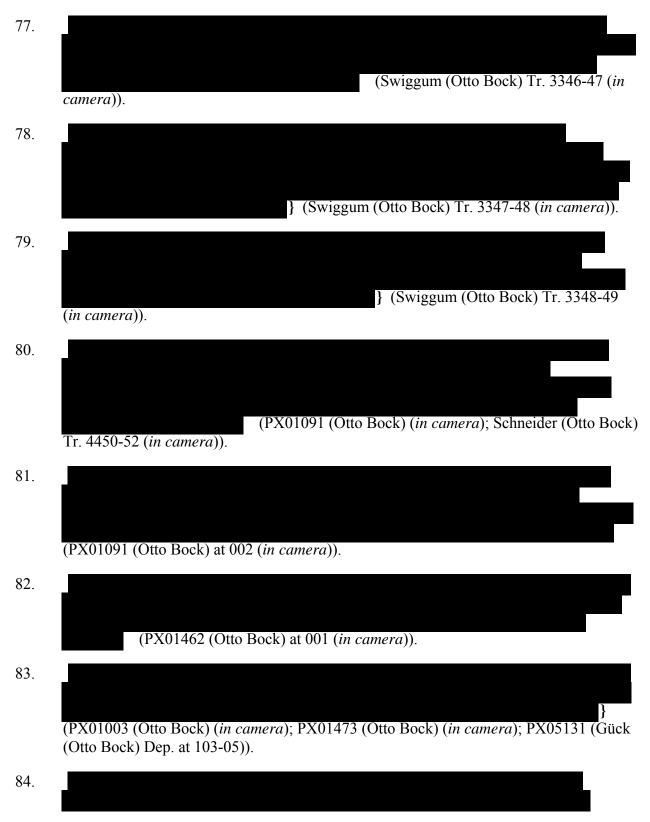
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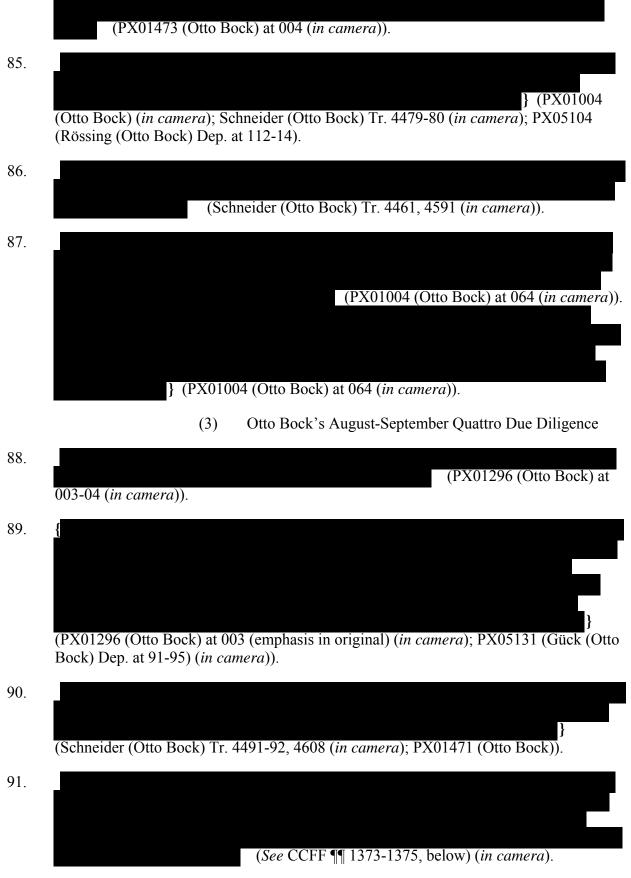
(Swiggum (Otto Bock) Tr. 3345 (*in camera*); PX05127 (Rössing (Otto Bock) Dep. at 118)).

75. Alexander Gück (Director of Strategy and M&A)'s team prepared materials for the Otto Bock participants in advance of the meeting, including an agenda, which appears at PX01300. (PX01300 (Otto Bock) (*in camera*); PX05131 (Gück (Otto Bock) Dep. at 75-76; PX05127 (Rössing (Otto Bock) Dep. at 126)).



(Rössing (Otto Bock) Dep. at 124) (confirming that this was a list of the attendees of the meetings in Irvine, California)).





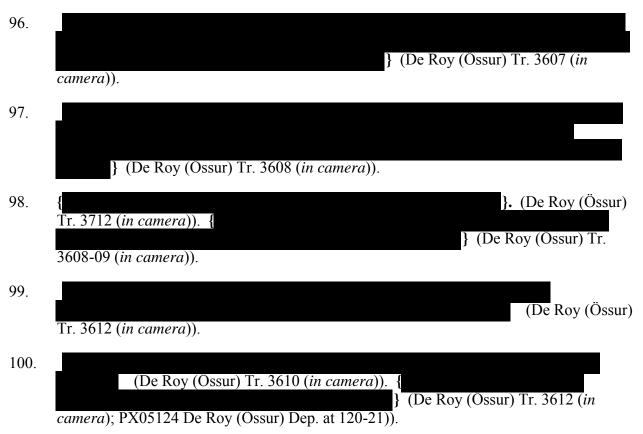
} (Swiggum (Otto Bock) Tr. 3388-

89 (in camera); PX01471 (Otto Bock) at 001)).

92.

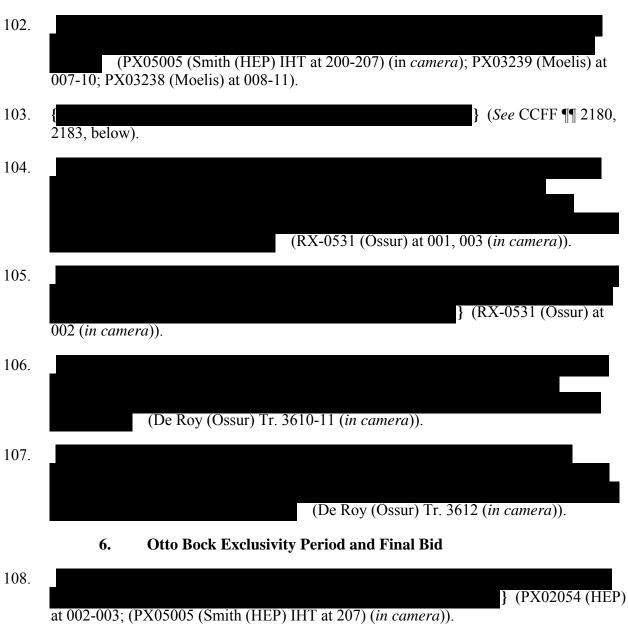
93. Following the in-person evaluation of the Quattro, Scott Schneider on September 19, 2017 circulated to Alexander Gück (Director of Strategy and M&A), Linus Cremer (Manager, Corporate Strategy and M&A), Helmut Pfuhl (Head of Strategic Business Unit, Prosthetics), Sönke Rössing (Chief Strategy and Human Resource Officer), and others a "Roosevelt Q Product Summary," signed on behalf of the four Otto Bock attendees of the in-person Quattro testing. (PX01471 (Otto Bock) at 001)).

- 94. (Schneider (Otto Bock) Tr. 4638 (*in camera*); PX01471 (Otto Bock) at 003)).
- 95. The "RISKS IF WE DO NOT CONTROL QUATTRO" included "Will have to put more Genium functions into C-Leg," "Ossur could have something that will compete better with C-Leg 4 because the stance phase functions will be much better than Rheo can acheive [sic]" and "Anyone who takes this product will cut in to C-Leg 4 market share. Especially in the US." PX01471 (Otto Bock) at 003 (Roosevelt Q Product Summary)).



b) <u>Due Diligence by Össur</u>

101. Mr. De Roy categorized the due diligence it was able to conduct before the final round of bidding as "quite limited." (PX05124 (De Roy (Össur) Dep. at 209)).



5. Second-Round Bids for Freedom

B. THE CONSUMMATION OF OTTO BOCK'S ACQUISITION OF FREEDOM

109. On September 22, 2017, Otto Bock acquired Freedom (the "Merger"). (PX07049 at 003 (¶ 1) (Otto Bock Amended Answer); JX001 at 001 (¶ 4)). The acquisition price was approximately \$80 million. (PX05010 (Schneider, IHT at 177); (PX05122 (Smith (HEP) Dep. at 179)).

- 110. The Merger was not reportable under the HSR Act. (Complaint Counsel's Opening Statement, Tr. 13).
- 111. Upon consummation of the Merger, Freedom became a wholly owned subsidiary of Otto Bock. (JX001 at 002 (¶ 9)).
- 112. Otto Bock purchased Freedom from its majority shareholder, Health Evolution Partners, and its minority shareholders including Parker Hannifin and various employees and individuals, pursuant to a share tender which followed a shareholder vote. (Carkhuff (Freedom) Tr. 311-13).
- 113. (PX05005 (Smith (HEP) IHT at 208-09) (*in camera*)).

C. FTC INVESTIGATION

1. Initiation of FTC Investigation

- 114. In September 2017, the FTC began its preliminary investigation into the Merger and its potential effects on competition for the sale of MPKs in the United States.
- 115. Hanger's outside counsel contacted the FTC near the onset of the investigation. (Asar (Hanger) Tr. 1462).
- 116. On November 3, 2017, the Commission issued a resolution authorizing the use of compulsory process for the FTC to obtain relevant information for the investigation. The authorized use of compulsory process included issuing Subpoenas *Duces Tecum* ("SDTs"), Subpoenas *Ad Testificandum* ("SATs"), and Civil Investigation Demands ("CIDs").
- 117. On November 9, 2017, the Commission issued SATs, SDTs, and CIDs to Otto Bock, Freedom, and HEP, as well as an SAT to Freedom's CEO at the time of the acquisition, David Smith. The Commission also issued SATs to Otto Bock and Freedom's customers, Hanger, Inc. ("Hanger"), The Center for Orthotics & Prosthetic Care ("COPC"), Jonesboro Prosthetic & Orthotic Laboratory ("Jonesboro"), and Empire Medical ("Empire"), in addition to other relevant third parties. The Commission also issued CIDs to MPK manufacturers including Össur Americas, Inc., Endolite USA, and a subsidiary of Nabtesco Corporation, as well as an additional SAT to Össur. Lastly, the Commission issued SDTs to Össur, Moelis & Company ("Moelis"), and Madison Capital Funding LLC ("Madison Capital").
- 118. On November 30, 2017, the Commission issued additional CIDs to Hanger and Fillauer Companies, Inc. ("Fillauer").

2. Investigational Hearings of Respondent Officials

- 119. From November 27, 2017 to December 8, 2017, Complaint Counsel conducted 10 investigational hearings ("IHs") during its investigation.
- 120. From Freedom, Complaint Counsel conducted IHs of John Robertson (Vice President of R&D and Mechatronics Manufacturing), Maynard Carkhuff (Chairman), and David Smith (CEO at the time of the Merger). (PX05006 (Robertson (Freedom) IHT); PX05007 (Carkhuff (Freedom) IHT); PX05005 (Smith (HEP) IHT)).
- 121. From Otto Bock, Complaint Counsel conducted an IH of Scott Schneider (Vice President of Government, Medical Affairs and Future Development). (PX05010 (Schneider (Otto Bock) IHT)).
- 122. Complaint Counsel also conducted six IHs of Respondents' customers and other relevant third-parties, including Jonathan Endrikat from Empire Medical, Vinit Asar from Hanger, Rob Yates from Jonesboro P&O Laboratory, Keith Senn from COPC, and Dr. Kenton Kaufman from Mayo Clinic. (PX05001 (Endrikat (Empire) IHT); PX05002 (Asar (Hanger) IHT); PX05003 (Yates (Jonesboro) IHT); PX05004 (Senn (COPC) IHT); PX05008 (Kaufman (Mayo Clinic) IHT)).

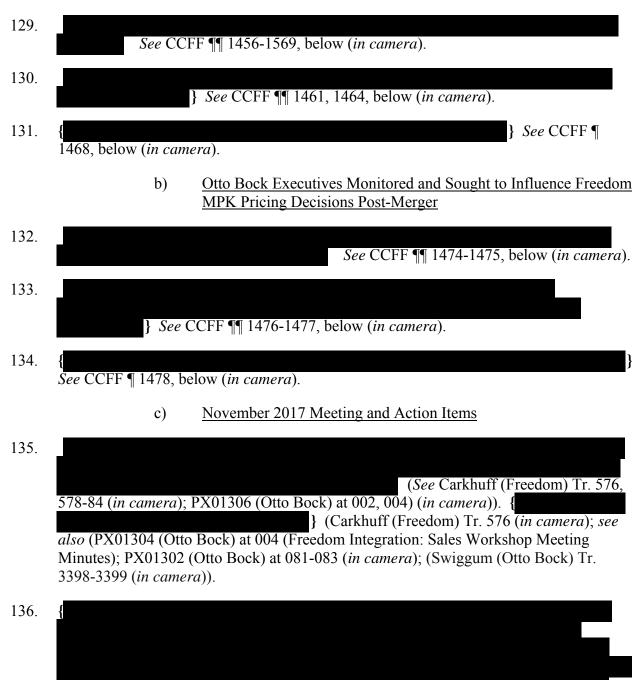
D. OTTO BOCK AND FREEDOM OPERATIONS POST-CLOSING UNTIL HOLD SEPARATE AGREEMENT

1. Otto Bock Replaced Freedom's CEO and Some Freedom Employees Left the Company

- 123. At the time of the Merger, Freedom's Chairman and CEO was David Smith. (PX05007 (Carkhuff (Freedom) IHT at 26)).
- 124. Freedom terminated David Smith as Chairman and CEO at the time of the Merger. Smith resigned three days before the Merger closed, after being informed that he would not be retained by Otto Bock. (PX05122 (Smith (HEP) Dep. at 7); PX05005 (Smith (HEP) IHT at 211-12)).
- 125. (Carkhuff (Freedom) Tr. 582 (*in camera*)).
- 126. On December 19, 2017, Otto Bock and the FTC entered into a Hold Separate and Asset Maintenance Agreement ("Hold Separate Agreement").
- 127. During his investigational hearing on December 5, 2017, Mr. Carkhuff, Freedom's current Chairman, testified that from the time of the Merger until early December 2017, he estimated up to five employees had left Freedom, including an engineer who he believed had been performing test validations on the Quattro. (PX05007 (Carkhuff (Freedom) IHT at 305-06)).

2. Changes in Freedom's Operations

- a) <u>Post-Merger, Otto Bock Halted Freedom's Pre-Merger Plan to</u> Launch the New Plié 4 in October 2017
- 128. After the Merger, Freedom "shared business plans both domestically and internationally prior to the Hold Separate Agreement" with its former rival, Otto Bock. (PX05109 (Carkhuff (Freedom) Dep. at 15-16).



	} (PX01306 (Otto Bock) at 002 (<i>in camera</i>); (Carkhuff (Freedom) Tr. 578-81 (<i>in camera</i>)).
137.	(PX01306 (Otto
	Bock) at 002 (<i>in camera</i>); (Carkhuff (Freedom) Tr. 581-82) (<i>in camera</i>)).
138.	(PX01306 (Otto Bock) at 002 (<i>in camera</i>); (Carkhuff (Freedom) Tr. 582 (<i>in camera</i>)).
139.	(<i>in cumera</i>), (Carkhun (Freedoni) 11: 382 (<i>in cumera</i>)).
157.	} (PX01306 (Otto Bock) at 001 (<i>in camera</i>)).
140.	582 (<i>in camera</i>); PX01306 (Otto Bock) at 004) (<i>in camera</i>)). (Suringwar (Otto Bock) Tr. 2401 02 (<i>in camera</i>))
	(Swiggum (Otto Bock) Tr. 3401-02 (<i>in camera</i>)).
	(Swiggum (Otto Bock) Tr. 3405) (<i>in camera</i>); (PX01302 (Otto Bock) at 003 (<i>in camera</i>)).
141.	(PX01302 (Otto Bock) at 081 (<i>in camera</i>); PX05148 (Swiggum (Otto Bock) Dep. at 175- 176) (<i>in camera</i>)).
	} (PX01302 (Otto Bock)
	at 081 (<i>in camera</i>)).
142.	
	(PX01306 (Otto Bock) at 004 (<i>in camera</i>)).
143.	(PX01306
	(Otto Bock) at 004) (<i>in camera</i>); Swiggum (Otto Bock) Tr. 3404 (<i>in camera</i>); Carkhuff (Freedom) Tr. 584 (<i>in camera</i>)).

3. Otto Bock and Freedom Halt All Integration Planning Work in Early December 2017

144. Otto Bock and Freedom stopped all integration and integration planning work in early December shortly after the investigational hearing of Scott Schneider, Vice President of Government, Medical Affairs and Future Development, on December 7, 2017. (PX05127 (Rössing (Otto Bock) Dep. at 186); *see also* PX05010 (Schneider (Otto Bock) IHT)).

E. AGREEMENT BETWEEN OTTO BOCK AND FTC TO HOLD SEPARATE

- 145. On December 19, 2017, Otto Bock and the FTC entered into a Hold Separate and Asset Maintenance Agreement ("Hold Separate Agreement").
- 146. Pursuant to the Hold Separate Agreement, Otto Bock agreed to "restore all services, locations, employees, products, operations or businesses" of Freedom that were transferred to or consolidated with Otto Bock after the Acquisition Date.
- 147. Otto Bock, appointed Joe Martin, Freedom's former COO, as its Hold Separate Monitor. (Carkhuff (Freedom) Tr. 313).
- 148. Mr. Martin "writes periodic reports to the FTC." (Carkhuff (Freedom) Tr. 314-15).
- 149. Otto Bock appointed Maynard Carkhuff as the "manager of the Hold Separate Agreement and Asset Maintenance Agreement." (PX05109 (Carkhuff (Freedom) Dep. at 9)).
- 150. Under the hold-separate agreement, "Otto Bock is required to provide [Freedom] certain assistance, such as providing cash resources to fund the business and some and legal assistance and distribution assistance internationally." (Carkhuff (Freedom) Tr. 314).
- 151. } (PX05109 (Carkhuff (Freedom) Dep. at 192-93) (*in camera*)).
 - F. OTTO BOCK AND FREEDOM OPERATIONS POST-HOLD SEPARATE
 - 1. Otto Bock
 - a) <u>Otto Bock Global Corporate Restructuring</u>
- 152. (Schneider (Otto Bock) Tr. 4658 (in camera)).
- 153. Post-Merger, Otto Bock HealthCare GmbH underwent a restructuring. (PX05101 (Schneider (Otto Bock) Dep. at 86)). Dr. Oliver Scheel became the new CEO of Otto Bock HealthCare GmbH. (PX05101 (Schneider (Otto Bock) Dep. at 87)). He reduced the number of executives that report to him and restructured the top management. He

also integrated global sales and marketing under one head. (PX05101 (Schneider (Otto Bock) Dep. at 87-88)).

- 154. Otto Bock HealthCare GmbH also changed its legal designation and name to Otto Bock "SE & Co. KGaA." (PX05155 (Ehrich (Otto Bock) Dep. at 60)).
- 155. (Schneider (Otto Bock) Tr. 4658 (*in camera*)).
 - b) <u>Otto Bock Personnel Changes</u>
- 156. Mr. Swiggum was the regional president and CEO of Otto Bock Healthcare North America from 2016 through February 2018 when he was terminated. (Swiggum (Otto Bock) Tr. 3310, 3313-14). {

} (Schneider (Otto Bock) Tr. 4659 (*in camera*)). Mr. Stuch was Otto Bock Healthcare GmbH's global Sales Leader. (Swiggum (Otto Bock) Tr. 3323).

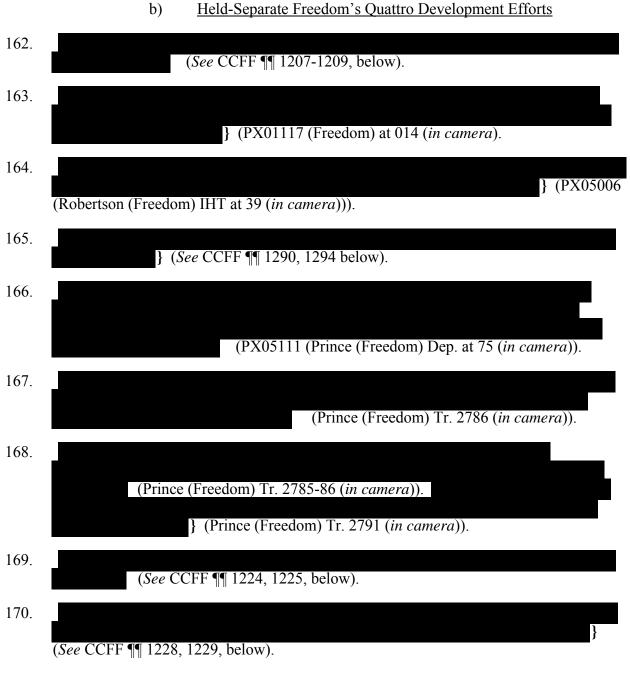
157. Mr. Swiggum testified that he was fired because "[t]here was a desire to reduce operating costs [\$]1.5 million at the expense of headcount." (Swiggum (Otto Bock) Tr. 3314).

(Swiggum (Otto Bock) Tr. 3366 (*in camera*)). Mr. Swiggum was directed to fire Brad Ruhl, Scott Schneider, Frank Oschelle, Chris Nolan and Mark Agro. (Swiggum (Otto Bock) Tr. 3366 (*in camera*)).

- 158. Mr. Swiggum was given two reasons for his termination: (1) because "we missed the number in 2017" and (2) "they didn't believe I was going to let the people go." (Swiggum (Otto Bock) Tr. 3430).
- 159. In February of 2018, after the corporate reorganization, Brad Ruhl became the Managing Director of North America, "which is really the CEO role." (Schneider (Otto Bock) Tr. 4274).

2. Held-Separate Freedom

- a) <u>Held-Separate Freedom's Continued Plié 3 Sales</u>
- 160. After the Hold Separate Agreement was executed on December 19, 2017, Freedom continued to sell the Plié 3 in the United States. PX05138 (Reissfelder (Freedom) Dep. at 22-23 (Plié sales in the U.S. in 2018 have been relatively flat, largely due to the departure of a key sales manager).
- 161. Jeremy Mathews, Freedom's Senior VP of Sales and Marketing, testified that Plié sales "continued to increase even after the acquisition." (PX05137 (Mathews (Freedom) Dep. at 196)).



c) <u>Held-Separate Freedom's Personnel Changes</u>

- 171. Since the transaction, Mr. Carkhuff has found it "challenging" to "maintain the business as a growing, competitive company in the marketplace, as is required by the hold-separate agreement." (Carkhuff (Freedom) Tr. 318).
- 172. Some employees have left Freedom "because they are concerned about the future of their jobs." (Carkhuff (Freedom) Tr. 318). Freedom has had "challenges" with employee morale as a result. (Carkhuff (Freedom) Tr. 318).

- 173. Since the Merger, 32 employees left the company. (Carkhuff (Freedom) Tr. 321). At the time of his trial testimony on July 19, 2018, Mr. Carkhuff explained that Freedom had seven open positions that it was attempting to fill. (Carkhuff (Freedom) Tr. 322). One of those positions is a domestic regional sales manager who resigned recently. (Carkhuff (Freedom) Tr. 322).
- 174. Erin Myers, a sales representative, also left Freedom in either December of 2017 or January 2018 to work at Fillauer. (PX05114 (Ferris (Freedom) Dep. at 190-191).
- 175. Since the Hold Separate Agreement was put in place, customers are experiencing "fear and uncertainty and doubt . . . as to whether Freedom will be around to service its warranties[.]" (Carkhuff (Freedom) Tr. 318). This "causes concern in the practitioners' minds[,]" which requires Freedom employees to "spend a lot of time answering these type concerns and trying to assuage those concerns when [they] really should be selling [Freedom's] products and teaching clinicians[.]" (Carkhuff (Freedom) Tr. 319). This "increasing challenge . . . has had a negative impact on [Freedom's] business." (Carkhuff (Freedom) Tr. 319).

G. PART 3 LITIGATION

1. Complaint Issuance

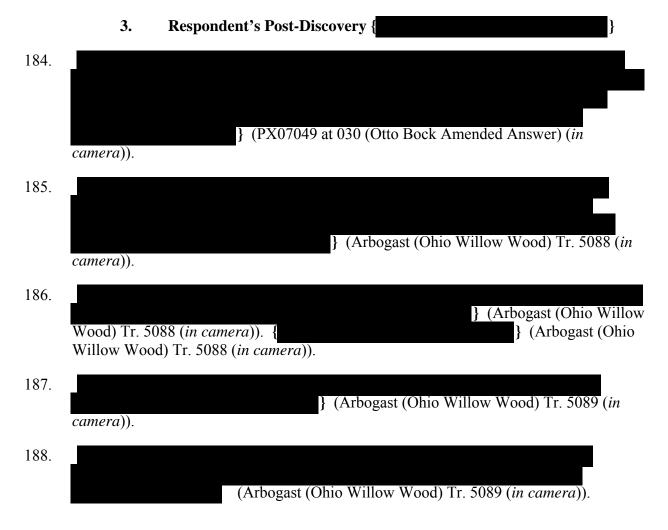
- 176. The administrative complaint, filed by the FTC on December 20, 2017, alleges that the Merger substantially lessened competition in the relevant market—MPKs—in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC act, as amended, 15 U.S.C. § 45. (Commission Complaint at ¶ 67).
- 177. The FTC alleges that the relevant market in which to analyze the effects of the Merger is no broader than the manufacture and sale of MPKs to prosthetic clinics in the United States. (Commission Complaint at \P 17).
- 178. On January 10, 2018, Otto Bock submitted an answer and affirmative defenses to the FTC's December 20, 2017 Complaint. (Otto Bock Answer). On February 15, 2018, Otto Bock submitted an amended answer and affirmative defenses to the FTC's Complaint. (PX07049 (Otto Bock Amended Answer)).

2. Discovery

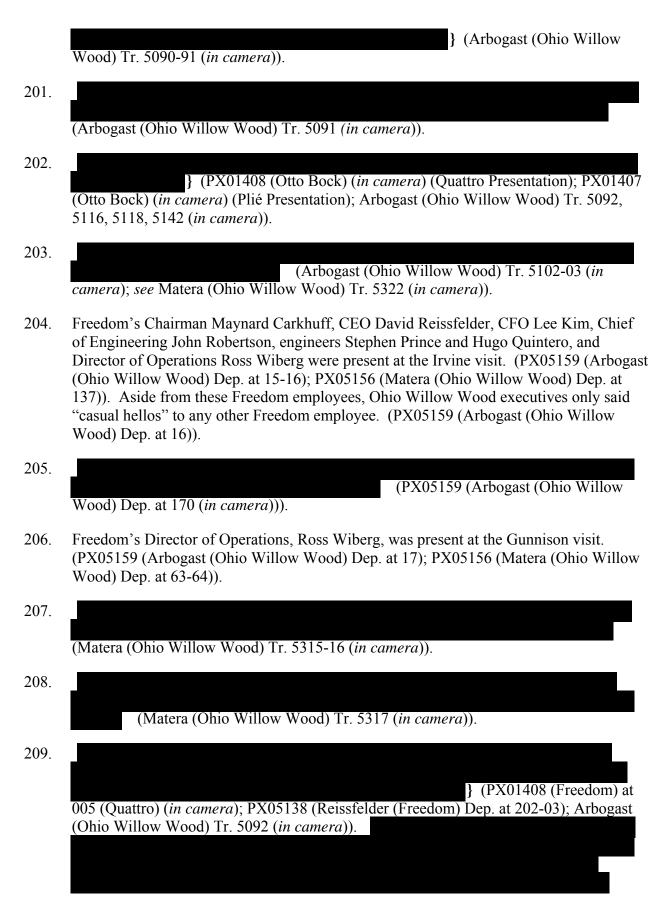
- 179. During discovery, Complaint Counsel conducted 73 depositions—27 depositions of Otto Bock and Freedom executives, 42 third-party depositions, and 4 expert depositions.
- 180. Complaint Counsel submitted two expert reports and two expert rebuttal reports in this matter. (PX06001A (Morton Expert Report); PX06002 (Hammer Expert Report); PX06003 (Morton Rebuttal Report); PX06004 (Hammer Rebuttal Report)).
- 181. Fiona Scott Morton's expert report was submitted on May 8, 2018, and her rebuttal report was submitted on June 1, 2018. (PX06001A (Morton Expert Report); PX06003 (Morton

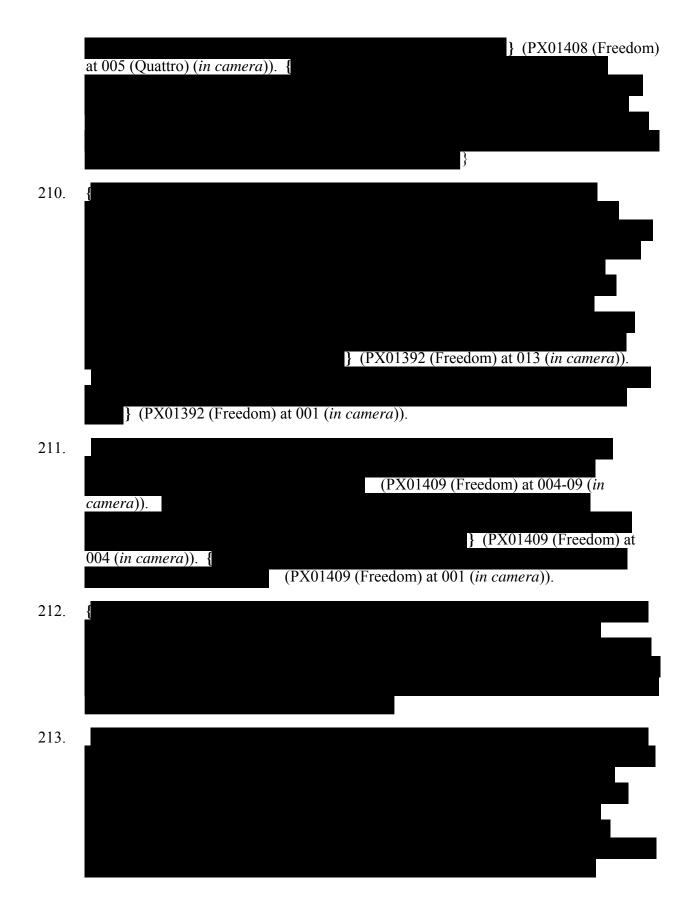
Rebuttal Report)). Dr. Scott Morton was tasked with, among other things, "assess[ing] the likely effects on competition due to the acquisition of FIH Group Holdings, LLC ('Freedom' or 'Freedom Innovations') by Otto Bock HealthCare North America ('Otto Bock')." (PX06001A at 006 (¶ 10) (Morton Expert Report)).

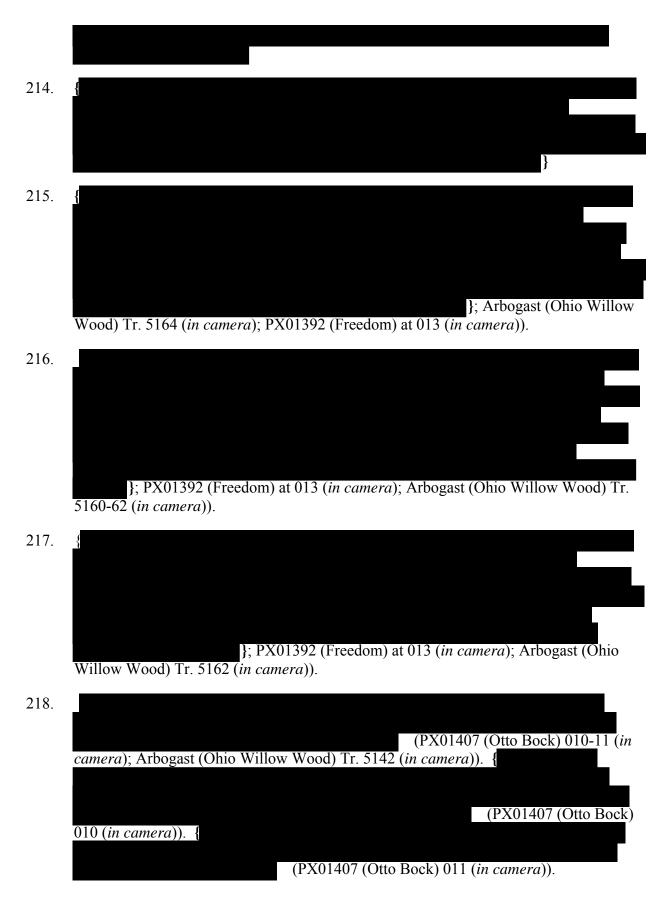
- 182. Christine Hammer's expert report was submitted on May 8, 2018, and her rebuttal report was submitted on June 1, 2018. (PX06002 (Hammer Expert Report); PX06004 (Hammer Rebuttal Report)). Ms. Hammer was tasked with "analyz[ing] and provid[ing] expert opinions and conclusions relating to whether Freedom qualifies as a 'failing firm'" and "relating to what, if any, efficiencies are likely to result from Otto Bock's acquisition of Freedom and be cognizable under the Merger Guidelines." (PX06002 at 005 (¶6) (Hammer Expert Report)).
- 183. Respondent submitted two expert reports in this matter. (RX1048 (Peterson Expert Report); RX1049 (Argue Expert Report)).

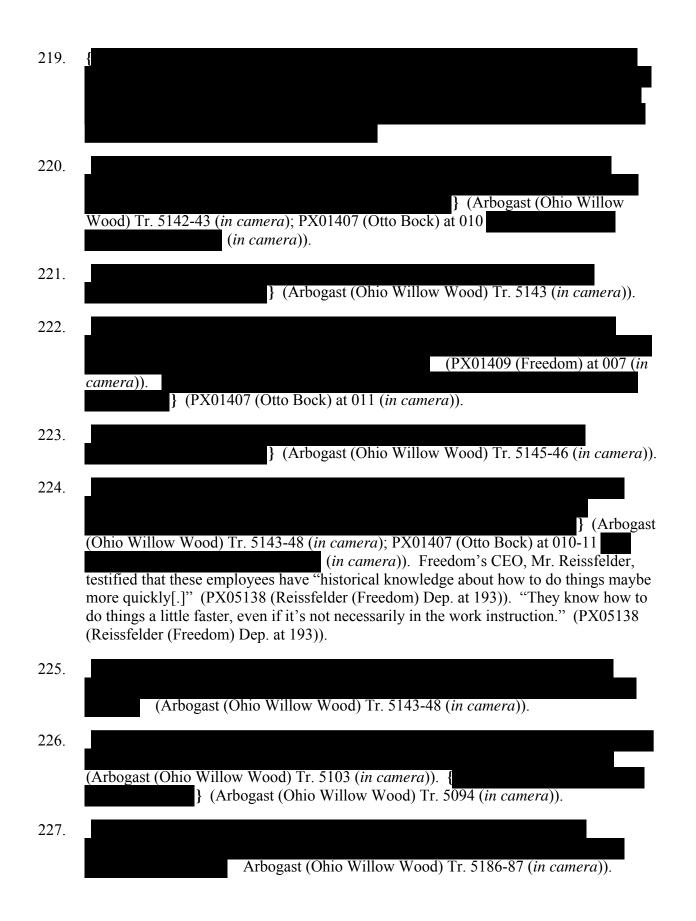


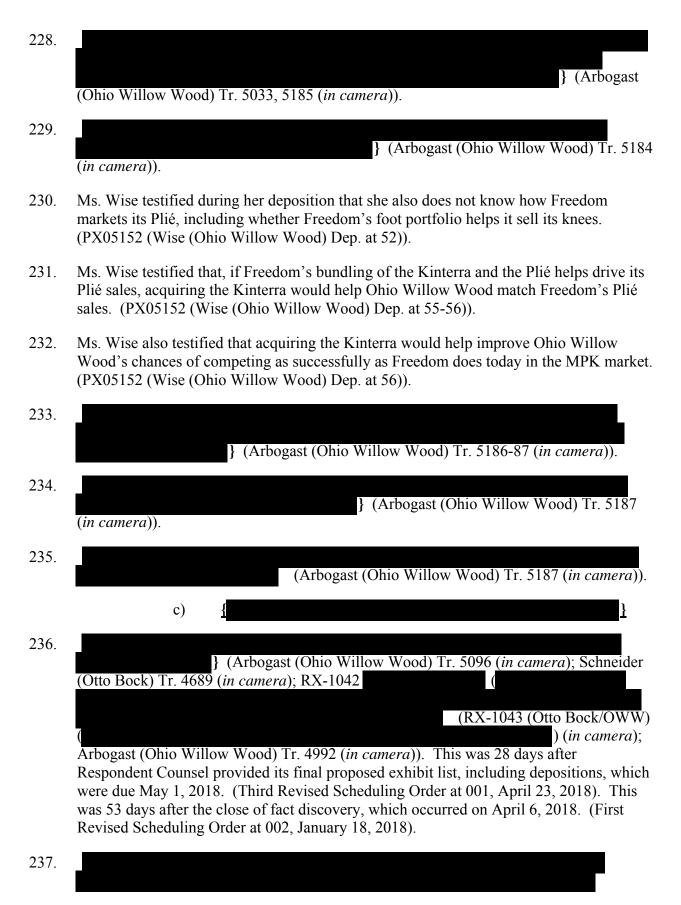
	a) {
189.	(Arbogast (Ohio Willow Wood)Tr. 5095 (<i>in camera</i>); PX03022 (Otto Bock) at 001).
190.	{ (Arbogast (Ohio Willow Wood) Tr. 5095 (<i>in camera</i>)). { (Arbogast (Ohio Willow Wood) Tr. 5095 (<i>in camera</i>)).
191.	} (Arbogast (Ohio Willow Wood) Tr. 4993 (in camera)).
192.	FTC staff deposed Mr. Arbogast on March 6, 2018 and April 6, 2018. (Arbogast (Ohio Willow Wood) Tr. 5068; PX05106 (Arbogast (Ohio Willow Wood)); PX05159 (Arbogast (Ohio Willow Wood))).
193.	(PX05106 (Arbogast (Ohio Willow Wood) Dep. at 100-101)).
194.	} (PX05106 (Arbogast (Ohio Willow Wood) Dep. at 137-38)).
195.	<pre>} (PX05159 (Arbogast (Ohio Willow Wood) Dep. at 141) (in camera)).</pre>
196.	On April 4, 2018, Complaint Counsel deposed Linda Wise, Chief Marketing Officer of Ohio Willow Wood. (PX05152 (Wise (Ohio Willow Wood) Dep. at 004)).
197.	On April 5, 2018, Complaint Counsel deposed John Matera, Chief Operations Officer of Ohio Willow Wood. (PX05156 (Matera (Ohio Willow Wood) Dep. at 004).
	b) <u>Ohio Willow Wood {</u> }
198.	(Arbogast (Ohio Willow Wood) Tr. 5089-95 (<i>in camera</i>)).
199.	{ (Arbogast (Ohio Willow Wood) Tr. 5089-90 (<i>in camera</i>)).
200.	



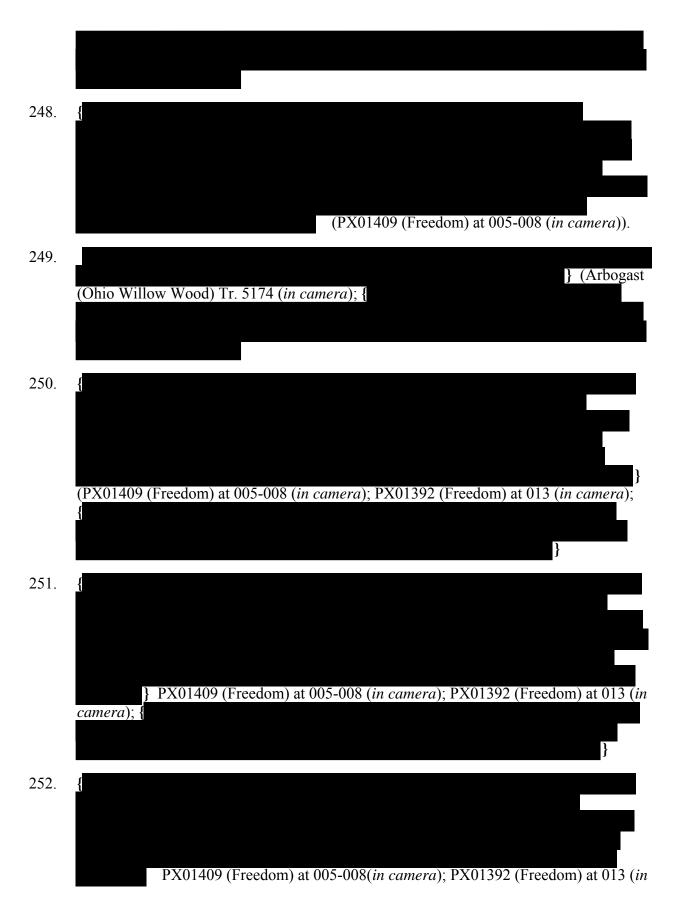


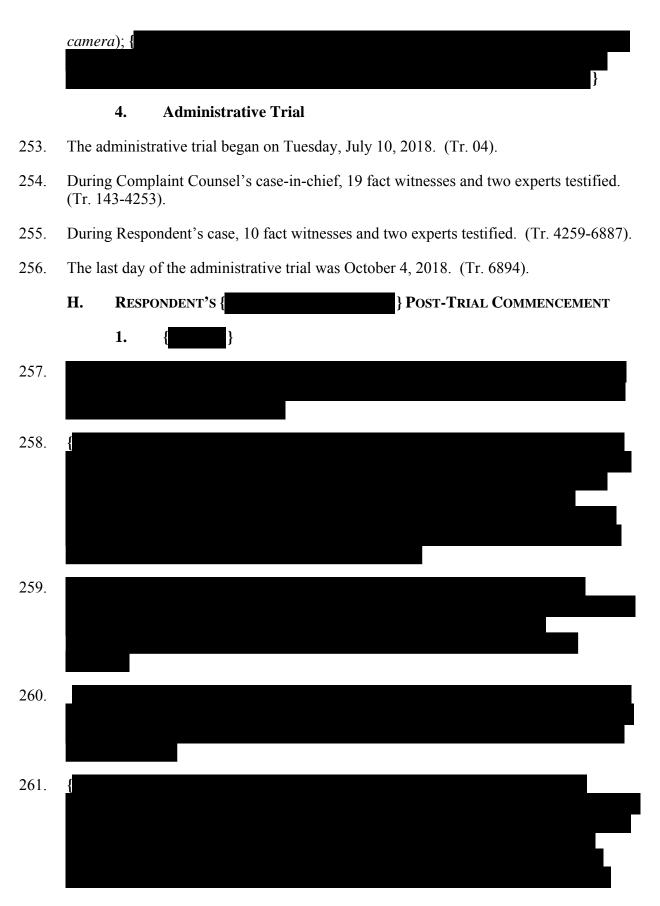


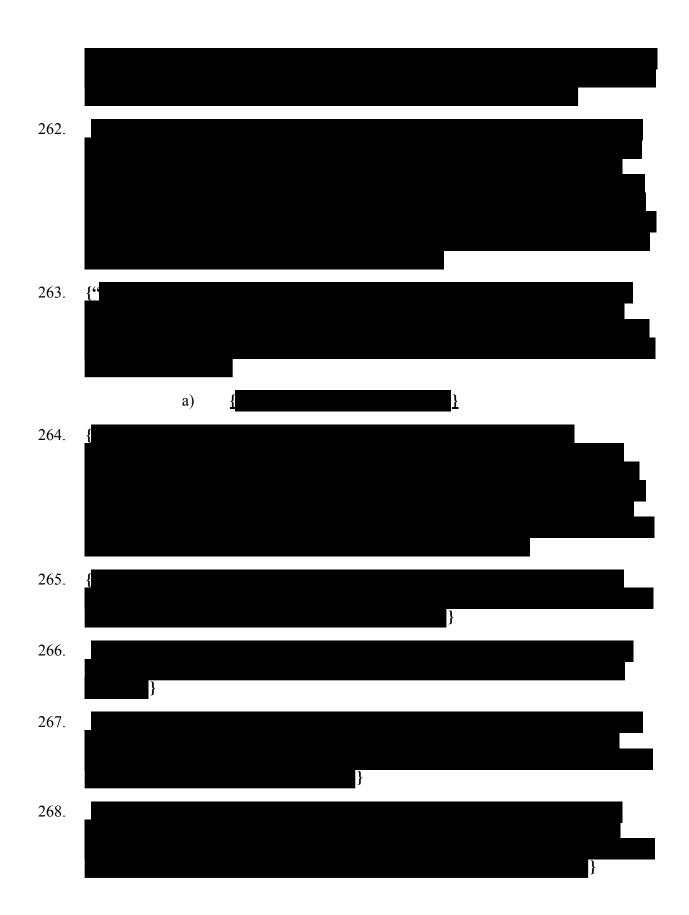


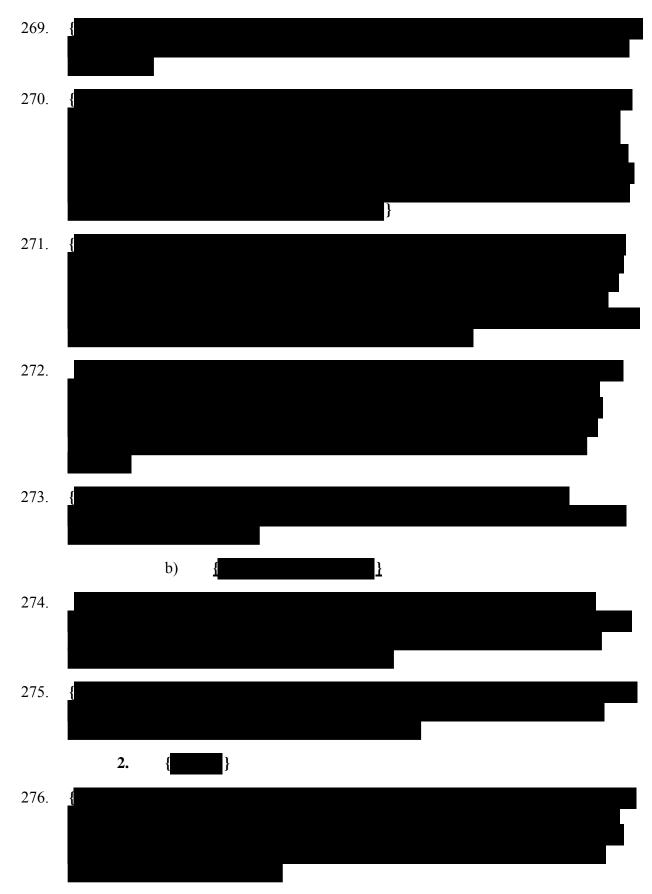


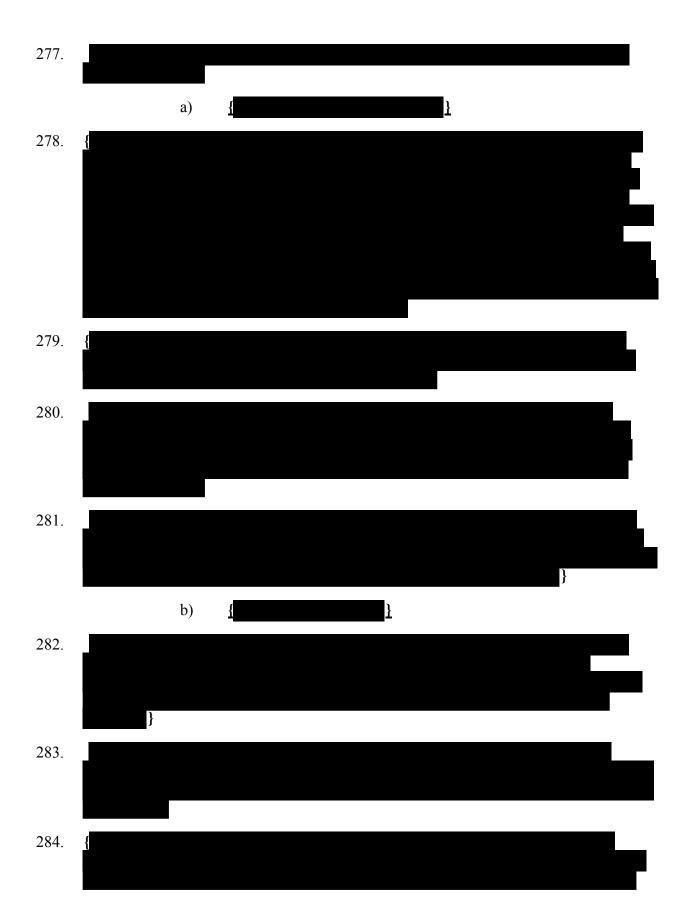
	} (Arbogast (Ohio Willow Wood) Tr. 5150-51 (<i>in camera</i>)).
238.	} (Arbogast (Ohio Willow Wood) Tr. 5097-98 (in camera)).
239.	
	(Arbogast (Ohio Willow Wood) Tr. 5061, 5097 (in camera)).
240.	(Arbogast (Ohio Willow Wood) Tr. 5098 (in camera)).
241.	}
242.	{ (Schneider (Otto Bock) Tr. 4706-08 (<i>in camera</i>); Arbogast (Ohio Willow Wood) Tr. 5096 (<i>in camera</i>).
243.	} (PX05138 (Reissfelder (Freedom) Dep. at 138-39); { (PX01681 (Freedom) at 011 (Operating Committee Meeting Presentation dated February 2016) (<i>in camera</i>)).
244.	{ (Arbogast (Ohio Willow Wood) Tr. 5121 (<i>in camera</i>); { }
245.	{ (Arbogast (Ohio Willow Wood) Tr. 5137-39 (<i>in camera</i>); Schneider (Otto Bock) Tr. 4703-04 (<i>in camera</i>)).
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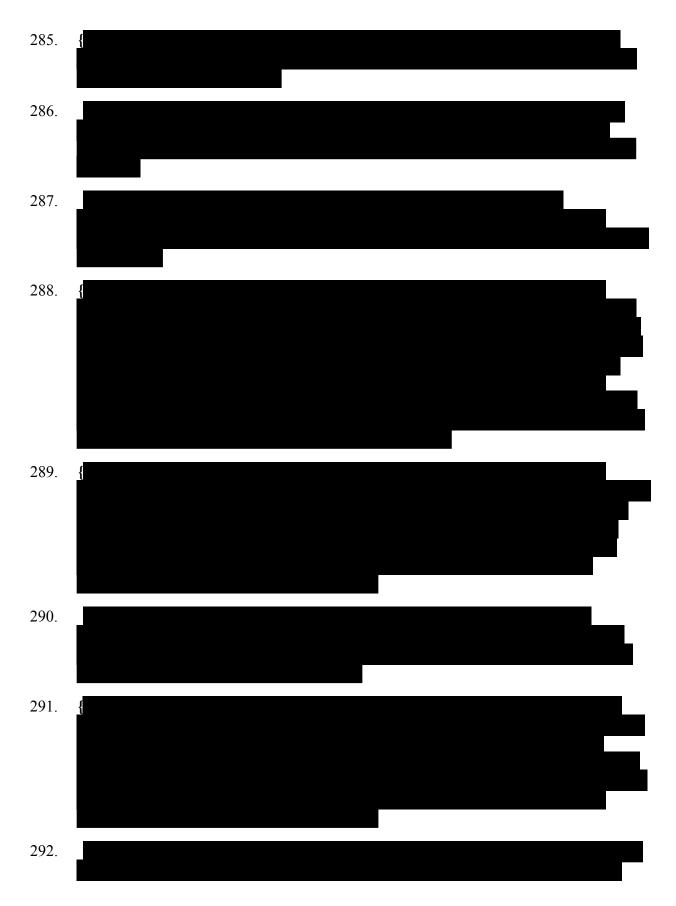


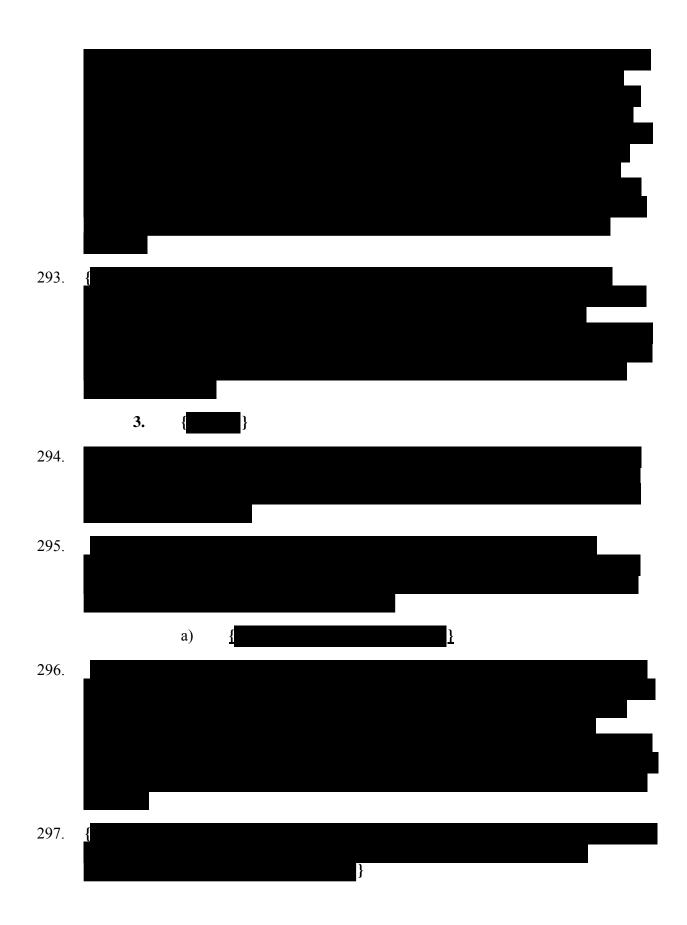














III. GENERAL PROSTHETICS INDUSTRY BACKGROUND

A. PATIENTS THAT RECEIVE AND USE PROSTHETIC KNEES

1. Causes of Amputation or Need for a Prosthetic Knee

- 303. An estimated 1.9 million individuals in the United States live with the loss of a limb, including slightly more than 350,000 individuals (or 18.5 percent) who are transfemoral, or above-the-knee, amputees. (PX08004 (RAND Report) at 007).
- 304. Congenital deformities or diabetes, vascular disease, and traumatic injury cause patients to lose their lower limbs. (Asar (Hanger) Tr. 1334; Ell (Mid-Missouri O&P) Tr. 1677).

305. Approximately 78 percent of lower-limb amputations were due to dysvascular disease, approximately 20 percent were due to trauma, and approximately two percent were due to cancer. (PX08072 at 004 (Kathryn Ziegler-Graham, et al., Estimating the Prevalence of Limb Loss in the United States: 2005 to 2050, 89 Archives of Physical and Med. Rehab. 422, 425 (2008)).

2. Types of Amputation

- 306. Lower-limb amputees are grouped according to the location of their amputation—abovethe-knee, below-the-knee, or knee disarticulation. (PX05164 (Highsmith (Dep't of Veterans Affairs) Dep. at 54)).
- 307. Above-the-knee amputees, or "transfemoral" amputees, have an amputation through the femur. (JX001 at 002 (¶¶ 14-15); Potter (Walter Reed) Tr. 754; Smith (Retired) Tr. 5988).
- 308. Knee-disarticulation amputees receive an amputation through the knee joint. (PX05164 (Highsmith (Veterans Affairs) Dep. at 54)).
- 309. Below-the-knee amputees, or "transtibial" amputees, have an amputation below the knee. (PX05164 (Highsmith (Dep't of Veterans Affairs) Dep. at 54)).
- 310. Transfemoral amputees make up the largest percentage of knee amputation patients. Surgeons in the United States perform substantially more transfemoral amputations than knee disarticulation amputations. (PX05143 (Smith (Retired) Dep. at 40-42)). A former surgeon for the U.S. Department of Veteran Affairs estimated that surgeons perform roughly 20 times more transfemoral amputations than knee disarticulation amputations. (PX05143 (Smith (Retired) Dep. at 40-42)).
- 311. MPKs are used by both above-the-knee amputees and knee-disarticulation amputees. On Otto Bock's website, under FAQs, it states: "Is a microprocessor knee system right for me? Most microprocessor knees can be used by people with amputation at the knee (knee disarticulation) and above the knee (transfemoral). They provide the same benefits to double amputees (bilateral limb deficiency) and people with an amputation at the hip (hip disarticulation). They also can be used by people with a hemipelvectomy amputation and good walking ability. Check each knee system to see their recommended 'indications,' or ask your prosthetist." (PX08013 (Otto Bock) at 003).

3. K-Levels of Patients that Use Prosthetic Knees

- 312. The K-level designations were developed by the Centers for Medicare and Medicaid Services ("CMS"), a United States Federal Agency in the United States Department of Health and Human Services. (JX001 at 002 ¶¶ 16-17)).
- 313. The K-Level definitions are used throughout the orthotic and prosthetics industry in the United States to classify amputees into five ascending mobility levels, K-Level 0 to K-Level 4. (JX001 at ¶ 18; PX05108 (Yates (Jonesboro P&O Lab) Dep. at 44-46); PX05143 (Smith (Retired) Dep. at 77-78); PX08068 (Michael S. Orendurff, et al.,

Functional level assessment of individuals with transtibial limb loss: Evaluation in the clinical setting versus objective community ambulatory activity, 3 Journal of Rehab. and Assistive Tech. Engineering 1, 2 (2016)) (table showing K level descriptions)).

- 314. K-Level 0 is described by CMS as Nonambulatory: "Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance quality of life or mobility." (JX001 at 002 (¶ 19)).
- 315. K-Level 1 is described by CMS as a Household Ambulator: "Has the ability or potential to use a prosthesis for ambulation on level surfaces at fixed cadence." (JX001 at 002 (\P 20)).
- 316. 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." (JX001 at ¶ 21).
- 317. 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 ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion." (JX001 at 003 (¶ 22); *see also* PX05166 (Watson (Fourroux) Dep. at 35)).
- 318. 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." (JX001 at ¶ 23; *see also* PX05166 (Watson (Fourroux) Dep. at 35-36).

B. PATH OF AN ABOVE-THE-KNEE AMPUTEE FROM SURGERY TO RECOVERY

1. Amputation Surgery

- 319. A transfemoral amputation is an amputation that is performed transosseously through the femur. (Potter (Walter Reed) Tr. 754). This involves cutting part of the thighbone to remove the rest of the extremity. (Potter (Walter Reed) Tr. 754) In lay terms, this is known as an above-knee amputation. (Potter (Walter Reed) Tr. 754).
- 320. A bilateral transfermoral amputation is an amputation that is performed transosseously through both of the patient's femurs. (Potter (Walter Reed) Tr. 755).
- 321. Assuming that the patient enters the operating room with an intact limb, the amputation begins with adequate anesthesia. (Potter (Walter Reed) Tr. 756).
- 322. The patient's leg is prepped sterilely and a skin incision is made, the level of which would vary based upon the pathology. (Potter (Walter Reed) Tr. 756). Generally, the incision is made just above the knee level. (Potter (Walter Reed) Tr. 756).
- 323. Next, the surgeon would reflect the skin flaps towards the hip, dissect down and divide the muscle so that it would be available to fold over the bone for both residual limb

control and padding. (Potter (Walter Reed) Tr. 756). The muscle is transected at that level. (Potter (Walter Reed) Tr. 756).

- 324. The femur is isolated and transected with a saw. (Potter (Walter Reed) Tr. 756).
- 325. After blood vessels and nerves are identified and dealt with, the surgeon proceeds with getting the limb closed up properly. (Potter (Walter Reed) Tr. 757).
- 326. Dr. Potter testified that the most important thing a surgeon can do during amputation is making sure that the residual limb heals. (Potter (Walter Reed) Tr. 758).

2. Rehabilitation Process

- 327. After surgery is complete, the patient stays inpatient for a period of a few days. (Potter (Walter Reed) Tr. 758). The average stay is approximately five days. (Potter (Walter Reed) Tr. 759).
- 328. Much of the time spent in the hospital is to "achieve adequate pain control and gradually get the patient weaned off of any regional anesthetic catheters or epidural catheters or any intravenous narcotics they are receiving and ultimately get the patient on an acceptable oral pain regimen." (Potter (Walter Reed) Tr. 759).
- 329. The hospital further ensures that the patient is "eating, peeing and pooping appropriately." (Potter (Walter Reed) Tr. 759). Once the patient has met the criteria for discharge, they are safe to be an outpatient. (Potter (Walter Reed) Tr. 759).
- 330. After the patient leaves the hospital, surgeons conduct additional evaluations to ensure proper recovery from the surgery. (Potter (Walter Reed) Tr. 760-62).
- 331. Then, after the patient begins the rehabilitation and fitting process, the surgeon will see the patient on an informal basis. (Potter (Walter Reed) Tr. 762-63).
- 332. After ensuring a patient is ready for a prosthetic fitting, a surgeon or a physiatrist provides a patient with a prescription to receive an initial prosthesis. (Potter (Walter Reed) Tr. 762, 764); Ell (Mid-Missouri O&P) Tr. 1681-82; Ford (POA) Tr. 919; PX05002 (Asar (Hanger Inc.) IHT at 16)).

3. Referral to the Prosthetic Clinic

- 333. To start the fitting process, a patient visits a clinic upon referral from a physician. (PX05002 (Asar (Hanger Inc.) IHT at 16)).
- 334. When evaluating a patient to be fit with a prosthetic leg, a prosthetist is "determining a lot of different factors about the patient, what is what is their limb shape, what is their current activity level, what are the things that we want to be able to do in the future, do they have caregivers, are they mobile at all." (Ford (POA) Tr. 981). Furthermore, the initial visit includes a medical history review. (Ford (POA) Tr. 981).

- 335. When evaluating a patient to be fit with a prosthetic leg, the prosthetist will focus in part on the patient's "activities of daily living" to determine the needs of the patient. These activities include "[w]ashing clothes, driving, cooking, taking kids to school, walking pets, taking care of pets. Anything you do in your day-to-day routine, or sometimes your weekly routine, or monthly routine that you choose to do or want to do." (PX05119 (Kahle (Prosthetics Design and Research) Dep. at 38-40).
- 336. A prosthetist's evaluation of a patient to be fit with a prosthetic leg, includes measuring the patient's range of motion, determining the patient's ambulatory capabilities, performing objective tests on the patient's functional potential as divided by K-level classifications, and discussing the patient's specific functional needs. To determine a patient's specific functional needs, a prosthetist will ask a patient about his or her typical day before the amputation, work life, hobbies, and living environment. (PX05108 (Yates (Jonesboro P&O Lab) Dep. at 38-40)).
- 337. Rob Yates, President and CEO of Jonesboro P&O Lab, testified, "Anything that would inform the design of the prosthesis to ensure comfort, safety, and function for the patient in their desired activities of daily living would be considered and then objectively what is their ability to use a prosthesis to accomplish those tasks." (PX05108 (Yates (Jonesboro P&O Lab) Dep. at 40)).
- 338. The prosthetist also will take measurements and impressions for use during the fabrication process. (Ford (POA) Tr. 983-84).
- 339. To construct an above-the-knee prosthesis, prosthetists most often design a liner, suspension system, a socket, a prosthetic knee, a pylon, and a prosthetic foot. (Ford (POA) Tr. 986-87; Ell (Mid-Missouri O&P) Tr. 1677-78).
- 340. The process for fitting a new transfemoral patient with an above-the-knee prosthesis can take between 10 to 20 visits spread out over six months to a year. (PX05108 (Yates (Jonesboro P&O Lab) Dep. at 43-44)).
- 341. (PX05140 (Weott (Orthotic Prosthetic Center Inc.) Dep. at 14-16) (*in camera*)).

4. The Mechanics of Walking for an Above-the-Knee Amputee

- 342. According to Otto Bock's website: "The gait cycle is divided into two major phases: stance phase and swing phase. The stance phase happens when your foot is on the ground, when you are applying weight to your leg. The swing phase is when your foot is in the air and swinging forward." (PX08013 (Otto Bock) at 001).
- 343. According to Otto Bock's website: "When your foot is in contact with the ground, your leg normally flexes, or bends, sometimes even when you are standing still. The amount of flexion (bending) is relatively small you don't want your knee to buckle under you! The muscles of a biological leg are adding resistance, or support, to prevent buckling. When

you take a step and put weight on your foot, your knee flexes a little, acting like a shock absorber. This is another time that your muscles are active to stabilize your knee. This also helps take stress off the rest of the body." (PX08013 (Otto Bock) at 001).

- 344. According to Otto Bock's website: "When you are in swing phase (your leg swinging forward as you take a step), your knee is also flexed, or bent. But in this case you don't need as much support or resistance, and in fact you want the knee to swing more freely when your foot is off the ground, so you can take that step forward." (PX08013 (Otto Bock) at 002).
- 345. "Fear of falling causes many people with lower limb amputations to compensate with changes in their walking style, like keeping their prosthetic knee straight with each step." (PX08013 (Otto Bock) at 002).
- 346. "Compensating motions for a stiff-knee gait create unnatural stresses in the ankle, hip, lower back and other leg that can result in long-term effects." (PX08013 (Otto Bock) at 002).
- 347. "When you receive a microprocessor knee, your physician usually prescribes additional therapy and gait training. If you have worn a mechanical knee for years, you may have to unlearn some compensating motions to achieve a smoother walking movement." (PX08013 (Otto Bock) at 002).

5. Long-Term Recovery Process

- a) <u>Temporary Prosthesis</u>
- 348. When a transfermoral amputee gets their first, provisional prosthesis, it is traditionally a mechanical knee with stance friction (or a "safety knee") because the patient is learning to walk on their amputated stump, a part of the body that was never designed for bearing so much weight. (Smith (Retired) Tr. 5999-6000).
- 349. During this time period, "goals can be set, habits can be formed, [and] the patient can work with a therapist" while wearing a mechanical knee, with the goal that the patient is "going to progress into an MPK." (PX05149 (Brandt (Ability) Dep. at 41-42)).
- 350. "Usually patients have mechanical knees first before you think about providing them with a microprocessor knee. It's pretty tough to convince and insurance company to pay for a microprocessor knee as the first knee after an amputation [I]nsurance companies usually say the patient has to try a mechanical knee first, and only if that is functionally and safety-wise insufficient, then we may discuss if a microprocessor knee is medically necessary." (PX05150 Kannenberg (Otto Bock) Dep. at 54-55).
 - b) <u>Permanent (Definitive) Prosthesis</u>
- 351. Prosthetists fit a final, definitive prosthesis following physical rehabilitation and training on a prepatory prosthesis. (Sanders (United) Tr. 5472-74).

- 352. After a period of three to six months on a temporary prosthesis, some patients on a mechanical knee progress to a microprocessor knee for their permanent prosthesis. (PX05149 (Brandt (Ability) Dep. at 41-42)).
- 353. A prosthetic clinic seeks reimbursement from payers only after a prosthetist completes the fitting process and the patient signs a "delivery acknowledgement" affirming receipt of the prosthesis. (Senn (COPC) Tr. 171-172).
 - c) Follow-up Visits and Changes to Prosthesis
- 354. A prosthetist will fit the prosthesis on the patient once the fabrication process is complete. Following the fitting, the prosthetist will continue to provide follow-up care as necessary for the patient. (PX05108 (Yates (Jonesboro P&O Lab) Dep. at 37-39)).
- 355. One clinic executive testified that his clinic asks patients to return every two weeks after the fitting of a prosthesis in order to check on the patient's progress with the device. The patient will return for visits every three approximately three months after the fitting of the device. One year after the fitting, the clinic asks patients to return every six months or as needed. (Senn (COPC) Tr. 181)

C. Types of Prosthetic Knees Fit on Above-the-Knee Amputees

- 356. According to Otto Bock's own website, "In general, there are two kinds of prosthetic knees: non-microprocessor (or 'mechanical') and microprocessor. Mechanical knees all use a mechanical hinge to replace your knee joint. How quickly or easily the hinge swings is often controlled by friction, some type of hydraulic system or a locking mechanism. Microprocessors, on the other hand, provide a more sophisticated method of control to a prosthetic knee. These more complex knee joints are designed to help you walk with a much more stable and efficient gait that more closely resembles a natural walking pattern." (PX08013 (Otto Bock) at 001).
- 357. Prosthetic clinic customers similarly testified that there are two types of prosthetic knees used by above-the-knee amputees mechanical knees and microprocessor knees. (Ell (Mid-Missouri O&P) Tr. 1675; Brandt (Ability) Tr. 3757).

1. Mechanical Knees

- 358. There are several types of mechanical knees. (Carver (College Park) Tr. 2019-20; Kaufman (Mayo Clinic) Tr. 819-20; PX05148 (Swiggum (Otto Bock) Dep. at 181-182).
- 359. Mechanical knees are divided into subcategories based on their design and function. (Carver (College Park) Tr. 2019-20; PX05117 (Choi (ST&G) Dep. at 39)). The type of mechanism used to generate the force and resistance in the cylinder of a mechanical knee and the structure of the knee differentiate the types of mechanical knees. (Carver (College Park) Tr. 2019-21; PX05160 (Kaufman (Mayo Clinic) Dep. at 48-49)).

a) <u>Friction Break and Spring</u>

360. Mechanical knees that use friction to provide the resistance and stance are known as "friction-brake" mechanical knees. (PX05160 (Kaufman (Mayo Clinic) Dep. at 49)).
"Friction-brake" mechanical knees are fit on K-2 patients more than K-3 patients. (PX05160 (Kaufman (Mayo Clinic) Dep. at 49)); *see* PX05117 (Choi (ST&G) Dep. at 40)). The design of "friction-brake" mechanical knees limits patients to a single walking speed because of the consistent resistance provided during swing phase. (PX05117 (Choi (ST&G) Dep. at 41)).

b) <u>Pneumatic and Hydraulic</u>

- 361. Mechanical knees that use air to regulate the cylinder are known as "pneumatic" knees. (Carver (College Park) Tr. 2020; PX05160 (Kaufman (Mayo Clinic) Dep. at 49)). The air pressure in the cylinder of a pneumatic mechanical knees regulates the swing of the leg during swing phase and stabilizes the knee in the stance phase of a user's gait. (Carver (College Park) Tr. 2020).
- 362. Mechanical knees that use liquids to regulate the cylinder are known as "hydraulic" knees. (PX05160 (Kaufman (Mayo Clinic) Dep. at 48-49); Carver (College Park) Tr. 2020-21). Similar to the function of the air in a pneumatic knee, the pressure from the liquids in the cylinder of a hydraulic knee regulates the swing and stance phase of a user's gait. (Carver (College Park) Tr. 2020-21).

2. Microprocessor Knees

- 363. MPKs use a microprocessor to regulate the movement and positioning of the knee. (De Roy (Össur) Tr. 3542-43; PX05117 (Choi (ST&G) Dep. at 42); PX05141 (Bright (North Bay P&O) Dep. at 45); PX05119 (Kahle (Prosthetic Design & Research) Dep. at 33-34).
- 364. According to Otto Bock's website: "The internal computer monitors each phase of your walking pattern (your 'gait cycle') using a series of sensors. The continuous monitoring and control of fluid allows the processor to make adjustments in resistance so you can walk more efficiently at various speeds and walk more safely down ramps and stairs." PX08013-001.
- 365. MPKs adjust in real time, as a user walks, by using sensors located in the knee to transmit information to a microprocessor that directs the knee how to respond to a user's motions. (De Roy (Össur) Tr. 3542-43; Kannenberg (Otto Bock) Tr. 1946-47; Ell (Mid-Missouri O&P) Tr. 1704; Carver (College Park) Tr. 2018-19; Blatchford (Endolite) Tr. 2104; PX05111 (Prince (Freedom) Dep. at 96; PX05160 (Kaufman (Mayo Clinic) Dep. at 46); PX05107 (Carver (College Park) Dep. at 19-20); PX05119 (Kahle (Prosthetic Design & Research) Dep. at 34-36)).
- 366. Össur's Executive Vice President of Research and Development, Kim De Roy testified that an MPK "is a prosthetic knee that relies on a microprocessor or computer to monitor the activity of a patient and steer the function of the knee to ensure appropriate reaction

and response of that knee to whatever situation the patient might find themselves in." (De Roy (Össur) Tr. 3542).

- 367. Mr. De Roy further elaborated that MPKs have "the ability to sense, think and act" By "sensing," he testified MPKs have "embedded sensors" that read a user's motions and the positioning of the knee. The sensors then relay the information to the microprocessor in the knee. Finally, the microprocessor uses the information received to adjust the knee to meet the user's needs. (De Roy (Össur) Tr. 3543).
- 368. Mr. Carver, President and COO of College Park, testified that an MPK "tak[es] sensory feedback to anticipate the environment to make decisions for the patient to reduce the chances of trip and fall accidents [and] to change the variance in the patient's speed and how fast the leg swings forward." (PX05107 (Carver (College Park) Dep. at 19)).

D. OTHER COMPONENTS OF LOWER LIMB PROSTHESES FOR ABOVE-THE-KNEE AMPUTEES

- 369. According to Otto Bock's website, "Prosthetic knees are designed for people who have amputations above their knee, and thus lack the knee joint and lower leg. In reality, you need more than just the knee. For one thing, you need a socket, the bucket-shell that encases your limb and attaches to the prosthetic knee joint on top. You also need something that attaches to the prosthetic knee joint on the bottom (a metal tube known as a pylon) and a prosthetic foot. All of these put together are known as a prosthetic "system" or prosthesis. Your prosthetic system will be unique to you and your needs." (PX08013 (Otto Bock) at 001).
- 370. A lower limb prosthesis for an above-the-knee amputee includes a socket, prosthetic knee, a foot, and a pylon, which connects the knee to the foot. (PX05010 (Schneider (Otto Bock) IHT at 47)).
- 371. A socket attaches the prosthetic componentry to a patient, which most often includes a vacuum system and a liner to ensure a secure fit between the prosthetic and the patient's residual limb. (PX05106 (Arbogast (Ohio Willow Wood) Dep. at 26)).

E. INSURERS INVOLVED IN THE REIMBURSEMENT OF PROSTHETIC KNEES IN THE UNITED STATES

- 372. (Brandt (Ability) Tr. 3772-73 (*in camera*)).
- 373. To receive reimbursement, payers often require clinics to provide prior authorization or pre-determination of coverage based on a medical provider's written clinical assessment of the patient. (PX05165 (Sanders (United HealthCare) Dep. at44-46).

1. Types of Insurers

374.

(PX01022 (Freedom) at 012; Senn (COPC) Tr. 198; Asar (Hanger) Tr. 1356-1358 (*in camera*); Oros (Scheck & Siress) Tr. 4812 (*in camera*), 4835 (*in camera*)).

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



× ,

2. L-Codes

- 377. Prosthetic clinics submit requests for reimbursement to payers following the fitting of an above-the-knee prosthesis on a patient. (Senn (COPC) Tr. 171-172; PX05118 (Testerman (Freedom) Dep. at 84-85); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 37-38)).
- 378. The L-Code system "was generated by the Centers for Medicare and Medicaid to put a descriptor and code number on each part or subpart of every aspect of a prosthetic which then allows for itemized billing and exact ordering regulatory processes from the prosthetist and through communication with the physician so that what is ordered is them itemized out." (PX05129 (Ell (Mid-Missouri Orthotics & Prosthetics) Dep. at56-57)).
- 379. L-Codes affect the reimbursement amount a clinic receives when the clinic fits a patient covered by insurance. (PX05117 (Choi (ST&G) Dep. at 47-49)).
- 380. Each L-Code has a reimbursement range that is associated with the specific L-Code. (Choi (ST&G) Dep. at 47-49)
- 381. (PX05145 (Ford (Prosthetic & Orthotic Associates) Dep. at 45); PX05165 (Sanders (United HealthCare) Dep. at 31) (*in camera*)).
- 382. The L-Code definitions are not manufacturer-specific. (JX001 at 003 (¶ 29)).
- 383. Clinics receive the same reimbursement for each L-Code, regardless of the manufacturer of the device provided to the patient. (PX05129 (Ell (Mid-Missouri O&P) Dep. at 65)).

384. There are no L-Codes for other parts of the prosthetic fitting process, including services related to the fitting and fabrication of the device or related support. (PX05145 (Ford (Prosthetic & Orthotic Associates) Dep. at 45-46)).

3. Audits

- 385. Medicare and other payers conduct Recovery Audit Contractor ("RAC") audits. (Senn (COPC) Tr. 210).
- 386. During a RAC audit, the payer reviews a patient file from a prosthetic clinic associated with a particular insurance reimbursement claim. (Senn (COPC) Tr. 210). If the patient's file does not contain the proper documentation, the payer may recoup the insurance reimbursement payment to the prosthetic clinic for that claim. (Senn (COPC) Tr. 210).
- 387. RAC audits existed before the Merger and have continued after the Merger. (Carkhuff (Freedom) Tr. 717). The Merger has not changed anything about the way RAC audits are conducted. (Carkhuff (Freedom) Tr. 717-18).
- 388. Before the Merger, the presence of RAC audits existed for every sale that Freedom has made. (Carkhuff (Freedom) Tr. 718).
- 389. RAC audits started to intensify in 2011. (Schneider (Otto Bock) Tr. 4745).
- 390. "STEP 6: THE AUDIT RESPONSE/PREPAYMENT CLAIM REVIEW RESPONSE/APPEAL" of Össur's "step-by-step guide to a successful claim" states, "You've done everything you're supposed to do. And sometimes, despite that, you still get thrown into prepayment claim review, get subjected to an audit or receive a denial from the payer." (PX03242 (Össur) at 009). Össur's guide also states that, "Getting documentation from a physician confirming the prosthetist's findings and recommendations is an important Medicare requirement. A huge percentage of denied claims since 2011 result from prosthetists' failure to make sure that the physician's records validate their own." (PX03242 (Össur) at 007).
- 391. Since 2011, U.S. prosthetic clinics have improved the processes they use to document patient need for MPKs, including ensuring that physician records are complete. *See* (See CCFF ¶¶ 2979-3006, below).

IV. FUNDAMENTALS OF THE PROCESS THAT DETERMINES WHETHER AN ABOVE-THE-KNEE AMPUTEE RECEIVES AN MPK OR MECHANICAL KNEE

A. PARTICIPANTS IN THE PROCESS OF DETERMINING WHETHER A PATIENT RECEIVES AN MPK OR MECHANICAL KNEE

392. "[I]n an ideal setting, there's a collaboration between the physician, the physical therapist, the prosthetist and the patient to design the prosthesis to maximize their function." (PX05108 (Yates (Jonesboro P&O Lab) Dep. at42)).

- 393. Otto Bock's website states that, "Selecting a computerized knee system depends largely on your individual activity level, age, health and lifestyle. Another factor to take into consideration is your walking pattern, or gait cycle. If you are more active, you may find that a microprocessor knee system is more suitable for your activity level, since it offers more assistance with assessing movement. For others, the high level of stability (preventing falls) provided by C-Leg or Genium is also important. Your health care team will work closely with you to make the decision." (PX08013 (Otto Bock) at 003 ("Computer controlled knees")).
- 394. Otto Bock's website also highlights the role that insurers and insurance coverage play in the decision to fit a patient with an MPK or mechanical knee. The FAQ section of Otto Bock's website states, "How do I get the cost of a microprocessor knee covered? Compared with mechanical knees, you'll find that computerized knees may be more expensive, but they take less energy to operate, which can be a huge benefit. Higher stability/fewer falls can also be demonstrated as an important contributor to maintaining good health. There are many ways to cover the cost. Again, work with your health care team, and check out the Financial Coverage section of this website." (PX08013 (Otto Bock) at 003 ("Computer controlled knees")).
- 395. Össur's "Rheo Knee: The step-by-step guide to a successful claim" provides an overview for prosthetic clinics of the process by which medical professionals select and prescribe a prosthetic knee and how clinics obtain approval from a patient's insurer. (PX03242 (Össur) at 001). Össur's guide begins with "STEP 1: INSURANCE INTAKE ('KNOW YOUR PAYER')" which states, "Before you can do anything for new patients, you must first understand what their insurer will pay for and what the patients' financial responsibility is." (PX03242 (Össur) at 002).
- 396. "STEP 2: THE PATIENT'S STORY ('KNOW YOUR PATIENT')," of Össur's "stepby-step guide to a successful claim" for prosthetic clinics states, "Now that you understand the scope of your patients' insurance coverage you need to understand them. What's their story? What kind of life do they want to live with a prosthesis? What's their current and potential functional level? To accurately and completely tell your patient's story, you need both social and personal patient information on the one hand, and clinical information on the other." (PX03242 (Össur) at 003).
- 397. "STEP 3: MATCHING THE PATIENT & PRODUCT," of Össur's "step-by-step guide to a successful claim" for prosthetic clinics states that, "Every patient has unique clinical needs. And every product offers unique clinical outcomes. Making sure that you map the two to each other is essential if you want (a) a happy and functional patient, and (b) to process your claim successfully." (PX03242 (Össur) at 005).
- 398. "STEP 4: GET PHYSICIAN CONFIRMATION" of Össur's "step-by-step guide to a successful claim" states that, "Getting documentation from a physician confirming the prosthetist's findings and recommendations is an important Medicare requirement. A huge percentage of denied claims since 2011 result from prosthetists' failure to make sure that the physician's records validate their own." (PX03242 (Össur) at 007).

399. "STEP 5: FINAL REVIEW BEFORE CLAIM SUBMISSION" of Össur's "step-by-step guide to a successful claim" for prosthetic clinics states, "You've collected all the necessary patient information. You've confirmed that other health care providers' notes corroborate yours. You're ready to proceed to delivery and filing the claim for reimbursement. But you still need to verify that: (1) your patient delivery sheet contains all of the required information, and (2) you have filled out the claim form completely." (PX03242 (Össur) at 008).

1. Role of Surgeons

- 400. Surgeons perform lower-limb amputations on patients. (Potter (Walter Reed) Tr. 744-45).
- 401. A surgeon may also work with a physiatrist to begin the rehabilitation process. (Ford (POA) Tr. 919). A physiatrist is a medical professional who analyzes a patient's mobility and functional capabilities. (Ell (Mid-Missouri O&P) Tr. 1680, 1682-83).
- 402. After ensuring a patient is ready for a prosthetic fitting, a surgeon or a physiatrist provides a patient with a prescription to receive an initial prosthesis. (Potter (Walter Reed) Tr. 762, 764); Ell (Mid-Missouri O&P) Tr. 1681-82; Ford (Prosthetic & Orthotic Assocs.) Tr. 919).
- 403. The prescription for a prosthesis generally includes identifying information, such as name, date of birth, height, and weight, as well as the patient's mobility K-level and the "specific goals of and justification for the device." (Potter (Walter Reed) Tr. 766-767).
- 404. Surgeons rarely include the specific brand of prosthetic knee in prescriptions for prosthetic knees. (Potter (Walter Reed) Tr. 767-68, 770-71.
- 405. After the patient leaves the hospital, surgeons conduct additional evaluations to ensure proper recovery from the surgery. (Potter (Walter Reed) Tr. 760-62).
- 406. Then, after the patient begins the rehabilitation and fitting process, the surgeon will see the patient on an informal basis. (Potter (Walter Reed) Tr. 762-63).
- 407. If the referring physician is in a specialty like physical medicine or rehabilitation, he or she may be more well versed in the different types of prosthetics than a general surgeon, and may take more of a role in determining which prosthetic is appropriate for a particular patient. (Brandt (Ability) Tr. 3751-52).

2. Role of Prosthetists

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

- 409. Prosthetists are certified by the American Board for Certification. (Ell (Mid-Missouri O&P) Tr. 1663-64; Brandt (Ability) Tr. 3749).
- 410. Prosthetic clinics typically employ one or more certified prosthetists to make and fit prostheses and manage patient care. These clinics provide comprehensive patient care for amputees, including the fitting of the prostheses. (Asar (Hanger) Tr. 1312-13; Ford (Prosthetic & Orthotic Assocs) Tr. 917-18; Senn (COPC) Tr. 152).
- 411. A prosthetist designs and fits the prosthesis to fit on lower-limb amputees. (Asar (Hanger) Tr. 1314-15; Sanders (United) Tr. 5473-74). Prosthetists fabricate the socket component of a prosthesis. (Oros (Scheck & Siress) Tr. 4777).
- 412. Although prosthetists do not write prescriptions for prosthetics, they help guide what the physician writes on the final prescription for a prosthetic. (PX05141 (Bright (North Bay) Dep. at 134); Ell (Mid-Missouri O&P) Tr. 1688)).
- 413.

(Ford (Prosthetic & Orthotic

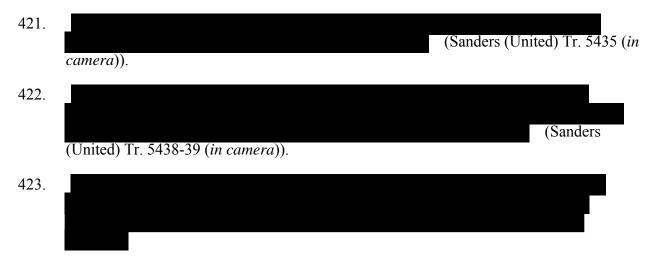
Assocs.) Tr. 924, 989; Asar (Hanger) Tr. 1334, 1381 (*in camera*), 1546-47 (*in camera*); Potter (Walter Reed) Tr. 770-71; Oros (Scheck & Siress) Tr. 4784-86, 4855-56, 4871; Brandt (Ability) Tr. 3751; 3799-3800 (*in camera*); Sanders (United) Tr. 5439 (*in camera*), 5401-02) (discussing PX03153); PX05119 (Kahle (Prosthetics Design and Research) Dep. at 38-39); PX05130 (Governor (Otto Bock) Dep. at 78); PX05144 (Blatchford (Endolite) Dep. at 151); PX05150 (Kannenberg (Otto Bock) Dep. at 23 (agreeing that prosthetists are the "direct customers")); PX05114 (Ferris (Freedom) Dep. at 48-49); PX05141 (Bright (North Bay) Dep. at 136-37); PX05128 (Senn (COPC) Dep. at 87); PX05108 (Yates (Jonesboro) Dep. at 42-43) (explaining that prosthetists are the "subject-matter expert in terms of the specific componentry" who is "driving that conversation"); PX05118 (Testerman (Freedom) Dep. at 13, 85) (explaining that a physician may "write a note" a "few select times"); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 108-10); PX05116 (Endrikat (Empire Medical) Dep. at 147-48); PX05137 (Matthews (Freedom) Dep. at 152-53)).

- 414. This includes decisions regarding prosthetics used on transfemoral amputees. A prosthetist designs and fits the prosthesis to fit on lower-limb amputees. (Asar (Hanger) Tr. 1314-15; Sanders (United) Tr. 5473-74).
- 415. Dr. Benjamin Potter, a surgeon for the Department of Defense, testified that prosthetists are "expert technicians who make the socket and appropriately fit the prosthesis." (Potter (Walter Reed) Tr. 766).
- 416. Mr. Sanders of United, an insurance company, testified that orthotic and prosthetic clinics "play an important role. So they work in concert with the prescribers and therapists that are providing the clinical direction, and they translate that into the actual device that the member will use to replace their missing body part." (Sanders (United) Tr. 5379).

417. Prosthetists have more specialized training than surgeons with respect to determining the type of knee that will be used in a prosthesis. "By training you can't expect every physician to know the make and model or technological features of a knee, a prosthetic knee. And that's where the prosthetist role is important, because while the physician will – will lay out the goal and the plan, it's the prosthetist who would use – if the physician is not familiar with them – would use their expertise to translate the physician's direction into a tangible product." (Sanders (United) Tr. 5401-02).

3. Role of Insurers

- 418. As "the person with the checkbook," the insurance company makes the final decision of whether it will pay for a patient to receive an MPK or mechanical knee. (Ford (Prosthetic & Orthotic Assocs.) Tr. 919-20; *see also* PX05141 (Bright (North Bay) Dep. at 144)).
- 419. Insurance providers conduct two types of reviews relevant to MPK coverage: pre-fitting reviews and post-fitting reviews. Some insurance plans require prior authorization before a clinic fits a patient with a prosthetic. When prior authorization is required, the clinic will "take the bio requirement, submit all of the elements for someone at the health plan to say yes, that meets the benefit structure or it doesn't." (Sanders (United) Tr. 5374-75). Some clinics seek predetermination from insurance plans before fitting a prosthetic, even if prior authorization is not required. A predetermination occurs when a clinic "think[s] they have met the criteria, but they'll send it to the health plan to get sort of the validation that it does meet the benefits." (Sanders (United) Tr. 5375). Both of these are "preservice, prepayment" reviews. (Sanders (United) Tr. 5375). The second major type of review is a medical claims review, which is a "post-service" review and can be either prepayment or post-payment. (Sanders (United) Tr. 5375). During a post-service review, a claim is sometimes looked at by a nurse or doctor to ensure it is correct.. (Sanders (United) Tr. 5375).
- 420. Insurers do not determine the functional needs of the patient. (Sanders (United) Tr. 5402) ("Q. And what role does United play, if any, in that determination of the functional needs of the beneficiary? A. We don't United doesn't play a role in making that determination.").



4. Role of Patients

- 424. "Evidence-based practice includes that the patient should participate [in determining what prosthetic they receive], along with the provider and best evidence." (PX05164 (Highsmith (VA) Dep. at 150)).
- 425. According to Dr. Douglas Smith, a former amputation surgeon, the patient and his or her family are primarily involved in deciding which prosthetic components the patient will receive. (Smith (Retired) Tr. 6002). The patient works with their physician, prosthetist, physical therapist, nurses, and potentially a mental health provider to decide which componentry is best for the particular patient. (Smith (Retired) Tr. 6003-04).
- 426. The patient's input extends to the decision of whether an MPK or mechanical knee is best. (PX05166 (Watson (Fourroux Prosthetics) Dep. at 180)).

5. Each Stakeholder Must Agree that an MPK is Appropriate or Else the Patient Typically Receives a Mechanical Knee

- 427. Patients only receive MPKs when multiple "filters" are satisfied. The patient's condition and activities of daily living must be appropriate for use of an MPK, they must have insurance coverage, which allows for MPKs and the financial ability to pay any co-pay, and they must, at least for Medicare patients, be K3 or K4, or have the ability to become a K3. (PX05010 (Schneider (Otto Bock) IHT at 85-87)).
- 428. Even when a prosthetist believes that an MPK would be appropriate for a patient, "you always have to look at the insurance situation of the patient." (PX05150 (Kannenberg (Otto Bock) Dep. at 78-79)).
- 429. Otto Bock provides evidence to prosthetists to help them convince physicians of the benefits' of MPKs, because "when the prosthetist wants to fit a microprocessor knee and the physician of the patient is not on board, it's almost impossible to get an approval." (PX05150 (Kannenberg (Otto Bock) Dep. at 105-06)).

B. HOW HEALTHCARE PROFESSIONALS DETERMINE THAT AN MPK IS THE BEST OPTION FOR A PATIENT FROM A MEDICAL PERSPECTIVE

1. Healthcare Professionals Engage in a Two-Step Process to Determine Whether an MPK is the Best Medical Option for a Patient

430. "[T]he way the system works is, a patient enters into a facility, a prosthetic and orthotic facility, usually with the prescription for a new prosthesis. That person will go through multiple evaluations to try to understand both the – the desired outcomes of the amputee, what they would like to try to accomplish. Also, they will try to determine what their K levels are by the basis of validated tests. They will also look at and ask questions about

their socioeconomic positioning, where they live, what they do, how they do this, if there's barrier[s], steps, rocks, what those kind of environmental concerns will be as such, trying to get a full picture of what the individual will have to maneuver and navigate in their activities of daily life." (PX05010 (Schneider (Otto Bock) IHT at 46-47)).

- a) <u>Step 1: Determine a Patient's K-Level</u>
- 431. To begin the fitting process, prosthetists evaluate the patient's current and potential mobility to determine his or her Medical Function Classification Level ("K-Level"). (JX001 at 002 (¶ 17); PX05145 (Ford (Prosthetic & Orthotic Assocs.) Dep. at 93-95); PX05010 (Schneider (Otto Bock) IHT at 46-48)).
 - b) <u>Step 2: For K3/K4 Patients, Use Patient-Specific Factors beyond</u> <u>K-Level to Determine Whether an MPK is More Beneficial Than a</u> <u>Mechanical Knee</u>
- 432. Once a K-level is assigned, the clinician needs to look at "the specific needs of the individual patient, what are they looking to do in their daily lives, the requirements that the patient may have when it comes to weight, functionality for the entire prosthesis." (PX05145 (Ford (Prosthetic & Orthotic Assocs.) Dep. at 93-95)).

2. An Amputee's K-Level Determines Whether a Patient is a Candidate for an MPK or Must Receive a Mechanical Knee

- a) <u>Process of Evaluating a Patient's K-Level</u>
- 433. "K levels are a system that CMS had proposed to subset amputee population, lower limb population.... K0 typically will not receive a prosthesis. K1 is a low household ambulatory. K2 is a household ambulatory with limited access, community ambulation. K3 is an unrestricted community ambulatory. K4 is a highly active individual." (PX05010 Schneider (Otto Bock) IHT at 45); *see also* JX001 at 002-003 (¶¶ 17-23)).

434.		
		(PX01054 (Otto Bock) at 005 (in
	camera)).	
		(PX03021 (Ohio Willow Wood) at 026
	(in camera)).	

- 435. A patient's K-Level may change over time following rehabilitation because of an improvement or decline in mobility. (Carver (College Park) Tr. 2028).
- 436.

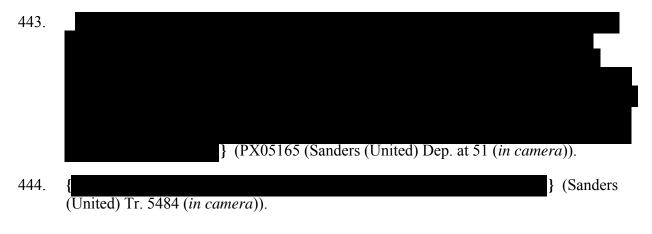
(PX01052 (Freedom) at 001 (in camera); PX05107 (Carver (College Park) Dep.

at 20-21); PX03027 (College Park) at 001 (*in camera*); PX05132 (Sabolich (Scott Sabolich Prosthetic and Research) Dep. at 47-49)).

- 437. Hanger, the largest clinic group in the United States, uses a standard questionnaire called a PAVET form that helps the clinician determine first, what K-level the patient is, and second, whether a microprocessor knee is appropriate for the patient. (Asar (Hanger) Tr. 1340).
- 438. The PAVET form has three sections: the first section asks whether the patient can do the basic actions of daily living such as going in and out of a car or walking on flat terrain; the second section asks about the patient's functionality, such as whether they can ambulate their limb or navigate small barriers; the third section tests the strength of the patient. (Asar (Hanger) Tr. 1342; PX03207 (Hanger) at 001 (PAVET Form)).
- 439. Each of the three sections contain several questions. (PX03207 (Hanger) at 001 (PAVET form)). The patients are graded on these questions and their scores are tallied, resulting in a K-level classification. (Asar (Hanger) Tr. 1346; PX03207 (Hanger) at 007 (PAVET form)).

b) <u>K0, K1, or K2 Determination Typically Precludes a Patient from</u> <u>Receiving a Microprocessor Knee</u>

- 440. If a patient is categorized as a K0, K1 or K2, CMS will not reimburse them for an MPK. (Ford (POA) Tr. 990-91). Some commercial payers or workers' compensation payers might reimburse for an MPK at those levels, but most insurers follow Medicare's guidelines. (Ford (POA) Tr. 990-91; PX05150 (Kannenberg (Otto Bock) Dep. at 56-57) ("limited community ambulators usually don't qualify for microprocessor knees")).
- 441. 99 percent of insurance policies which consider MPKs medically necessary for some individuals do so only for K3 or K4 amputees. (PX05150 (Kannenberg (Otto Bock) Dep. at 57)).
- 442. If the patient is not a K3 or K4, the clinician knows he or she will have to fit the patient in a mechanical knee and will work on determining which mechanical knee is best. (Ford (POA) Tr. 990-91).



- c) <u>K3 or K4 Determination Makes a Patient a Candidate for a</u> <u>Microprocessor Knee</u>
- 445. Medicare and most third-party payers will only provide reimbursement for MPKs on K-3 or K-4 patients. (Kannenberg (Otto Bock) Tr. 1831, 1839; Ell (Mid-Missouri O&P) Tr. 1764; {
 PX05141 (Bright (North Bay) Dep. at 67)).
- 446. In order for a patient to receive insurance reimbursement for an MPK, the prosthetist or clinic submits various categories of information on their behalf. (Kannenberg (Otto Bock) Tr. 1830). {

} (Kannenberg (Otto Bock) Tr. 1830-31; Kannenberg (Otto Bock) Tr. 1890-91 (*in camera*)).

3. For K3/K4 Patients, an Evaluation of Additional Patient-Specific Factors Determines Whether an MPK is More Beneficial than a Mechanical Knee

- 447. Dr. Kaufman of the Mayo Clinic testified that "[f]or K-3 and K-4 amputees," "the preference is for a microprocessor knee, [but] it will depend on the individual patient's circumstances." (PX05160 (Kaufman (Mayo) Dep. at 130).
- 448. After the K-level evaluation, a prosthetist will take into account a patient's "whole daily life" when deciding whether an MPK is appropriate. (Ford (POA) Tr. 995-96). This includes how much of their day is spent standing, whether they are going into and out of cars, and their daily environment. (Ford (POA) Tr. 995-96).
 - a) <u>Overview of Evaluations of Patient-Specific Factors beyond K-</u> Level to Determine Whether an MPK is Appropriate
- 449. To determine which prosthetic components to purchase, prosthetists must determine which components fit the amputee's lifestyle and activity goals after K-level testing is complete. (Ell (Mid-Missouri) Tr. 1768-70; Ford (POA) Tr. 995-96; *see also* Solorio (Otto Bock) Tr. 1640).
- 450. This determination is "very patient-specific." (De Roy (Össur) Tr. 3554). Mr. De Roy, Össur's Executive Vice President of Research and Development, explained that the decision of whether a K-3 or K-4 level patient gets an Össur MPK or a mechanical knee is based on whether a user is "looking for that extra stability, the ability to change speeds, the adaptivity of the knee[,]" which is a decision that comes down to the particular user. (De Roy (Össur) Tr. 3554).
- 451. "[T]he decision of what prosthetic components are most appropriate for an individual patient is always a very individual one." (Kannenberg (Otto Bock) Tr. 1985); *see also*

PX05166 (Watson (Fourroux) Dep. at 111 ("[e]ach individual patient's needs are different, and that's the way they're treated, on an individual basis."))

- 452. Prosthetists typically must evaluate a patient's health, physical abilities, and need to engage in different physical activities regularly in order to establish what type of knee is most appropriate for them. (PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 27-28)).
- 453. Dr. Kenton Kaufman of the Mayo Clinic emphasized that "you have to know all the circumstances regarding the patient's health, their living conditions, the status of the residual limb, any social demographic factors" to determine the appropriate prosthetic knee (e.g., an MPK or a mechanical knee) for a particular patient. (PX05160 (Kaufman (Mayo) Dep. at 129-30).
- 454. Respondent's expert, Dr. Argue, agrees that a patient's living and working environment are factors that can influence the decision of whether a patient ultimately receives an MPK. (PX05173 (Argue (Respondent) Dep. at 135-136)).
- 455. Hanger, the largest clinic group in the United States, uses a standard questionnaire called a PAVET form that helps the clinician determine first, what K-level the patient is, and second, whether a microprocessor knee is appropriate for the patient. (Asar (Hanger) Tr. 1340).
- 456. The PAVET form has three sections: the first section asks whether the patient can do the basic actions of daily living such as going in and out of a car or walking on flat terrain; the second section asks about the patient's functionality, such as whether they can ambulate their limb or navigate small barriers; the third section tests the strength of the patient. (Asar (Hanger) Tr. 1342; PX03207 (Hanger) at 001 (PAVET Form)).
- 457. (Asar (Hanger) Tr. 1482 (*in camera*)).
- 458. Mr. Watson of Fourroux, a prosthetic clinic company, testified as follows: "Q.... What factors do prosthetists at Fourroux consider when deciding whether to fit a patient with a microprocessor knee?" "A. Factors affecting prosthetists' clinical decisions concerning which type of prosthetic knee to fit on a particular patient are varied, numerous and interrelated. Medical necessity for a prosthetic knee is based on the patient's potential functional ability. Potential functional ability is based on the reasonable expectation of both the ordering physician and the prosthetist, considering factors including, but not limited to the patient's past history, including prior prosthetic use, if applicable, and the patient's current condition, including the status of their residual limb and the nature of other medical problems, comorbidities and the patient's desire to ambulate." (PX05166 (Watson (Fourroux) Dep. at 34-35).
- 459. In Össur's "Rheo Knee: The step-by-step guide to a successful claim" for prosthetic clinics seeking to fit an MPK on a patient, under "STEP 4: GET PHYSICIAN CONFIRMATION," there is a "PHYSICIAN DOCUMENTATION CHECKLIST" that

includes, among other things: (1) "Documentation re. functional level of patient both before and after amputation?"; (2) "Explanation of current and potential functional level, including an explanation for the difference between the two, if any?"; (3) "History of present medical condition(s) and past history relevant to functional deficits?"; (4) "Symptoms limiting ambulation or dexterity?"; (5) "Diagnoses causing these symptoms?"; (6) "Documentation of ambulatory assistance (cane, walker, wheelchair, caregiver) currently being used by patient (either in addition to prosthesis or before amputation)?"; (7) "Description of activities of daily living and how impacted by deficit(s)?"; (8) "Physical examination that's relevant to the functional deficit(s)?"; (9) "Weight and height, including any recent weight loss/gain?"; (10) "Patient's desire to ambulate?"; (11) "Documentation confirming the patient's motivation to ambulate?"; and (12) "Documentation showing that the physician examined the patient recently?". The physician checklist notes that: "*Records of other health care professionals (e.g., other physicians and PT's) can become part of the prescribing physician's medical records if attested to, signed, and dated by her." (PX03242 (Össur) at 007).

460. North Bay Prosthetics conducts "a series of functional testing on the patient" to assess their K level and determine whether to fit the patient with an MPK or a mechanical knee. This testing includes walking tests, standing up tests, and the Ampro test, which involves "approximately 30 different events you have the patient attempt, and they test their balance, strength, ability to walk at varying cadences, there's many different things, and those all help us guide them to their functional level." (PX05141 (Bright (North Bay) Dep. at 146-47)).

b) Importance of the Patient's Age, Health, and Fitness

- 461. Physical characteristics such as height and especially weight can affect whether a patient is a good candidate for an MPK. (PX05141 (Bright (North Bay) Dep. at 69-70)).
- 462. A factor in recommending a prosthetic device is the patient's health and activity level before the amputation. If a patient says they want a knee they can hike on, for example, the prosthetist will ask whether that was an activity they engaged in before their amputation. (PX05149 (Brandt (Ability) Dep. at 44-47); *see also* PX05141 (Bright (North Bay) Dep. at 140-41)).
- 463. A patient who is active enough that they would benefit from the stability factor a microprocessor knee offers, but is not athletic, is the "sweet spot" to benefit from an MPK. (PX05134 (Oros (Scheck & Siress) Dep. at 73-74)).
- 464. Prosthetists evaluate a patient's "overall health profile, age, weight, height, [and] strength." (PX05141 (Bright (North Bay) Dep. at 141-42); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 50); see also PX05168 (Sprinkle (Sprinkle) Dep. at 27) (prosthetist evaluates strength, range of motion, among other factors)).
- 465. As a person ages, their likelihood of falling increases. Because MPKs have been demonstrated to help reduce falls, age is a factor that a clinician considers in determining whether an MPK is appropriate. (PX05134 (Oros (Scheck & Siress) Dep. at 67-68); *see*

also Kaufman (Mayo) Tr. 821-22 (testifying that Dr. Kaufman's articles have shown that MPKs reduce falls relative to mechanical knees)).

- 466. Brian Hafner and Douglas Smith wrote an article titled "Differences in function and safety between Medicare Functional Classification Level-2 and -3 transfemoral amputees and influence of prosthetic knee joint control" that was published in November of 2009 in the Journal of Rehabilitation Research & Development. (PX08059 (Otto Bock) at 001). In the article, they explain that "[c]hoice of components is based on a number of factors, including the patient's age, weight, etiology of the amputation, physical health, history, functional goals, personal motivation, and medical coverage." (PX08059 (Otto Bock) at 002).
- 467. To choose the best prosthetic knee for an amputee, "you have to know all the circumstances regarding the patient's health, their living conditions, the status of the residual limb, [and] any social demographic factors. All that goes into the decision about the prosthesis, a provision of prosthetic care to an amputee." (PX05160 (Kaufman (Mayo) Dep. at 129-130)).

c) Importance of Activities in which the Patient Engages or Desires to Engage

- 468. To assess whether a microprocessor knee is a medical necessity, a prosthetist will typically "have a consultant interview with the patient and ask[] questions around activities of daily living of how they ambulate in their neighborhood, what their neighborhood looks like, does it have an elevator, do they have to ascend or descend stairs, do they have uneven walking terrain that they incorporate in their activity of church or school or community." The prosthetist may also have the patient take one or more "validated tests like the stand up and go six-minute walk test." (PX05139 (Schneider (Otto Bock) Dep. at 89)). The insurance submission will then connect the patients' activities of daily living to peer-reviewed articles showing the benefits of microprocessor knees to patients engaging in those activities. (PX05139 (Schneider (Otto Bock) Dep. at 89-90)).
- 469. Activities of daily living that could indicate that a microprocessor knee is a medical necessity for a patient include "[a]mbulating uneven terrain, ambulating in very confined spaces, ambulating over a greater distance, the requirement of greater balance, the requirement of stress relief to the spine and/or hip on the sound side or on the amputated side[.]" (PX05139 (Schneider (Otto Bock) Dep. at 91)).
- 470. A patient who has a moderately physically demanding occupation that encounters normal environmental barriers would be considered a good MPK candidate. (Oros (Scheck & Siress) Tr. 4862-63).
- 471. A K3 amputee with insurance coverage who works in an office would also be a good MPK candidate. (Oros (Scheck & Siress) Tr. 4862).
- 472. MPKs are likely beneficial for the subset of K3 amputees that engage in the following activities, including, but not limited to, "going up the stairs, going down the stairs with

variable speed. . . . [g]oing down a hill, walking down a hill with variable speed, climbing up sometimes, sometimes jogging. . . . [s]emi-jump from curb to the street, things of that nature." In addition to those activities, it also includes navigating environmental barriers, crowded areas, icy streets, going through shrubs and leaves, and having to regularly walk on mulch or uneven ground. (PX05117 (Choi (ST&G) Dep. at 192-93)).

- 473. Michael Fillauer of Fillauer testified that the segment of the population that would "greatly benefit" from MPKs includes individuals "walking at a variable cadence but who may occasionally stumble or who may have to change their gait due to various reasons. Maybe they have other injuries that slow them down or some kind of health condition that may cause them to occasionally have to change the way they walk, and the microprocessor system could adapt better to that person." (PX05105 (Fillauer (Fillauer) Dep. at 23-24)).
- Keith Watson, the President of Fourroux Prosthetics, testified that "[a] discussion of 474. clinical factors might include completing an evaluation with the patient to determine K level activities; discussing activities including obstacles, terrain, distance and slopes on a typical day, including functional K level activities prior to the amputation and those activities that the patient desires to get back to at home, work, therapy, exercise and leisure; evaluating and discussing possible K-3 activities, long distance ambulation, variable cadence walking speed. Does the patient experience falls, stumbles or inability to change gait speed? Describe any ambulatory problems that may impact the use of a prosthetic knee, for example, phantom limb pain, residual limb pain, conditions of the sound side limb. If problems are identified that might impact the end -- that impact the use of a prosthetic device, discuss a plan to mitigate that problem. Describe any ambulatory assistance, cane, walker, wheelchair, currently used in addition to the prosthesis. If the patient is using a mobility aid, discuss a plan to ambulate without mobility aids in the near future using the prosthetic device. Discuss the complete history of the patient's prior prosthetic use or the problems with current prosthetic components." (PX05166 (Watson (Fourroux) Dep. at 36-37)).
- 475. Patients benefiting from MPKs rather than mechanical knees include those who "are able to move at varying cadences," "go up stairs and go down ramps and step over curbs," "walk in the outside community," or like to hike or dance. (PX05141 (Bright (North Bay) Dep. at 149-50)).
- 476. Rob Yates of Jonesboro P&O Labs testified that prosthetists consider the patient's "desired activities of daily living" and their "ability to use a prosthesis to accomplish those tasks." (PX05108 (Yates (Jonesboro) Dep. at 39-41)).
- 477. Prosthetists ask questions about an amputee's daily activities in evaluating what type of knee to fit. These include questions related to "the daily function of the person," and typically include inquiries such as: whether the amputee needs to climb stairs on a regular basis; whether the amputee needs to traverse uneven ground regularly; and whether the patient needs to negotiate crowded environments regularly? (PX05160 (Kaufman (Mayo) Dep. at 39-41)).

- d) Importance of Stumbles, Falls, and Other Negative Consequences Experienced by the Patient on a Mechanical Knee
- 478. Prosthetists evaluate whether patients frequently stumble or fall using their current prosthetic knee or avoid activities due to safety concerns, lack of balance, or lack of confidence. For instance, Scott Sabolich testified that each patient attends an evaluation appointment where the prosthetist determines a patient's "fall risk, their speed of walking ... [as well as] how much they alter their patterns of gait when they sit, [and] stand. ..." (PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 27-28)).
- 479. Falling is more likely for an amputee with a mechanical knee than an MPK, all else being equal. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs and Future Development, testified to this principle in his investigational hearing, stating that "[t]he more simpler the knee, the more likely they would fall." (PX05010 (Schneider (Otto Bock) IHT at 68)).
- 480. "When the patient has used the mechanical prosthesis for quite a while and, you know, experiences frequent stumbles and falls, and is not able to do activities that he needs to do or wants to do on a regular basis, that is where you would consider using a microprocessor knee, from the prosthetic or – or technological perspective." (PX05150 (Kannenberg (Otto Bock) Dep. at 78)).
- 481. Jack Sanders, the Senior Clinical Program Consultant at United Healthcare testified at trial: "Q. And if you're an amputee who is prone to, for example, stubbing your toe, having an MPK will [help] you recover could make a huge difference for that patient, correct? A. It certainly could make a difference." (Sanders (United) Tr. 5470).
- 482. Patient preference for a microprocessor knee may be linked to performance outcomes; that is, for those patients, MPKs allow them to walk faster, have a more efficient gait, and stumble and fall less. (PX05164 (Highsmith (VA) Dep. at 39-40)).
- 483. For some patients, "you could cover all spectrums with mechanical knees. But with microprocessor knees, you have features that would be advantageous to certain patients when it comes to things like stumble control and the regulation of the hydraulics as they go through gait cycle. So I'd say there's crossover, but I would also say that there is a certain segment of the patient population that's going to greatly benefit from microprocessor knees." (PX05105 (Fillauer (Fillauer) Dep. at 21-23).
 - e) <u>Importance of the Patient's Comfort with and Preference for a</u> <u>Microprocessor Knee</u>
- 484. "[P]references of the patient" are a consideration in choosing between a mechanical knee and an MPK. (PX05150 (Kannenberg (Otto Bock) Dep. at 54)).

- 485. Michael Bright, a prosthetist at North Bay, testified that he considers a patient's "comfort and preference" with a microprocessor knee when determining which is the best prosthetic for them. (PX05141 (Bright (North Bay) Dep. at 140-41)).
- 486. Some patients prefer microprocessor knees over mechanical knees. (PX05107 (Carver (College Park) Dep. at 195-96).
- 487. Once a patient has been trained on a microprocessor knee, "patients significantly tend to prefer a microprocessor knee over a non-microprocessor [knee] alternative." (PX05164 (Highsmith (VA) Dep. at 37-38)).

C. AFTER HEALTHCARE PROFESSIONALS DETERMINE AN MPK IS APPROPRIATE AND SEEK INSURANCE COVERAGE, INSURERS DECIDE WHETHER TO REIMBURSE A CLINIC FOR AN MPK

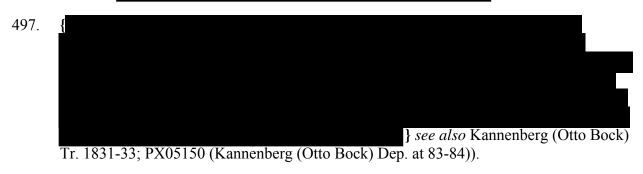
488. (Brandt (Ability) Tr. 3772-73 (*in camera*)).

- 489. To receive reimbursement, payers often require clinics to provide prior authorization or pre-determination of coverage based on a medical provider's written clinical assessment of the patient. (PX05165 (Sanders (United) Dep. at43-46).
- 490. When reimbursing for an MPK, insurance policies—including Medicare and private insurance—are agnostic as to the MPK manufacturer. (Kannenberg (Otto Bock) Tr. 1872; **[**].
- 491. Insurance policies usually allow patients to receive a new MPK after four to seven years, approximately the lifecycle of the device. After that time, the insurance policy will provide reimbursement for a new MPK. (Solorio (Otto Bock) Tr. 1651; *see also* Senn (COPC) Tr. 181 (testifying that a patient can use an MPK for approximately three to five years)).
- 492. In order for a patient to receive insurance reimbursement for an MPK, the prosthetist or clinic submits various categories of information on their behalf. (Kannenberg (Otto Bock) Tr. 1830). It is important that this submission include a demonstration that a patient is an unlimited community ambulatory, or K3, because private insurers and Medicare only cover MPKs for K3 and K4 patients. (Kannenberg (Otto Bock) Tr. 1830-31).
- 493. To demonstrate that a patient is a K3-level amputee, many insurers require proof of certain capabilities, such as the ability to walk with different walking speeds or variable cadence; or certain patient needs, such as the need to walk a significant distance each day, or a need to negotiate uneven terrain, slopes and stairs on a regular basis. (Kannenberg (Otto Bock) Tr. 1831-32).

494. When prosthetists submit claims for microprocessor knees, they need to "show that the microprocessor that they have selected is most appropriate for that patient, and that they need to fit the requirements of being in the appropriate K level, as one indication." (PX05139 (Schneider (Otto Bock) Dep. at 89)).



- 1. Overview of Insurers' "Medical Necessity" Requirements to Obtain Coverage for an MPK
- 496. If the prosthetist determines that a patient is a K3 or K4, and would benefit from an MPK, the prosthetist must also show that there is a medical necessity in order to receive reimbursement for the MPK. (Carkhuff (Freedom) Tr. 346; Ell (Mid-Missouri O&P) Tr. 1694; Kannenberg (Otto Bock) Tr. 1891; *see also* PX05165 (Sanders (United) Dep. at 43-46); {



- 498.
- 499. Dr. Kannenberg testified that, in justifying medical necessity, the focus should be on what functionality the microprocessor knee would provide that is not provided by a mechanical knee. (Kannenberg (Otto Bock) Tr. 1834-35; PX05150 (Kannenberg (Otto Bock) Dep. at 100-101)). This is equally true under both Medicare and private insurance coverage requirements. (Kannenberg (Otto Bock) Tr. 1835).
- 500. The most important unmet need highlighted in justifying the necessity of an MPK is a need for more safety. For example, if a patient with a mechanical knee experiences

excessive falls that can be attributed to the mechanical knee, that fact could be documented to justify an MPK. (Kannenberg (Otto Bock) Tr. 1834-35).

501. Otto Bock assists customers in demonstrating the medical necessity of an MPK to insurance providers in several ways. (Kannenberg (Otto Bock) Tr. 1849-50;

}; PX05148 (Swiggum (Otto Bock) Dep. at 34-36)).

502. Dr. Kannenberg has prepared and delivered presentations to assist prosthetists with the process for establishing the medical necessity of an MPK to insurance providers. (Kannenberg (Otto Bock) Tr. 1833). {

}; see also PX05139 (Schneider (Otto Bock) Dep. at 96) (Otto Bock conducts presentations "on several reimbursement topics, including claim submittals, new coding, reimbursement systems.")).

503. } (Kannenberg (Otto Bock) Tr. 1890 (*in camera*) (discussing PX01543)).

 504.

 } (Kannenberg (Otto Bock) Tr. 1887-88 (in camera)

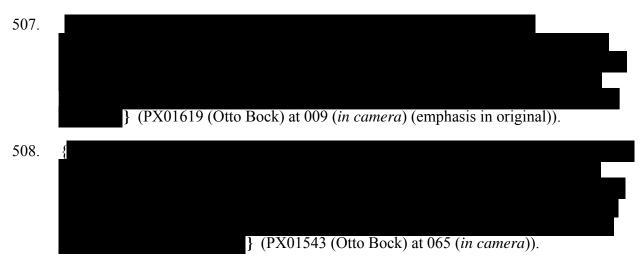
(discussing PX01543)).

505. To assist in the reimbursement process, Otto Bock's reimbursement group, led by Dr. Kannenberg, provides clinics and prosthetists with guidance to help demonstrate the medical necessity of an MPK for a patient. (*See, e.g.*, PX01489 (Otto Bock) at 034). Otto Bock identifies "[s]afety," "[s]lope negotiation," "[s]tair negotiation," and "[n]egotiation of uneven terrain" as factors that prosthetists must demonstrate to establish the medical necessity of an MPK for a patient when seeking reimbursement from insurance providers. (PX01489 (Otto Bock) at 033-34; {

}; PX05150 (Kannenberg

(Otto Bock) Dep. at 83-84)).

506. Dr. Kannenberg contributed to Otto Bock's Microprocessor Knees Physician's Documentation Guide for Medicare, dated May 2017. (PX01489 (Otto Bock) at 003; Kannenberg (Otto Bock) Tr. 1836-37). This documentation guide states that "[m]edical necessity for a microprocessor knee is based on the beneficiary's 'potential' functional ability. Potential functional ability is based on the reasonable expectation of the ordering physician and prosthetist, considering factors including, but not limited to:" "[t]he beneficiary's past history," "[t]he beneficiary's current condition[,]" and "[t]he beneficiary's desire to ambulate." (PX01489 (Otto Bock) at 003).



509. Otto Bock's reimbursement group provides customers with clinical research articles and other academic literature showing the benefits of MPKs. (Kannenberg (Otto Bock) Tr. 1850; *see also, e.g.*,

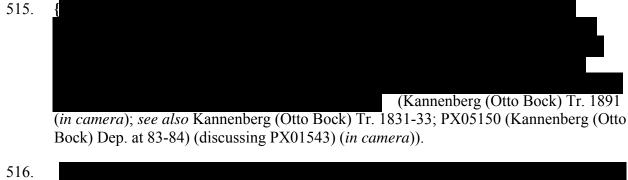
. Otto Bock provides this evidence in expectation that customers will rely on these materials in seeking insurance reimbursement for Otto Bock MPKs. (Kannenberg (Otto Bock) Tr. 1850;

. These articles are provided on Otto Bock's website and directly via email. (Kannenberg (Otto Bock) Tr. 1850; PX05150 (Kannenberg (Otto Bock) Dep. at 91-92)).

- 510. Insurers are "pretty generous in accepting" evidence supporting the use of an MPK, even when the evidence was developed using a different MPK than will be fit to the patient. (PX05150 (Kannenberg (Otto Bock) Dep. at 85-86)).
- 511. Otto Bock also assists its clinic and prosthetist customers by offering to review their reimbursement claims prior to submission to insurers. (PX05150 (Kannenberg (Otto Bock) Dep. at 25)).
- 512. Otto Bock will "analyze the the requirements of the insurance plan and coverage of the patient and help the prosthetist to produce the documentation that is needed to meet these criteria that the insurance companies have defined." (PX05150 (Kannenberg (Otto Bock) Dep. at 89)).
- 513. Clinics have begun using internal procedures to ensure prosthetists comply with payer's documentation requirements for the reimbursement of MPKs and only fit the products on patients who meet eligibility criteria. (*See, e.g.*, PX05134 (Oros (Scheck and Siress)

Dep. at 46-47; 228-29; Ford (POA) Tr. 972-75 (explaining POA's internal 27-step reimbursement process before releasing a claim to be billed to an insurer)).

- 514. Clinics often submit clinical research showing the benefits of MPKs to insurance providers when submitting paperwork to establish the medical necessity of an MPK. (*See, e.g.*, PX05119 (Kahle (Prosthetic Design & Amputee Research) Dep. at 53-54) (highlighting that prosthetists include clinical studies in their clinical notes when denied reimbursement); Kannenberg (Otto Bock) Tr. 1850; PX05139 (Schneider (Otto Bock) Dep. at 89-90)).
 - 2. Information a Clinic Needs to Meet Insurers' "Medical Necessity" Requirements and Receive Reimbursement for Fitting an MPK







518. At Hanger clinics, the PAVET form, which evaluates a patient's ability to partake in activities of daily living, their functionality, and strength, is submitted with a physician's

notes regarding a patient. (Asar (Hanger) Tr. 1341-43). Because the form has been around for "a couple of decades," some payers use the form to determine if a patient has the appropriate device. (Asar (Hanger) Tr. 1341).

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

3. Consequences of Not Meeting Insurers' "Medical Necessity" Requirements for MPK Coverage

- 520. {
- 521. "So if you're not and usually you have to provide documentation for all of these criteria. So if the patient doesn't have to negotiate uneven terrain, slopes and stairs outside the home of the patient on a regular basis, then the insurance usually denies the claim for a microprocessor knee." (PX05150 (Kannenberg (Otto Bock) Dep. at 83-84).
- 522.

}; see also Ell (Mid-Missouri O&P) Tr. 1722-24

(explaining that patients designated by a physician as a K3 who do not meet medical necessity requirements for a microprocessor generally get a different non-microprocessor K3 knee, such as a mechanical knee)).

523. Patients not receiving coverage for an MPK very rarely purchase one out of pocket. Otto Bock's Dr. Andreas Kannenberg testified that fewer than one percent of MPKs are paid for entirely out of pocket. (PX05150 (Kannenberg (Otto Bock) Dep. at 60).

D. PATIENTS ARE NOT SWITCHED FROM MPKS TO MECHANICAL KNEES BASED ON PRICES PAID BY CLINICS FOR THOSE PRODUCTS

524. Prosthetists have an ethical and reputational obligation to fit a patient with a prosthetic knee that best meets his or her medical needs. (PX05129 (Ell (Mid-Missouri O&P) Dep. at 141, 154-155) ("Q. So your ethical duties with regard to maximizing patient outcomes really drives your decision of which knee to fit on a prosthetic patient, correct? A. Yes, sir."); PX05119 (Kahle (Prosthetic Design & Amputee Research) Dep. at 66-67);

; PX05145 (Ford (POA) Dep. at 95-96 ("Q. Is maximizing patient outcomes the biggest factor in fitting an MPK at POA? A. Yes. Q. Do POA's clinicians

have ethical guidelines that factor into their daily work? A. All of our clinicians are certified by ABC, and there are ethical guidelines that are part of that certification.").

- 525. There is no evidence in the record that medical professionals have moved patients from MPKs to mechanical knees (or vice versa) based on the prices that the clinics pay for MPKs or mechanical knees. (Tr. 143-6895; JX002).
- 526. None of the seven clinic customers that testified at trial said that their prosthetists had ever switched a patient from an MPK to a mechanical knee based solely on price. (Senn (COPC) Tr. 148-280; Ford (POA) Tr. 901-1067; Asar (Hanger) Tr. 1306-1571; Ell (Mid-Missouri O&P) Tr. 1658-1816; Brandt (Ability) Tr. 3741-3845; Oros (Scheck & Siress) Tr. 4770-4920; Sabolich (Scott Sabolich Prosthetics) Tr. 5787-5960).
- 527. None of the fifteen clinic customers that testified in a deposition or investigational hearing said that their prosthetists had ever switched a patient from an MPK to a mechanical knee based solely on price. (PX05002 (Asar (Hanger) IHT); PX05153A & PX05153B (Asar (Hanger) Dep.); PX05003 (Yates (Jonesboro) IHT; PX05108 (Yates (Jonesboro) Dep.); PX05004 (Senn (COPC) IHT); PX05128 (Senn (COPC) Dep.); PX05129 (Ell (Mid-Missouri O&P) Dep.); PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep.); PX05134 (Oros (Scheck & Siress) Dep.); PX05135 (Weber (Prosthetic & Orthotic Care) Dep.); PX05140 (Weott (Orthotic Prosthetic Center Inc.) Dep.); PX05141 (Bright (North Bay) Dep.); PX05145 (Ford (POA) Dep.); PX05149 (Brandt (Ability) Dep.); PX05151 (Patton (Prosthetic Solutions) Dep.); PX05166 (Watson (Fourroux) Dep.); PX05167 (Filippis (Wright & Filippis) Dep.); PX05168 (Sprinkle (Sprinkle) Dep.)).
- 528. Respondent's own expert testified that he could not identify any testimony in the record of a customer who has switched from fitting MPKs to fitting mechanical knees on the basis of price where the patient was able to demonstrate medical necessity and insurance coverage for an MPK. (Argue, Tr. 6274; PX05173 (Argue (Respondent) Dep. at 232)).
- 529. Prosthetists testified that the choice between fitting a patient with an MPK or a mechanical knee (if insurance coverage were available for both products) is a clinical decision and not based on the relative prices a clinic pays for MPKs and mechanical knees. For instance, Michael Fillauer, who used to be a practicing prosthetist, testified as follows: "Q. When you were a clinician, did you decide whether to fit your patients in mechanical or microprocessor knees based on was that a clinical decision, or a price decision? A. I would like to say that it was mostly a clinical decision. Obviously funding is a factor. If you can't get the device paid for, you can't fit it. But the goal was always for it to be a clinical decision." (PX05105 (Fillauer (Fillauer) Dep. at 24)).



} (PX05166 (Watson

(Fourroux) Dep. at 61 (in camera)).

E. THE U.S. HEALTHCARE SYSTEM RESULTS IN TWO TYPES OF K3/K4 PATIENTS: THOSE WITH ACCESS TO MPKS AND THOSE WITHOUT

530. Össur's Executive Vice President of Research and Development, Kim De Roy, testified that MPKs and mechanical knees "don't really compete for the same population." He described the patient population for an MPK as "people with access to certain funds," and explained that "[i]f they have access to a microprocessor knee, they'll buy a microprocessor knee." Patients who do not have access to an MPK will buy a mechanical knee. (PX05124 (De Roy (Össur) Dep. at 184-85)).

1. Most K3/K4 Patients Approved for MPK Insurance Coverage Receive and Wear an MPK

- 531. Michael Bright, a certified prosthetist and owner of North Bay prosthetic clinic, testified as follows: "Q. Okay. If you determine as a prosthetist that a microprocessor knee would be best to serve a patient and the patient's insurance covered the cost of that MPK, would you fit the patient for a mechanical knee instead?"..."A. No, I would not. Q. Why not? A. Because they will fall and they will hurt themselves, and I don't like it when my patients fall and hurt themselves." (PX05141 (Bright (North Bay) Dep. at 160-61)).
- 532. {
 } (PX05107 (Carver (College Park) Dep. at 46 (*in camera*)).
- 533. Vinit Asar, CEO of Hanger, the largest prosthetic clinic company in the country, testified as follows: "A patient that qualifies for a microprocessor knee based on, you know, the PAVET score and the K level, of course, would get a microprocessor knee. I wouldn't think that any clinician would say, you know, that a mechanical knee would benefit a patient more than a microprocessor knee. I think they would be shortchanged." (PX05153B (Asar (Hanger) Dep. at 54-55)).
- 534. K-3 and K-4 patients usually get an MPK because "they're going to be more efficient in their day-to-day activities when they're walking on a microprocessor knee. They're putting less effort into controlling the knee because the microprocessor is helping them do that. So it's a more efficient knee, and it may be a safer knee." (PX05105 (Fillauer (Fillauer) Dep. at 96-97)).

- 535. Keith Senn, the President of COPC, testified at trial that MPKs are "a much better knee, and if a patient is [an] eligible candidate for one, that is the knee they would prefer and deserve." (Senn (COPC) Tr. 198).
- 536. Asked if a mechanical knee would be suitable for a patient who qualified for an MPK, DAW's President testified that "[i]f a patient qualifies for microprocessor knee, a K3 patient qualify for microprocessor knee which is the best of the best of function, then why go for less?" (PX05147 (Belzidsky (DAW) Dep. at 82)).
- 537. Jeffrey Brandt of Ability Prosthetics & Orthotics testified that most patients would benefit from an MPK, and that at Ability, the practice is that "people need to be ruled out of microprocessor technology, not ruled in." (PX05149 (Brandt (Ability) Dep. at 42-43)).

2. Reasons Some K3/K4 Patients Receive Mechanical Knees

- a) <u>Insurers Deny MPK Coverage for Some K3/K4 Patients</u>
- 538. Insurance companies do not always reimburse for microprocessor knees; in those cases, a patient may get a mechanical knee given the high out-of-pocket cost of buying an MPK without insurance. { }; PX05151 (Patton (Prosthetic Solutions) Dep. at 24-25); PX05134 (Oros (Scheck & Siress) Dep. at 91); { }; PX05108 (Yates (Jonesboro) Dep. at 161)); PX05128 (Senn (COPC) Dep. at 93)).
- 539. "[P]rivate health insurance may consider a microprocessor knee medically necessary for certain patients in their policy, but they sell they may sell plans that don't cover microprocessor prosthetic components. So although they consider these products medically necessary in their policy, if the patient has a plan that does not include microprocessor components, they will not pay for them." (PX05150 (Kannenberg (Otto Bock) Dep. at 78-79)).
- 540. Curt Patton of Prosthetic Solutions testified that if a patient came to his clinic with a prescription for an MPK and Medicaid did not cover it, while he would not prefer to fit a mechanical knee, he may have to. (PX05151 (Patton (Prosthetic Solutions) Dep. at 24-25)).
- 541. Customers with insurance plans that do not cover MPKs—including MediCal and Medicaid—are instead fit with mechanical knees. (PX05141 (Bright (North Bay) Dep. at 68)).
- 542.

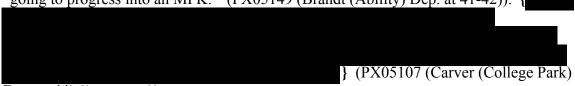
} (PX03025 (College Park) at 002 (*in camera*) (College Park Report: New Product Proposal – Capital Hydraulic Knee)).

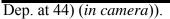
> b) <u>Medical Professional Do Not Recommend an MPK for Some</u> <u>K3/K4 Patients Due to Health, Work, or Lifestyle Issues</u>

- 543. Several witnesses testified that if a patient's lifestyle involves being in water on a regular basis, the patient is better served with a mechanical knee than the microprocessor they could otherwise qualify for. (Smith (Retired) Tr. 6008; Ell (Mid-Missouri O&P) Tr. 1722-24; PX05134 (Oros (Scheck & Siress) Dep. at 91-95)). For instance, Dr. Smith testified that he would tell his rural patients who enjoy fly fishing using waders that a "microprocessor knee probably wouldn't fit that lifestyle." (Smith (Retired) Tr. 6008). Fishermen almost always get mechanical knees because they do not want their microprocessor knees to short out on the water. (Smith (Retired) Tr. 6008; Ford (Prosthetic & Orthotic Assocs.) Tr. 994-98).
- 544. Some mechanical knees are waterproof, or even salt-waterproof, making them preferable for fishermen, or others who enjoy water activities. (Kannenberg (Otto Bock) Tr. 1985; PX05150 (Kannenberg (Otto Bock) Dep. at 54-55)).
- 545. Some K3 or K4 amputees with young children prefer mechanical knees to MPKs because mechanical knees better enable kneeling, and entering water to teach a child to swim or to rescue them. (Sanders (United) Tr. 5396).
- 546. Mechanical knees may provide greater knee flexion angle, which may make them preferable for parents with small kids who want the ability to kneel on the ground. (Kannenberg (Otto Bock) Tr. 1985. See also Sanders (United) Tr. 5389).
- 547. Some patients may do better with a mechanical knee because it is simpler to operate than an MPK. (PX05121 (Potter (Walter Reed) Dep. at 77)).
- 548. Patients who do not have access to chargers for their knees may be better suited to mechanical knees because they do not need to be charged. (Smith (Retired) Tr. 6012; Ell (Mid-Missouri O&P) Tr. 1722-24).
- 549. } (Asar (Hanger) Tr. 1482 (*in camera*)).
- 550. Since MPKs need to be charged, patients with mental deficits who would otherwise qualify for an MPK are often fitted with a mechanical knee. (PX05134 (Oros (Scheck & Siress) Dep. at 91-95); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 37-38); PX05145 (Ford (Prosthetic & Orthotic Assocs.) Dep. at 93-95); see also PX05173 (Argue (Respondent) Dep. at 135-36) (agreeing that a patient's cognitive abilities are evaluated in order to determine whether an MPK or mechanical knee is more suitable to a particular patient))).
- 551. Mechanical knees have been developed for specific types of sports; these knees may be preferable to MPKs for patients engaging in those sports. (PX05150 (Kannenberg (Otto Bock) Dep. at 51-52)).
- 552. Patients who would otherwise wear an MPK might feel more comfortable using mechanical knees for specific activities include cycling, weightlifting and Crossfit.
 (Potter (Walter Reed) Tr. 783-84). Mechanical knees are more appropriate than MPKs

for these activities because they are cheaper, more durable, and easier to replace if they break. (Potter (Walter Reed) Tr. 784).

- 553. Some very high end users prefer mechanical knees as well, because they are more durable. (Smith (Retired) Tr. 6008). A K-3 patient who runs often, for instance, may be better served by a mechanical knee even though they could be fitted with an MPK. (PX05151 (Patton (Prosthetic Solutions) Dep. at 24-25); PX05134 (Oros (Scheck & Siress) Dep. at 91-95); PX05105 (Fillauer (Fillauer) Dep. at 21-23); PX05150 (Kannenberg (Otto Bock) Dep. at 51-52); PX05141 (Bright (North Bay) Dep. at 156-57)). The user would have to have enough hip extension strength to stabilize the lock of the knee. (Ell (Mid-Missouri O&P) Tr. 1773-77).
- 554. { (Asar (Hanger) Tr. 1480 (*in camera*)).
- 555. Jack Sanders of United Health testified that some K3 or K4 members prefer mechanical knees to MPKs where they work in "environmental conditions that are not suitable" for MPKs, or where they are "highly active people that are involved with working with large weight." (Sanders (United) Tr. 5390-91). Additionally, hunters may prefer non-MPKs to avoid the need to recharge the knee, and for mechanical knees' ability to handle wet or cold environments. (Sanders (United) Tr. 5391).
 - c) <u>Mechanical Knees are Typically Used for Initial or Temporary</u> <u>Prosthesis</u>
- 556. When a transfermoral amputee gets his or her first, provisional prosthesis, it is usually made of "simpler components" than an MPK because the patient is learning to walk on their amputated stump, a part of the body that was never designed for bearing so much weight. (Smith (Retired) Tr. 5999-6000).
- 557. During this time period, "goals can be set, habits can be formed, [and] the patient can work with a therapist" while wearing a mechanical knee, with the goal that the patient is "going to progress into an MPK." (PX05149 (Brandt (Ability) Dep. at 41-42)). {





- 558. "Usually patients have mechanical knees first before you think about providing them with a microprocessor knee. It's pretty tough to convince an insurance company to pay for a microprocessor knee as the first knee after an amputation [I]nsurance companies usually say the patient has to try a mechanical knee first, and only if that is functionally and safety-wise insufficient, then we may discuss if a microprocessor knee is medically necessary." (PX05150 Kannenberg (Otto Bock) Dep. at 54-55; see also PX05150 Kannenberg (Otto Bock) Dep. at 79)).
 - d) <u>Some K3/K4 Patients Prefer to Use a Mechanical Knee</u>

- 559. Michael Bright, owner of North Bay Prosthetics, a prosthetic clinic company, testified as follows: "Q. Are there some K3 level ambulators that you fit with a mechanical knee because of patient preference, even though they might be eligible for a microprocessor knee through insurance or Medicare? A. Yes. Q. Why is that? A. You just said it, patient preference. We have patients that are amputees from World War II that are still using metal and leather joints on their prosthesis. It's just it's antiquated technology, but they just it's what's always worked for them, and it's what they always want. In that case that's typically it, they don't want to change." (PX05141 (Bright (North Bay) Dep. at 68-69); see also PX05164 (Highsmith (Veteran's Affairs) Dep. at 148-50) (describing study showing that 26% of mechanical knee wearers who were trained on a C-Leg returned to a mechanical knee, mostly because they were "long time users" who had been in a mechanical knee "for at least ten years")).
- 560. Mr. Belzidsky, President of DAW, testified as follows: "Q. Do you know if any K3 level patients have a preference for using a mechanical knee rather than the microprocessor knee even if they might qualify for a microprocessor knee? A. I can't think of any logical reason except that the only reason I can think of because I've been a long time in this business is patients sometimes are used to something that's before they were amputees, before microprocessor knees and therefore wants to stick to what they've been used to." (PX05147 (Belzidsky (DAW) Dep. at 82-83)).
- 561. "[S]ome people have worn mechanical knees and have no desire to have a microprocessor knee." (PX05140 (Weott (Orthotic Prosthetic Center Inc.) Dep. at 68-69)).

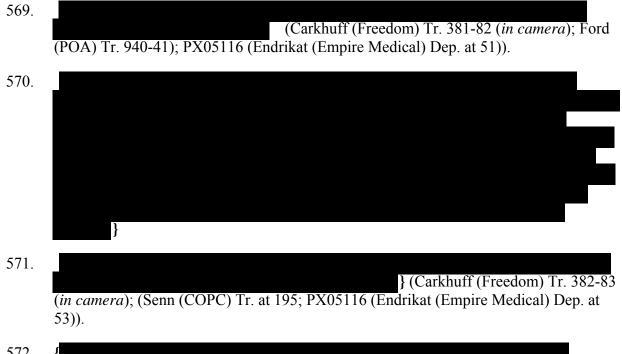
V. FUNDAMENTALS OF COMPETITION AMONG MPK SUPPLIERS FOR SALES OF MPKS TO U.S. PROSTHETIC CLINICS

- A. U.S. PROSTHETIC CLINICS PURCHASE MPKS FROM MANUFACTURERS TO MEET THE NEEDS OF K3/K4 PATIENTS TREATED AT THEIR FACILITIES WHO BENEFIT SIGNIFICANTLY FROM USING AN MPK
- 562.
 } (Solorio (Otto Bock) Tr. 1625-26 (*in camera*); Kannenberg (Otto Bock) Tr. 1825; Blatchford (Endolite) Tr. 2101)).
- Prosthetic clinic customers typically purchase MPKs directly from prosthetic manufacturers. (Ell (Mid-Missouri O&P) Tr. 1688; PX05128 (Senn (COPC) Dep. at 21, 196-97)).
- 564. (PX05007 (Carkhuff (Freedom) IHT at 120-121 (*in camera*)).
 565. (*PX05153B* (Asar (Hanger) Dep. at 55 (*in camera*)).

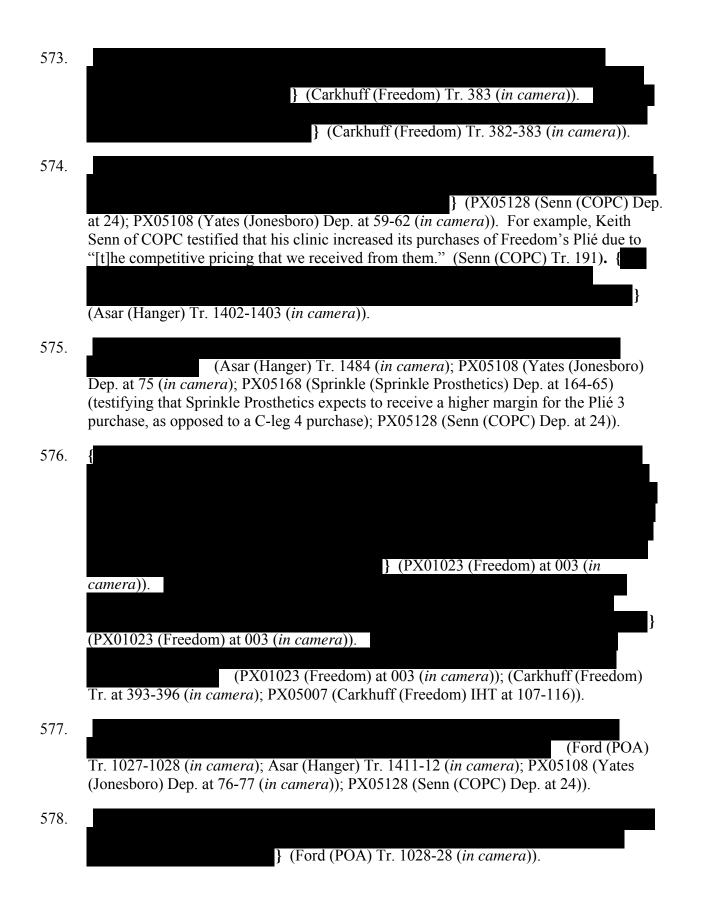
- 566. Mr. Senn of COPC testified that it is "rare" for any of COPC's K3 or K4 patients to be fit with a mechanical knee instead of a microprocessor knee because the "MPK is the best available knee that's available to those patients, so we want to provide, you know, what those patients deserve and what works best." (Senn (COPC) Tr. at 180-81). Mr. Senn explained that it "would be a disservice to the patients and poor patient care" to threaten to shift COPC's MPK volume to mechanical knees because MPKs are "a much better knee, and if a patient is [sic] eligible candidate for one, that is the knee they would prefer and deserve." (Senn (COPC) Tr. at 198).
- 567. Clinics purchase microprocessor knees based on prosthetist feedback about which products are "working the best and which ones we would prefer to use the most." (Senn (COPC) Tr. at 168-69). Clinics procure the MPK that their clinicians prefer. (Ford (POA) Tr. at 904-05, 940-42) (testifying that the clinicians "make the final decision about the products" but that he is involved at a "high level" in negotiating the with manufacturers).

B. U.S. PROSTHETIC CLINICS ENGAGE IN ONE-ON-ONE NEGOTIATIONS WITH MPK SUPPLIERS TO DETERMINE THE PRICE AND TERMS OF THE MPKS FIT ON PATIENTS

568. Customers negotiate pricing for MPKs with the MPK suppliers. (PX05116 (Endrikat (Empire Medical) Dep. at48-49).







}).

579. Mr. Senn of COPC testified that his clinic uses cost savings to "hiring residents with facilities, with programs that we put in support of the patient care, such as compliance." (PX05128 (Senn (COPC) Dep. at 34; *see also* Senn (COPC) Tr. at 227 (*in camera*)

580.

} (PX07008 at 005 (Respondent's Responses to Complaint Counsel's First Set of Requests for Admissions); *see also* PX05108 (Yates (Jonesboro) Dep. at 73-74) (*in camera*)).

C. THE BARGAINING LEVERAGE OF U.S. CLINICS IN NEGOTIATIONS WITH MPK SUPPLIERS

- 581. A clinic's bargaining leverage in negotiations with an MPK supplier turns on the clinic's ability to credibly threaten to switch some portion of its purchases to another MPK. (PX05007 (Carkhuff (Freedom) IHT at 121-22) (testifying that if the threat is credible, the clinic may use that to negotiate lower prices from Freedom for the Plié 3).
- 582. Mr. Endrikat of Empire Medical testified that during pricing negotiations, he has two things to leverage: "our volume purchases and the price of other manufacturers." (PX05116 (Endrikat (Empire Medical) Dep. at 33-34)).
- 583.
 3 (Blatchford (Endolite) Tr. 2163 (*in camera*); Ford (POA) Tr. 1004-05; PX05108 (Yates (Jonesboro) Dep. at 115 (*in camera*)); PX05116 (Endrikat (Empire Medical) Dep. at 58)).
- 584.

(Carkhuff (Freedom) Tr. 383 (in camera)). {

(Carkhuff (Freedom) Tr. 404 (in camera)).

585. **}** (Carkhuff (Freedom) Tr. at 402 (*in camera*): PX05007 (Carkhuff (Freedom), IHT at 122: Testerma

(Freedom) Tr. at 402 (*in camera*); PX05007 (Carkhuff (Freedom), IHT at 122; Testerman (Freedom) Tr. at 1280-81 (*in camera*); PX01023 (Freedom) at 004 (*in camera*)).

586. Mr. Ell of Mid-Missouri testified that Otto Bock has matched Freedom prices for microprocessor knees. (Ell (Mid-Missouri) Tr. at 1751). This usually happens when he "reports this is what we are actually paying from one vendor, a sales representative will say, 'We'll match that price.'" (Ell (Mid-Missouri) Tr. at 1751).

- 1. Clinics Use the Availability of Close Substitute MPKs to Negotiate the Most Favorable MPK Prices and Terms Possible from a Manufacturer
- 587. Customers use pricing from other MPK firms in order to get Freedom to decrease its pricing on the Plié. (PX05137 (Mathews (Freedom) Dep. at 158).
- 588. (Carkhuff (Freedom) Tr. 404 (in camera)). 589. } (Carkhuff (Freedom) Tr. 382 (in camera)). 590. (Carkhuff (Freedom) Tr. 383 (in camera)). 591. Mr. Ford testified that he has used the presence of the Freedom Plié 3 in negotiations with Otto Bock to get better pricing for the C-Leg 4. (Ford (POA) Tr. 1004-05). 592. (Senn (COPC) Tr. 227 (in camera); (PX05116 (Endrikat (Empire Medical) Dep. at 35-36) (testifying that "[i]t has happened" that his Otto Bock sales representative will cut him a deal on the C-Leg if he says that he will buy Pliés instead)). 593. Mr. Ford of POA testified that having both Freedom and Otto Bock allows him to "negotiate with both companies knowing there are alternatives, that our clinicians are both – are comfortable with both alternatives, so it allows us to negotiate." (Ford (POA) Tr. at 1004-05)). 594.
 - } (Blatchford (Endolite) Tr. 2165-66 (*in camera*)).
- 595. Mr. Senn of COPC testified that after COPC started using more Pliés in 2015, Otto Bock responded with "increasingly more aggressive pricing on their MPKs, on their C-Leg 3 and C-Leg 4, and working to continue to try to increase their overall volume to Ottobock, not just the knees but in their -- their line of business, so we can reach dollar thresholds for increased discounts" (PX05128 (Senn (COPC) Dep. at 24-25). Mr. Senn elaborated that by "increasingly more aggressive, he meant that the "discounts were greater." (PX05128 (Senn (COPC) Dep. at 24-25)).
- 596. Mr. Endrikat of Empire Medical testified that he uses "ballpark" pricing to play the microprocessor knee manufacturers off of each other during price negotiations. (PX05116 (Endrikat (Empire Medical) Dep. at 58). He testified further that he only uses MPK competitor pricing to negotiate extra discounts for MPKs. (PX05116 (Endrikat (Empire Medical) Dep. at 59)).

2. Mechanical Knees Do Not Play a Significant Role in Negotiations

- 597. Microprocessor knees prices do not respond to price changes of non-microprocessor knees. (PX05004 (Senn (Center for O&P) Dep. at 151);
- 598. Keith Senn, President and COO for Kentucky of the Center for Orthotic & Prosthetic Care, testified that he has never threatened to shift the clinic's MPK purchases to mechanical knees as a negotiating tactic because the shift "would be a disservice to patients and poor patient care." He further elaborated that MPKs are a "much better knee" and the clinic will continue to fit "eligible candidates" because eligible patients "would prefer and deserve" an MPK. (Senn (COPC) Tr. 198).
- 599. According to Mr. Senn of COPC, non-microprocessor mechanical knee prices do not respond to price changes of MPKs. (PX05004 (Senn (Center for O&P) Dep. at 150)).
- 600. Össur does not set the price of its microprocessor knees against the price of mechanical knees because "they don't really compete for the same population" of people with access to certain funds since "[i]f they have access to a microprocessor knee, they'll buy a microprocessor knee." PX05124 (De Roy (Össur) Dep. at 184-185)).
- 601. Prices of mechanical knees do not respond to charges in the prices charged for MPKs. (PX05116 (Endrikat (Empire Medical) Dep. at 68).
- 602. Endolite's Executive Chairman, Stephen Blatchford, testified that Endolite "only look[s] at other MPKs" and not mechanical knees when analyzing competition for the Orion 3 because "the price point is completely different" and "customers don't tend to think of [the two types of knees] in the same way." (Blatchford (Endolite) Tr. 2143-44).
- 603.
 (Blatchford (Endolite) Tr. 2154-55 (*in camera*)).
 604.

} (De Roy (Ossur) Tr. 3603 (*in camera*); see also (PX05124 (De Roy (Ossur) Dep. at 184-85).

3. Role of Clinic Purchase Volumes in Negotiations

- 605. The overall volume of MPKs a clinic customer purchases also affects the discounts they receive from MPK suppliers. (Senn (COPC) Tr. at 196-97); (PX05004 (Senn (COPC), IHT at 38) (testifying that "we could obtain a higher discount from Freedom, if we're able to drive more of the MPK volume to Freedom" and that "Otto Bock has offered the same thing"); (PX05132 (Sabolich (Sabolich Research) Dep. at 91-92).
- 606. Mr. Endrikat, CEO of Empire Medical, testified that he negotiates the lowest price possible for microprocessor knees through volume by saying "we did X amount of

business, and therefore we warrant this amount of discount." (PX05116 (Endrikat (Empire Medical) Dep. at 58).

VI. THE SALE OF MPKS TO PROSTHETIC CLINICS IS A RELEVANT PRODUCT MARKET

A. MPKs Possess Distinct Characteristics

1. Physical Attributes of MPKs Differ from Mechanical Knees

- 607. As of January 18, 2018, Otto Bock's publicly available website stated that "Generally, there are two kinds of prosthetic knees: non-microprocessor (or "mechanical") and microprocessor" knees. Otto Bock distinguishes microprocessor knees as providing a "more sophisticated method of control to a prosthetic knee." (PX08013 (Otto Bock) at 001).
- 608. Freedom's CEO at the time of the Merger, David Smith, testified that Freedom's MPK and mechanical knees are "completely different products [at] completely different price points." (PX05122 (Smith (HEP) Dep. at 106-07). To distinguish a mechanical knee from an MPK, David Smith explained: "[o]ne is rudimentary and one is sophisticated. One doesn't allow mobility and ambulation and one does. One restricts activity or limits your activity, or you want it limited for safety reasons because the patient is incapable. The other one allows it and facilitates it." The differences, he highlighted, are because "one of them has different componentry and different functionality than the other one." (PX05122 (Smith (HEP) Dep. at 202-03).
- 609. The microprocessor in an MPK reads sensors located throughout the device to help position the knee during a user's gait cycle. These adjustments can predict a user's activities and the walking terrain with each step. (Kannenberg (Otto Bock) Tr. 1946-47).
- 610.

} (PX04001 at 001 (Blatchford (Endolite), Decl.) (*in camera*); see also PX05144 (Blatchford (Endolite) Dep. at 168-69) (discussing PX04001)).

- 611. Mr. Blatchford further testified that an MPK 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 (Endolite) Tr. 2104).
- 612. The use of a microprocessor allows an MPK to function differently than a mechanical knee. (Potter (Walter Reed) Tr. 775-76; Ford (POA) Tr. 916; PX05119 (Kahle (Prosthetic Design and Research) Dep. at 33-34); PX05144 (Blatchford (Endolite) Dep. at 166-67)).
- 613. William Carver, President and COO of College Park, which manufactures mechanical knees, testified that the microprocessor in an MPK acts as the "brain" of the knee that

"can unleash the potential of that technology" by adjusting the knee to match a user's motions. In contrast, he testified, mechanical knee users instead must rely on a prosthetist to "set th[e] knee to a setting" and cannot adjust this setting without a prosthetist. (Carver (College Park) Tr. 2023-24)).

(Carver (College Park) Tr. 2054 (in camera)).

- 614. Jason Kahle, a certified prosthetist who performs research on prosthetic knees, testified that the "benefit of a microprocessor is it thinks instantaneously" which is attributed to the microprocessor itself. ." (PX05119 (Kahle (Prosthetic Design and Research) Dep. at 33-35)). The ability to think "instantaneously" allows an MPK to respond to a patient's movements. (Kahle (Prosthetic Design and Research) Dep. at 35-36)). Alternatively, a mechanical knee "has to go through a cycle for the knee to figure out what to do" and cannot respond "until it goes through that cycle." (PX05119 (Kahle (Prosthetic Design and Research) Dep. at 33-34)).
- 615. Ryan Arbogast, CEO of Ohio Willow Wood testified that "[m]icroprocessor knees provide additional features and benefits and function that mechanical knees could not." Mr. Arbogast elaborated that "[m]icroprocessor knees, in general, use sensors to assess what's happening with the knee and make changes in the function of the knee as a result." (PX05106 (Arbogast (Willow Wood) Dep. at 19-20)).
- 616.

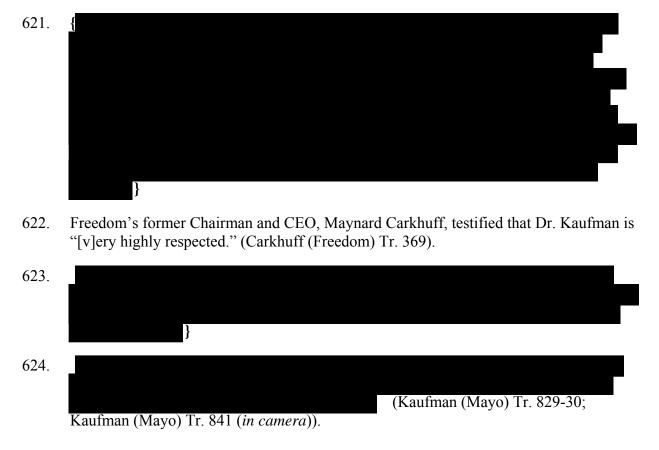
} (PX01164 (Freedom) at 063 (*in camera*); *see also* PX05109 (Carkhuff (Freedom) Dep. at 109-13) (discussing PX01164)). Maynard Carkhuff, the Chairman of Freedom, agreed that MPKs "involve higher technology" than mechanical knees. (PX05109 (Carkhuff (Freedom) Dep. at 112 (discussing PX01164)).

} (PX01164 (Freedom) at 024 (*in camera*)).

- 2. MPKs Provide Significant Safety and Performance Benefits Not Provided by Mechanical Knees
 - a) <u>Clinical Research Establishes that MPKs Provide Safety</u>, <u>Performance</u>, and other Benefits over Mechanical Knees
 - (1) Published Studies Showing the Benefits of MPKs
- 617. Peer-reviewed research articles have found increased safety and performance of MPKs over mechanical knees. (*See, e.g.*, Kaufman (Mayo) Tr. 820-21, 826; Blatchford (Endolite) Tr. 2119-20). Dr. Kenton Kaufman of the Mayo Clinic, a leading expert on MPK research, testified that "[t]he published articles have shown improved safety,

[MPKs] have improved mobility, better satisfaction, and one of the recent articles show[s] that in a ten-year time frame they would have less arthritis." (Kaufman (Mayo) Tr. 826).

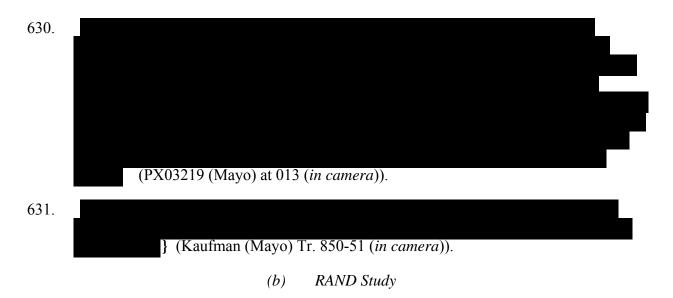
- 618. Authors of clinical research frequently present their findings to prosthetists and clinic owners. (*See, e.g.,* PX05119 (Kahle (Prosthetics Design and Research) Dep. at 54-55) (discussing PX08018); Kaufman (Mayo) Tr. 828).
- 619. To determine what knees to fit on patients, some prosthetists and clinic owners consider clinical research studies related to MPKs. (Asar (Hanger) Tr. 1339; PX05108 (Yates (Jonesboro) Dep. at 49-50)).
- 620. Prosthetic clinics testified that the benefits ascribed to MPKs in these studies are also evident in their own practices. (PX05108 (Yates (Jonesboro) Dep. at 26-27 ("Q. What are the clinical benefits of a microprocessor knee? A. There is research that has supported that patients have a decreased incidence of falls, a decreased incidence of complications from the use of their prosthesis, an increased level of satisfaction with their device, an increased confidence in their device. That is the primary benefit that's supported by the literature. Q. Have you seen those benefits in the patients that you see at Jonesboro? A. Absolutely."); *see also* PX05129 (Ell (Mid-Missouri) Dep. at 44-48)).



(a) Dr. Kaufman's Fast K2 Study

PUBLIC





- 632. A 2017 study by the RAND Corporation entitled "Economic Value of Advanced Transfemoral Prosthetics" reviewed existing literature and utilized a simulation model "to assess the differential clinical outcomes and costs of microprocessor-controlled knees compared with non-microprocessor controlled knees." (PX08004 (Liu et al., Economic Value of Advanced Transfemoral Prosthetics, RAND Corporation (2017) ("RAND Report") at 003).
- 633. The RAND study was initiated and funded by AOPA. (Kannenberg (Otto Bock) Tr. 1861).
- 634. Among those acknowledged for contributing to the report were Andreas Kannenberg, Executive Medical Director of Otto Bock, Dr. Kenton Kaufman of the Mayo Clinic, Stephen Blatchford of Chas A. Blatchford and Sons, Ltd./Endolite, Kim De Roy of Össur, and Maynard Carkhuff, Chairman of Freedom. (PX08004 (RAND Report) at 008). Mr. Carkhuff testified that the contributors were some of the best and brightest clinical researchers in the MPK space. (Carkhuff (Freedom) Tr. 369).
- 635. The RAND study concluded that "[o]verall, we found that compared with NMPKs, MPKs are associated with meaningful improvement in physical function and reductions in incidences of falls and osteoarthritis." (PX08004 (RAND Report) at 020). Asked to explain this conclusion, Dr. Kaufman testified that, "This is the projection based on the simulation that over time you'll have improved safety by reduction in falls, and because of the improvement of gait, you'll have less arthritis, when using a microprocessor knee compared to a non-microprocessor knee." (Kaufman (Mayo) Tr. 867 (discussing PX08004 at 020)).
- 636. In a section titled "Clinical Benefits: Physical Function" the RAND study states that "[o]verall, there is strong evidence suggesting that compared with NMPKs, MPKs are associated with improvements in walking speed, gait symmetry, and the ability to negotiate obstacles in the environment" (PX08004 (Rand Report) at 020). Dr. Kaufman explained, regarding this conclusion, that "these are some of the biomechanical

factors that show improvement when using a microprocessor knee compared to a nonmicroprocessor knee." (Kaufman (Mayo) Tr. 867 (discussing PX08004 at 020)).

- 637. Elsewhere in the RAND study, the authors conclude that, "In summary, the existing published literature shows that among transfemoral amputees, MPKs are superior to NMPKs in improving parameters of physical function, such as walking speed, gait symmetry, and obstacle assessments. Those improvements lead to fewer falls and lower incidences of osteoarthritis in the intact limb." (PX08004 (RAND Report) at 033). Asked about this conclusion, Dr. Kaufman testified that "[t]hese are some of the short-term and long-term benefits of using a microprocessor knee compared to a non-microprocessor knee." (Kaufman (Mayo) Tr. 868 (discussing PX08004 at 033)).
- 638. Maynard Carkhuff, Freedom's Chairman, testified that the study showed that MPKs reduce stumbles and falls, relative to other technologies, and provide a good value to the healthcare system. (Carkhuff (Freedom) Tr. 364). Mr. Carkhuff agreed that the importance of the RAND Report includes establishing that MPKs are safer than mechanical knees and provide greater stability for patients, both of which will help lower healthcare costs associated with falls for MPK users. (Carkhuff (Freedom) Tr. 364).
- 639. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified that he presented the results of the RAND study to multiple members of Congress or their staff in November 2017. (Schneider (Otto Bock) Tr. 4739-40, 4742-44). Mr. Schneider provided a "leave behind" regarding the RAND study's conclusions with the legislators in order to highlight that the funds provided by Congress for prosthetics are helping beneficiaries, cost efficient, and effective. (Schneider (Otto Bock) Tr. 4739-40, 4742-44 (discussing PX01380); PX01380 (Otto Bock) at 004; PX05139 (Schneider (Otto Bock) Dep. at 61-65)).
- 640. Otto Bock's "leave behind" noted, in its discussion of the RAND study, that "82% of patients receiving non-MPK limbs will fall compared to only 26% of MPK users." (PX01380 (Otto Bock) at 004)).

(c) Other MPK Studies

641. Clinical research has found that microprocessor knee users improve their gait mechanics and stability as compared to mechanical knee users. (PX08010 at 001 (Kaufman et al., *Gait and Balance of Transfemoral Amputees Using Passive Mechanical and Microprocessor-Controlled Prosthetic Knees*, 26 Gait & Posture 489 (2007)) ("Gait and Balance of Transfemoral Amputees")) ("Transfemoral amputees using a microprocessor-controlled knee have significant improvements in gait and balance.")). Dr. Kaufman testified that it is important for an amputee to have improved gait and balance "[s]o they would have less falls." (Kaufman (Mayo) Tr. 856-57). When testifying about PX08010, Dr. Kaufman noted that "[t]he overall findings are that [amputees] have improved function, both their gait and their balance, when using a microprocessor knee" rather than a mechanical knee. (Kaufman (Mayo) Tr. 858 (discussing PX08010)). PX08010 is a document that Dr. Kaufman has presented at prosthetics industry conferences. (Kaufman (Mayo Clinic) Tr. 858-59).

- 642. Clinical research has found that microprocessor knee users have increased ability to walk on difficult terrain as compared with mechanical knee users. (PX08059 at 001 (Hafner and Smith, *Differences in Function and Safety Between Medicare Functional Classification Level-2 and -3 Transfemoral Amputees and Influence of Prosthetic Knee Joint Control*, 46 J. of Rehab. R&D 417) (2009) ("Hafner and Smith")) ("Active knee control [i.e., MPK] was associated with significant improvements (p < 0.05) in hill and stair gait, speed (hills, obstacle course, and attentional demand task), and ability to multitask while walking for both cohorts.")).
- 643. Clinical research has found that microprocessor knee users experience fewer falls as compared with mechanical knee users. (PX08059 (Hafner and Smith) at 001 ("Results suggest that active knee control [i.e. MPKs] improves function and reduces the frequency of adverse events in a population that is at risk for falls. Use of active knee control may allow persons with amputation to expand their functional domain, transition to a higher MFCL, and access additional prosthetic options.")). Medicare Functional Classification Levels (MFCLs) are effectively equivalent to K-Levels. (PX05150 (Kannenberg (Otto Bock) Dep. at 36-37).
- 644. Clinical research has found that microprocessor knee users engage in more physical activity than mechanical knee users and experience overall improvement in quality of life. (PX08011 at 001 (Kaufman et al., *Energy Expenditure and Activity of Transfemoral Amputees Using Mechanical and Microprocessor-Controlled Prosthetic Knees*, 89 Arch Phys Med Rehab. 1380 (July 2008)) ("People ambulating with a microprocessor-controlled knee significantly increased their physical activity during daily life, outside the laboratory setting, and expressed an increased quality of life.")). Dr. Kaufman, the principal investigator for the study, testified that, "[w]hat we showed is that people spontaneously became more active, that is, they burned more energy, when using a microprocessor knee versus the mechanical knee." He noted that MPK users "burn more energy, which means that they're more active in their free living environment." (Kaufman (Mayo) Tr. 860-61 (discussing PX08011)).
- 645. Other clinical research has further established the benefits of MPKs relative to mechanical knees. (See, e.g., PX08002 at 001 (Sawyers and Hafner, Evidence Note: Outcomes Associated with the Use of Microprocessor- and Non-Microprocessor-Controlled Prosthetic Knees after Unilateral Transfemoral Limb Loss, American Academy of Orthotists and Prosthetists (2011)) ("At this time, there is evidence to suggest that microprocessor-controlled prosthetic knees (MPKs) provide greater ambulatory safety and improve environmental obstacle negotiation when compared to non-microprocessor-controlled prosthetic knees (NMPKs) among individuals with unilateral transfemoral limb loss."); PX08003 at 001 (Kannenberg et al., Benefits of Microprocessor-Controlled Prosthetic Knees to Limited Community Ambulators: Systemic Review, 51 J. of Rehab. R&D 1469 (2014)) ("MPK use may significantly reduce uncontrolled falls by up to 80% as well as significantly improve indicators of fall risk. Performance-based outcome measures suggest that persons with MFCL-2 mobility grade may be able to walk about 14% to 25% faster on level ground, be around 20% quicker on uneven surfaces, and descend a slope almost 30% faster when using an MPK.")); PX08032 at 001 (Highsmith et al, Ramp Descent Performance With the C-Leg and

Interrater Reliability of the Hill Assessment Index, 37 Prosthetics and Orthotics Int'l 362 (2013)) ("This study confirms that the C-Leg improves ramp descent performance and the Hill Assessment Index's interrater reliability.")).

- (2) Testimony from Clinical Researchers
- 646. Dr. Kaufman of the Mayo Clinic testified that the key findings of his research on MPKs "are a recurring theme that the patients have more safety, they have improved mobility, and they have better quality of life." (Kaufman (Mayo) Tr. 820). Dr. Kaufman's research has "demonstrated that people using microprocessor knees have less falls than when using non-microprocesor knees" because "the microprocessor knee is able to adapt to the environment more rapidly than a mechanical knee and allows a patient to prevent stumbles and falls." (Kaufman (Mayo) Tr. 820-22). MPKs also offer "health benefits" which "relate to the increased activity" an MPK user experiences compared to a mechanical knee user. (Kaufman (Mayo) Tr. 836-37). Dr. Kaufman testified that relative to MPKs, mechanical knees is "outdated" and based on "World War II technology." (PX05160 (Kaufman (Mayo) Dep. at 17-18)).
- 647. Dr. Kaufman testified that prosthetists use his published clinical studies in their practice. Dr. Kaufman described these research studies as "objective evidence for evidence-based practice." (Kaufman (Mayo Clinic) Tr. 836-37).
- 648. Mr. Kahle of Prosthetics Design and Research testified that, based on his research of MPKs, the reduction in stumbles and falls is "the biggest benefit of a microprocessor knee." (PX05119 (Kahle (Prosthetic Design and Research) Dep. at 33)). He further explained, "[i]t's the reason why microprocessor knees are paid for by both CMS and most insurance companies, in my opinion." (PX05119 (Kahle (Prosthetic Design and Research) Dep. at 36)). The microprocessor in an MPK "can adjust the speed levels in both swing and stance. And then, primarily, it can reduce stumbles and falls by sensing where the knee is in space." (PX05119 (Kahle (Prosthetic Design and Research) Dep. at 35)). Mr. Kahle further testified that microprocessor users experience an improved quality of life thanks to the reduction in stumbles and falls. (PX05119 (Kahle (Prosthetic Design & Research) Dep. at 37-38)).
 - b) <u>Surgeons, Prosthetists, and Prosthetics Clinics Recognize that</u> <u>MPKs Provide Benefits Compared to Mechanical Knees</u>
- 649. Dr. Benjamin Potter, a surgeon at Walter Reed National Military Medical Center testified that it is usually in a patient's best interest to receive a microprocessor knee. Dr. Potter testified at the trial that "I would say at this point it's medical fact that they can provide improved function." (Potter (Walter Reed) Tr. 775). Dr. Potter elaborated that "a well-functioning, well-aligned microprocessor knee attached to a well-designed comfortable socket can provide function that's superior to a mechanical knee or certainly no knee in a peg leg in terms of the patient's ability to walk symmetrically, their balance, their risk for falls, their energy expenditure when walking you name it better better function in activities of daily living like walking, standing and sitting." (Potter (Walter Reed) Tr. 775-76). A more symmetrical gait can, in turn, lead to faster walking as well as a lower

"risk for things like low back pain and osteoarthritis in joints above or on the other side of their amputation and for years in the future." (Potter (Walter Reed) Tr. 777). Dr. Potter further testified that MPKs provide greater balance than mechanical knees because they are "designed ideally not to buckle or give out on you when they're not supposed to be bending." (Potter (Walter Reed) Tr. 778-79).

- 650. The Department of Defense and the Department of Veteran's Affairs collaborated on a set of Clinical Practice Guidelines for Rehabilitation of Individuals with Lower Limb Amputation. (PX08005 (Dep't of Veteran's Affairs) at 001). These guidelines "suggest offering microprocessor knee units over non-microprocessor knee units for ambulation to reduce risk of falls and maximize patient satisfaction. There is insufficient evidence to recommend for or against any particular socket design, prosthetic foot categories, and suspensions and interfaces." (PX08005 (Dep't of Veteran's Affairs) at 007). Dr. Michael Highsmith, a contributor to the Clinical Practice Guidelines explained that this is the current recommendation from the VA and DoD and was based on the best available evidence at the time it was drafted and the consensus of the people that contributed to the recommendation. (PX05164 (Highsmith (Dep't of Veteran's Affairs) Dep. at 28-29) (discussing PX08005)). These Guidelines are not limited by K-level and do not force a clinician to use one specific make and model of prosthetic. (PX05164 (Highsmith (Dep't of Veteran's Affairs) Dep. at 28-29).
- 651. Dr. Robert Gailey, the Director of the Functional Outcomes and Research Evaluation Center at the University of Miami, testified that MPKs "across the board are smoother, they are more responsive to various terrains, going up and down ramps, being able to use stairs and that type of thing." (PX05142 (Gailey (University of Miami) Dep. at 35-36)). Dr. Gailey testified that "with prosthetists at both Walter Reed and Center for the Intrepid, [it's] pretty much a standard that a microprocessor knee is given to most veterans coming back and then they will also, if they choose, to have a mechanical knee in case there is failure with the microprocessor knee." (PX05142 (Gailey (University of Miami) Dep. at 86-87)). Based on his experience with veterans, Dr. Gailey "absolutely" thinks that U.S. veterans have benefited from MPKs. He testified, "Microprocessors have allowed folks to be able to use a prostheses with greater ease. They have been able to adapt to using a prostheses with less effort" and MPK technology "has enabled [a] far greater population of people to use prosthetic devices than we have ever seen before." (PX05142 (Gailey (University of Miami) Dep. at 88-89)).
- 652. Clinic customers (including prosthetists and clinic owners) testified that MPKs provide benefits over mechanical knees. Keith Senn, President of the Center for Orthotic and Prosthetic Care, testified that K3 amputees at COPC are typically fit with MPKs because "[w]e feel, and so does the industry, that the MPK is a better knee for the patient, and K3 is the first level that Medicare has said is eligible to receive the MPK knee." (Senn (COPC) Tr. 179). Michael Oros, President and CEO of Scheck & Siress Prosthetics, stated in a press release relating to the release of the RAND study regarding the benefits of MPKs, that "[t]his is not a case of amputees wanting to have access to new technology just because it is new. To the contrary, new tech versus old tech can be a life-and-death issue for an amputee." (PX05134 (Oros (Scheck & Siress) Dep. at 79-82); *see also* Oros (Scheck & Siress) Tr. 4901).

- 653. Clinic customers testified that MPKs provide more safety and stability than mechanical knees, leading to fewer stumbles and falls. For example, Tracy Ell, owner and Chief Prosthetist of Mid-Missouri Orthotics and Prosthetics testified that the "[i]nherent stability of the microprocessor knees are far superior than mechanical knees," and that the benefits of MPKs include reducing falls, allowing more variation in walking speed, improving gait patterns and efficiency, and decreasing the wear and tear on a patient's body. (Ell (Mid-Missouri O&P) Tr. 1698-703)). Keith Senn, President of the Center for Orthotic and Prosthetic Care testified that a "big benefit" of MPKs is "stumble recovery, so there's less falls. They feel more stable." (Senn (COPC) Tr. 174-75). Michael Oros, President and CEO of Scheck & Siress Prosthetics, testified that MPKs provide greater safety to amputees because they are more responsive to sudden movements than mechanical knees because of the microprocessor in the knee. (Oros (Scheck & Siress) Tr. 4860-61; see also PX05134 (Oros (Scheck & Siress) Dep. at 72, 76-77) ("So the microprocessor knee is going to provide the highest level stability of any prosthetic knee."); see also Ford (POA) Tr. 996-1000 ("There's no question that [MPKs] reduce the amount of falls that amputees can experience. Their ability to recover from stumbles, toes, hitting your toes, those kind of things, are all benefits that prevent the patient from falling."); PX05108 (Yates (Jonesboro) Dep. at 26-27, 47-48, 168-69) (safety is the primary benefit to a patient of an MPK over a mechanical knee, including a decreased incidence of falls; complaints about falls are "significantly less common" with MPKs); PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 41-42) (explaining why MPKs are typically a safer choice than a mechanical knee)).
- 654. Clinic customers testified that MPKs allow patients to more easily traverse everyday environmental barriers, such as curbs, steps, and slopes, as well as walk in crowded areas. Mark Ford, President and Managing Partner of Prosthetic and Orthotic Associates, testified that an MPK "can accommodate variable cadence, it can accommodate different types of terrain, it can accommodate ramps, steps, much more fast and more responsively than a mechanical knee." (Ford (POA) Tr. 1002). Michael Bright, owner of North Bay Prosthetics and Orthotics testified that patients who want to maneuver in crowds are "definitely" more likely to benefit from MPKs relative to mechanical knees. (PX05141 (Bright (North Bay) Dep. at 149-50); *see also* PX05134 (Oros (Scheck & Siress) Dep. at 75-76) ("Q. Are there benefits to amputees using microprocessor knees on kind of a sloped terrain? A. Absolutely.")).
- 655. According to clinic customers, MPK-users demonstrate a much better gait, and are better able to walk with variable cadence, compared with users of mechanical knees. Mr. Senn of COPC testified that "[y]ou know, from my observation, they're able to have a much better gait, which means to walk better, as well as amputees go, to be able to improve their gait." (Senn (COPC) Tr. 174-75). Mr. Oros of Scheck & Siress Prosthetics, testified that MPKs respond to variable cadence much faster than mechanical knees, make adjustments more rapidly than mechanical knees, provide a higher level of stability than mechanical knees, and provide benefits walking down slopes relative to mechanical knees. (Oros (Scheck & Siress) Tr. 4858-59); *see also* (Ford (POA) Tr. 1002; PX05108 (Yates (Jonesboro) Dep. at 50-51)).

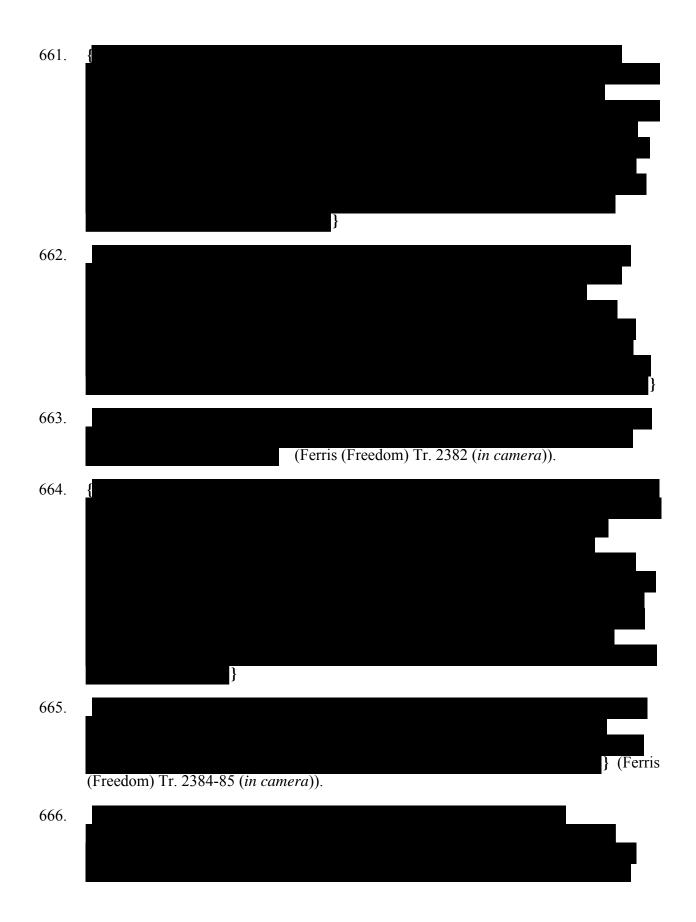
656. Clinic customers testified that MPKs are associated with fewer health risks, such as back pain and osteoarthritis, compared to mechanical knees. Rob Yates, President and CEO of Jonesboro Prosthetic & Orthotic Laboratory, testified that the documented benefits of MPKs include "a lower incidence of complications from, you know, compensatory gait deviations, such as low back pain, sound side complications from arthritis, and other involvement that could present on the sound side." (PX05108 (Yates (Jonesboro) Dep. at 47); *see also* Ell (Mid-Missouri) Tr. 1699 (recent literature on MPKs shows that they lead to decreased instances of osteoarthritis and decreased "wear and tear on a patient's body, even subsequently extending their life span")).

c) <u>Respondent Recognizes the Benefits of MPKs over Mechanical</u> <u>Knees</u>

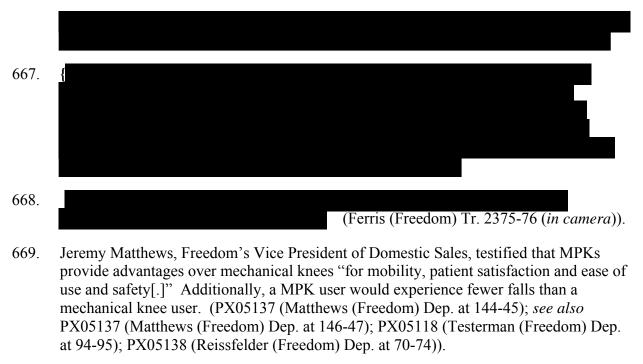
657. Testimony of Freedom executives demonstrates the perceived benefits of MPKs relative to mechanical knees. For example, Freedom Chairman Maynard Carkhuff testified that Freedom markets its Plié MPK as improving the stability of stance for amputees while ascending or descending stairs, relative to mechanical knees. (PX05109 (Carkhuff (Freedom) Dep. at 98)). Mr. Carkhuff further agreed that mechanical knee users generally must "give more thought to controlling the knee in both the stance and swing phases of walking" as compared to microprocessor knees. (PX05109 (Carkhuff (Freedom) Dep. at 97-98) (discussing PX01164)).



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at 024) (*in camera*); *see also, e.g.*, PX01453 (Freedom) at 001 (circulating conclusions from the RAND study included in a draft of the study regarding the benefits of MPKs over mechanical knees)).

- A 2015 Freedom presentation titled "Microprocessor Controlled Knees" includes slides titled "What makes MPC Knees different?" (PX00814 (Freedom) at 007-08). The listed benefits of MPKs are "Increases stability and confidence," "Reduces cognitive burden because of stumble recovery feature," "Studies have shown that MPC knees can elevate some user's functional abilities (K-level) compared to conventional knees," "Studies also suggest that [MPKs] actually are responsible for variable cadence achievement," "Stability can reduce fear of falling," "Studies show 88.1% increase in confidence," "Reported that MPC knees can decrease frequency of falls by as much as 64%," and "Amputees no longer have to watch every step." (PX00814 (Freedom) at 007-08).
- 672. Freedom's website includes Plié 3 materials for use by Freedom customers seeking reimbursement that claim benefits of MPKs over mechanical knees. (PX08009 (Freedom)). The materials include a "Microprocessor Knee Literature Review" collected and summarizing clinical research articles "in an effort to understand where the research in Microprocessor Knees (MPK) has been focused and to determine where significant

outcomes exist. These articles can be utilized within your initial Letter of Medical Necessity or could be used in refuting an appeal." (PX08009 (Freedom) at 017). The Freedom materials state that "research has been able to show that the [MPK] user feels more stable on stairs, inclines, and uneven terrain, while reducing the cognitive demand required for walking." (PX08009 (Freedom) at 017). Moreover, according to these Freedom materials, "the user experiences less stumbles and falls while expressing a higher level of satisfaction and stability with MPKs." (PX08009 (Freedom) at 017).

- 673. Freedom's internal training materials, part of its "Freedom Institute of Technology" list the "Benefits of MPK's[.]" (PX00805 (Freedom) at 370-71). The listed benefits include "MPC stumble recovery," "Customizable swing initiation," "Yielding for ramps, slopes, stairs and sitting," "Programming for different walking speeds," "Different modes," "Better outcomes long-term," and "Documenting variable cadence[.]" (PX00805 (Freedom) at 371).
- 674. Otto Bock executives also testified about the benefits of MPKs. For example, Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified that, "Microprocessors are proven to have stumble recovery, making them very, very safe. They also make microprocessors allow for more cadence variance, so walking fast or slow, so the computer can adjust to those speed differences. Microprocessors can enable people to have more comfort because it gives them additional features and benefits that they do not have to overcompensate with their muscular structure. So there's many, many ways in which an end user transfemoral amputee can benefit from a microprocessor knee." (PX05010 (Schneider (Otto Bock) IHT at 73-74)).
- 675. Andreas Eichler, Otto Bock's Head of Business Unit, Prosthetics, Lower Limb Mechatronic Systems, testified that the primary benefits of MPKs are "safety and comfort." He elaborated that safety meant "[t]hat patients can rely on their knee joints that it will be stiff when it's supposed to be stiff and it will be pliable when it's supposed to be pliable," and comfort meant "Less pain. So less pain and subsequent damages as a result of everyday use and walking on the prosthetic." (PX05133 (Eichler (Otto Bock) Dep. at43-44)). Mr. Eichler also agreed that microprocessor knees are more responsive than mechanical knees, and he testified mechanical knees "are not responsive at all." (PX05133 (Eichler (Otto Bock) Dep. at 51-52)
- 676. Otto Bock's Executive Medical Director, Dr. Andreas Kannenberg, testified in his deposition that K2 patients would benefit from MPKs over mechanical knees. He explained, "First and foremost, in terms of improved safety. So they would stumble less and fall less, which is the foundation for developing more trust and better trust in the prosthesis, and becoming more mobile and active, doing more activities than they could do on a mechanical prosthesis." (PX05150 (Kannenberg (Otto Bock) Dep. at 39-40)).
- 677. Dr. Kannenberg further testified that for unlimited community ambulators, MPKs also provide a benefit in terms of a reduction in stumbles and falls. For this group, the benefit is also "about increasing their mobility and being able to do activities that they couldn't

do or wouldn't dare to do on a mechanical knee." (PX05150 (Kannenberg (Otto Bock) Dep. at 42-43)).

- 678. Dr. Kannenberg testified the C-Leg, due to its microprocessor, provides greater mobility than a mechanical knee because "the microprocessor control allows a knee to do more activities without the threat of collapsing and causing a fall." Additionally, "the resistances that are produced in the knee [are] much more flexible and adaptable to many more activities that you encounter in your daily life than a mechanical control. So when you when you adjust the mechanical and mechanical knee, it is usually quite nice for level walking, but as soon as you have to negotiate uneven terrain, slopes and stairs, you're in trouble." (PX05150 (Kannenberg (Otto Bock) Dep. at 44-45)).
- 679. Dr. Kannenberg agreed that for a given safety level, an MPK provides greater functionality than a mechanical knee, and that, for a given functionality level, an MPK would tend to provide greater safety than a mechanical knee. (PX05150 (Kannenberg (Otto Bock) Dep. at 83)).
- 680. Brad Ruhl, currently Otto Bock's Managing Director for North America, testified that "[t]he benefits of microprocessor control, specifically in C-Leg, is that it has features that will help patients avoid stumbles and falls. Again, as I mentioned earlier this is as a lower-limb amputee, especially transfemoral amputee, the thing you're most concerned about when you walk is falling, tripping and and falling." (PX05162 (Ruhl (Otto Bock) Dep. at 35)).
- 681. Otto Bock's internal documents and marketing materials espouse the benefits of MPKs over mechanical knees. For example, Otto Bock posted to its website a summary of a publication by Dr. Highsmith, Mr. Kahle, and Dr. Kaufman entitled "Safety, Energy Efficiency, and Cost Efficacy of the C-Leg for Transfemoral Amputees." (PX08007 (Otto Bock)). The Oto Bock summary quoted the conclusion of the study that "Though methodological quality varied across the selected topic areas, there was sufficient evidence to suggest that the C-Leg provided increased efficacy in safety, energy efficiency, and cost effectiveness when compared with other [non-microprocessor controlled] prosthetic knees for transfemoral amputees." (PX08007 (Otto Bock) at 001) (alteration in the original)).





- 684. In a letter advocating for Medicare coverage of MPKs for K2s, Otto Bock stressed the benefits of MPKs over mechanical knees. (PX01480 (Otto Bock) at 004-07). The authors (Kim Hanson and Andreas Kannenberg of Otto Bock) wrote that "While there is no doubt that the unlimited community ambulatory receives tremendous benefit from fluid and microprocessor knee control, it is clear that this same technology may equally provide tremendous benefits to patients with MFCL-2 mobility grade. In these beneficiaries, stumble recovery and improved stability while ambulating on all terrains create a solid foundation for improvement of overall function and mobility." (PX01480 (Otto Bock) at 007)).
- 685. Otto Bock has regularly provided customers with clinical research and other documentation discussing the benefits of MPKs relative to mechanical knees. Over the last several years, Otto Bock employees have sent clinical research studies to its customers in order to market its MPK products. (*See, e.g.*, PX05150 (Kannenberg (Otto Bock) Dep. at 193-194); PX05148 (Swiggum (Otto Bock) Dep. at 36-38)).

686.

} (Kannenberg (Otto Bock)

Tr. 1893 (*in camera*)). For example, On May 6, 2015, Dr. Kannenberg sent to Sam Liang, then and currently the President of Hanger, an article entitled "Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: Systemic review," by Andreas Kannenberg, MD, PhD; Britta Zacharias, Dipl-Ing (FH), CPO; and Eva Pröbsting, Dipl-Ing (FH), CPO (an article in evidence as PX08003). (PX01494 (Otto Bock at 001; see also PX00848 (Otto Bock) at 001, 040, (Aug. 18, 2015 email from Otto Bock on behalf of Dr. Kannenberg sending several research articles highlighting the benefits of MPKs to insurer Select Health, including "Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature," by M. Jason Highsmith; Jason T. Kahle; Dennis R. Bongiorni; Bryce S. Sutton; Shirley Groer; and Kenton R. Kaufman (article in evidence as PX08001)); PX00849 (Otto Bock) at 001, 022 (Sept. 23, 2015 email from Dr. Kannenberg to Phil Stevens, prosthetist and orthotist at Hanger, attaching several articles highlighting the benefits of MPKs including "Gait and balance of transfemoral amputees using passive mechanical and microprocessorcontrolled prosthetic knees," by Kenton R. Kaufman; J.A. Levine; R.H. Brey (article in evidence as PX08010)); PX01497 (Otto Bock) at 002, 004 (Nov. 3, 2015 email from Dr. Kannenberg attaching several articles highlighting the benefits of MPKs for transmittal to

Deanna Hines of Russell Prosthetics including "Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees: A review of the literature," by M. Jason Highsmith; Jason T. Kahle; Dennis R. Bongiorni; Bryce S. Sutton; Shirley Groer; and Kenton R. Kaufman (article in evidence as PX08016); PX01620 (Otto Bock) at 001 (March 25, 2016 email from Dr. Kannenberg sending several articles highlighting the benefits of MPKs to Lee Childers PhD, MSPO, CP of Alabama State University Prosthetics and Orthotics); PX01480 (Otto Bock) at 002, 017 (April 25, 2016 email from Otto Bock's Kimberly Hanson, Director of Reimbursement for North America, attaching several articles highlighting the benefits of MPKs to Stacey Brennan of Anthem, including "Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference," by Jason T. Kahle, CPO, LPO; M. Jason Highsmith, DPT, CP; and Sandra L. Hubbard, PhD, OTR/L, ATP (article in evidence as PX08018)); PX00852 (Otto Bock) at 001 (Nov. 17, 2016 email from Dr. Kannenberg sending several articles highlighting the benefits of MPKs to Courtney Boniello of A Step Ahead Prosthetics)).

- 687. Otto Bock employees have directed customers to the RAND website, and specifically to the article "Economic Value of Advanced Transfemoral Prosthetics," by Hangsheng Liu et al. (article in evidence as PX08004). (PX05150 (Kannenberg (Otto Bock) Dep. at 193)).
 - d) <u>Other Prosthetic Manufacturers Tout the Benefits of MPKs over</u> <u>Mechanical Knees</u>
- 688. Other MPK manufacturers testified about advantages of MPKs over mechanical knees. For example, Kim De Roy, Executive Vice President for R&D at Össur, testified that "microprocessor-controlled knees were originally designed to overcome shortfalls related to the safety and stability of the amputee, so if you don't have a knee that thinks and that senses for the patient, the patient is 100 percent relying on his own ability to utilize that knee to make sure that he's – he or she is stable when standing. The microprocessor knee, because of the interpretation of the data, will help them prevent a stumble, will help them prevent a fall, by constantly monitoring what the position of the patient is and making sure that the knee is in fact locked or provides the necessary type of resistance when that's required. So the sensation of the patient will be one of additional safety, additional stability. And the research that has been done over the last decade relating to microprocessor knees shows that there is actually a reduction in the amount of falls with those patients and an increased feeling of proprioception or control over the prosthesis by the users." (De Roy (Össur) Tr. 3543-44).
- 689. Mr. De Roy further testified that research on MPKs "shows that people that transfer from a mechanical knee over to the microprocessor knee experience more safety, experience reduced falls. And in some cases it's even shown that they have reduced comorbidities, such as back pain, because their gait normalizes. They walk better. They don't use their muscles in straining matters; therefore, the risk for developing those types of issues is lower. There's also a benefit to the sound side leg, because typically people are amputated on one side, and the advantages that these types of knees reduce the impact on the sound side, which has proven to be related to or have a positive impact on reducing

the chances of developing knee OA on the sound side, osteoarthritis." (De Roy (Össur) Tr. 3546-47).

- 690. Össur highlights the benefits of microprocessor knees compared to mechanical knees to market its MPKs. (*See, e.g.*, PX03097 (Össur) at 011; *see also* De Roy (Össur) Tr. 3549). The benefits listed include "associated with increased quality of life and improved mobility in transfemoral amputees, as measured by transitioning from nonmicroprocessor, mechanical knees." (PX03097 (Össur) at 006 ("Health Economic Analysis, The case for Rheo Knee 3 | Rheo Knee XC")).
- 691. Össur also uses research studies showing the benefits of MPKs to market its products because the studies prove the benefits of MPKs to insurance companies and other payers. (De Roy (Össur) Tr. 3552).
- 692. For example, Össur has used the article, "Economic Value of Advanced Transfemoral Prosthetics," by Hangsheng Liu et al. to market its MPKs (article in evidence as PX08004). (De Roy (Össur) Tr. 3552-53). Mr. De Roy described this study as a "health economic study" that "relate[s] the functional/clinical benefits of a device to the economic factors" in order to highlight the "overall cost of care" for the patient. (De Roy (Össur) Tr. 3552-53).
- 693. Stephen Blatchford, Executive Chairman of Endolite, testified that the main clinical benefits the company highlights for its Orion 3 MPK "are the fact that the user will need less energy to walk with the knee because on average they will walk more quickly, so their self-selected speed, to use a horrible phrase, is higher than it would be without a microprocessor knee" and also that "[t]he knees reduce the instance of falling very considerably." (Blatchford (Endolite) Tr. 2119-20).
- 694. According to Mr. Blatchford, Endolite's MPKs provide "several advantages" over its non-MPKs: "If you look at it from the amputee's perspective, the consequence of the fact that the knee reacts to more exactly to what the user is doing means that the user on average will walk faster there's clinical studies which will support that that the user uses less energy, further clinical studies that will support that, that there is less distortion in the gait of the amputee so that when you compare the gait on the sound side with the gait on the amputated side, there's more symmetry, which means a consequence of more symmetry is that there's less bad force I couldn't think of the right phrase because it's more symmetrical, it applies less adverse force on the patient's skeletal system, and therefore, you can get less things like back pain, and so on." (Blatchford (Endolite) Tr. 2114-15).
- 695. Endolite's marketing materials list clinical benefits of its Orion 3 MPK, including "greater stability," "less effort," "improved gait," "reduced compensation," and "greater patient satisfaction." (PX03176 (Endolite) at 031-36).
- 696. Endolite encourages its sales representatives to highlight the clinical benefits of the Orion
 3 MPK during sales calls with prosthetists. (PX05144 (Blatchford (Endolite) Dep. at175-80).

697.

(Carver (College Park) Tr. 2059-60 (*in camera*); *see also* PX03025 (College Park) at 002 (*in camera*) (describing a new mechanical knee in development as a good option for amputees whose insurance will not reimburse for an MPKs, which are described as the "first choice"); PX05107 (Carver (College Park) Dep. at 19-20)).

- 698. Ryan Arbogast, CEO of Ohio Willow Wood, testified that "[m]icroprocessor knees provide additional features and benefits and function that mechanical knees could not." (PX05106 (Arbogast (Willow Wood) Dep. at 19)). He elaborated that, "[m]icroprocessor knees, in general, use sensors to assess what's happening with the knee and make changes in the function of the knee as a result." Further, he testified "[t]hat could be a benefit when an amputee is changing their mode of activity or has a potential for instability or for a fall." With respect to instability and falling, he testified that "[m]echanical knees have certain design characteristics to prevent amputees from falling. Those are called lock or stance phases. Microprocessor knees improve upon that or aim to improve upon that function by using sensors to better understand what's happening with the knee." (PX05106 (Arbogast (Willow Wood) Dep. at 19-20)).
- 699. Mr. Arbogast testified that he expected insurance coverage of MPKs to expand in the future to encompass individuals at lower K levels "because we're starting to see studies showing long-term healthcare costs and the related benefits to a microprocessor knee or a microprocessor prosthetic, preventing healthcare cost occurrences such as stumbling, falling, lack of mobility, lack of activity." (PX05106 (Arbogast (Willow Wood) Dep. at 195-96)).
- 700. Glenn Choi, President of mechanical knee manufacturer ST&G, testified that the benefits of having an MPK are that it "[p]rovides stability, safety, and better resistance and adjustments for the patient during gait cycle." (PX05117 (Choi (ST&G) Dep. at 43)). Unlike a constant friction mechanical knee, "a microprocessor knee changes in real time constantly throughout the entire gait cycle, both swing and stance, providing variable resistance and stability based on various input or load being applied to the knee during different phase of the gait cycle." (PX05117 (Choi (ST&G) Dep. at 43-44)). He also testified that, unlike a pneumatic or hydraulic mechanical knee, an MPK is constantly adjusting the resistance provided during the swing phase. The benefit to the amputee is that "[a]s the patient's activity changes or movement changes within the gait cycle, the input of the load forces being applied is not always the same, nor is it predictable, so the microprocessor compensates for the unpredictability in the load that's being applied to the knee in both stance and swing phase" which creates greater safety and stability. (PX05117 (Choi (ST&G) Dep. at 44-45)).

B. MPK PRICES AND REIMBURSEMENT AMOUNTS DIFFER SIGNIFICANTLY FROM THOSE OF MECHANICAL KNEES

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1. Clinics Pay Significantly Higher Prices for MPKs than for Mechanical Knees

701.

(Blatchford (Endolite) Tr. 2123-24; De Roy (Össur) Tr. 3554-56; PX05109 (Carkhuff) Dep. at 112; Schneider (Otto Bock) Tr. 4355-56; Senn (COPC) Tr. 197-98); PX05141 (Bright (North Bay) Dep. at 74); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 57-58); PX05108 (Yates (Jonesboro) Dep. at 55, 119-20) (*in camera*)); Ford (POA) Tr. 945); Asar (Hanger) Tr. 1374 (*in camera*); PX05001 (Endrikat (Empire Medical) Dep. at 17-18)).

702.

} (Blatchford (Endolite) Tr. 2123-24; De Roy (Ossur) Tr. 3554-56; PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 57-58 ("the average [price] for a microprocessor is 17,000, and the average [price] for a mechanical knee is 1,500.")); Ford (POA) Tr. 945 (manufacturers charge "five to eight times" more for MPKs than mechanical knees)); Senn (COPC) Tr. 197-98 (COPC pays between \$10,000 and \$15,000 for an MPK and between \$3,000 and \$5,000 for a mechanical knee); PX05141 (Bright (North Bay) Dep. at 74 (average price for an MPK is around \$16,000 while mechanical knees range from \$400 to \$3000));

; PX05001 (Endrikat

(Empire Medical) Dep. at 17-18 (Empire pays \$16,000 on average for MPKs and between \$250 and \$3,000 for mechanical knees))).

703.

(Collins (Cascade) Tr. 3290 (in camera)).

- 704. According to Michael Fillauer of Fillauer, "a mechanical knee could be anywhere under a thousand dollars to a couple of thousand dollars . . . whereas, a microprocessor knee might be close to 20,000 or more. So it's a pretty significant price difference." (PX05105 (Fillauer (Fillauer) Dep. at 97-98)).
- 705.

} (PX06001 (Scott Morton Report) at ¶¶ 50, Table 3 (*in camera*))).

} (PX06001 (Scott

Morton Report) at ¶¶ 51, Table 4 (*in camera*))).

706. Respondent's expert witness, Dr. David Argue, testified that the manufacturers charge higher prices for MPKs than non-MPKs. (PX05173 (Argue) Dep. at 134).

2. Clinics Receive Substantially More Reimbursement from Insurers for MPKs than Mechanical Knees

707.	} PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 37-40).
708.	<pre>{ (PX05109 (Carkhuff (Freedom) Dep. at 112); Kaufman (Mayo) Tr. 834; Senn (COPC) Tr. 250; Ford (POA) Tr. 980 (POA is reimbursed "[f]our to five times" higher for fitting an MPK over a mechanical knee)); Asar (Hanger) Tr. 1360 (<i>in camera</i>) { . </pre>
709.	
	(Sanders (United) Tr. 5492-93 (in camera)).

- 710. Prosthetic manufacturers agree that the reimbursement by both private payers and Medicare is substantially greater for MPKs than it is for mechanical knees. (PX05117 (Choi (ST&G) Dep. at 51-52(regarding Medicare and private payers)); Blatchford (Endolite) Tr. 2127 ("reimbursement rates for just the MPK part of it are several times higher than the reimbursement rates for the non-MPK part of a prosthesis which didn't have a microprocessor knee")).
- 711. Dr. Argue, Respondent's economic expert, testified that he concluded in his expert report that prosthetic clinics receive larger reimbursement amounts for MPKs than non-MPKs. (Argue, Tr. 6270; PX05173 (Argue Dep. at 134); see also (RX-1049 at 013 (¶¶ 18-19) (Argue Expert Report) (estimating that the Medicare reimbursement rate for MPKs ranged from approximately \$26,000 to \$35,000, while the Medicare reimbursement amount for non-MPKs of \$5,000 to \$8,000).

C. MPK PRICES ARE NOT SENSITIVE TO MECHANICAL KNEE PRICES

- 712. According to Keith Senn, President and COO for Kentucky of the Center for Orthotic & Prosthetic Care, MPK prices do not respond to price changes of non-microprocessor knees. (PX05128 (Senn (Center for O&P) Dep. at 152). According to Mr. Senn, prices of mechanical knees do not respond to price changes of microprocessor knees. (PX05004 (Senn (COPC) IHT at 20; PX05128 (Senn (Center for O&P) Dep. at 151). Mr. Senn testified at trial that he has never threatened to shift the clinic's MPK purchases to mechanical knees as a negotiating tactic because the shift "would be a disservice to patients and poor patient care." (Senn (COPC) Tr. 198).
- 713. Mr. Endrikat of Empire Medical testified that prices of mechanical knees do not respond to changes in the prices charged for microprocessor knees. (PX05001 (Endrikat (Empire

Medical) IHT at 18) ("Q: In your experience do non-microprocessor mechanical knee prices respond to price changes of microprocessor knees? A: They do not.")). Mr. Endrikat of Empire Medical testified that he uses "ballpark" pricing to play the microprocessor knee manufacturers off of each other during price negotiations. (PX05116 (Endrikat (Empire) Dep. at 58)). He testified further that he only uses MPK competitor pricing to negotiate extra discounts for MPKs. (PX05116 (Endrikat (Empire Medical) Dep. at 59). Mr. Endrikat explained that he is unable to use pricing of mechanical knees when negotiating with manufacturers for the price of MPKs because "[i]t's a different product category." (PX05116 (Endrikat (Empire) Dep. at 58-59)).

- 714. (Blatchford (Endolite) Tr. 2155 (*in camera*)). { *camera*)).
- 715. Dr. Argue, Respondent's economic expert, could not identify any clinic customers that have switched from fitting MPKs to mechanical knees in the past. (PX05173 (Argue Dep. at 232)).

716.

} (Tr. 143-6895 (partial in camera); JX002). {

} (Senn (COPC)

Tr. 148-280 (partial in camera); Ford (Prosthetic & Orthotic Assocs.) Tr. 901-1067 (partial in camera); Asar (Hanger) Tr. 1306-1571 (partial in camera); Ell (Mid-Missouri) Tr. 1658-1816 (partial in camera); Brandt (Ability) Tr. 3741-3845 (partial in camera); Oros (Scheck & Siress) Tr. 4770-4920 (partial in camera); Sabolich (Scott Sabolich Prosthetics) Tr. 5787-5960 (partial in camera)).

(PX05002 (Asar (Hanger) IHT (*partial in camera*)); PX05153A & PX05153B (Asar (Hanger) Dep. at (*partial in camera*)); PX05003 (Yates (Jonesboro P&O) IHT (*in camera*)); PX05108 (Yates (Jonesboro P&O) Dep. at (*in camera*)); PX05004 (Senn (COPC) IHT; PX05128 (Senn (COPC) Dep.); PX05129 (Ell (Mid-Missouri) Dep.); PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep.); PX05134 (Oros (Scheck & Siress) Dep. at (*partial in camera*)); PX05135 (Webster (Prosthetic & Orthotic Care) Dep.); PX05140 (Weott (Orthotic Prosthetic Center Inc.) Dep. at (*in camera*)); PX05141 (Bright (North Bay) Dep.); PX05145 (Ford (Prosthetic & Orthotic Assocs.) Dep.); PX05149 (Brandt (Ability) Dep. at (*partial in camera*)); PX05151 (Patton (Prosthetic Solutions) Dep.); PX05166 (Watson (Fourroux) Dep. at(*partial in camera*)); PX05167 (Filippis (Wright & Filippis) Dep. at(*partial in camera*)); PX05168 (Sprinkle (Sprinkle) Dep.)).

D. RESPONDENT'S ACTIONS AND ANALYSES IN THE ORDINARY COURSE OF BUSINESS DEMONSTRATE MPKS ARE A RELEVANT MARKET

1. Respondent Analyzes MPKs as a Distinct Market from Mechanical Knees in the Ordinary Course of Business

- 717. Otto Bock has consistently characterized the market that its microprocessor knee, the C-Leg, competes in, as a microprocessor knee market. Matthew Swiggum, Otto Bock's CEO at the time of the Merger, testified that Otto Bock internally generates market share estimates of the U.S. microprocessor knee market on a regular basis. (PX05148 Swiggum (Otto Bock) Dep. at 40-44).
- 718. For example, on January 30, 2015, Otto Bock estimated its own share (78%) and Freedom's Plié's share (11%) in the U.S. MPK market. (PX01382 (Otto Bock) at 002). The only other products included in Otto Bock's "Estimated market size and share" in the MPK market were Össur's Rheo (10% share) Endolite's Orion (1% share). (PX01382 (Otto Bock) at 002). {

	(Schneider (Otto Bock) Tr. 4563-65) (in camera)).	

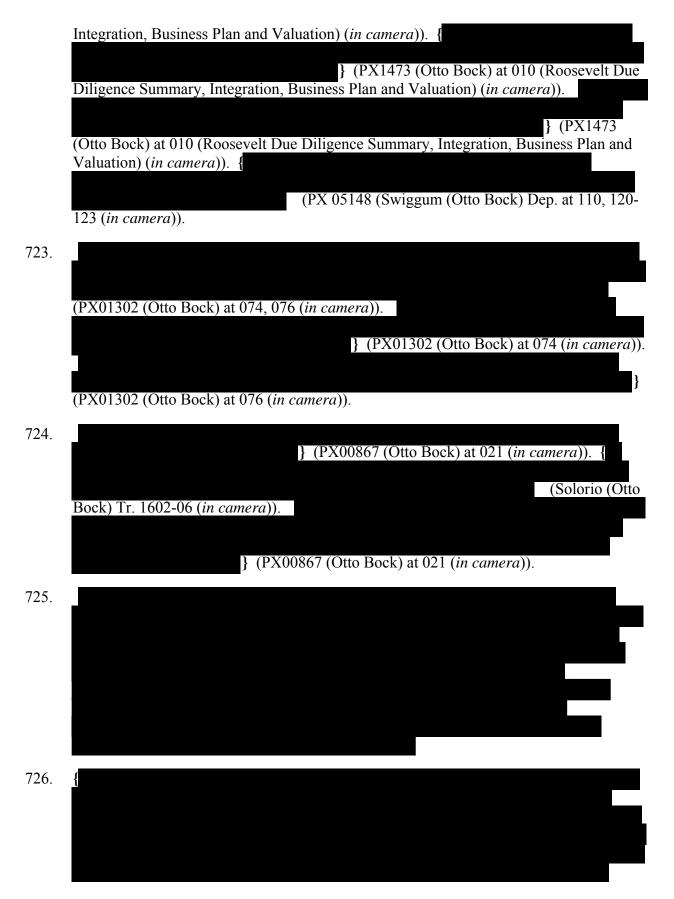
(PX01382 (Otto Bock) at 002).

719. When preparing for the launch of the C-Leg 4, Mr. Schneider sent Otto Bock estimates of shares and positioning in an "MPK market" on February 20, 2015 to his "cross-functional" launch team; the analysis did not mention any mechanical knees. (PX01518 (Otto Bock) at 001-002; 009).



(PX01518 (Otto Bock) at 001-002; 009).

720. Cali Solorio, Otto Bock's Senior Prosthetics Marketing Manager, estimated market size and shares of an MPK market that did not include mechanical knees in a November 18, 2015 presentation. (PX01002 (Otto Bock) at 006 (MPK Portfolio Alignment)). In the presentation, Ms. Solorio estimated Otto Bock had a 81% share of the MPK market, Freedom's Plié had an 10% share, Össur's Rheo had an 8% share, and Endolite's Orion had a 1% share. (PX01002 (Otto Bock) at 005). At trial, Ms. Solorio testified that she presented this entire presentation to her regional management team. (Solorio (Otto Bock) Tr. 1593-94). { (Solorio (Otto Bock) Tr. 1601 (*in camera*)).



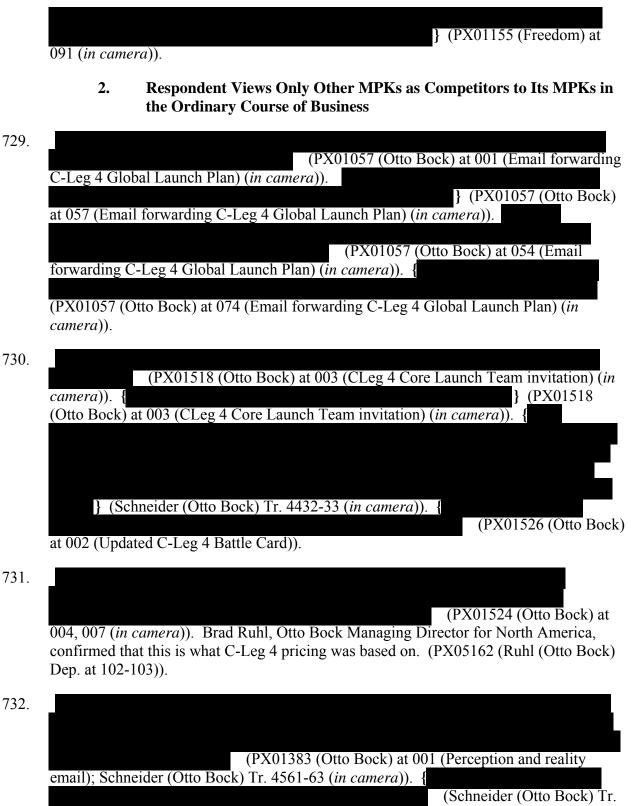
 {PX01164 (Freedom) at 016, 024-028 (Mechanical Knee Market Data) camera)). (PX01164 (Freedom) at 005 (Mechanical Knee Market Data) (<i>in camera</i>) 		
727.	(<i>in camera</i>)). {	
	(Freedom) at 006 (<i>in camera</i>)). (PX01024	

(PX01024 (Freedom) at 006) (in camera)).

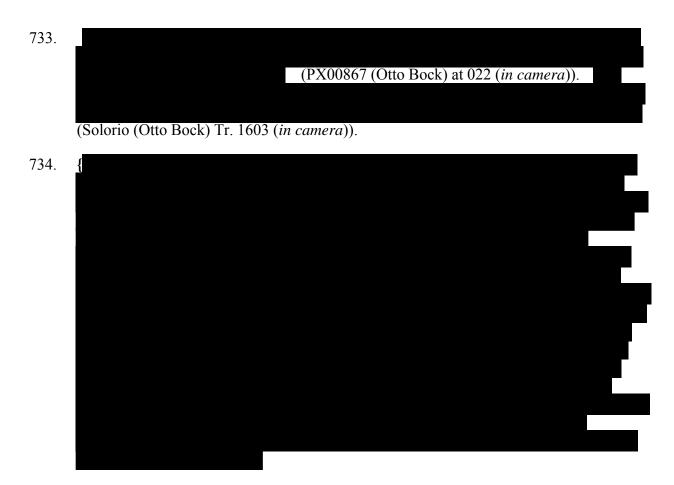


(PX01155 (Freedom) at 091 (in camera)).

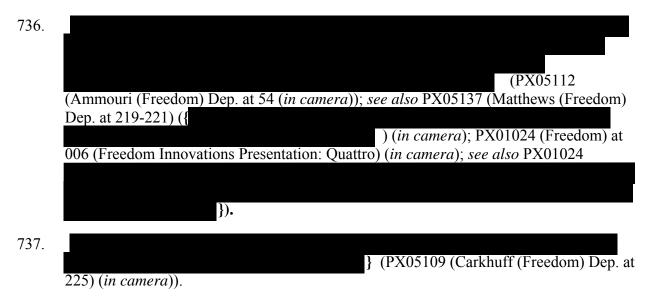
(PX05109 (Carkhuff (Freedom) Dep. at 194-96 (*in camera*)); Carkhuff (Freedom) Tr. 438-39 (*in camera*)). {



^{4561-63 (}in camera)).



735. Freedom only identified other MPKs as competitors to its Plié. Mark Testerman, Vice President of National and Key Accounts, testified that when Freedom sets of the price of the Plié 3, Freedom is "looking at trying to take share from all other microprocessor knees, we look at pricing of the Plié 3 versus those knees." (Testerman (Freedom) Tr. 1144). He agreed that he does not look to pricing of mechanical knees. (Testerman (Freedom) Tr. 1144).



- 738. Freedom created a Battle Card for the Plié 3, comparing the features of the Plié 3 to the C-Leg 4. (PX01214 (Freedom) at 030 (Plié 3 Fact Sheet)). Manar Ammouri, Senior Product Manager for the Plié, confirmed that she had not created a battle card comparing the Plié to any mechanical knees. (PX05112 (Ammouri (Freedom) Dep. at 103)).
- 739. When positioning the Plié against its competition, Ms. Ammouri testified that, "I'm primarily targeting the segment for the Plié's competition, which is other microprocessors." (PX05112 (Ammouri (Freedom) Dep. at 118; *see also* PX01172 (Freedom) at 003-04 (Plié versus Competitors Positioning)).
- 740. As part of the Plié 3 Selling Guide, Freedom created a Benefits Matrix, which compares functionality, adaptability, safety, versatility, and other factors between the Plié and its competitors. (PX05112 (Ammouri (Freedom) Dep. at 147-48; PX01182 (Freedom) at 026 ("Benefits Matrix")). The benefits matrix only lists microprocessor knees. (PX05112 (Ammouri (Freedom) Dep. at 149)).



- E. THE INDUSTRY VIEWS MPKS AS DISTINCT FROM MECHANICAL KNEES
 - 1. MPKs and Mechanical Knees Have Distinct L-Codes
- 742. Medicare and other payers use the Healthcare Common Procedure Coding System ("HCPCS") Level II codes, commonly referred to as "L-Codes," to assign reimbursement amounts to prosthetic devices. (PX05165 (Sanders (United) Dep. at 22-23)).
- 743. } (Sanders (United) Tr. 5489-90 (*in camera*); PX05141 (Bright (North Bay) Dep. at 62-63)).
- 744. L-Codes describe the function of specific prosthetic device components. (PX05133 (Eichler (Otto Bock) Dep. at 54-56); PX05165 (Sanders (United) at 26-28)).
- 745.

Kannenberg (Otto Bock) Tr. 1872; Sanders (United) Tr. 5434 (*in camera*); PX05129 (Ell (Mid-Missouri O&P) Dep. at 65); Asar (Hanger) Tr. 1382 (*in camera*)).

746.

(PX05150 (Kannenberg (Otto Bock) Dep. at 77); PX05105 (Fillauer (Fillauer) Dep. at 24); PX05129 (Ell (Mid-Missouri Orthotics & Prosthetics) Dep. at 64-65); PX05151 (Patton (Prosthetic Solutions) Dep. at 70-73); Senn (COPC) Tr. 250; De Roy (Össur) Tr. 3557-60; Sanders (United) Tr. 5491-93 (*in camera*); PX05173 (Argue (Respondent) Dep. at 134)).

- 747. The L-Codes commonly used for an MPK are L5856, L5828, L5845, and L5848. (*See, e.g.*, Ell (Mid-Missouri O&P) Tr. 1802-03; PX01062 (Otto Bock) at 004). All MPKs, regardless of manufacturer, qualify for reimbursement under these codes. (PX05149 (Brandt (Ability) Dep. at 54-55); PX05141 (Bright (North Bay) Dep. at 86-87); PX05134 (Oros (Scheck & Siress) Dep. at 65-66)). A clinic's acquisition cost does not impact the reimbursement that an insurer will provide for a particular MPK.
- 748. The base L-code designating an MPK is L5856. (Schneider (Otto Bock) Tr. 4293-94; PX05129 (Ell (Mid-Missouri O&P) Dep. at 61-62); PX05141 (Bright (North Bay) Dep. at 62-63); PX05134 (Oros (Scheck & Siress) Dep. at 102-103); Sabolich (Scott Sabolich Prosthetics & Research) Tr. 5923). L-Code 5856 covers "Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, [and] swing and stance phase." (Carkhuff (Freedom) Tr. 714-15).
- 749. L-5856 applies to the Plié 3, C-Leg 4, Rheo 3 and Orion. (PX05007 (Carkhuff (Freedom) IHT at 139-40)). In order to apply the L-5856 code, a knee "requires a microprocessor that controls both the swing and the stance." (PX05010 (Schneider (Otto Bock) IHT at 91-92)).
- Mechanical knees do not qualify for reimbursement under L5856. (PX05129 (Ell (Mid-Missouri O&P) Dep. at 64-65); PX05150 (Kannenberg (Otto Bock) Dep. at 76-77);
 PX05149 (Brandt (Ability) Dep. at 54-55); PX05141 (Bright (North Bay) Dep. at 168-69); PX05116 (Endrikat (Empire) Dep. at 40); PX05117 (Choi (ST&G) Dep. at 47-48)).
- 751. A clinic would not be able to use an L-code for a mechanical knee with an MPK candidate because "it's against Medicare supplier standards because it doesn't adequately describe what was actually provided, so [the clinic would] be in trouble with CMS." (Ford (POA) Tr. 979-80). Mr. Ell of Mid-Missouri O&P testified that fitting a patient with a mechanical knee and claiming L code 5856 for reimbursement "would be illegal." (Ell (Mid-Missouri O&P) Tr. 1730; see also PX05130 (Governor (Otto Bock) Dep. at 93-

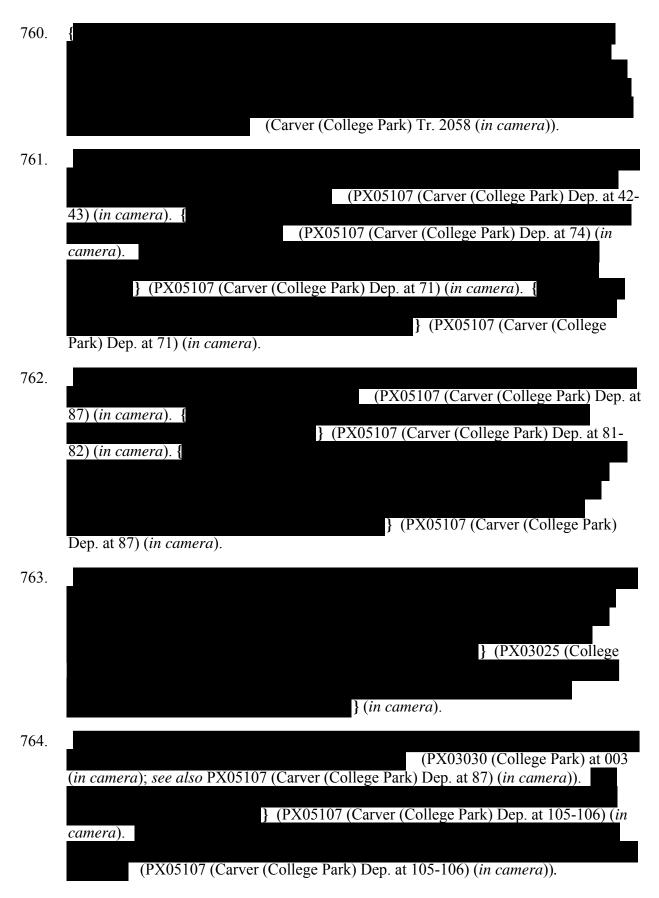
94)(agreeing that apart from committing a crime, mechanical knees cannot be reimbursed under L-Code 5856)).

2. Other MPK Manufacturers Do Not View Mechanical Knees as Competitors

752. (De Roy (Ossur) Tr.

3613-14 (in camera)).

- 753. Össur's Executive Vice President of Research and Development, Kim Peter Vivianne De Roy, testified that MPKs and mechanical knees "don't really compete for the same population." He described the patient population for an MPK as "people with access to certain funds," and explained that "[i]f they have access to a microprocessor knee, they'll buy a microprocessor knee." Patients who do not have access to an MPK will buy a mechanical knee. (PX05124 (De Roy (Össur) Dep. at 184-85)).
- 754. (PX03245 (Össur) at 023 (Gate 2 – Business Case Review) (*in camera*)).
- 755. Össur does not look at the price of mechanical knees when setting the price of its MPKs. (PX05124 (De Roy (Össur) Dep. at 184-185)).
- 756. Endolite's Executive Chairman, Stephen Blatchford, testified that Endolite "only look[s] at other MPKs" and not mechanical knees when analyzing competition for the Orion 3 because "the price point is completely different" and "customers don't tend to think of [the two types of knees] in the same way." (Blatchford (Endolite) Tr. 2143-44).
- 757. Endolite's sales and marketing materials for the Orion 3 differentiate its MPK from its mechanical knees by highlighting the clinical benefits of MPKs and the "technical features of the knee in terms of how it works, why it works, why it's safe." (Blatchford (Endolite) Tr. 2118).
- 758.
 (Blatchford (Endolite) Tr. 2154-55 (*in camera*)).
 3. Mechanical Knee Suppliers Do Not View MPKs as Competitors
- 759.
- (De Roy (Össur) Tr. 3603 (in camera)).



765. } (PX05105 (Fillauer (Fillauer) Dep. at 24-25)). } (PX05105 (Fillauer (Fillauer) Dep. at 24-25)).

766. Cascade, a distributor of mechanical knees, also testified that the microprocessor knee category is distinct from the mechanical knee category. (PX05120 (Collins (Cascade) Dep. at 50).

F. THE HYPOTHETICAL MONOPOLIST TEST SHOWS THAT THE SALE OF MPKS TO PROSTHETIC CLINICS IS A RELEVANT MARKET

- 767. Complaint Counsel's economic expert, Dr. Scott Morton, concluded that the appropriate relevant market in which to analyze the likely competitive effects of the acquisition is the manufacture and sale of microprocessor prosthetic knees to prosthetic clinics in the United States. (PX06001A at 6, 45-46, 58 (¶¶ 12, 52, 77) (Scott Morton Report)).
- 768. Dr. Scott Morton's analysis of the industry led her to conclude that microprocessor knees are distinguished from mechanical knees by many features, including price, safety, performance, and functionality. (PX06001A at 14-19, 42-46 (¶¶ 21-25, 50-52) (Scott Morton Report)).
- 769. (PX06001A at 45-46, 54, 58 (¶¶ 52, 68, 77) (Scott Morton Report); Scott Morton Tr. 3862, 3905-06 (*in camera*)).
- 770. Dr. Scott Morton based her product market findings on the analytical framework in the U.S. Department of Justice & Federal Trade Commission Horizontal Merger Guidelines (2010) ("Merger Guidelines") and she conducted a Hypothetical Monopolist Test. (PX06001A at 54-58 (¶¶ 69-77) (Scott Morton Report)).
- 771. The Merger Guidelines provide that "[t]he hypothetical monopolist test requires that a product market contain enough substitute products so that it could be subject to post-merger exercise of market power significantly exceeding that existing absent the merger. Specifically, the test requires that a hypothetical profit-maximizing firm, not subject to price regulation, that was the only present and future seller of those products ('hypothetical monopolist') likely would impose at least a small but significant and non-transitory increase in price ('SSNIP') on at least one product in the market, including at least one product sold by one of the merging firms." (PX08040 at 012 (§ 4.1.1) (Merger Guidelines)).
- 772. The Merger Guidelines provide that "[w]hen the necessary data are available, the Agencies also may consider a 'critical loss analysis.'" The Merger Guidelines describe this analysis as "ask[ing] whether imposing at least a SSNIP on one or more products in a candidate market would raise or lower the hypothetical monopolist's profits." Further, the Merger Guidelines explain, "A price increase raises profits on sales made at the

higher price, but this will be offset to the extent customers substitute away from products in the candidate market." (PX08040 at 015 (§ 4.1.3) (Merger Guidelines)).

773. In the "critical loss analysis," the Merger Guidelines define a "critical loss" as "the number of lost unit sales that would leave profits unchanged." A "predicted loss" is defined as "the number of unit sales that the hypothetical monopolist is predicted to lose due to the price increase." Using these calculations, "[t]he price increase raises the hypothetical monopolist's profits if the predicted loss is less than the critical loss." (PX08040 at 015 (§ 4.1.3) (Merger Guidelines)).

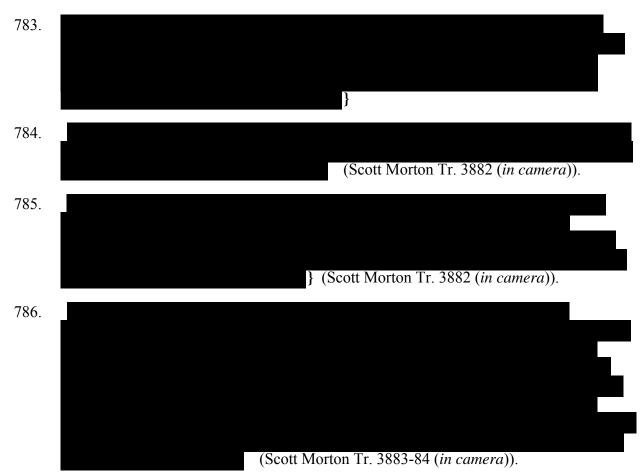
1. Dr. Scott Morton's Critical Loss Analysis Demonstrates MPKs Constitute a Relevant Market

- 774. Dr. Scott Morton uses the critical loss analysis as described in the Merger Guidelines to "test if it would be profitable for a hypothetical monopolist to impose a SSNIP on a candidate market limited to the microprocessor knees sold in the United States by Freedom and Otto Bock." (PX06001A at 74-75(¶ 93) (Scott Morton Report)). If it is profitable for the two firms to raise prices, then that candidate market is a relevant antitrust market. (PX06001A at 74-75 (¶ 93) (Scott Morton Report)).
- 775. Dr. Scott Morton performs two separate critical loss tests, a symmetric critical loss test and an asymmetric critical loss test. (PX06001A at 75-79 (¶¶ 96-105) (Scott Morton Report)).
- 776. Dr. Scott Morton performs an asymmetric critical loss test, which "assumes that each firm in the market sells a single product, but allows the prices and margins of those products to differ" and "evaluates the profitability of increasing the price of only one product in the candidate market, rather than all products." (PX06001A at 75 (¶ 96) (Scott Morton Report)).
- 777. To perform the asymmetric critical loss test, Dr. Scott Morton uses Respondent's own margin data and diversion analysis. (PX06001A at 75-77 (¶¶ 96-100) (Scott Morton Report)).
- 778. } (PX06001A at 77-78 (¶100 n.193) (Morton Expert Report) (*in camera*)).
- 779. Dr. Scott Morton uses a diversion rate of { in her asymmetric critical loss analysis, calculated using Respondent's own diversion analysis. (PX06001A at 77-78 (¶100 n.195) (Morton Expert Report) (*in camera*)).
- 780. Respondent's expert witness, Dr. David Argue, testified that he and Dr. Scott Morton used "very similar margins" in their critical loss analyses. (Argue, Tr. 6171).
- 781.

} (RX-1049 at 21-23 (¶¶ 37-39) (Argue Expert Report); *see also* Argue, Tr. 6284-85, 6292 (*in camera*)).

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782. Dr. Argue uses a diversion rate of **[111]** in his symmetric critical loss analysis. (RX-1049 at 096 (¶214) (Argue Expert Report) (*in camera*)).



- 787. Dr. Scott Morton performs a symmetric critical loss test, which assumes "that each firm in the candidate market has a single product with the same price and marginal cost" and "that the hypothetical monopolist imposes a [small but significant price increase] on all products in the candidate market." (PX06001A at 79 (¶ 101) (Scott Morton Report)).
- 788. Dr. Scott Morton uses an aggregate diversion rate of **{ 1000 }** in her symmetric critical loss analysis. (PX06001A at 80 (¶ 104) (Morton Expert Report) (*in camera*)).
- 789. Dr. Scott Morton uses a percentage margin of **{ 1000 }** in her symmetric critical loss analysis, calculated using data produced by Respondent. (PX06001A at 80 (¶ 104) (Morton Expert Report) (*in camera*)).
- 790.

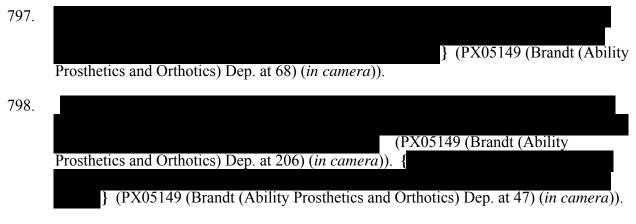
(PX06001A at 76-77(¶ 100) (Scott Morton Report)); Scott Morton Tr. 3892-96 (*in camera*)).

} (PX06001A at 80 (¶ 104) (Scott Morton Report); Scott Morton Tr. 3897-98 (*in camera*)).

- 792. Dr. Scott Morton confirms that if the narrow candidate market of Otto Bock's C-Leg 4 and Freedom's Plié 3 is a relevant antitrust market, then "a wider market consisting of all microprocessor knees sold in the United States is also a relevant antitrust market." (PX06001A at 74-75, 82 (¶¶ 93, 109) (Scott Morton Report)) (concluding that "if it is profitable for a hypothetical monopolist to impose a SSNIP in the narrow market, then it is profitable for a hypothetical monopolist to impose a SNIP in the wider market as well.")).
- 793. Even though Dr. Scott Morton performs both the symmetric and asymmetric critical loss tests to evaluate the product market in this case, Dr. Scott Morton confirms that the most appropriate critical loss test to apply in this matter is the asymmetrical critical loss test because it assumes "that each firm in the market sells a single product, but allows the prices and margins of those products to differ." (PX06001A at 75 (¶ 96) (Scott Morton Report); PX06003 at 8-9 (¶ 12) (Scott Morton Rebuttal Report)).

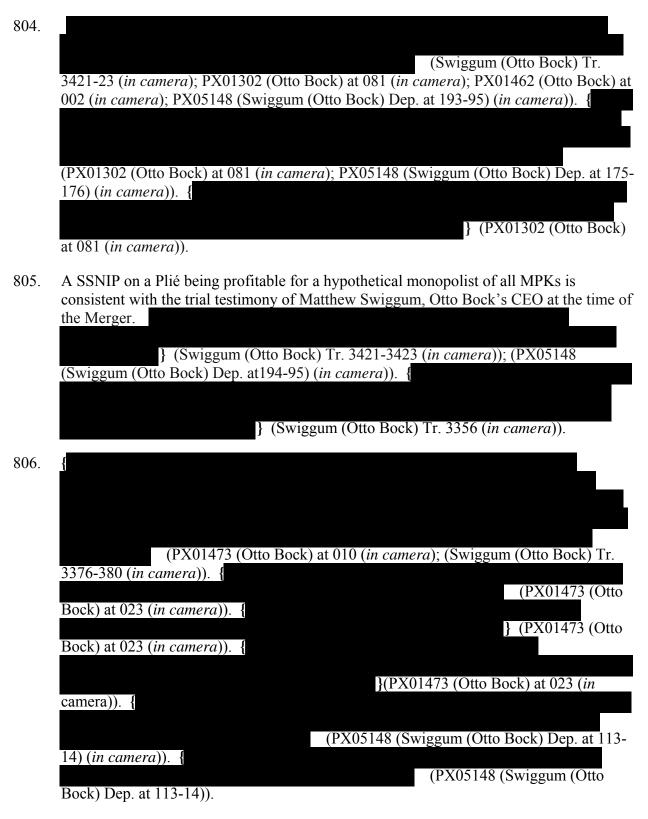
794.		(Argue, Tr. 6293 (<i>in</i>
	camera)).	
	2.	Qualitative Evidence Confirms that Customers Would Not Switch to Mechanical Knees if Faced with a 5-10% Increase in the Price of MPKs
		a) <u>Clinic Customers Testified They Would Not Switch to Mechanical</u> <u>Knees in Response to an MPK SSNIP</u>
795.	} (See PX05149 (Brandt (Ability Prosthetics & Orthotics) Dep. at 68) (<i>in camera</i>); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 49); PX05004 (Senn (Center for O&P) IHT at 21); PX05108 (Yates (Jonesboro) Dep. at 56-57) (<i>in camera</i>)).	
796.		

6.	
	(PX05108 (Yates (Jonesboro) Dep. at 54-
	55) (in camera)). {
	(PX05108 (Yates (Jonesboro) Dep. at 56) (in camera)).



- 799. According to Keith Senn, the President of Kentucky/Indiana Operations at the Center for Orthotic and Prosthetic Care, his clinics would not begin recommending more nonmicroprocessor mechanical knees if the priced charged by manufacturers for MPKs increased by 5 to 10 percent. (PX05004 (Senn (COPC) IHT at 21)).
- 800. Jeff Sprinkle, the co-owner of Sprinkle Prosthetics, testified in April 2018 that he would typically not switch a patient who would otherwise medically benefit from an MPK and whose insurance provided coverage for an MPK to a mechanical knee if the cost that Sprinkle Prosthetics pays for an MPK were to rise by 5 to 10 percent. (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 48-49)). He testified that at the time of his deposition, in April 2018, Sprinkle Prosthetics paid \$18,159 for the C-Leg and \$16,447 for the Plié. (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 56-57)).
- 801. Paul Weott, the owner of Orthotic and Prosthetic Centers, testified that he does not believe he would start looking for other alternatives to a Plié if the price for the MPK were to rise by \$1,000. (PX05140 (Weott (Orthotic and Prosthetic Centers) Dep. at 117-18)).
 - b) <u>Respondent's Ordinary Course Analyses Are Consistent with the</u> <u>Conclusions of Dr. Scott Morton's Hypothetical Monopolist Test</u>
- 802. The Merger Guidelines provide that "[t]he hypothetical monopolist's incentive to raise prices depends both on the extent to which customers would likely substitute away from the products in the candidate market in response to such a price increase and on the profit margins earned on those products." (PX08040 at 014 (§ 4.1.3) (Merger Guidelines)).
- 803. (PX01091 (Otto Bock) at 004 (*in camera*)).

(Schneider (Otto Bock) Tr. 4453, 4583-84 (in camera)).



3. A SSNIP by a Hypothetical Monopolist of MPKs Would Not Cause Clinics to Lose Money Fitting Lower-Limb Prostheses with MPKs on Patients

a) <u>Clinics Fit MPKs on Patients When it is Medically Appropriate</u> and the Clinic Can Earn a Profit on the Lower-Limb Prosthesis

- 807.
 Bep. at 33, 57-58 (*in camera*)); PX05124 (De Roy (Ossur) Dep. at 133) (*in camera*)); PX05138 (Reissfelder (Freedom) Dep. at 69-70); PX05105 (Fillauer (Fillauer) Dep. at 24) (*in camera*)).
- 808. Clinics often must demonstrate the "medical necessity" of an MPK to insurance providers in order to receive reimbursement for the provision of an MPK. (See CCFF ¶¶ 496-498, above).
- 809. Prosthetists and clinic executives testified that safety is the primary concern when deciding which prosthetic knee to fit on a patient. (*See, e.g.*, PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 26-27); PX05108 (Yates (Jonesboro) Dep. at 46); PX05138 (Reissfelder (Freedom) Dep. at 69-70)).
- 810. Jeff Sprinkle, the co-owner of Sprinkle Prosthetics, testified that his clinic's primarily goal for each patient is patient safety and the enabling of patients to perform certain activities. He elaborated that, so long as the clinic is making money, his clinic will fit what is best for the patient. (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 162-63)).
- 811. } (Brandt (Ability

Prosthetics and Orthotics) Tr. 3786 (in camera)).

- 812. Mark Ford, President and Managing Partner of Prosthetic and Orthotic Associates, testified that a prosthetist "is a medical professional who has been trained in providing prosthetic devices and prosthetic patient care services to patients living with limb loss." He further elaborated that a prosthetist's job "is to determine the needs of the patient and then to help design and create a prosthetic device that will be suitable for the patient, comfortable for the patient and allow the patient to get back to their activities of daily living." (PX05145 (Ford (POA) Dep. at 23-24)).
- 813. Mr. Ford also testified that, "[d]ifferent patients need different function out of their devices." He explained further that prosthetists at POA are "looking at what the patient's past history is, what their medical history is, and all of that - all of those different variables go into the decision-making process that the clinician goes through, so there's a lot of discussion back and forth about what those are." Ultimately, with respect to MPKs, POA is "[t]rying to find the right product to match up with the right patient." (Ford (POA) Tr. 925).

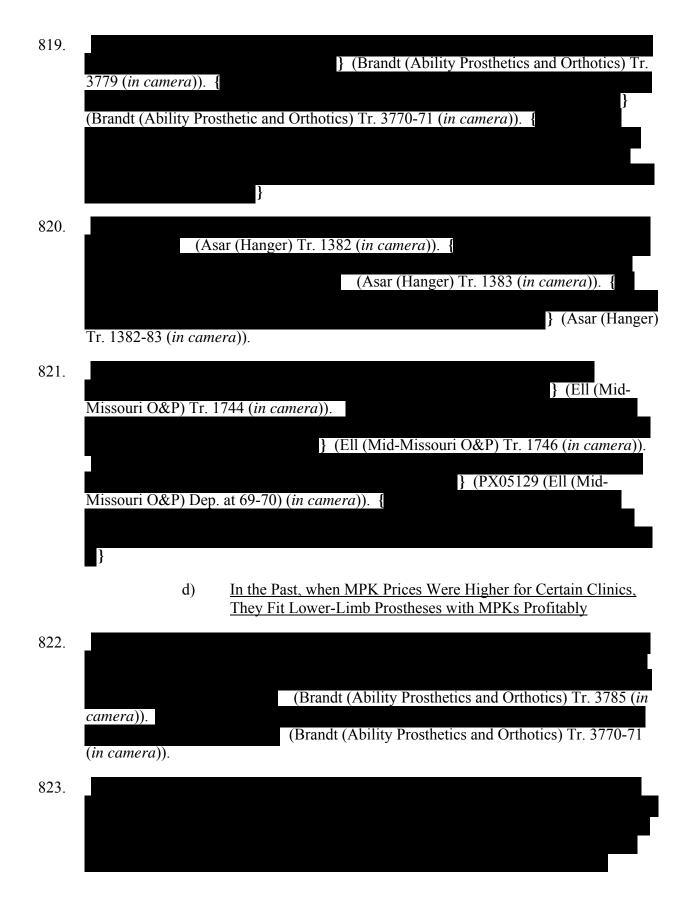
b) <u>Clinics Have an Ethical Obligation to Fit Patients with Only</u> <u>Medically Appropriate Prostheses</u>

- 814. (PX05149 (Brandt (Ability Prosthetics and Orthotics) Dep. at 213-15 (*in camera*)); PX05129 (Ell (Mid-Missouri Orthotics & Prosthetics) Dep. at 141, 154-55); PX05119 (Kahle (Prosthetic Design & Research) Dep. at 66-67)).
- 815. Jim Weber, the President and CEO of Prosthetic & Orthotic Care, testified that ethics is "a fundamental requirement of [his] business." (PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 137-38). He further elaborated, "it's kind of the nature of what we do, we provide the best outcome and so I expect full, you know, quality of ethics from our practitioner's standpoint." (PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 137-38)). When asked whether a prosthetist would have an ethical duty to provide an MPK to a patient who the prosthetist had determined qualified for an MPK and the MPK was medically best, Mr. Weber explained, "I guess if there was an ethical reason for them not to provide it, I would be really curious to know what that would be." (PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 137-38)).
- 816. Robert Yates, the President and CEO of Jonesboro Prosthetic & Orthotic Laboratory, described the ethical requirements pertaining to the prosthetists' duties to patients as "[i]n general, our obligation to the patient is to treat them in the most appropriate manner, to maintain their best interests at the forefront of our activities, to not partake in practices that would be a breach of our trust with them and, in the event that we're not qualified to provide the care that they need, to direct them to other providers who are." (PX05108 (Yates (Jonesboro) Dept. at 85)). With respect to fitting prosthetic knees, Mr. Yates agreed that these ethical obligations cover recommending prosthetic devices for patients that he believes are suitable for a patient's medical needs. (PX05108 (Yates (Jonesboro) Dep. at 86))).
 - c) <u>Clinics Currently Fit Lower-Limb Prostheses with MPKs</u> <u>Profitably</u>
- 817. (Senn (COPC) Tr. 277 (*in camera*)). { } (Senn (COPC) Tr. 222-23 (*in camera*)).
- 818. Robert Yates, the President and CEO of Jonesboro Prosthetic & Orthotic Laboratory, testified that his clinic profits off the fitting of an MPK. When asked, he responded "Yes. I think so. I hope so." (PX05108 (Yates (Jonesboro) Dep. at 54-55)).

(PX05108 (Yates

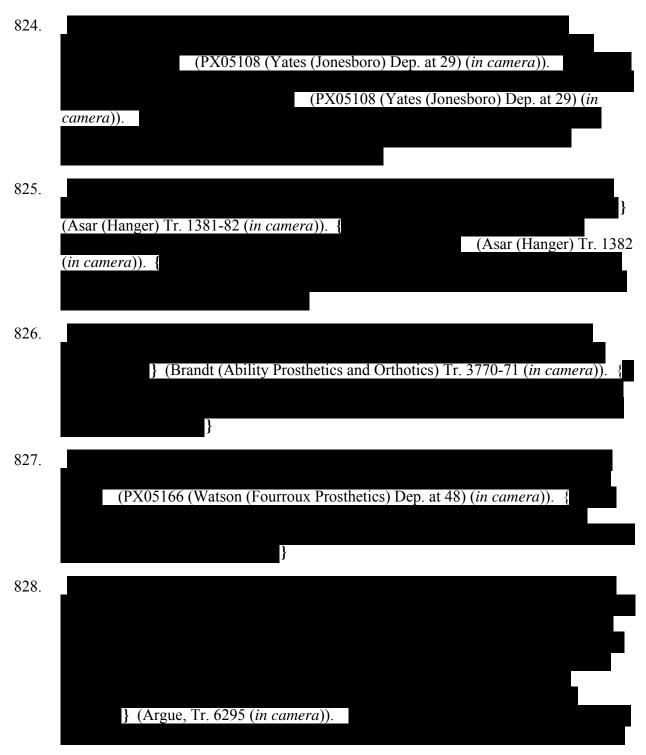
(Jonesboro) Dep. at 52-55) (in camera)).

PUBLIC



{ (Sabolich (Scott Sabolich Prosthetics and Research) Tr. 5879-80 (*in camera*)).

e) <u>MPK Purchasing Data Shows Clinics Would Still Earn a Profit</u> <u>Fitting Lower-Limb Prostheses with MPKs Post-SSNIP</u>



VII. THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

A. RESPONDENT STIPULATED THAT THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

- 829. Respondent has admitted the United States constitutes the Relevant Geographic Market for the purposes of analyzing the effects of the Acquisition. When asked by the Court during Opening Statements, Counsel for Respondent agreed that there is no dispute on the Relevant Geographic Market is the United States. (Resp't Opening Statements Tr. 91).
- 830. Respondent's economic expert, Dr. David A. Argue, agrees that the United States is the relevant geographic market. At the trial, Dr. Argue testified that in his analysis of the prosthetic knee and feet markets, he used the United States as the geographic market. (Argue, Tr. 6267 (agreeing that he "used the U.S. geographic market for [his] knee and foot markets because clinic customers are not going to go to suppliers outside of the U.S. to purchase knees or feet"); *see also* (PX05173 (Argue (Respondent) Dep. at 69) (testifying that he used a U.S. geographic market in his analysis because "based on the information I've gathered over the time that I've been evaluating this, it seems that both the feet and the knees have a U.S. geographic market. Customers are not going to be going to suppliers outside of the area to purchase knees and feet."); (RX1049 at 21 (¶ 36) (Argue Expert Report) (stating that "[f]or purposes of this report, I do not dispute that the United States is a properly defined geographic market.")).
- 831. Dr. Argue defines the relevant geographic market in his report as the United States. (RX1049 at 020-21 (¶¶ 34, 36) (Argue Expert Report)). Dr. Argue explained in his deposition that "[t]here's no evidence to indicate that the market, geographic market, was broader than the United States." (PX05173 (Argue (Respondent) Dep. at 91)).

B. QUALITATIVE EVIDENCE DEMONSTRATES THAT THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

1. Unique Regulatory and Reimbursement Features in the United States

832. In the United States, Medicare and private payer reimbursement rules play a key role in how competition works in the MPK market. (Carkhuff (Freedom) Tr. 378 (testifying that the two largest sources of reimbursement in the MPK market in the United States are Medicare and private insurance, comprising roughly 80% of all MPKs that are fit and reimbursed); Senn (COPC) Tr. 200-02 (testifying that Medicare defines the L-Codes that determine the reimbursement amounts for MPKs regardless of the manufacturer, which are also used by private insurers); Sanders (United) Tr. 5438-39 (*in camera*) (indicating that

}; see also

(PX05150 (Kannenberg (Otto Bock) Dep at 38-39, 103)) (testifying that "most insurance

companies, including Medicare, reserve [MPKs] for patients with higher mobility" and that, for Medicare and private payers, a key aspect of medical justification is documenting the functionality provided by a microprocessor knee that the patient is not receiving from a mechanical knee); Carkhuff (Freedom) Tr. 377 (indicating that private insurers generally follow Medicare's fee-for-service schedule when reimbursing for prosthetic knees)).

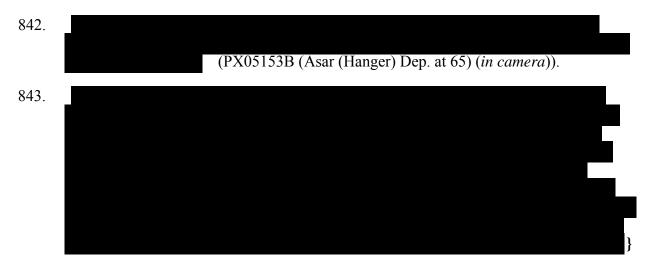
833. For example, third-party payers often must determine which patients have a medical necessity for an MPK, rather than a mechanical knee. (Sanders (United) Tr. 5481, 5484-85 (*in camera*) (testifying that {

; Carkhuff
(Freedom) Tr. 534 (in camera) (testifying that {
}; PX03151 (United) at 003-05 (a United
HealthCare "Coverage Determination Guideline" listing "Functional level is 3 or above"
as the description for L5856, the L-code associated with MPKs)).

- 834. The U.S. market has characteristics that are "very unique and different from other places in the world." (PX05123 (Solorio (Otto Bock) Dep. at 94-95)).
- 835. (Carkhuff (Freedom) Tr. 529-30 (*in camera*)).
- 836. Within the United States, reimbursement for microprocessor and non-microprocessor knees are based on L-Codes set by CMS. (Senn (COPC) Tr. 200-02 (testifying that Medicare defines the L-Codes, which are also used by private insurers, that determine the reimbursement amounts for MPKs regardless of the manufacturer); PX05141 (Bright (North Bay) Dep. at62-63)).
- 837. In the United States, reimbursement rules created by Medicare and U.S. private insurers impact how MPKs are purchased and sold: in particular, only K3 and K4 patients are eligible to be considered for a microprocessor knee under Medicare and most private insurance plans. (*See* CCFF ¶¶ 440-441, 445, above).
- 838. Dr. Kannenberg testified that "in other countries, to take my home country Germany as an example, we don't have that tie of K levels to coverage of certain prosthetic technologies, so a K2 patient who is physically capable enough to control a microprocessor knee or a mechanical knee can receive that." (Kannenberg (Otto Bock) Tr. 1942).
- 839. The President of Wright & Filippis, Anthony Filippis, testified that he considered setting up a location in Canada, but it "is very, very difficult" to get approval due, in part, to the differences in the reimbursement system. (PX05167 (Filippis (Wright & Filippis) Dep. at 91)).

2. Importance of Prosthetic Manufacturers' U.S. Business Presence

- 840. U.S. prosthetic clinics testified that they rely on MPK manufacturers' sales and clinical employees to fit, program, and maintain their patients' MPKs at their facilities. (Ford (POA) Tr. 964-67 (testifying that MPK manufacturers' sales and clinical employees are "very important" and demonstrate products to clinicians to ensure the MPKs are optimized for each patient); PX05145 (Ford (POA) Dep. at 34-36) (describing the importance of clinical and technical staff from MPK suppliers); PX05108 (Yates (Jonesboro) Dep. at30-31 (describing the support provided to clinic by MPK sales representatives); PX05141 (Bright (North Bay) Dep. at 223); see also PX05118 (Testerman (Otto Bock) Dep. at 51-53) (discussing the interaction between Freedom sales reps and prosthetic clinic customers)).
- 841. Many clinic customers have testified that United States sales representatives from prosthetic manufacturers play an important role in the clinic's purchasing decisions. (Ford (POA) Tr. 962; PX05141 (Bright (North Bay) Dep. at 223); PX05151 (Patton (Prosthetic Solutions) Dep. at 109-10, 115)).



- 844. The Chairman of Freedom, Maynard Carkhuff, testified that "having a full complement of salespeople, however you have the nation configured, visiting customers on a regular basis is important" because "if we're out of sight, we're out of mind." (PX05109 (Carkhuff (Freedom) Dep. at 130)).
- 845. Mark Ford from POA testified that, when something goes wrong with an MPK, he relies first on "input from the local salesperson" to resolve the issue. (Ford (POA) Tr. 968).
- 846. Jeffrey Sprinkle of Sprinkle Prosthetics testified that "I'm not going to order a knee from, you know, Argentina that doesn't have any representatives here." (PX05168 (Sprinkle (Sprinkle) Dep. at 71)).
- 847. Clinics have further testified that non-sales presence is also important. (Ford (POA) Tr. 964, 968; PX05168 (Sprinkle (Sprinkle) Dep. at 71); PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 70-71) (testifying that loaner knees are important)).

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- 848. For example, Mr. Sprinkle testified that it is important that an MPK manufacturer provide "local technical support for that knee." (PX05168 (Sprinkle (Sprinkle) Dep. at 71)).
- 849. Freedom's Vice President of National and Key Accounts, Mark Testerman, testified that Freedom's continuing education programs offered to clinicians at their offices give Freedom "a good, solid, aggressive strategy to try to differentiate ourselves from the competition" by "sav[ing] the account time, energy and funds to send their practitioners somewhere else." (Testerman (Freedom) Tr. 1107-08).
- 850. At trial, no clinic customer testified that they would switch MPK purchases to an MPK not currently sold in the U.S. through a U.S. sales force. (Senn (COPC) Tr. 148-280; Ford (POA) Tr. 901-1067; Asar (Hanger) Tr. 1306-1571; Ell (Mid-Missouri) Tr. 1658-1816); Brandt (Ability Prosthetics and Orthotics) Tr. 3741-3846; Oros (Scheck & Siress) Tr. 4769-4920; Sabolich (Sabolich Prosthetics and Research) Tr. 5787-5960).

3. Respondent Conducts Business Reflecting Recognition of a U.S. Market

- 851. Internal Respondent documents distinguish the "U.S." MPK market from the rest of the world. (*See, e.g.*, PX01022 (Freedom) at 007-30 (analyzing the "United State Market" separately from the "European Market"); {
- 852. Matt Swiggum testified that Otto Bock "regularly produced" documents that analyzed the U.S. MPK business. (PX05148 (Swiggum (Otto Bock) Dep. at 24-25)).
- 853. Freedom's 2014 marketing plan identified three separate markets: the United States, the European Union, and the rest of the world. (PX01022 (Freedom) at 031).
- 854. For a given customer with multiple clinic locations in the U.S., Freedom's MPK prices are consistent throughout the United States. (PX05007 (Carkhuff (Freedom) IHT at 106)).
- 855.

(PX05144 (Blatchford (Endolite) Dep. at 204) (in camera)). {

(Blatchford (Endolite) Tr. 2158-59 (in camera)).

C. THE HYPOTHETICAL MONOPOLIST TEST CONFIRMS THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

856. Dr. Scott Morton performed a Hypothetical Monopolist Test to confirm that the relevant geographic market is the United States. (PX06001A (Scott Morton Report) at 066-76 (¶¶ 85-90) (Scott Morton Expert Report)).

- 857. Dr. Scott Morton finds that "patients in the United States are not likely to seek treatment" outside the United States "following a SSNIP" for numerous reasons, including patient visit requirements, follow-up care, and unwillingness of third-party payers to reimburse for the cost of knees fitted outside the United States. (PX06001A (Scott Morton Report) at 067-69 (¶ 87) (Scott Morton Expert Report)).
- 858. Further, Dr. Scott Morton concludes that clinics in the United States could not turn to suppliers or products sold outside the United States to overcome a SSNIP on microprocessor knees. (PX06001A at 069-70 (¶ 88) (Scott Morton Expert Report)). Dr. Scott Morton finds that there are no other significant manufacturers of MPKs sold outside the United States. (PX06001A at 069-70 (¶ 88) (Scott Morton Expert Report)).
- 859. Professor Scott Morton concludes, "the options of clinics in the United States are limited to the microprocessor knee manufacturers that currently have a presence in the United States." (PX06001A at 073-74 (¶ 90) (Scott Morton Expert Report)).
- 860. Dr. Argue, agrees, having testified that "[c]ustomers are not going to be going to suppliers outside of the [United States] to purchase knees or feet." (PX05173 (Argue (Respondent) Dep. at 069)).
- 861. Dr. Argue agrees with Dr. Scott Morton that the relevant geographic market is the United States. (RX1049 at 020, 021 (¶¶ 34, 36) (Argue Expert Report); PX05173 (Argue (Respondent) Dep. at 91)).
- 862. Several clinics in the United States indicated that they could not easily turn to firms without a substantial U.S. presence for MPKs. (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 71) ("I'm not going to order a knee from, you know, Argentina that doesn't have any representatives here"); PX05141 (Bright (North Bay) Dep. at 190) (explaining that an MPK manufacturer's lack of a U.S. local distribution and sales force would create problems for his clinic); {

VIII. HIGH MARKET SHARES AND CONCENTRATION LEVELS ESTABLISH A STRONG PRESUMPTION OF HARM TO COMPETITION

- A. MARKET STRUCTURE
 - 1. Otto Bock
- 863. Otto Bock currently manufactures and sells five lines of MPKs the Kenovo, Compact, C-Leg, Genium, and X3. (PX05133 (Eichler (Otto Bock) Dep. at 57).
 - a) <u>Otto Bock's Top-Selling C-Leg 4</u>
- 864. Otto Bock designed the C-Leg MPK for K3 level ambulators. (Solorio (Otto Bock) Tr. 1634-1635). After launching the first version of the C-Leg in 1999, Otto Bock launched the C-Leg 4 in 2015. The C-Leg 4 is still the current model sold by Otto Bock in the United States. (PX05010 (Schneider (Otto Bock) IHT at 99-100)).

865. The C-Leg supports a maximum patient weight of 300 lbs/136 kg. (PX01599 (Otto Bock) at 012). {

} The battery life is approximately 2 days. (PX01599 (Otto Bock) at 012). The C-Leg is weatherproof with a IP67 rating. (PX01599 (Otto Bock) at 012). The maximum possible knee flexion angle without flexion stop is 130 degrees. (PX01599 (Otto Bock) at 012).
866.
866.
} Michael Bay, owner of North Bay Prosthetics and Orthotics, testified that his clinic's acquisition cost for a C-Leg 4 is approximately \$16,300. (PX05141 (Bright (North Bay) Dep. at 54-55). {
867.
868.
\$868.

869. Otto Bock employs 28 sales representatives divided into separate regions located across the United States. Each of Otto Bock's sales representatives sells the full suite of prosthetic components. (Schneider (Otto Bock) Tr. 4285-86; Solorio (Otto Bock) Tr. 1638-1639). Matthew Swiggum, Otto Bock's CEO at the time of the Merger, estimated that Otto Bock sales representatives visited U.S. clinics owned by its largest customer more than 2,000 times each year. (PX05148 (Swiggum (Otto Bock) Dep. at 58-59)).



b) <u>Otto Bock's Kenevo and Compact MPKs</u>

- 871. The microprocessor in Otto Bock's Kenovo knee controls only the stance phase of a user's gait. (Kannenberg (Otto Bock) Tr. 1956-57). The Kenovo does not qualify for L5856 the base L-code that accounts for the greatest share of reimbursement a clinic receives for an MPK. (Kannenberg (Otto Bock) Tr. 1999; PX05111 (Prince (Freedom) Dep. at 95-96); *see also* PX05133 (Eichler (Otto Bock) Dep. at 57 (explaining that only microprocessor knees that have swing and stance phase controls can be reimbursed under L-Code 5856)).
- 872. Otto Bock's Senior Prosthetics Marketing Manager, Cali Solorio, testified that Otto Bock targets different patient populations for sales of the Kenovo and the C-Leg 4. (Solorio (Otto Bock) Tr. 1639). Specifically, Otto Bock markets the Kenovo to K2 level ambulators because of its design. (Solorio (Otto Bock) Tr. 1633-34; PX08097 (Otto Bock) at 001 (Otto Bock)).
- 873. Similarly, the microprocessor in Otto Bock's Compact knee controls the stance phase of a user's gait only. (Kannenberg (Otto Bock) Tr. 1955-56; Solorio (Otto Bock) Tr. 1634). Otto Bock focuses on high K2 and low K3 level ambulators for sales of the Compact. (Solorio (Otto Bock) Tr. 1634). Similar to the Kenovo, the Compact does not qualify for L5856. (Kannenberg (Otto Bock) Tr. 1999; PX05007 (Carkhuff (Freedom) IHT 139-40)).
- 874. Otto Bock plans to discontinue the Compact in 2018. (PX05133 (Eichler (Otto Bock) Dep. at 64-65)).
- 875.

c) Otto Bock's Higher-End MPKs: Genium and X3

- 876. Otto Bock designed the Genium for "higher activity K3 patient[s] into the K4 level." (Solorio (Otto Bock) Tr. 1635-1636).
- 877. Because of reimbursement limitations set by most private insurers, typically only patients at the Department of Defense, Veteran's Affairs Administration, and those who receive health benefits paid by some worker's compensation programs have access to insurance reimbursement for the Genium. (Solorio (Otto Bock) Tr. 1636-1637).
- 878.
- 879. Otto Bock initially developed the X3 MPK for active duty military users. Higher activity users are still the primary users of this MPK. (Kannenberg (Otto Bock) Tr. 1959-60).

- 880.
- 881. Because of reimbursement limitations set by most private insurers, typically only patients at the Department of Defense, Veteran's Affairs Administration, and those who receive health benefits paid by some worker's compensation programs have access to insurance reimbursement for the X3. (Solorio (Otto Bock) Tr. 1636-1637).

2. Freedom

- a) <u>Freedom's Plié 3</u>
- 882. Today, Freedom sells the Plié 3 MPK, which was launched in 2014. (Carkhuff (Freedom) Tr. 294; PX1071 (Freedom) at 023). The original Plié was released in 2007, followed by the Plié 2 in 2010. (Carkhuff (Freedom) Tr. 293-94; PX1071 (Freedom) at 023).
- 883. {
- 884. The Plié is marketed by Freedom as a swing and stance MPK, Freedom recommends that customers seek reimbursement for the Plié under L-Code 5856, which is for microprocessor swing and stance knees, and the Plié is reimbursed as a swing and stance MPK, under L-Code 5856. (*See* CCFF ¶¶ 3065-3070, 3072, below.) Market participants consider the Plié to be an MPK. (*See* CCFF ¶¶ 3073-3074, below.)
- 885. As of March 2018, Freedom employed a team of approximately 19 employees responsible for sales. This team includes 13 sales representatives located across the United States and 3 clinical sales representatives who are licensed certified prosthetists and certified prosthetists and orthotists. (PX05137 at 007-08 (Matthews (Freedom) Dep. at 25-26)). Freedom also offers reimbursement support to assist clinics in the process of filing for reimbursement. (Ferris (Freedom) Tr. 2355).



b) <u>Freedom's Quattro</u>

- 888. (Carkhuff (Freedom) Tr. 422 (*in camera*); PX05111 (Prince (Freedom) Dep. at 58); PX07049 at 022 (¶¶ 49-50) (Otto Bock Amended Answer) (*in camera*)).
- 889. Prior to the Merger with Otto Bock, Freedom internally listed the launch date for the Quattro as mid-2018. (*See* CCFF ¶¶ 1207-1209, below).
- 890. Prior to the Merger with Otto Bock, Freedom's internally projected Quattro to generate sales greater than \$51 million in revenue over three years. *See* CCFF ¶¶ 1273-1274, below.
- 891. Otto Bock, proposed Freedom divestiture buyers, and third-parties who tested the Quattro all indicated that the Quattro offered functional improvements over Otto Bock's C-Leg 4. *See* CCFF ¶¶ 1295-1309, 1311-1312, below.
 - c) <u>Freedom's Plié 4/Plié 3 Fast Fit</u>

892.	1466, below (<i>in camera</i>).	} See CCFF ¶¶ 1456-1460,
893.	below (<i>in camera</i>).	} See CCFF ¶¶ 1457-1458,
894.	1464, below (<i>in camera</i>).	} See CCFF ¶¶ 1461,

- 3. Össur
- 895. In the United States, Össur currently sells the Rheo MPK, Rheo XC MPK, and the Power Knee. (De Roy (Össur) Tr. 3576). Össur also sells the Symbionic Leg, a combination of the Rheo MPK and Propio ankle. (De Roy (Össur) Tr. 3576).
- 896. Össur has its headquarters in Reykjavik, Iceland. (De Roy (Össur) Tr. 3537).
- 897. The current version of the Rheo MPK—the Rheo 3—was launched in September 2017. (De Roy (Össur) Tr. 3576).



- 899. Össur targets moderate to high-level K3 and some K4 users for sales of the Rheo XC. (De Roy (Össur) Tr. 3583). Össur's Executive VP of R&D testified that Otto Bock's high-end Genium and X3 MPKs are the primary competitors for the Rheo XC. (De Roy (Össur) Tr. 3584).
- 900.Only the Department of Veterans Affairs, some private payers, and worker's

Solution of Veterans Affairs, some private payers, and worker's compensation plans reimburse clinics for the fitting of a Rheo XC. Medicare does not reimburse clinics for the fitting of a Rheo XC. (De Roy (Össur) Tr. 3583-84).

- 901. Össur's Rheo and Rheo XC rely on magnetorheological technology to regulate the cylinder used in the MPK. The Rheo's magnetorheologic technology "utilizes electromagnetic force to rapidly alter the viscosity of magnetic fluid in the knee. Thus, RHEO KNEE 3 is capable of shifting almost instantaneously from the high resistance required for stability in stance phase to the low resistance needed for a dynamic, free swing phase." (PX03099 (Össur) at 02). Össur's Executive VP of R&D testified that this technology uses "magnetical particles that are contained in an oil which is kept in a cylinder between blades." (De Roy (Össur) Tr. 3576-77). To regulate the magnetic fluid, the MPK uses magnets that "control the input and the outtake of the fluid." (Ford (POA) Tr. 950)).
- 902. The magnetorheological technology is unique to Össur's Rheo and Rheo XC and not used by other MPK manufacturers. (De Roy (Össur) Tr. 3578).
- 903. Kim De Roy, Vice President of Össur, testified that the Rheo's magnetorheological technology is different from the hydraulic technology that is used in the C-Leg 4 and Plié 3. Whereas hydraulic knees are stance default knees, the Rheo 3 is a swing default knee, "which means that it's always free swinging unless you put it on the floor and trigger the electric field to be created". (PX05124 De Roy (Össur) Dep. at 149-153). Mr. De Roy further testified that a Rheo 3 user "needs to have better control, voluntary control over the leg in case the leg runs out of battery." (PX05124 (Össur) Dep. at 149-153).
- 904. Össur's Rheo transitions to "free swing" mode when the battery in the MPK dies because of the magnetorheological technology used in the knee. A user wearing the Rheo can either continue walking in "free swing" mode, without variable cadence, or engage a mechanical lock that allows the MPK to function like a "peg leg." (De Roy (Össur) Tr. 3580-81).
- 905. A clinic executive described the differences between Össur's Rheo and MPKs that use a hydraulic fluid system as "chang[ing] the way that the knee operates" and agreed that there is a "fundamental difference in design and operation" between the Rheo and C-Leg, in particular. (Ford (POA) Tr. 950-51).
- 906. In contrast to other MPKs, including the Rheo and Rheo XC, Össur's Power Knee uses a motor to provide power and momentum for the MPK. The motor in the Power Knee functions like "your quad muscle" to enable a user to rise out of a chair and propel a

person "throughout every step." (De Roy (Össur) Tr. 3584-85). Össur's Executive VP of R&D testified that, "there's no real comparable technology [to the Power Knee] on the market today." (De Roy (Össur) Tr. 3585-86).

}

- 907. The Power Knee costs approximately twice as much as the Rheo, and other MPKs on the market, and is only reimbursed by payers on a "case-by-case" basis. (De Roy (Össur) Tr. 3585-86). {
- 908. Össur employs a team of approximately 50 sales representatives and clinicians responsible for technical support located across the United States. (De Roy (Össur) Tr. 3568).
- 909. {

4. Endolite

- 910. Chas. A Blatchford & Sons Ltd., d/b/a Endolite, sells prosthetic components, including MPKs, in the United States. (JX001 at ¶ 39).
- 911. Chas. A Blatchford & Sons Ltd. was founded in 1890 as a family-owned business. (Blatchford (Endolite) Tr. 2090). Chas. A. Blatchford & Sons Ltd. is currently headquartered in Basingstoke, England. (Blatchford (Endolite) Tr. 2093). Endolite is the trade name for Blatchford's prosthetic business. (Blatchford (Endolite) Tr. 2099-3000).
- 912.
- 913. Endolite has 80 employees in the United States, including 15 sales representatives and 5 clinical support specialists located across the country. The majority of the remaining employees in the United States work at Endolite's manufacturing facility in Miamisburg, Ohio. (Blatchford (Endolite) Tr. 2100-01).
- 914. Endolite has been selling MPKs for more than 20 years. (PX04001 at 002 (Blatchford (Endolite) Decl.) Endolite currently sells three MPK products—the Orion 3, the Linx Limb System ("Linx"), and the Smart IP. (PX04001 at 001-02 (Blatchford (Endolite) Decl.); Blatchford (Endolite) Tr. 2133).
- 915. The Orion is Endolite's only microprocessor-controlled swing and stance knee without a prosthetic foot attached. (Blatchford (Endolite) Tr. 2133-34). Endolite began selling the

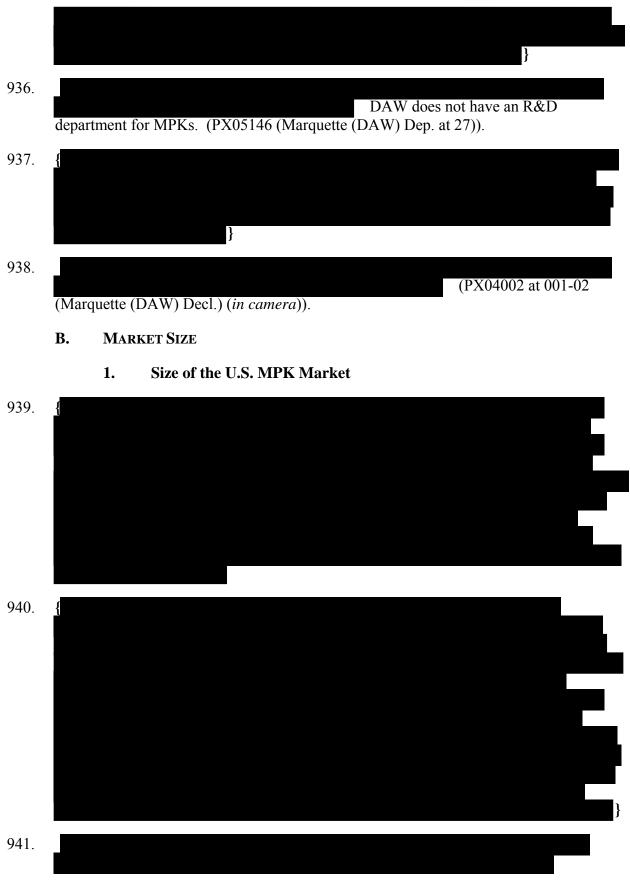
Endolite launched the Orion 3 in September 2016. (Blatchford (Endolite) Tr. 2109-10). 916. } 917. } 918. The Linx Limb System is an "integrated limb system" with a microprocessor-controlled knee connected to a microprocessor-controlled foot. (Blatchford (Endolite) Tr. 2110). 919. The SmartIP is a microprocessor-controlled swing knee that does not offer microprocessor-control for stance phase, which Endolite's Executive Chairman described as an "older-technology product." (Blatchford (Endolite) Tr. 2133-34). 920. } (PX06001A (Scott Morton Report) Table A1 and Table A2 (in camera)). 921. (Blatchford (Endolite) Tr. 2176-77 (in camera)). 922. (Blatchford (Endolite) Tr. 2178 (in camera)). 923. } (Asar (Hanger) Tr. 1390-91 (*in camera*)). 5. **Fringe MPK Manufacturers** a) Nabtesco

Orion in 2010, which was later upgraded with the release of the Orion 2 in 2014.

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

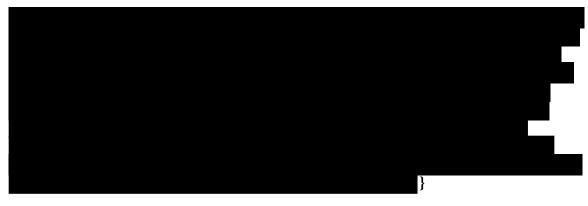
- 925. Nabtesco is headquartered in Kobe, Japan, where the company manufacturers all of its products. Nabtesco does not manufacture any products in the United States. (PX03004 (Nabtesco) at 001; PX05161 (Mattear (Proteor Inc.) Dep. at 26:02-06)).
- 926. In the past, all of Nabtesco's sales in the United States were made through four distributors—Cascade Orthopedic Supply, Inc., Southern Prosthetic Supply, Inc. ("SPS"), PEL LLC, and Proteor Inc. Nabtesco does not make any sales directly to prosthetic clinics in the United States. (PX03004 (Nabtesco) at 001).
- 927. As of September 1, 2018, Proteor, Inc. (d/b/a Nabtesco & Proteor in USA) is the exclusive distributor of prosthetic devices manufactured by Nabtesco Corporation and Proteor S.A. (Mattear (Proteor Inc.) Tr. 5521-22). Proteor Inc. was based out of Muskego, Wisconsin until June 2018 when it relocated to Tempe, Arizona. (Mattear (Proteor Inc.) Tr. 5510).
- 928. Nabtesco currently manufactures and sells three microprocessor knee products—the Intelligent Knee, the Hybrid Knee, and the Allux. (PX05161 (Mattear (Proteor Inc.) Dep. at 35)).
- 929. U.S. sales for both designs of Nabtesco's Intelligent knee—the single-axis and 4-bar designs—include 2 knees in 2014, 1 knee in 2015, 3 knees in 2016, and 2 knees between January 1 and October 31, 2017. (PX03004 (Nabtesco) at 005).
- 930. U.S. sales for Nabtesco's Hybrid knee include 9 knees in 2014, 4 in 2015, 0 in 2016, and 1 between January 1 and October 31, 2017. (PX03004 (Nabtesco) at 005).
- 931. Nabtesco has been selling the Allux MPK in the United States since 2015. (PX03004 (Nabtesco) at 005; Mattear (Proteor Inc.) Tr. 5718). In total (through all U.S. sales channels), Nabtesco sold 13 Allux knees in 2015, 12 knees for 2016, and 29 knees between January 1 and October 31, 2017. (PX03004 (Nabtesco) at 005).
- 932. Several clinic customers testified that they are not familiar with MPKs manufactured by Nabtesco. (*See* CCFF ¶¶ 1593-1598, below). Other clinic customers who had heard of MPKs manufactured by Nabtesco testified they would not fit a Nabtesco MPK on a patient because of difficulties with customer service or concerns about the reliability of the MPK. (*See* CCFF ¶¶ 1599-1602, below).
 - b) <u>DAW Industries</u>
- 933. DAW Industries ("DAW") sells prosthetic components, including MPKs, in the United States. (JX001 at ¶ 40).
- 934. DAW does not manufacture its own MPKs. Instead, DAW serves as a distributor of MPKs manufactured by a company named Teh Lin, located in Taipei, Taiwan. (PX05146 (Marquette (DAW) Dep. at 15-17)).

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2. U.S. MPK Market Is Poised to Grow

946. (Carkhuff (Freedom) Tr. 465

(in camera)).

947. Currently, if a patient is categorized as a K0, K1 or K2, CMS will not reimburse them for an MPK. Some commercial payers or workers' compensation payers might reimburse for an MPK at those levels, but most insurers follow Medicare's guidelines. *See* CCFF ¶¶ 440, 445, above).



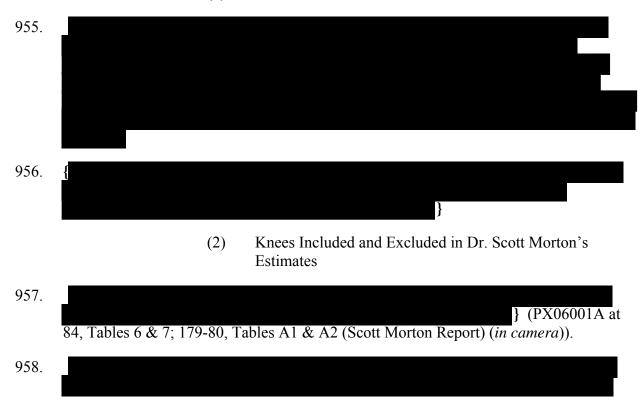
- 950. Dr. Kannenberg believes CMS may begin reimbursing clinics for the provision of MPKs on K2 patients covered by Medicare within the next five to ten years. (Kannenberg (Otto Bock) Tr. 1996-97).
- 951. Freedom's Chairman, Mr. Carkhuff, testified that K2 patients can benefit medically from MPKs. (Carkhuff (Freedom) Tr. 615; *see also* PX05150 (Kannenberg (Otto Bock) Dep. at 39 (MPKs have attributes making them superior to mechanical knees for "the majority of [K2] patients."))



C. THE MARKET FOR MPKs SOLD TO U.S. PROSTHETIC CLINICS IS HIGHLY CONCENTRATED

1. Dr. Scott Morton's Share and Concentration Estimates

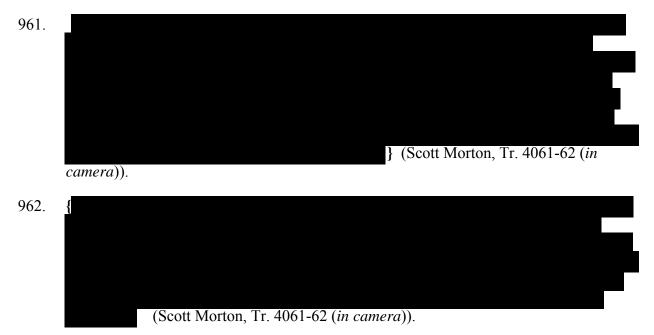
- 953. Complaint Counsel's industry expert, Dr. Scott Morton, calculated market shares in both dollars and unit sales for 2015, 2016, and 2017 for the six providers of microprocessor knees in the United States—Otto Bock, Freedom, Össur, Endolite, Nabtesco, and DAW—using sales data provided by these companies. (PX06001A at 82-84 (¶¶ 111-14) (Scott Morton Report); see also {
- 954. According to the Merger Guidelines, markets with an HHI above 2500 are classified as "Highly Concentrated Markets." (PX08040 at 018-19 (§ 5.3) (Merger Guidelines)). In "Highly Concentrated Markets," "Mergers resulting in highly concentrated markets that involve an increase in the HHI of more than 200 points will be presumed to be likely to enhance market power." (PX08040 at 018-19 (§ 5.3) (Merger Guidelines)).
 - a) <u>Dr. Scott Morton's Methodology</u>



(1) Data Used for Dr. Scott Morton's Estimates

	camera)).	} (PX06001A at 083, Table 7 (Scott Morton R	leport) (in
959.			
	082, n.205 (Scott Morton	Report) (in camera)).	} (PX06001A at

- (3) Appropriateness of Revenue-based versus Unit-based Share Estimates
- 960. Dr. Scott Morton concluded that it is more appropriate to calculate market shares by revenue because the products in the market are not homogenous—they have different features and price points. (PX06003 at 19-20 (¶ 38) (Scott Morton Rebuttal Report)).



- 963. Notwithstanding the foregoing, Dr. Scott Morton concluded that the relevant market is highly concentrated and the Merger results in a strong presumption of competitive harm whether market shares are calculated in units sold or dollar revenue. (PX06001A at 84 (¶ 114) (Scott Morton Report)).
 - b) Dr. Scott Morton's Market Share and HHI Calculations for the Broader All MPK Market
- 964. Dr. Scott Morton concluded that the pre-Merger HHIs confirm that the market for microprocessor knees in the United States was already highly concentrated and that the change in HHIs post-Merger established a strong presumption that the Merger will likely enhance market power in the merged firm. (PX06001A at 84 (¶ 113) (Scott Morton Report)). The tables containing these market shares are reproduced below.

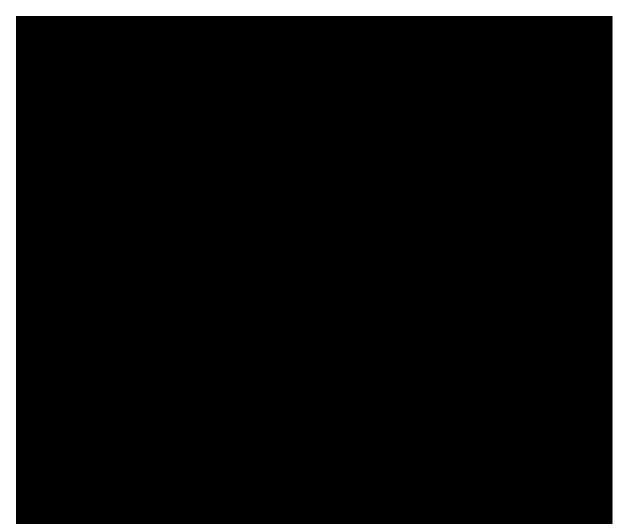


(PX06001A at 83, Tables 6 & 7 (Scott Morton Report) (in camera)).

- c) <u>Dr. Scott Morton's Alternative Market Share and HHI Calculations</u> for the Narrower MPK Market
- 965. Dr. Scott Morton also calculates market shares excluding both high-end and low-end microprocessor knees, in both dollars and unit sales for 2015, 2016, and 2017, for the six providers of microprocessor knees in the United States—Otto Bock, Freedom, Össur, Endolite, Nabtesco, and DAW—using sales data provided by these companies. (PX06001A at 82, n.205; 179-180, Tables A1 & A2 (Scott Morton Report) (*in camera*)).
- 966. Dr. Scott Morton's concludes that the pre-Merger HHIs confirm that the narrower MPK market in the United States is also highly concentrated and that the change in HHIs post-Merger establish a strong presumption that the Merger will likely enhance market power

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in the merged firm. (PX06001A at 179-180, Tables A1 & A2 (Scott Morton Report) (*in camera*)). The tables containing these market shares are reproduced below.



(PX06001A at 179-180, Tables A1 & A2 (Scott Morton Report) (in camera)).

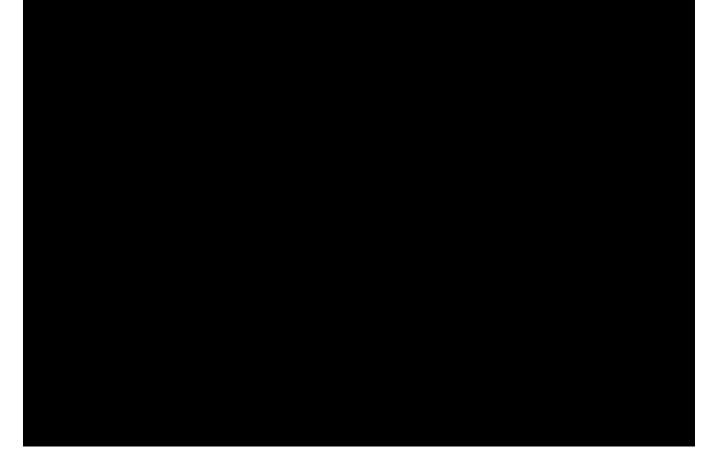
- 2. Respondent's Ordinary Course Market Share Estimates
 - a) <u>Respondent's Ordinary Course Market Share Estimates are</u> <u>Consistent Across Time</u>
- 967. Matthew Swiggum, the CEO of Otto Bock at the time of the Merger, testified that Otto Bock internally generates market share estimates of the U.S. microprocessor knee market. (PX05148 Swiggum (Otto Bock) Dep. at 40-41). Cali Solorio, Otto Bock's Senior Prosthetics Marketing Manager, is responsible for generating internal market share estimates at Otto Bock. (PX05148 Swiggum (Otto Bock) Dep. at 40-41).

968.



}

969. At the time of the C-Leg 4 launch in early 2015, Otto Bock estimated that, in the MPK market, it had a 78% market share, Freedom had an 11% market share, Össur had 10% market share, and Endolite had 1% market share, as shown in the chart below. (PX01518 (Otto Bock) at 009, 050; PX01382-02).



(PX01518 (Otto Bock) at 009).

970. Otto Bock's "2016 Marketing Plan" for "Lower Limb Mechatronics" indicated that Otto Bock had an 81% market MPK share, Freedom had a 10% MPK market share, Össur had an 8% MPK market share, and Endolite had a 1% MPK market share. (PX01002 (Otto Bock) at 005; *see also*



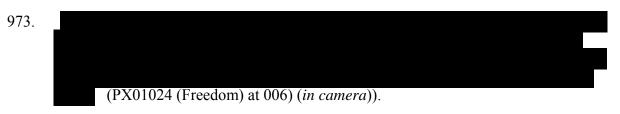
(PX01002 (Otto Bock) at 005).



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(PX01473 (Otto Bock) at 010) (in camera)).





(PX01024 (Freedom) at 006) (in camera)).





(PX01302 (Otto Bock) at 074) (in camera)).



(PX01302 (Otto Bock) at 076) (in camera)).



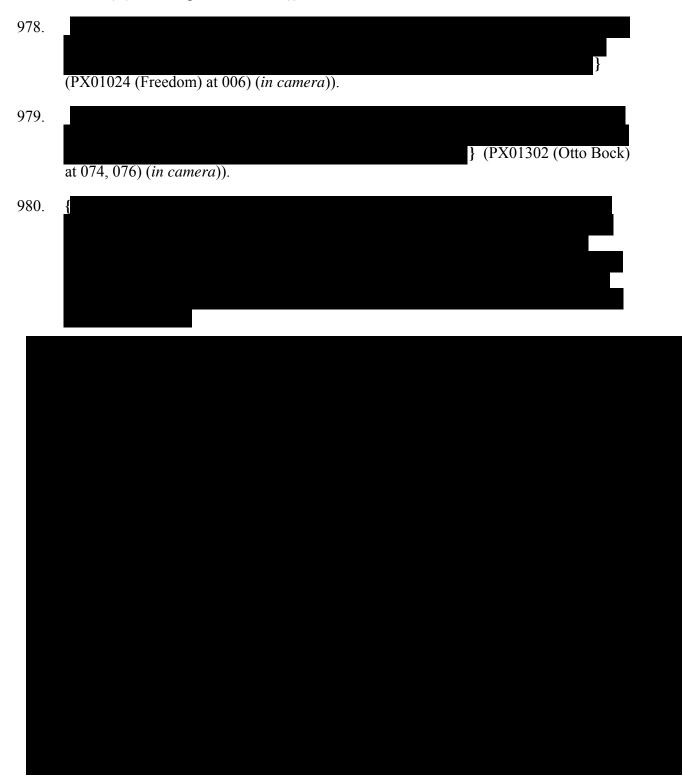
(Solorio (Otto Bock) Tr. 1602-06 (in camera) (discussing PX00867 (Otto Bock) at 021) (in camera))).

- b) Respondent's Ordinary Course Market Share Estimates are Consistent Across Different Business Settings
- 976. During the product development and launch preparation of the C-Leg 4, Otto Bock estimated that it had a 78% market share in the MPK market, Freedom had an 11% market share, Össur had a 10% market share, and Endolite had a 1% market share. (PX01518 (Otto Bock) at 009); PX01382 (Otto Bock) at 002)).

977.



(PX01473 (Otto Bock) at 010) (*in camera*); (Swiggum (Otto Bock) Tr. 3376-380 (*in camera*) (discussing PX01473-010)).



(PX00867 (Otto Bock) at 021) (in camera)).



3. Third-Party MPK Market Concentration Assessments

984. Scott Sabolich, owner and clinical director of Scott Sabolich Prosthetics and Research, LLC, testified that the "main three [MPKs] used in the United States" with Medicare reimbursement are the Otto Bock C-Leg, the Össur Rheo, and the Freedom Plié. (PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 69)).

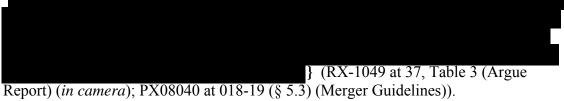
4. Respondent's Expert Agrees the Merger is Presumptively Unlawful

985. Respondent's economic expert witness, Dr. Argue, calculated market shares for a market that included microprocessor knees (except high-end and integrated types) as well as K3-level and K4-level non-MPKs sold in the United States. (RX-1049 at 35 (¶ 58) (Argue Report)). Dr. Argue's market share calculations are reproduced below.



(RX-1049 at 37, Table 3 (Argue Report) (in camera)).





- 987. Dr. Argue testified in his deposition that his proposed relevant market is highly concentrated and the Merger raises the presumption of competitive harm. (PX05173 (Argue Dep. at 91-92)).
- 988. Dr. Scott Morton concluded that "even given Dr. Argue's relevant market definition, a merger between Otto Bock and Freedom is presumptively anticompetitive." (PX06003 at 19 (¶ 36) (Scott Morton Rebuttal Report)).
- 989. Dr. Scott Morton concluded that Dr. Argue's use of units to calculate market shares was less appropriate than using revenue to calculate market shares. (PX06003 at 19 (¶¶ 37-38) (Scott Morton Rebuttal Report)).
- 990. Dr. Scott Morton calculated market shares based on revenue for Dr. Argue's proposed market and concluded that the pre-Merger HHI and change in HHI were similar to the pre-Merger HHI and change in HHI for the relevant market she defined. (PX06003 at 20-21 (¶¶ 40-41) (Scott Morton Rebuttal Report)). Dr. Scott Morton's market share calculations are reproduced below.



(PX06003 at 20-21, Table 2 (Scott Morton Rebuttal Report) (in camera)).

IX. THE MERGER SUBSTANTIALLY REDUCED COMPETITION IN THE U.S. MPK MARKET

- 991. Otto Bock "admits that it competed with Freedom Innovations prior to the Merger." (PX07049 at 004 (Otto Bock Amended Answer)). Specifically, Otto Bock and Freedom competed in the sale of MPKs. (Kannenberg (Otto Bock) Tr. 1884-85; Swiggum (Otto Bock) Tr. 3343-3344 (*in camera*)).
- 992. According to the Merger Guidelines, "A merger between two competing sellers prevents buyers from playing those sellers off against each other in negotiations. This alone can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it, and less favorable to the buyer, than the merging firms would have offered separately absent the merger." (PX08040 at 022 (§ 6.2) (Merger Guidelines)).
- 993. Prior to the Merger, Otto Bock was Freedom's biggest competitor in terms of size. (Kim (Freedom) Tr. 2538; Carkhuff (Freedom) Tr. 621;

} (Kim (Freedom) Tr. 2595 (*in camera*); PX01319 at

001 (Freedom)).

994. Moreover, in terms of function, Otto Bock and Freedom are each other's closest competitors. In 2015, as depicted below, Freedom published on its website a document titled "Plié 3 Microprocessor Knee Fact Sheet" that compares the Plié 3's functions directly to Otto Bock's C-Leg 4. (PX08008 at 001 (Plié 3 Fact Sheet); (Carkhuff (Freedom) Tr. 348-350)).

		Р	LIÉ3
		MICRO	CT SHEET
Key Benefits Comparison	PI	ié 3	C-Leg 4
	1983) 1993	iseconds	
Microprocessor response time Weight		seconds 7 lbs	2.7 lbs
Customized stumble recovery	4.1	A. 102	£.7 BJ3
Seamless variable speeds (incl: run and jog)		* *	
Fully Submersible		~	
Ability to make manual adjustments		~	
Interchangeable batteries		~	
Ability to wear any foot under warranty		v	
Remote access with manufacturer		~	~
Ability to generate a cadence report		J	~
Sitting mode"			×
Standing mode**			<i></i>
Made in the USA		~	
*Sting mode – knee moves to free Beaton when it detects the us **Scanding mode – knee provides dampering in slightly flexed po Ottobock Claims vs Reality (From C-Leg 4 vs Competition, Ottobock, 2015)	Plié 3 C-Leg 4 TRUT	cts the lack of move	Reality
Real-time swing and stance control	* *	Plié 3 sample	nd C-Leg 4 have swing and stance control. es data at rate of 1000Hz which is 10x faster 4. The speed of Plié 3 processor makes it Real Tim
Reliable stance release on challenging surfaces	· ·	Plié 3 release	es on a wide range of challenging surfaces.
Clinically proven stumble recovery	· ·		ad to head clinical settings comparison, Plié 3 e preferred choice by patients and prosthetists.
Weatherproof with IP67 rating			d IP67, and therefore weatherproof and up to 3 feet for 30 minutes.
Adjustable modes for special activities	>		the user to make manual adjustments to ride range of activities with different settings.
	* *		n Innovations clinical staff will gladly assist in nt support questions without a fee.
No-charge reimbursement support			required for reimbursment.

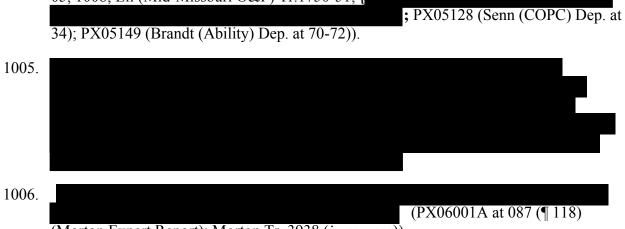
(PX08008 at 001 (Plié 3 Fact Sheet)).

The Plié 3 fact sheet highlights a number of areas in which the Plié 3 and C-Leg 4 have comparable functions. For example, the Plié 3 Fact Sheet shows that both the Plié 3 and 995.

C-Leg 4 have real-time swing and stance control, reliable stance release on challenging surfaces, clinically proven stumble recovery, weatherproof with IP67 rating, adjustable modes for special activities, and No-charge reimbursement support. (PX08008 at 001 (Plié 3 Fact Sheet)).

- 996. According to Maynard Carkhuff, Freedom's CEO at the time, the Plié 3 Fact Sheet also highlights a number of features where the Plié 3 compares favorably to the C-Leg 4. (Carkhuff (Freedom) Tr. 348).
- 997. For example, the Plié 3 Fact Sheet shows that the Plié 3 has a faster microprocessor response time than Otto Bock's C-Leg 4, a customizable stumble recovery feature (C-Leg 4 is not customizable), seamless variable speeds that are superior to the C-Leg 4, and the ability to be fully submersed in water (C-Leg 4 cannot be submersed). (PX08008 at 001 (Plié 3 Fact Sheet); (Carkhuff (Freedom) Tr. 348-349)).
- 998. Clinic customers confirm that the Plié 3 and C-Leg 4 compete closely. (Ford (POA) Tr. 948-49; { }; De Roy (Össur) Tr. 3592-93).
- 999. Mark Ford, President and Managing Partner of Prosthetic and Orthotic Associates ("POA"), testified that Otto Bock's C-Leg 4 and Freedom's Plié 3 "have a lot of similarities in terms of the base function that they work off of using hydraulic cylinders, the microprocessor." (Ford (POA) Tr. 948-49).
- 1000. Otto Bock admits that, prior to the Merger, Otto Bock "competed with the Freedom Business for the sale of prosthetic device components including prosthetic knees to prosthetic clinics on several bases" including price. (PX07008 at 005 (Respondent's Responses to Complaint Counsel's First Set of Requests for Admissions); Kannenberg (Otto Bock) Tr. 1884-85).
- 1001. Otto Bock also admits that it "competed with the Freedom Business" for the sale of prosthetic knees on the basis of "product features." (PX07008 at 005 (Respondent's Responses to Complaint Counsel's First Set of Requests for Admissions); (PX07049 at 020 (Otto Bock Amended Answer)).
- 1002. According to Otto Bock, "Ottobock's and Freedom Innovations' microprocessor controlled prosthetic knees have provided amputees with significant improvements in prosthetic devices used by amputees." (PX07049 at 003 (Otto Bock Amended Answer)).
- 1003. Many of Otto Bock's and Freedom's clinic customers view Otto Bock and Freedom as their first and second choices for MPKs. ({
 Ford (POA) Tr. 937; Ell (Mid-Missouri O&P) Tr. 1731). According to Mr. Ford of POA, "C-Legs and the Plie knees are our clinicians' preference." (Ford (POA) Tr. 937).

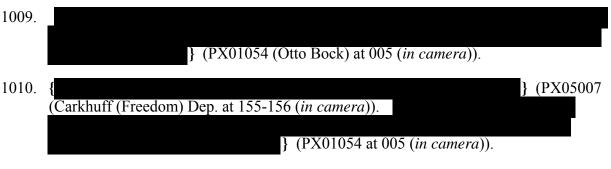
1004. Clinic customers have benefitted from head-to-head competition between Otto Bock and Freedom for their MPK business in terms of price and innovation. (Ford (POA) Tr. 1004-05, 1008; Ell (Mid-Missouri O&P) Tr.1750-51; {



- (Morton Expert Report); Morton Tr. 3938 (in camera)).
- 1007. According to Dr. Morton, "[t]he impact of Otto Bock's acquisition of Freedom is likely to be a very substantial lessening of competition. That lessening of competition will arise because of the very strong nature of head-to-head competition between Freedom and Otto Bock, and it will have three main channels of effect: price, quality and innovation. And the decline in quality and innovation, the increase in price, all of these are harms, and these harms will affect the end users of these devices, namely the amputees. (Morton Tr. 3858-59).

A. THE MERGER ELIMINATED THE AGGRESSIVE HEAD-TO-HEAD MPK COMPETITION BETWEEN OTTO BOCK'S C-LEG 4 AND FREEDOM'S PLIÉ 3

- 1. Otto Bock's MPK Market Dominance Prior to the Launch of the Plié 3
- 1008. Bradley Ruhl, Otto Bock's Managing Director for North America, testified that when Otto Bock launched the first version of its C-Leg in 1999, it commanded 100% of the MPK market. (PX05162 (Ruhl (Otto Bock) Dep. at 92-93)).



- 2. Freedom's Plié 3 Launch in 2014
- 1011. Freedom launched its current generation MPK, the Plié 3, in September 2014. (PX07049 at 004 (Otto Bock Amended Answer); PX05112 (Ammouri (Freedom) Dep. at 107)).

1012.

(Carkhuff (Freedom) Tr. 492 (in camera)).

- a) <u>Innovation of the Plié 3</u>
- 1013. The Plié 3 improved upon Freedom's prior MPKs with "improved stance performance," "improved swing performance, "better control over a wider range of speeds," and "water resistance." (PX01165 (Freedom) at 005 (Freedom's Product Pipeline presentation, Nov. 15, 2012); PX01181 (Freedom) at 003-004).
- 1014.

(Asar (Hanger) Tr. 1414-1415 (in camera)).

- 1015. Maynard Carkhuff, Chairman of Freedom, testified that the Plié 3 has performance that clinicians love, has great performance in terms of stumble recovery, enables patients to walk more effectively, and prevents patient falls. (Carkhuff (Freedom) Tr. 333).
- 1016. Freedom positioned the Plié 3 as a superior knee to Otto Bock's C-Leg. (Carkhuff (Freedom) Tr. 325). According to Mr. Carkhuff, the Plié 3 is, in fact, superior. (Carkhuff (Freedom) Tr. 325).
- 1017. Freedom differentiated the Plié 3 from Otto Bock's C-Leg, touting its customized stumble recovery, variable speeds, full submersibility, interchangeable batteries, remote access, and real-time data display. (PX01181 (Freedom) at 003-04; PX08014 (Freedom) at 002-03).
- 1018. The Plié 3 is the only MPK with an interchangeable battery, which "is a very good factor for patients who are in remote areas or just aren't technology oriented or, frankly, just forgets to charge their knee." (Carkhuff (Freedom) Tr. 340). In contrast, the C-Leg needs to be plugged in. (Carkhuff (Freedom) Tr. 341).
- 1019. The Plié 3 also has a faster microprocessor than the C-Leg. (Carkhuff (Freedom) Tr. 348; PX08008 (Freedom) at 001).
- 1020. In addition, the Plié 3 is waterproof, whereas the C-Leg 3 was not. (Ford (POA) Tr. 1007; De Roy (Össur) Tr. 3598-99). This waterproof feature was particularly attractive to MPK customers. (Testerman (Freedom) Tr. 1174; PX05162 (Ruhl (Otto Bock) Dep. at 93-94); PX05112 (Ammouri (Freedom) Dep. at 96-97); PX05001 (Endrikat (Empire) IHT at 21); PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 34)).
- 1021. According to Freedom's Chairman, Maynard Carkhuff, the Plié 3's technological advantages made it the new "industry standard" MPK. (PX05007 (Carkhuff) IHT at 284-85).
- 1022. Freedom used the technological advancements of the Plié 3 to sell the product to customers. (Testerman (Freedom) Tr. 1180-1181).

- 1023. Clinic customers liked the Plié 3. Keith Senn, President of COPC testified that "based on the feedback of practitioners . . . they like the Plié 3" and it "works well with their patients." (Senn (COPC) Tr. 180). {
- b) <u>Pricing of the Plié 3</u>
 1024.

} (Carkhuff (Freedom) Tr. 388 (*in camera*); PX01023 (Freedom) at 003-04 (*in camera*); PX01024 (Freedom) at 004 (*in camera*)); PX05130 (Governor (Otto Bock) Dep. at 131-32)).

1025.

} (Carkhuff (Freedom) Tr. 491-92 (in camera); PX02025 (HEP) at 003; PX01506 (Otto Bock) at 002; PX05162 (Ruhl (Otto Bock) Dep. at 92-93)).
} (Asar (Hanger) Tr. 1389-1390 (in

camera)).

- c) Impact of Plié 3 Launch on Otto Bock
- 1026. After the Plié 3 launched, Otto Bock's MPK sales decreased. Otto Bock executives attributed its sales decline to the launch of Freedom's Plié 3. (PX05162 (Ruhl (Otto Bock) Dep. at 92-93 (explaining that improvements to the Plié; allowed it to "gain market share" at the same time Otto Bock was "steadily losing market share"); PX01506 (Otto Bock) at 001, 002 (noting Freedom made "inroads" with the Plié 3)).
- 1027. Otto Bock's Executive Medical Director for North America testified that, "Freedom was driving a very aggressive marketing and promotional campaign with pretty high discounts and giveaways of additional products." (PX05150 (Kannenberg (Otto Bock) Dep. at 127)).
 - 3. Otto Bock's Competitive Response to the Plié 3 from 2014-2015
 - a) <u>Pricing and Promotional Responses</u>
- 1028. Bock) at 004-05; PX03008 (Madison Capital Funding) at 004 (*in camera*)).
- 1029. According to Walter Governor, Otto Bock's National Sales Director, in the first quarter of 2015 Otto Bock sold 44 C-Leg 3 MPKs to customers under a promotion, 21 of which received a \$2,500 discount. (PX01519 (Otto Bock at 001)). In response to this information, Brad Ruhl, then the President of Prosthetics Business Unit for North America, wrote "Feels like momentum BABY!!" (PX01519 (Otto Bock at 001)).

- 1030. Dr. Helmut Pfuhl, Otto Bock's executive vice president, wrote to colleagues in early 2015 that "pricing keeps me up at night more than anything else!" while highlighting that Freedom was pricing the Plié 3 significantly below the C-Leg 3, which in his view was a significant reason Otto Bock was losing sales. (PX01506 (Otto Bock) at 001).
- 1031. } (PX05140 (Weott (Orthotic & Prosthetic Centers) Dep.

at 40) (*in camera*)).

- 1032. Another customer testified that after he began purchasing more Plié 3 MPKs, Otto Bock offered "increasingly aggressive pricing on their MPKs." (PX05128 (Senn (COPC) Dep. at 24-25)).
- 1033. In addition to more aggressive pricing, Otto Bock provided its sales and marketing team with "arguments to convince customers to not walk away from the C-Leg and continue to buy C-Legs and fit C-Legs on their patients instead of Plies." (PX05150 (Kannenberg (Otto Bock) Dep. at 128-29); PX01499 (Otto Bock) (presentation entitled "Responding to Marketing Claims Freedom Innovation Plie")).
 - b) <u>Otto Bock's Launch of the C-Leg 4 in 2015</u>
- 1034. In mid-2015, Otto Bock launched its next generation MPK, the C-Leg 4. (
 PX07049 at 021 (Otto Bock Amended Answer);
 PX08077 (Otto Bock) at 001 (Press release announcing the C-Leg 4 launch in North America)).
 - (1) C-Leg 4 Launch Goals, Strategies, and Pricing
- 1035. Prior to the launch of the C-Leg 4, a cross-functional team comprised of Otto Bock sales, marketing, clinical, and service employees created various launch materials for the C-Leg 4. These contained information on the C-Leg 4's benefits, features, functions, reimbursement opportunities, launch tasks and timeline, and marketing materials. (PX01518 (Otto Bock)).
- 1036. According to Bradley Ruhl, then President of Otto Bock Healthcare North America, who led the C-Leg 4 launch in the United States, the purpose of the launch materials was "to prepare our employees, our sales team, our professional and clinical service team, marketing teams, to ultimately be in a position to launch product in the market and help customers learn and become educated ...about the product." (PX05162 (Ruhl (Otto Bock) Dep. at51-52)).
- 1037. The C-Leg 4 launch materials touted the C-Leg 4 as "quite simply the best C-Leg of all time, significantly improving users' ability to handle their daily activity." (PX01518 (Otto Bock) at 024).
- 1038. The C-Leg 4's new features included a lower system height, new carbon frame construction, integration of all sensors, Bluetooth compatibility, a knee-bending angle of

130 degrees, and weatherproofing. (PX01518 (Otto Bock) at 024, 027 (Mechatronics Launch Package); PX05162 (Ruhl (Otto Bock) Dep. at 42).

- 1039. The C-Leg 4 launch materials focused extensively on the Plié 3. For example, the launch packet circulated on February 20, 2015 contained market share estimates for a market described as "MPK," estimating that Otto Bock had a 78% share and identifying Freedom as the next-largest competitor with an 11% share. (PX01518 (Otto Bock) at 009, 050).
- 1040. Additionally, the February 2015 launch packet compared L-codes, reimbursement, and list prices for the C-Leg 4 versus the Plié, Rheo, and Orion. (PX01518 (Otto Bock) at 036 (C-Leg 4 Launch Packet)).

1041.	
	} (PX01057 (Otto Bock) at 016 (C-Leg 4 Launch Plan) (<i>in camera</i>)).
1042.	(PX01057 (Otto Bock) at 018 (C-Leg 4 Launch Plan) (<i>in camera</i>)).
1043.	(PX01057 (Otto Bock) at 023 (C-Leg 4 Global Launch Plan) (<i>in camera</i>); Schneider (Otto Bock) Tr. 4556-57 (<i>in camera</i>); PX05163 (Stuch (Otto Bock) Dep. at 225-27); PX05157 (Pfuhl (Otto Bock) Dep. at 70)).
1044.	
	}
1045.	} (Schneider (Otto Bock) Tr. 4556-57 (<i>in camera</i>); (PX05010 (Schneider (Otto Bock) IHT at 122 (<i>in camera</i>))
1046.	{PX01572 (Otto Bock) at 001 (<i>in camera</i>)).

1047. The C-Leg 4 responded to the "additional user benefits" introduced by the Plié 3. (PX05010 (Schneider (Otto Bock) IHT at 115-16). Among these benefits included the ability to walk backwards, weatherproofing, and an improved battery life. (Testerman (Freedom) Tr. 1173-1176; Ford (POA) Tr. 1007-08; PX01213 (Freedom)).

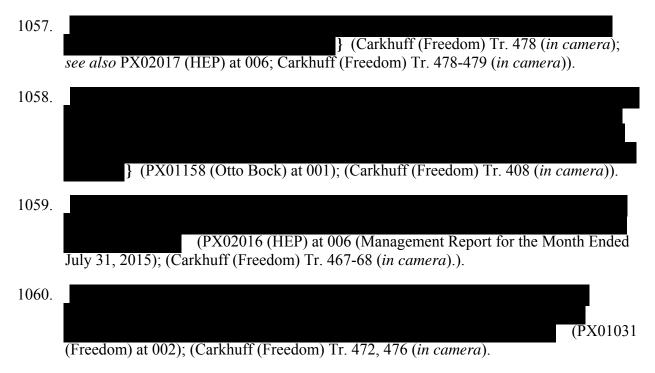
1048.		
		} (Carkhuff
	(Freedom) Tr. 497 (in camera)). {	
		(Carkhuff (Freedom) Tr. 497
	(<i>in camera</i>); PX02025 (HEP) at 004).	

- 1049. Otto Bock differentiated the C-Leg 4 from the Plié 3, noting that the C-Leg 4 has a greater knee flexion angle, longer battery life, Bluetooth compatibility, and a protective cover. (PX01518 (Otto Bock) at 003).
- 1050. According to notes from an internal Otto Bock call, "C-Leg 4 is going to blow the Plié out of the water no comparison—Brad wasn't excited before—but is very excited about this MPK—your customers will be blown out of the water." (PX01570 (Otto Bock) at 001).
- 1051. Otto Bock also sent letters to insurers to convince them of the benefits of the C-Leg 4 over the Plié 3 for reimbursement purposes. (PX01548 (Otto Bock); PX01491 (Otto Bock); PX01855 (Otto Bock)).
- 1052. (PX01524 (Otto Bock) at 004, 007 (*in camera*)).
- 1053. As then-President of the US Prosthetics Business (and current Managing Director of Otto Bock North America) explained, Otto Bock considered the prices of those three products because those are the three microprocessor knees that were "most prevalent in the market" at that time. (PX05162 (Ruhl (Otto Bock) Dep. at 109-110)).
- 1054. The sales and marketing team also developed "battle cards" for the C-Leg 4 that contrasted the features and functions of the C-Leg 4 versus the Plié, Rheo, and Orion. (PX01526 (Otto Bock) at 002-003 (C-Leg 4 Battle Card); PX05162 (Ruhl (Otto Bock) Dep. at114-116)).
- 1055. The battle cards were used by the sales and marketing team, as well as published in industry periodicals. (PX05162 (Ruhl (Otto Bock) Dep. at114-116)).
 - (2) Impact of the C-Leg 4 on Freedom's Plié 3 Sales

1056.

(Carkhuff (Freedom) Tr. 492 (in camera); PX02025 (HEP) at 003; PX01158

(Freedom) at 001 (email from Kim to Freedom board of directors dated Aug. 7, 2015); Kim (Freedom) Tr. 2552 (*in camera*)).



- 1061. In October 2015, Rob Cripe, Freedom's Executive Vice President for North American Commercial Ops and Global Marketing, wrote to Maynard Carkhuff after the launch of the C-Leg 4 that "[w]ith the C-leg, we are up against a new product and everyone wants to try it – you know the drill. Fending off someone trying it is the fight we are in ... down the road, the fight will be on reordering it. We have tools, promos and action plans in place to combat this... rolling out as we speak. " (PX01163 (Freedom) at 001) (ellipsis in original).
- 1062. In November 2015, Lee Kim, Freedom's CFO, sent another management report to Freedom's creditors, stating, "Plié MPC knee and related product sales decreased 28% compared to the prior year. MPC knee unit sales decreased from 93 to 64. Plié sales in the U.S. were impacted by the introduction of the updated Otto Bock MPC knee. Total revenues for October 2015 were 89% of plan and are at 97% of plan year to date. Foot and related revenue attainment against plan for the month was 96% and knee and related revenues attained 80% of plan. The shortfall from plan was largely due to competitive challenges in the Hanger and SPS Independent channels due largely to the release of an updated MPC knee by Otto Bock." (PX02017 (HEP) at 006 (Management Report For the Month Ended October 31, 2015)).
- 1063. In December 2015, Lee Kim, Freedom's CFO, sent another management report to Freedom's creditors, stating, "Plié sales in the U.S. have been impacted by the introduction of the updated Otto Bock MPC knee." (PX02018 (HEP) at 006). Mr. Kim also wrote, "Total revenues for November 2015 were 79% of plan and are at 93% of plan year to date. Foot and related revenue attainment against plan for the month was 84%

and knee and related revenues attained 79% of plan. The shortfall from plan was largely due to competitive challenges in the Hanger and SPS Independent channels due largely to the release of an updated MPC knee by Otto Bock." (PX02018 (HEP) at 006).

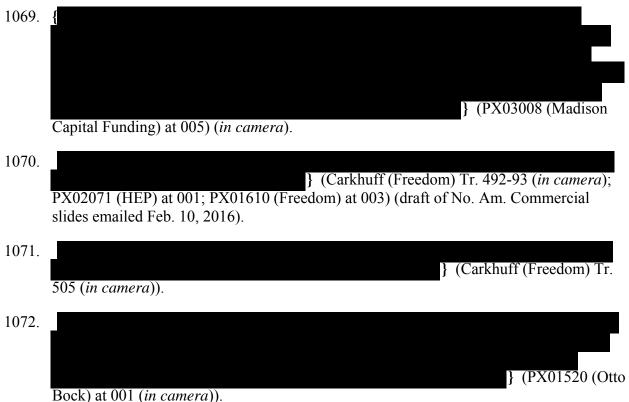
1064. In March 2016, Maynard Carkhuff, Freedom's then-CEO, sent a graph illustrating the effect of the C-Leg 4 launch on Plié 3 sales to Freedom board member Ned Brown as part of a "Diagnostics" assessment of Freedom's revenue decline, as shown below. (PX02025 (HEP) at 003; *see also* PX05007 (Carkhuff (Freedom) IHT at 158-59)).



(PX02025 (HEP) at 003).

- 1065. In this graph, Freedom's worldwide sales are depicted by an orange line. (PX02025 (HEP) at 003; PX05007 (Carkhuff (Freedom) IHT at 160)).
- 1066. According to this graph, after the Plié 3 was released, worldwide and U.S. direct sales increased right up until the launch of the C-Leg 4. (PX02025 (HEP) at 003; PX05007 (Carkhuff (Freedom) IHT at 160-61).
- 1067. After the C-Leg 4 was introduced, Freedom's worldwide, U.S. direct, Hanger, and SPS sales all decreased. (PX02025 (HEP) at 003; PX05007 (Carkhuff (Freedom) IHT at 160-61)).

1068. Accompanying this graph, Mr. Carkhuff noted in a page titled "Diagnostic" that Freedom achieved growth through June 2015, but in July 2015, "Otto Bock introduced the C-leg 4 which closed the technology gap with Freedom's Plie MPC knee." (PX02025 (HEP) at 004).



1073. In March 2016, Ned Brown, a member of Freedom's board of directors, wrote to Thomas Chung, Vice President of HEP, and others at HEP that, "The Hangar [sic] 2015 softness is related primarily to knees (vs the more general description of the 'Hangar [sic] Channel') – I would be more specific, and I would highlight the impact of OB's new C leg launch which correlates exactly with the decline in our Hangar [sic] knee business. We didn't respond fast enough to their competitive attack, and we are seeing a broadening competitive impact across our knee business into 2016." (PX02071 (HEP) at 001; see also PX05113 (Chung (HEP) Dep. at 87-88)).

4. Freedom's Response to the C-Leg 4 Launch in 2015-2017

- 1074. In July 2015, in a management report from Lee Kim, Freedom's CFO, to Freedom's creditors, Mr. Kim explained that, in light of the decline in Plié sales as a result of the C-Leg 4 launch, "[w]e have developed promotions and other sales materials to regain momentum in knee sales." (PX02016 (HEP) at 006).
- 1075. In a contemporaneous memo to the sales team at Freedom, Freedom equipped its sales team with new materials specifically highlighting the advantages of the Plié 3 over the C-Leg 4. (PX01213 (Freedom) at 001-003).

- 1076. This memo instructed the sales team, "don't forget that our positioning statement, STRONGER, SMARTER, SUBMERSIBLE is still true, and we already have examples of head-to-head trials against the C-leg 4 where we have won when we sell the benefits." (PX01213 (Freedom) at 003).
- 1077. In that same memo, the sales team was told "[t]he presence of new competition means we/you have made an impact now go defend it! Stay tuned for additional tools being created to demonstrate the [sic] how well Plie 3 stands up to this new competitor and others in the market." (PX01213 (Freedom) at 003).
- 1078. In a fall 2015 Sales Meeting, Freedom sales members, marketing members, and executives reviewed a detailed "Competitor Info" comparison on the Plie 3 versus the C-Leg 4. (PX01168 (Freedom) at 001-02 (email and attachment sent by Ammouri on Mar. 19, 2016, referencing meeting). The Freedom sales team, members of the executive team, and marketing team attended this meeting. (PX05112 (Ammouri) Dep. at 107). At this meeting, the various Freedom employees "spent a lot of time discussing" the C-Leg 4 versus the Plié. (PX05112 (Ammouri) Dep. at 108). The "Competitor Info" document was created to help the Freedom sales and marketing team win versus the C-Leg 4. (PX05112 (Ammouri) Dep. at 114). Winning versus the C-Leg 4 means a customer buying the Plié 3. (PX05112 (Ammouri) Dep. at 114).
 - a) <u>Creation of the Ideal Combo</u>

1079. (Testerman (Freedom) Tr. 1201; (Ferris (Freedom) Tr. 2395 (*in camera*); Solorio (Otto Bock) Tr. 1588, 1607 (*in camera*); PX00867 (Otto Bock) at 022 (*in camera*) (2018 North America Marketing & Sales Plan)). 1080. {

- 1081. Otto Bock's Scott Schneider, Vice President of Government, Medical Affairs, and Future Development, testified that after the launch of the C-Leg 4, Freedom responded with "promotional campaigns for other free products or coupling the knee with a popular foot choice." (PX05010 (Schneider) IHT at 123-124). Mr. Schneider saw these promotions being offered by Freedom through September 2017. (PX05010 (Schneider) IHT at 123-124).
- 1082. Otto Bock's Senior Prosthetics Marketing Manager, Cali Solorio wrote about Freedom to the Otto Bock sales team under the heading "Countering Freedom's Latest Promo" in September of 2015 that "C-Leg 4 has undoubtedly put considerable pressure on the

competition – just look at the unique promos they've been running." (PX01272 (Otto Bock) at 001); Solorio (Otto Bock) Tr. 1589-91).



1084. The "Ideal Combo" provides free or discounted prosthetic feet to prosthetic clinics with the purchase of Freedom's Plié 3. (Testerman (Freedom) Tr. 1145-46; *see also* {



- 1085. One version of the Ideal Combo involved offering a discount off of Freedom's Kinterra prosthetic ankle system with the purchase of a Plié 3. (PX01181 (Freedom) at 005; Testerman (Freedom) Tr. 1145-46; PX01158 (Freedom) at 001). The discount off of the Kinterra has at times been as high as \$1,000. (PX00824 (Freedom) at 002).
- 1086. In addition to large discounts off the Kinterra, Freedom also offered as part of the Ideal Combo any Freedom graphite prosthetic foot free with the purchase of a Plié 3. (*see*, *e.g.*, PX00824 (Freedom) at 002). Below is an example of a Freedom advertisement promoting this version of the Ideal Combo, as well as the version offering a discount off of the Kinterra.

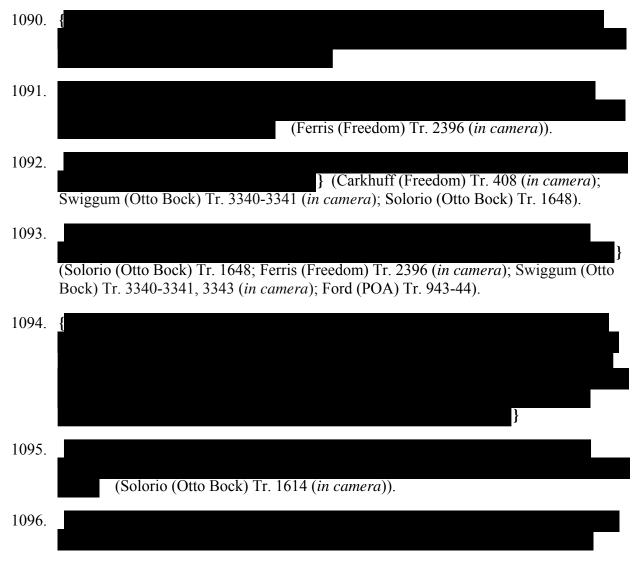


(PX00833 (Freedom) at 007).

1087. The Agilix, DynAdapt, Highlander, and Kinterra are top selling feet pursuant to the Ideal Combo promotion. (Carkhuff (Freedom) Tr. 712-13 (discussing RX0439 (Freedom) at 004)). {



- 1088. } (Solorio (Otto Bock) Tr. 1611 (*in camera*); PX05116 (Endrikat (Empire) Dep. at 61)).
- 1089. Freedom advertised and promoted its Ideal Combo at the October 2015 AOPA conference. Freedom's promotional materials for this conference stated "[d]iscover why the 'ideal combo' of pairing the Kinterra foot/ankle system with a Plie 3 MPC Knee provides AK users with rock solid stability and safety, while maintaining a gait that is fluid and natural on all terrains. The features and benefits of the Kinterra and the Plie 3 will be closely examined in an interactive hands-on setting with patient models along with a live demonstration of the Plie 3 MPC Knee programming." (PX00803 (Freedom) at 003).





- b) Discounted Plié 3 Pricing and Aggressive Marketing versus the C-Leg 4
- 1098. Following the launch of the C-Leg 4, Freedom's sales team sought to regain market share from Otto Bock. A bulletin to Freedom's sales team concerning the response to the launch of the C-Leg 4 stated, "[t]he presence of new competition means we/you have made an impact now go defend it!" (PX01213 (Freedom) at 003).
- 1099. Freedom's Vice President of National and Key Accounts, Mark Testerman, testified that, when the C-Leg 4 was launched, it was "important for our sales team to understand how we're going to compete versus that product." (Testerman (Freedom) Tr. 1178-1179). Accordingly, Freedom marketing and clinical teams created presentations comparing the features of the Plié 3 to the C-Leg 4. (Testerman (Freedom) Tr. 1178-1179 (discussing PX01213 (Freedom))).
- 1100. Freedom's marketing team contemplated several actions to take in response to the C-Leg 4 launch, including "initiate a value-added selling model versus C-Leg 4," launching a Plié 3 "demo program with our top Key Accounts," and "revisit [the Plié 3] pricing structure and overall terms." (Testerman (Freedom) Tr. 1190-1194 (discussing PX01247 (Freedom) at 001).
- 1101.
- 1102. Freedom's sales materials touted the benefits of the Plié 3 over the C-Leg 4, positioning the Plié 3 as "STRONGER, SMARTER, SUBMERSIBLE." (PX08008 (Freedom) 002; Carkhuff (Freedom) Tr. 330-331 (discussing PX08008); PX01213 (Freedom) at 003). According to Mr. Carkhuff, "the marketing team came up with these categories of stronger, smarter, submersible to really distinguish and kind of categorize the new features and improvements in the product." (Carkhuff (Freedom) Tr. 331-33).
- 1103. Freedom also created a publically available "Fact Sheet," in part to rebut certain claims that Otto Bock had made about the Plié 3. (PX08008 (Freedom) at 001).
- 1104. For example, Freedom publicly stated in this Fact Sheet that "Both Plié 3 and C-Leg 4 have swing and stance control" and "Plié 3 samples data at rate of 1000Hz which is 10x faster than C-Leg 4. The speed of Plié 3 processor makes it Real Time." (PX08008 (Freedom) at 001 ("Ottobock Claims vs Reality").

- 1105. The Fact Sheet also stated that the Plié 3 has "Reliable stance release on challenging surfaces." (PX08008 (Freedom) at 001).
- 1106. The Fact Sheet also stated that the Plié 3 has "Clinically proven stumble recovery." The Fact Sheet elaborated that, "In various head to head clinical settings comparison[s], Plié 3 has been the preferred choice by patients and prosthetists." (PX08008 (Freedom) at 001).
- 1107. The Fact Sheet also stated that the Plié 3 is "Weatherproof with IP67 rating" and "submersible up to 3 feet for 30 minutes." (PX08008 (Freedom) at 001).
- 1108. The Fact Sheet also stated that the Plié 3 has "Adjustable modes for special activities" and "allows the user to make manual adjustments to adapt to a wide range of activities with different settings." (PX08008 (Freedom) at 001).
- 1109. The Fact Sheet also addressed Otto Bock's claim that the Plié 3 is not PDAC verified, explaining that, "PDAC is not required for reimbursement." (PX08008 (Freedom) at 001). Indeed, Maynard Carkhuff, Freedom's former CEO and current Chairman, testified at trial that despite not having PDAC verification, Freedom has made a lot of sales in the marketplace. (Carkhuff (Otto Bock) Tr. 357-358).
- 1110. { (PX05114 (Ferris (Freedom) Dep. at 175-76; Solorio (Otto Bock) Tr. 1588; Carkhuff (Freedom) Tr. 485 (*in camera*); (Testerman (Freedom) Tr. 1202-04 (one pricing action was to discuss reduced pricing for Freedom's largest customer, Hanger); PX00859 (Freedom) at 003 (same); PX01173 (Freedom) at 004 ({ }) (*in camera*); PX05153B (Asar (Hanger) Dep. at

103-104 (in camera)). {

} (Swiggum (Otto Bock) Tr. 3344 (in camera)).

- 1111. Cali Solorio, Senior Prosthetics Marketing Manager at Otto Bock, testified that after the launch of the C-Leg 4, she saw Freedom react to the competitive pressure by dropping prices of its Plié microprocessor knee. (Solorio (Otto Bock) Tr. 1588). Ms. Solorio wrote in August 2015 that Freedom is "surely feeling the pressure and as a result, dropping prices." (PX01269 (Otto Bock) at 001).
- 1112.

} (PX01002 (Otto Bock) at t she meant competitive

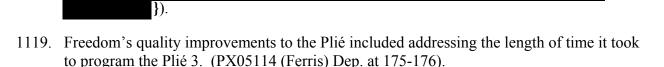
006 (*in camera*)). By "pressure," Ms. Solorio testified that she meant competitive pressure from the launch of the C-Leg 4." (Solorio (Otto Bock) Tr. 1596).

1113. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified that Freedom began to offer its reduced pricing "shortly after the launch of C-Leg 4." (PX05010 (Schneider) IHT at 124). Mr. Schneider explained that Freedom responded to competition from Otto Bock's C-Leg 4 with "reduced price or aggressive pricing" as well as an increased discount structure. (PX05010 (Schneider) IHT at 123).

- 1114. }
- 1115. As Keith Senn, President of COPC testified, "[w]e have a higher margin on the Freedom Plié" than on the Otto Bock C-Leg. (Senn (COPC) Tr. 207-208).
- 1116.
 }
 c) Plié 3 Quality Improvements
- 1117. In addition to offering new promotions as well as lowering the price of the Plié, Freedom continued to make quality improvements to the Plié 3 after the launch of the C-Leg 4. David Smith, Freedom's CEO at the time,

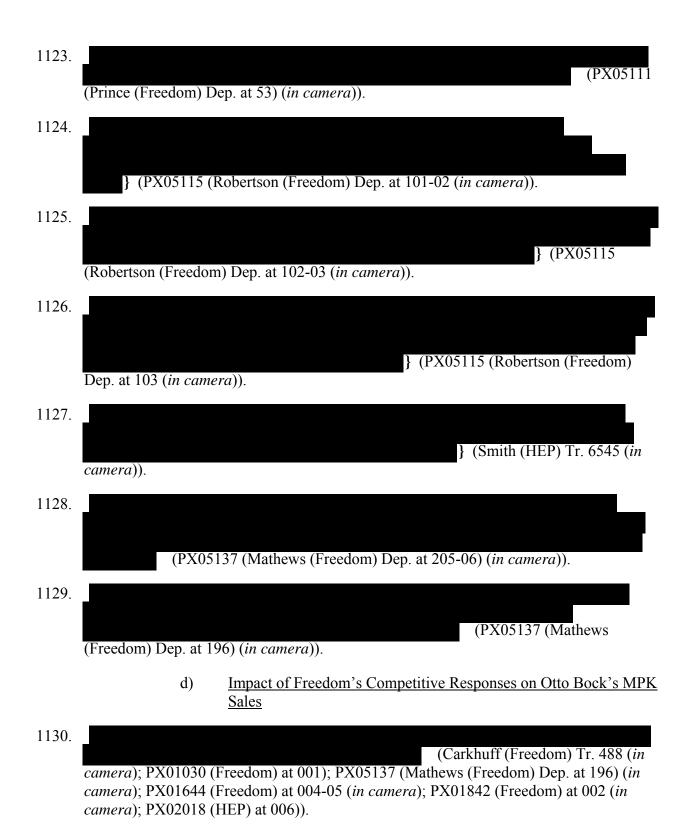
} (Smith (HEP) Tr. 6537, 6543 (*in camera*)).

1118. Specifically, in 2016, Freedom put initiatives in place to improve the quality of the Plié 3. (Kim (Freedom) Tr. 2515; *see also* (PX02034 (HEP) at 049 (*in camera*) (



- 1120. These quality improvements also included making the Plié 3 more durable. (PX05114 (Ferris) Dep. at 175-176).
- 1121. Dr. Prince, Freedom's Quattro Project Manager and Technical Lead, testified that subsequent to the Plié 3's release, he assisted with diaphragm material improvements "to find a suitable replacement." (Prince (Freedom) Tr. at 2674-75).
- 1122. Dr. Prince testified that he helped guide "some new engineers working on the electrical system" for the Plié 3. (Prince (Freedom) Tr. at 2675); *see also* (PX05111 (Prince (Freedom) Dep. at 12) (testifying that he worked on "sustaining efforts" for the Plié 3 including "the diaphragm material improvements" and improving the battery lid, as well as help to "guide other engineers on other discipline aspects of the project such as cable routing and process improvements to the product.").

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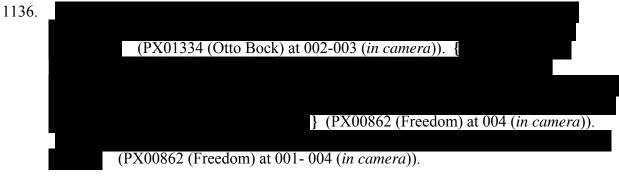


1131. In a November 2015 compliance package that Lee Kim, Freedom's CFO, sent to Freedom's creditors, Mr. Kim stated "Plié MPC knee and related product sales increased 32% compared to the prior year. MPC knee unit sales increased from 70 to 98. Plié sales in the U.S. have been impacted by the introduction of the updated Otto Bock MPC knee. However, it appears that the marketing initiatives launched recently to recapture knee trials are having success. Monthly U.S. knee unit sales increased from 53 in October to 78 in November." (PX02018 (HEP) at 006).

- 1132. Additionally, in a November 2015 flash report that Mr. Kim was preparing for the board of directors, he noted that, "knee unit sales did increase substantially from October. As mentioned in Maynard's email last month, the sales teams have been given new marketing programs to counter the impact of the new C-leg 4 on customer trials and it appears these programs are having a positive impact." (PX01030 (Freedom) at 001).
- 1133. Otto Bock executives recognized that "[p]ressure from the C-Leg 4 has driven lower prices and bundle promotions with feet" from Freedom. (Solorio (Otto Bock) Tr. 1596; PX01002 (Otto Bock) at 006; PX5010 (Schneider (Otto Bock) IHT at 123)).

(PX05123 (Solorio (Otto Bock) Dep. at 116) (in camera)).

- 1134. (PX01278 (Otto Bock) at 001 (*in camera*); Solorio (Otto Bock) Tr. 1617-18 (*in camera*)).
- 1135. In response to Freedom's promotions, Otto Bock provided its sales team with guidance on "Countering Freedom's Latest Promo." (PX01272 (Otto Bock) at 001). Otto Bock also offered customers various promotions of its own, including a \$2,500 discount on the C-Leg 4. (PX01519 (Otto Bock) at 001).



e) <u>Initiation of Development of the Quattro MPK</u>

- 1137. Freedom began working on its next-generation MPK to further combat Otto Bock's C-Leg 4. (PX05111 (Prince (Freedom Dep. at 88).
- 1138. Dr. Stephen Prince, Freedom's Quattro Project Manager and Technical Lead, testified that the C-Leg 4 "was targeted early on in the [Quattro] project." (PX05111 (Prince (Freedom Dep. at 88).

1139.

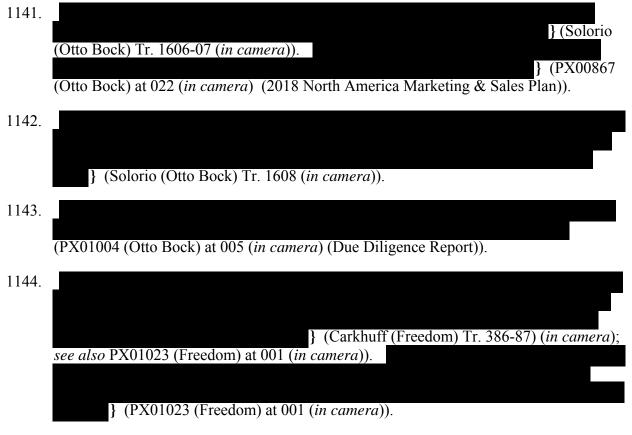
(PX05111 (Prince (Freedom) Dep. at 108 (in camera)).

5. Customers Benefitted from this Head-to-Head Competition between Otto Bock and Freedom through Lower Prices

1140. Customers and amputees benefitted from aggressive head-to-head competition between Otto Bock and Freedom by receiving lower prices, better technology, and improved customer service. (*See, e.g.*, Ell (Mid-Missouri O&P) Tr. 1750-51; PX05129 (Ell (Mid-Missouri O&P) Dep. at 78-79); Ford (POA) Tr. 1004-06; {
FX05128 (Senn (COPC) Dep. at 34); PX05149 (Brandt

(Ability Prosthetics & Orthotics) Dep. at 70-72)).

a) <u>Customers Benefited from Price Competition between the Plié and</u> <u>C-Leg</u>



- 1145. Maynard Carkhuff, Freedom's Chairman, testified that Freedom sells high quality products but is willing to price competitively to win business. (PX05109 (Carkhuff (Freedom) Dep. at 192).
- 1146. When asked how he would describe Freedom's pricing of the Plié 3 as compared to the pricing of other MPK manufacturers, Stephen Blatchford, Executive Chairman of Endolite, stated, "Well, our understanding of their pricing is that they tend to be lower than the other manufacturers." (Blatchford (Endolite) Tr. 2148).

1147. Customers testified that they pay much less for the Plié 3 than they do the C-Leg 4. For example, Michael Bright, owner of North Bay Prosthetics, pays approximately \$15,000 for the Plié and about one thousand dollars more for the C-Leg. (PX05141 (Bright (North Bay) Dep. at 125)).

} (Senn (COPC) Tr. 222-223 (*in camera*)). Tracy Ell, from Mid-Missouri O&P, pays "\$2,000 less" for the Plié 3 than the C-Leg 4. (Ell (Mid-Missouri O&P) Tr. 1742). Mark Ford, from POA, pays "[t]hree to four thousand dollars less" for the Plié than the C-Leg. (Ford (POA) Tr. 947).

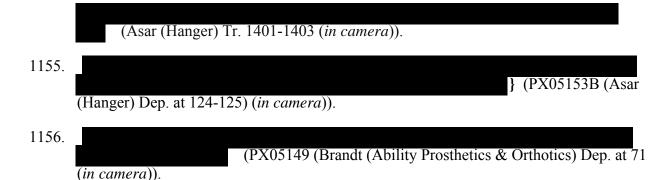
- 1148. According to Dr. Kannenberg, Otto Bock's Executive Medical Director, "[t]he primary reason [that prosthetists choose Freedom's Plié 3] was the lower price and the better margin, because the reimbursement for all microprocessor knees by health insurances is the same." (Kannenberg (Otto Bock) Tr. 1990).
- 1149. } (PX05108 (Yates (Jonesboro) Dep. at 61-62) (*in camera*)).
- 1150. Keith Senn, President of Kentucky/Indiana Operations for the COPC, testified that COPC purchased a majority of its MPKs from Freedom in 2017 because "the prosthetists like the MPK from Freedom and we have a very good discount agreement with them." (Senn (COPC) Tr. 190). Mr. Senn further testified that COPC increased its purchases of Freedom's Plié in 2017 due to "[t]he competitive pricing that we received from them." (Senn (COPC) Tr. 191).
- 1151. Keith Senn, President of Kentucky/Indiana Operations for the COPC, explained that COPC has been able to use the cost savings to benefit patients by hiring more staff and "hiring residents with facilities, with programs that we put in support of the patient care, such as compliance." (PX05128 (Senn (COPC) Dep. at 34)).
- 1152.

{ (Senn (COPC) Tr. 221-222 (*in camera*); *see also* (PX05128 (Senn (COPC) Dep. at 24-25) (testifying that when COPC switched from Otto Bock's C-Leg MPK to Freedom's Plié, he saw Otto Bock provide "increasingly more aggressive pricing on their MPKs ")).

1153.

(PX03118 (COPC) at 001 (*in camera*)).





- 1157. Jeff Brandt, CEO of Ability Prosthetics & Orthotics, testified that C-Leg's "price has come down significantly . . . I think that it's probably pretty well documented that it's competition with Freedom's Plié that has contributed to that, at least some." (PX05149 (Brandt (Ability Prosthetics & Orthotics) Dep. at 71)). Mr. Brandt clarified that "well documented" means that it is "common knowledge just among providers and manufacturers that it's obvious from where I sit that [Freedom and Ottobock] are that [Freedom and Ottobock] are, you know, very traditionally one-upping each other and trying to do pack more into a knee for the same price or less." (PX05149 (Brandt (Ability Prosthetics & Orthotics) Dep. at 71-72)).
- 1158. Robert Yates, President and CEO of Jonesboro, testified that competition between Otto Bock and Freedom led to "relatively competitive pricing structures from both manufacturers," "demo units for use in our offices," "educational support, robust customer service," and "education/marketing opportunities to the physical therapy community from both Otto Bock and Freedom." (PX05108 (Yates (Jonesboro) Dep. at 74)).
- 1159. Tracy Ell, the owner and Chief Prosthetist at Mid-Missouri Orthotics and Prosthetics, testified that his clinic has benefited from competition between Otto Bock and Freedom "in two manners[:] . . . one being the potential to reduce a service purchase price as well as facilitate the continued evolution of technology in microprocessor control knee field, that then benefits my business as well as the patients." (PX05129 (Ell (Mid-Missouri) Dep. at 78-79)).
- 1160. Mark Ford, President and Managing Partner of POA, testified that he has used the presence of Freedom's Plié 3 to obtain better prices from Otto Bock for its C-Leg 4. (Ford (POA) Tr. 1004-05).
- 1161. Clinic customers are concerned that, now that Freedom is owned by Otto Bock, they will lose leverage in negotiations against Otto Bock for MPKs. Mark Ford of POA testified that he is concerned "that the price of MPKs can go up over time" and that POA would lose leverage in negotiations against Otto Bock for MPKs. (Ford (POA) Tr. 1014-15).

1162.

(Senn (COPC) Tr. 227-28 (in camera)).

b) <u>Customers Benefitted from Innovation Competition Between</u> <u>Freedom and Otto Bock</u>

1163.

(PX07008 at 005 (¶

12) (*in camera*) (Respondent's Responses to Complaint Counsel's First Set of Requests for Admissions)).

- 1164. (Carkhuff (Freedom) Tr. 468 (*in camera*)). For example, when Freedom introduced a waterproof MPK, "the demand for waterproofing and weatherproofing did increase." As a result, Otto Bock and Össur responded with a waterproof solution of their own. (De Roy (Össur) Tr. 3597-99).
- 1165. Robert Yates, President and CEO of Jonesboro, testified that Otto Bock competes with Freedom for sales of MPKs "based on the features of the products, the research that has been conducted with the C-Leg" (PX05108 (Yates (Jonesboro) Dep. at 72-73)).
- 1166. Mr. Yates testified that patients have benefited from more innovative C-Leg and Plié products because "over time the products have become better. They have become more reliable. They've, you know, become more feature-rich due to what amputees require from their devices." (PX05108 (Yates (Jonesboro) Dep. at 77-78)).
- 1167. Mark Ford, President and Managing Partner of POA, testified that he has observed Freedom and Otto Bock engage in an innovative tit-for-tat between each other in terms of MPK features. (PX5145 (Ford (Prosthetic & Orthotic Associates) Dep. at 66-67)). He explained that "[b]ecause Freedom and Otto Bock had built their MPK designs on similar ideas and similar platforms, there was an inherent stronger competition between those two companies to essentially one-up each other to keep the attention of clinicians as to which product did they prefer. As they added new benefits, that created interest in their new versions." (Ford (POA) Tr. 1015-1016).
- 1168. Mr. Ford, testified that competition between Otto Bock and Freedom "has made them both better. They make the product better because they have to continue to essentially grab attention from our clinicians, so they make the products better." (PX5145 (Ford (POA) Dep. at 64-65)). For example, Mr. Ford observed improvements to the Plié 3 that made it superior to the C-Leg 3, including waterproofing and longer battery life. (Ford (POA) Tr. 1007).
- 1169. Mark Ford, President and Managing Partner of POA, testified that when the C-Leg 4 was released, it included improvements to its battery life, software, and water-resistance. (Ford (POA) Tr. 1007). For example, the C-Leg 4 introduced "[i]mproved battery life and the improved ability to deal with water" which Freedom's Plié already had. (Ford (POA) Tr. 1007-08). Mr. Ford testified that POA patients have benefited from product improvements to the Plié 3 and C-Leg 4. (Ford (POA) Tr. 1008).

1170.	} (Asar (Hanger) Tr. 1408-1409 (<i>in camera</i>)).
1171.	(Asar (Hanger) Tr. 1458 (<i>in camera</i>)).
1172.	(Asar (Hanger) Tr. 1408-1409 (<i>in camera</i>); <i>see also</i> (Asar (Hanger) Tr. 1411

- 1173. Tracy Ell, the owner and Chief Prosthetist at Mid-Missouri Orthotics and Prosthetics, testified that his clinic has benefited from competition between Freedom and Otto Bock through the "general progression and growth of technology." (Ell (Mid-Missouri O&P) Tr. 1750). Mr. Ell explained, "Generally, if you have a design of a component and their competitor exceeds the design by some characteristic, then it's only common nature to evolve your product, as in the C-Leg 1 through 4 and the Plié 1, 2, and 3." (Ell (Mid-Missouri O&P) Tr. 1750-51).
- 1174. Accordingly, customers are concerned that the Merger will lead to decreased innovation.

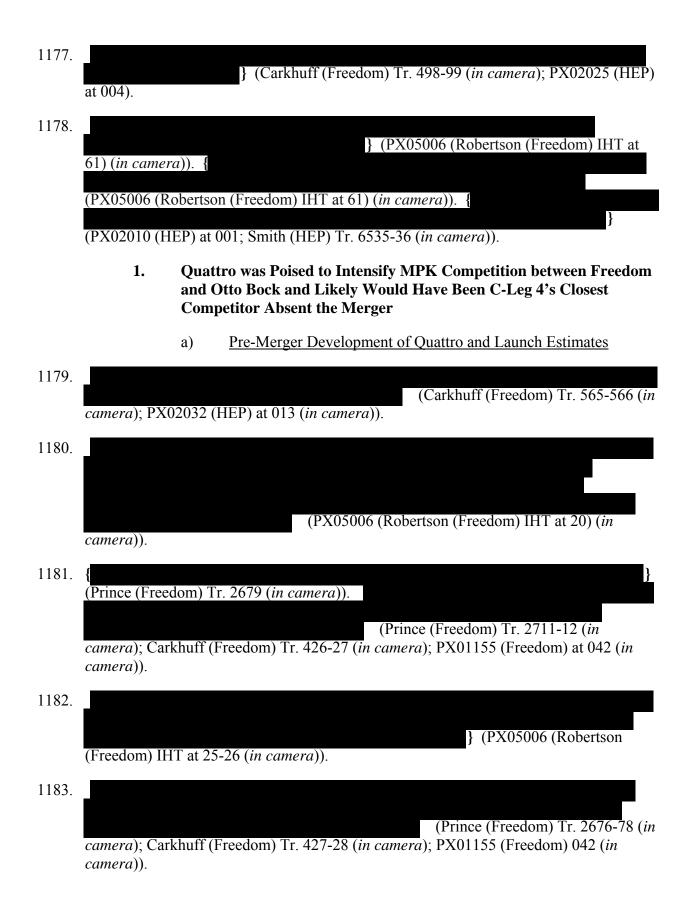
(Senn (COPC) Tr. 227-028 (*in camera*)). Similarly, Mark Ford, of POA, testified he is concerned by the Merger, and stated, "what will happen with the future development of MPKs, if there's less competition, how will they continue to improve for patients." (Ford (POA) Tr. 1014-1015).

B. THE MERGER ELIMINATED COMPETITION THAT WAS SET TO INTENSIFY BETWEEN FREEDOM AND OTTO BOCK'S NEXT-GENERATION MPKS

- 1175. (Carkhuff (Freedom) Tr. 422 (*in camera*); PX05111 (Prince (Freedom) Dep. at 58); PX07049 at 022 (¶¶ 49-50) (Otto Bock Amended Answer) (*in camera*)).
- 1176.

} (Carkhuff

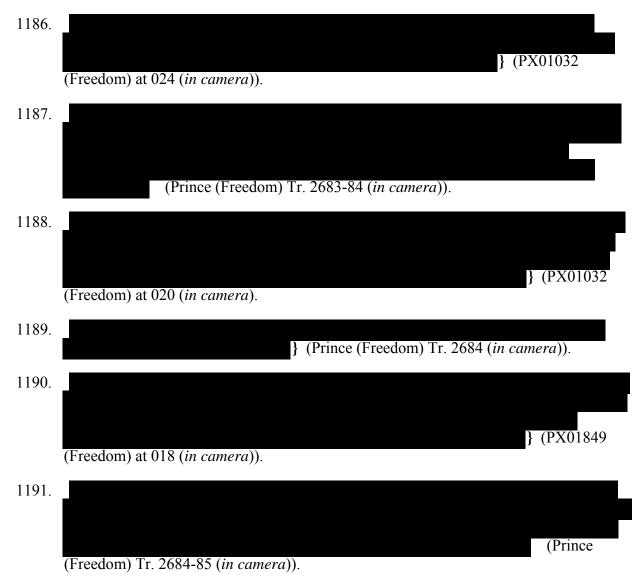
(Freedom) Tr. 679 (in camera)).

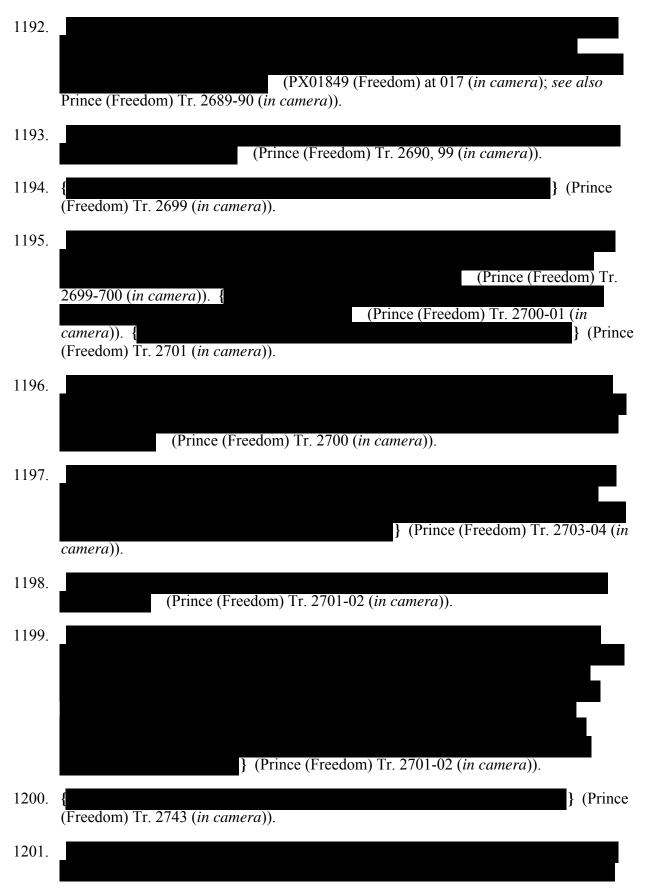


1184.

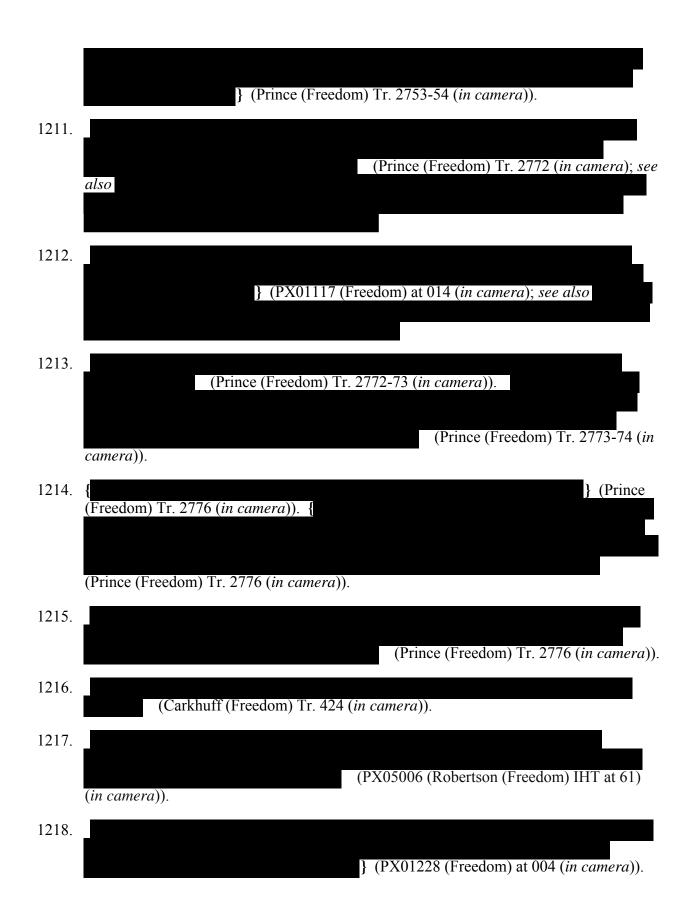
Freedom) Tr. 2691-93 (*in camera*) (discussing PX01849 (Freedom) at 21 (*in camera*))).

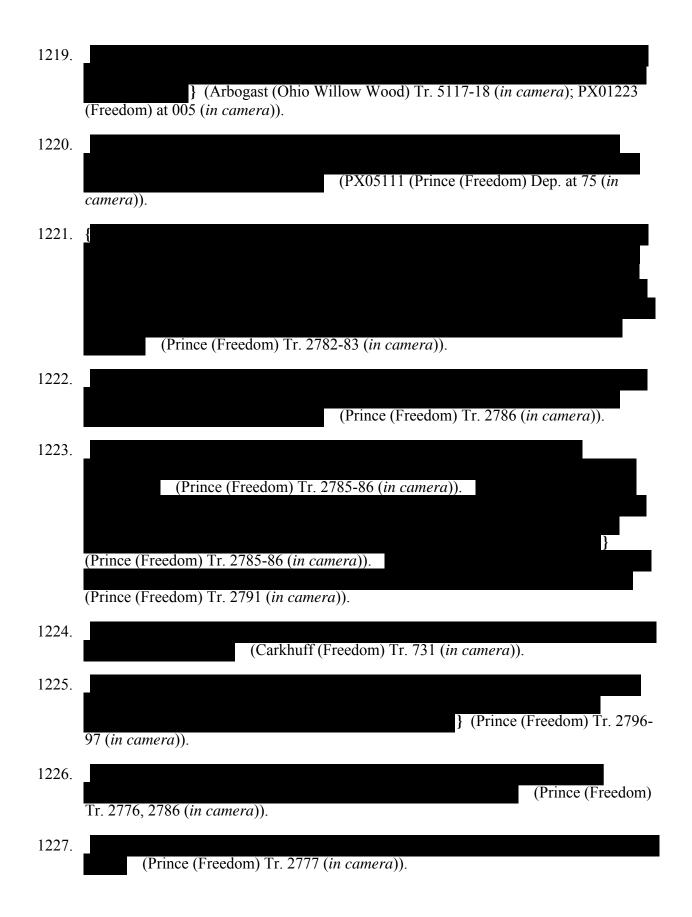
1185. Internally Freedom refers to its process for developing a product as the "product development process" ("PDP"). The PDP consists of six phases—Phase A through Phase F. In order for a project to proceed, a "product approval committee" ("PAC") must approve each stage of the PDP following a "PAC review meeting." The product approval committee includes Freedom's CEO, CFO, VP of marketing, VP of R&D, and senior director of quality. (Prince (Freedom) Tr. 2680-81). Phase E is the product release phase. (Prince (Freedom) Tr. 2777). Phase F is the "market surveillance phase," and occurs after the product has become commercially available. (Prince (Freedom) Tr. 2778).

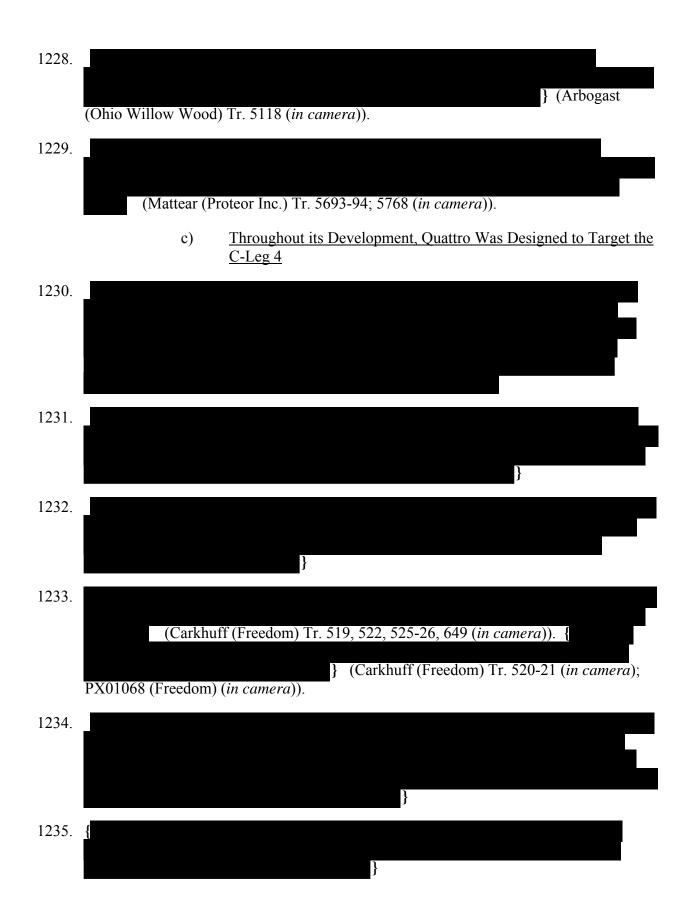


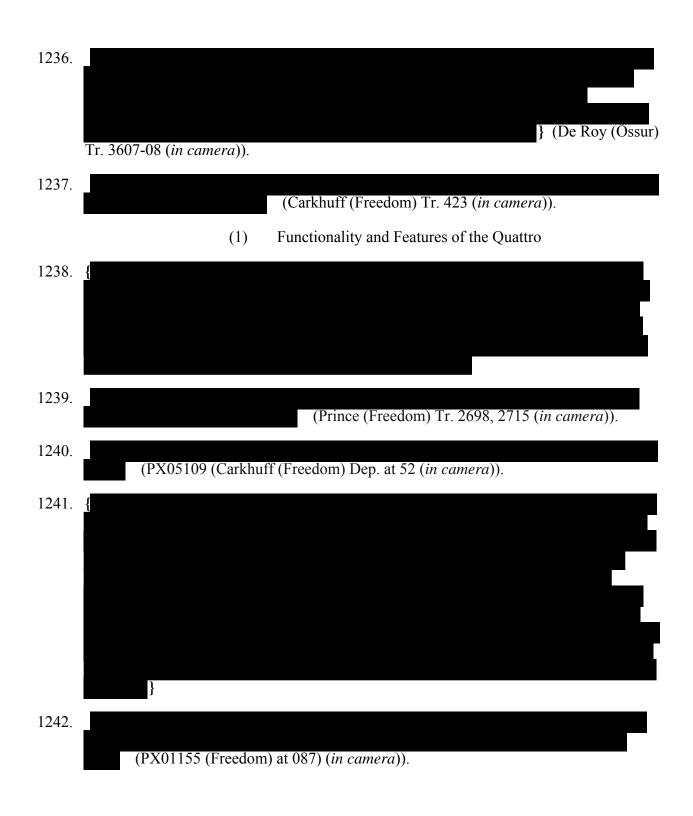


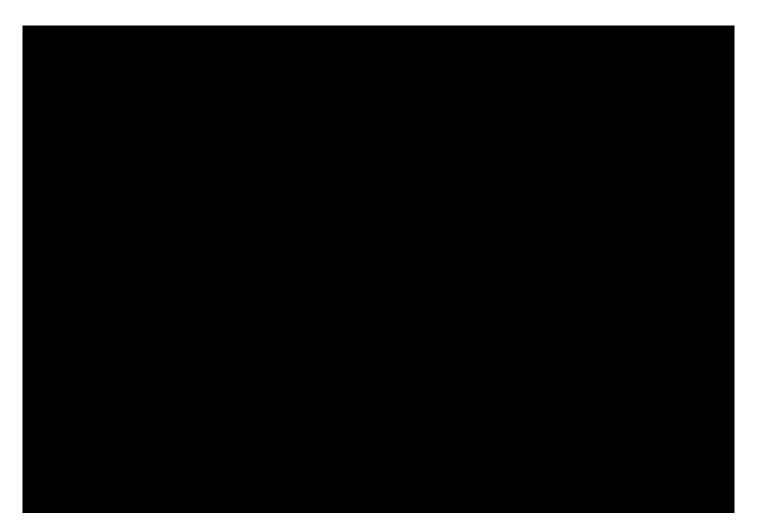
	} (Prince (Freedom) Tr. 2717 (in camera)).
1202.	{ (Prince (Freedom) Tr. 2743 (<i>in camera</i>)).
1203.	
	(Prince (Freedom) Tr. 2719-20 (in camera)).
1204.	{ True down) at 008 (i) Prince (Free down) True 2744 (i
	(Freedom) at 008 (<i>in camera</i>); Prince (Freedom) Tr. 2744 (<i>in camera</i>)). } (Prince (Freedom) Tr. 2720 (<i>in camera</i>), 2744 (<i>in camera</i>)).
1205.	{ (PX01116 (Freedom) at 008 (<i>in camera</i>); Prince (Freedom) Tr. 2743 (<i>in camera</i>)).
1206.	(Prince (Freedom) Tr. 2743 (in camera)).
1207.	} (PX02032 (Freedom) at 13 (<i>in camera</i>) (Board of Directors Meeting Presentation, April 19, 2017); Carkhuff (Freedom) Tr. 566 (<i>in camera</i>)).
1208.	(PX01157 (Freedom) at 011 (<i>in camera</i>)).
1209.	
	b) <u>Post-Merger Development of Quattro and Launch Estimates</u>
1210.	{ (Prince (Freedom) Tr. 2752 (<i>in camera</i>)). {







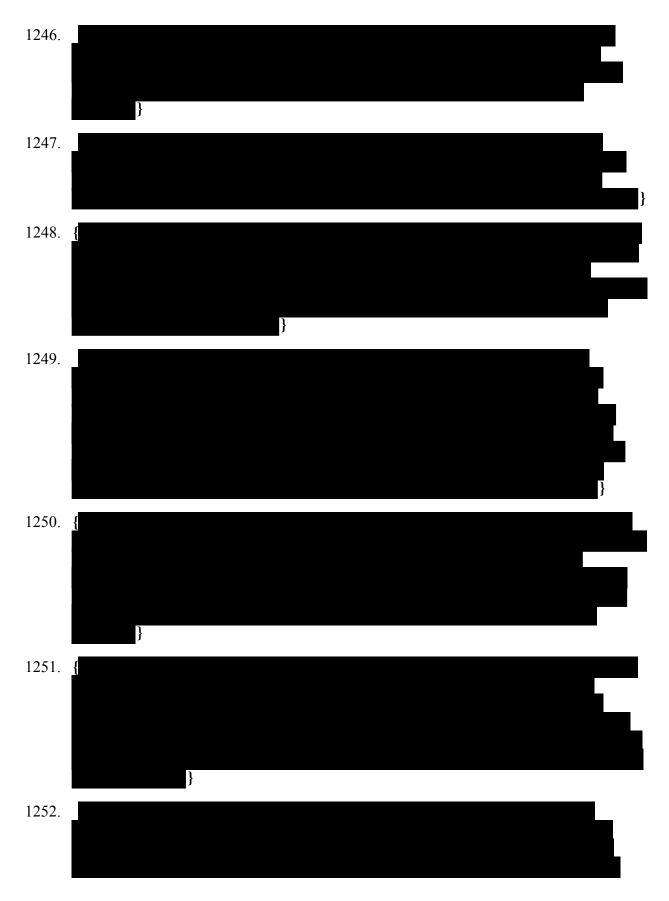


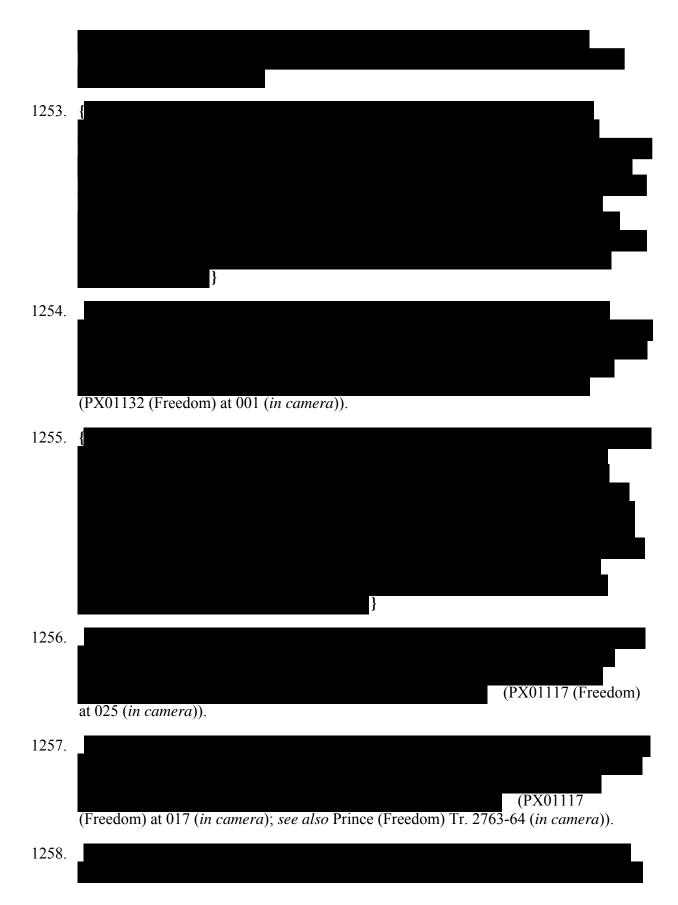


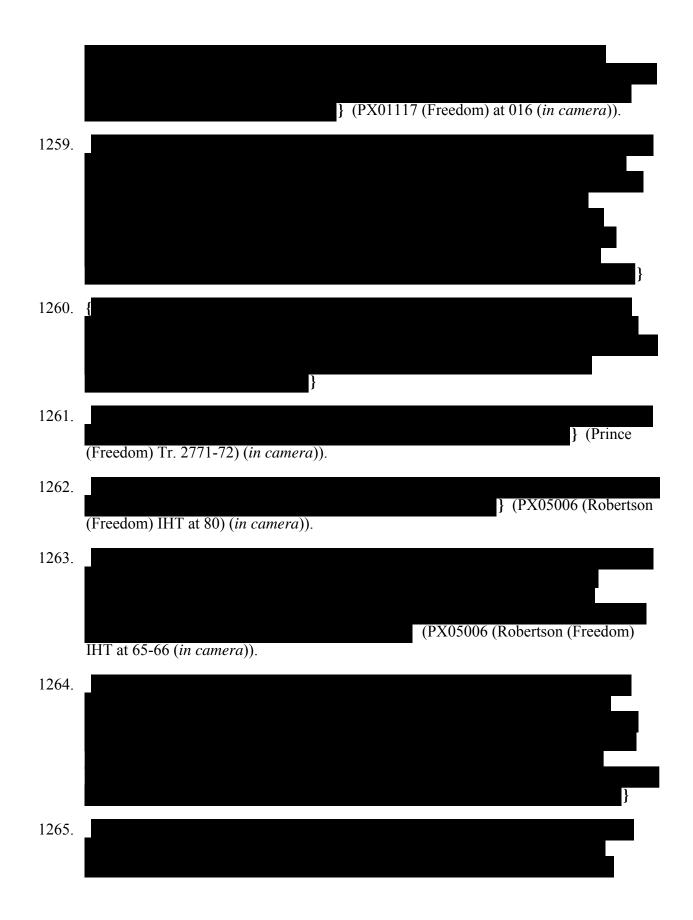
(PX01155 (Freedom) at 087) (in camera)).

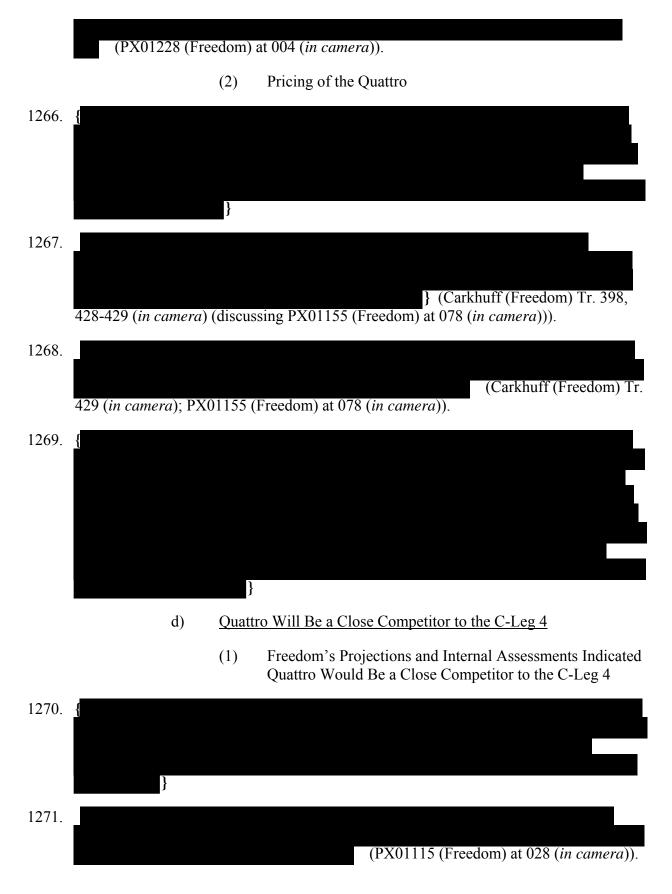


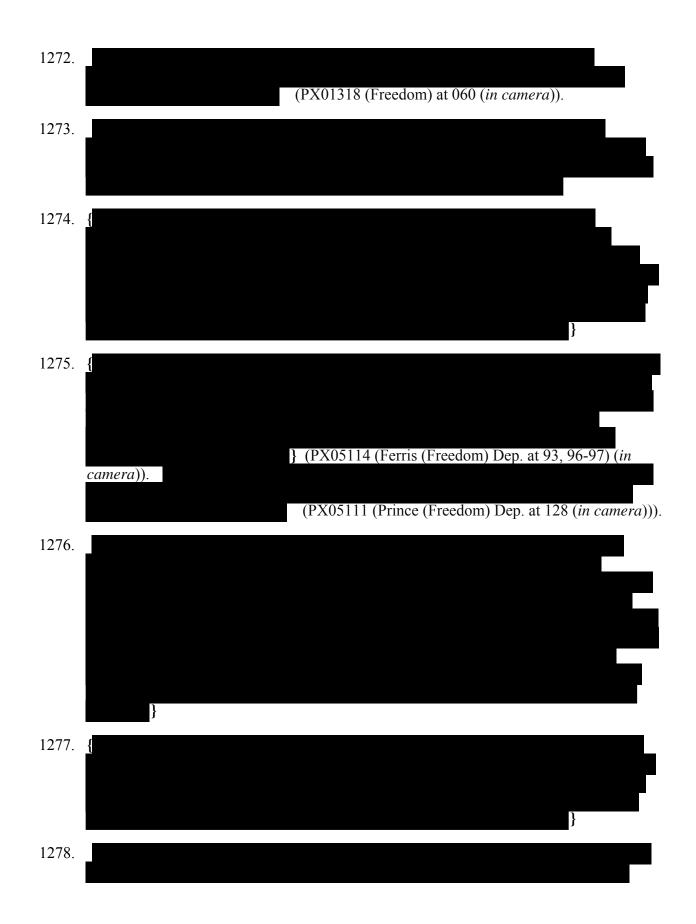
1245. David Smith, Freedom's CEO at the time, confirmed that one advantage of the Quattro design over other MPKs was a shorter build height. (Smith (HEP) Tr. 6528 (*in camera*)). As Mr. Carkhuff testified, the build height of the Quattro was expected to be superior to the C-Leg 4. (Carkhuff (Freedom) Tr. 533 (discussing PX01068 (Freedom) at 031); see also PX01117 (Freedom) at 017 (*in camera*)).

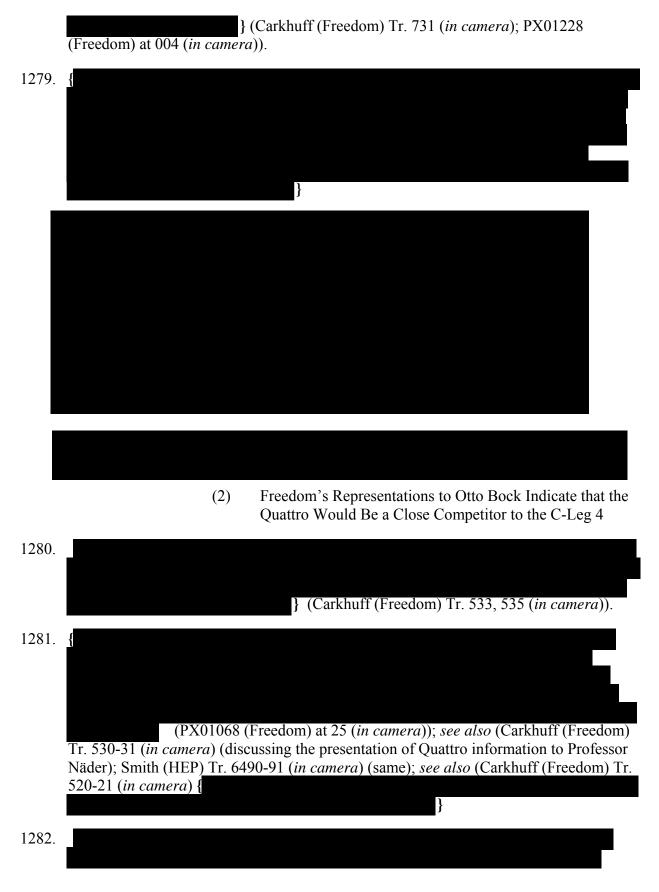






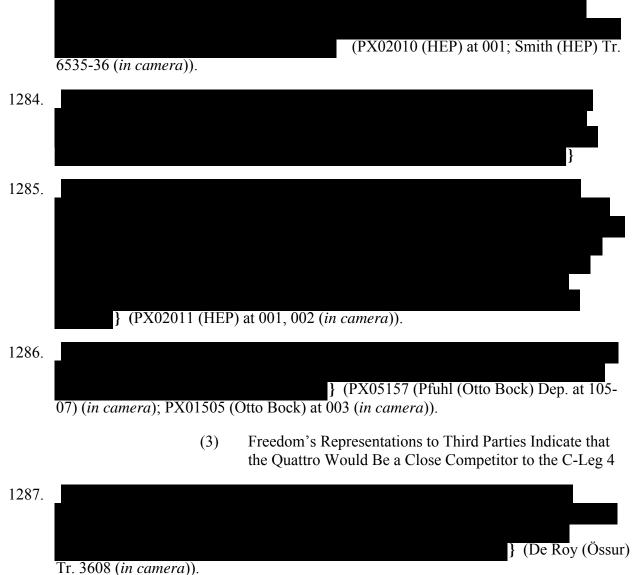




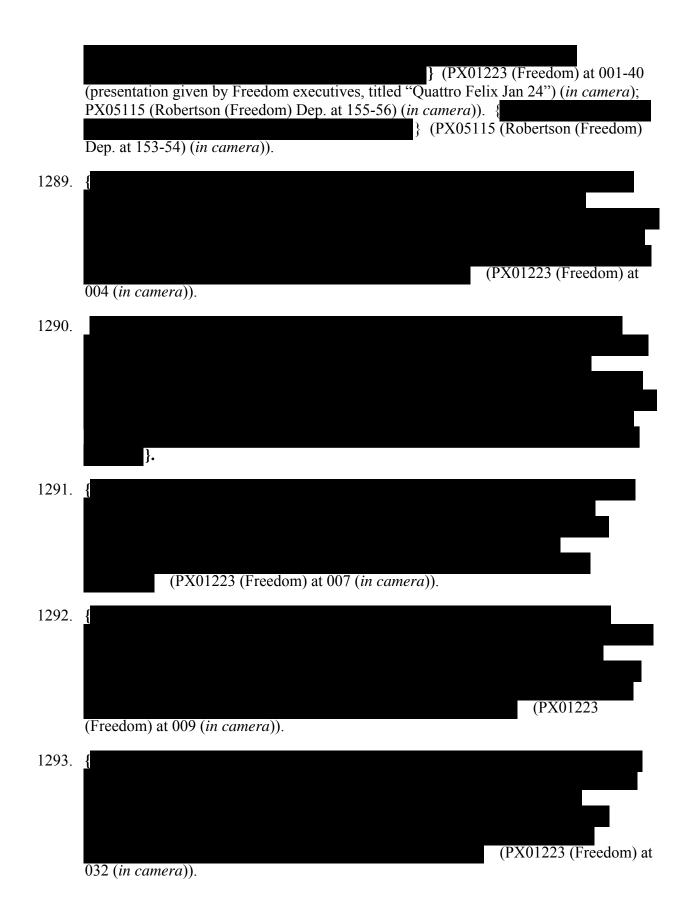


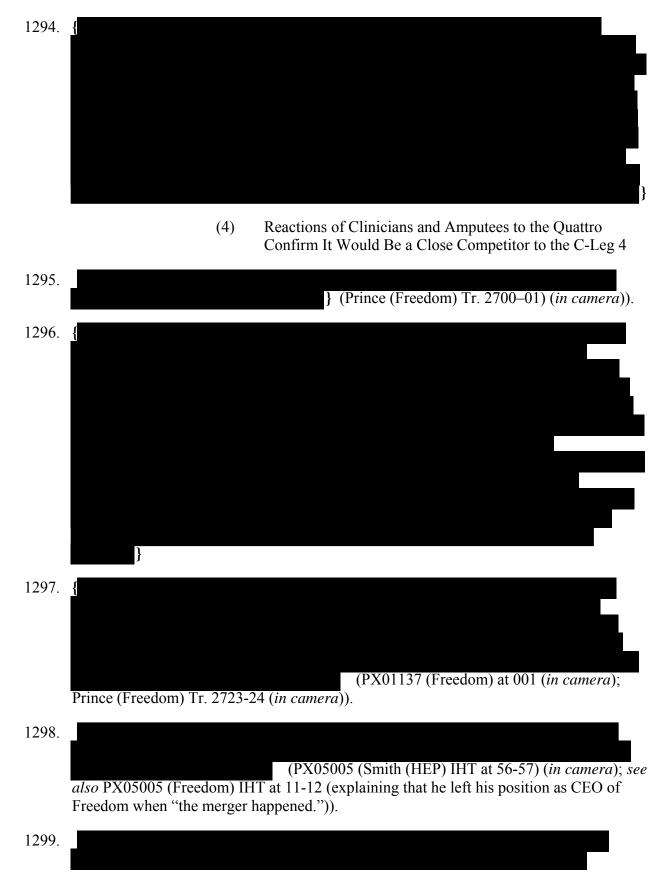


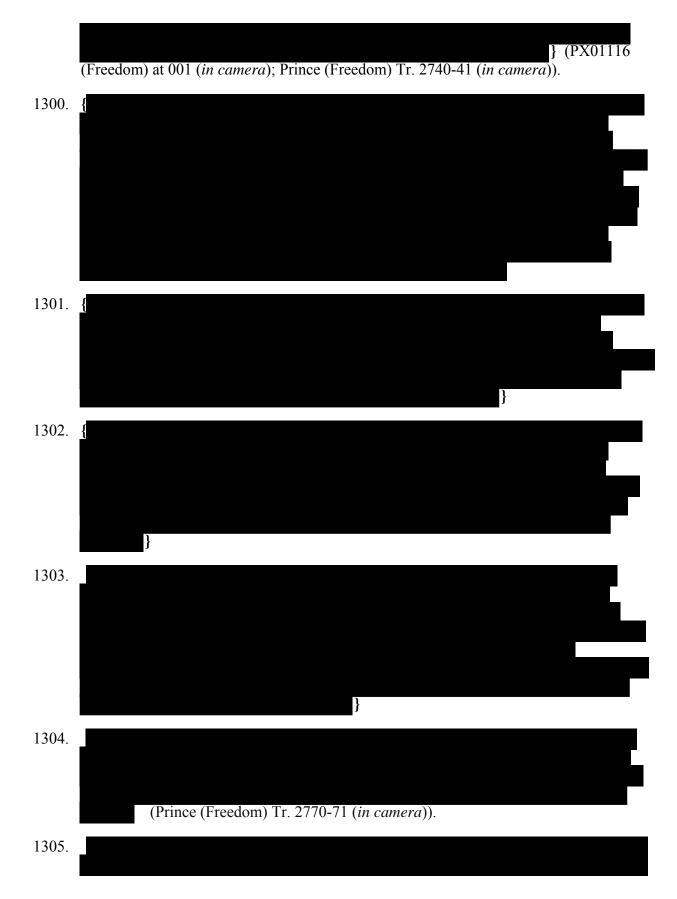
1283. In July 2017, Rolf Classon, a Freedom board member, met with Hans Georg Näder, the CEO of Otto Bock, to discuss a potential sale of Freedom to Otto Bock. David Smith, another Freedom board member, provided Mr. Classon with talking points for the meeting. (PX05122 (Smith (HEP) Dep. at 36-38; PX05005 (Smith (HEP) IHT at 73-74; *see also* PX02010 (HEP) at 001).

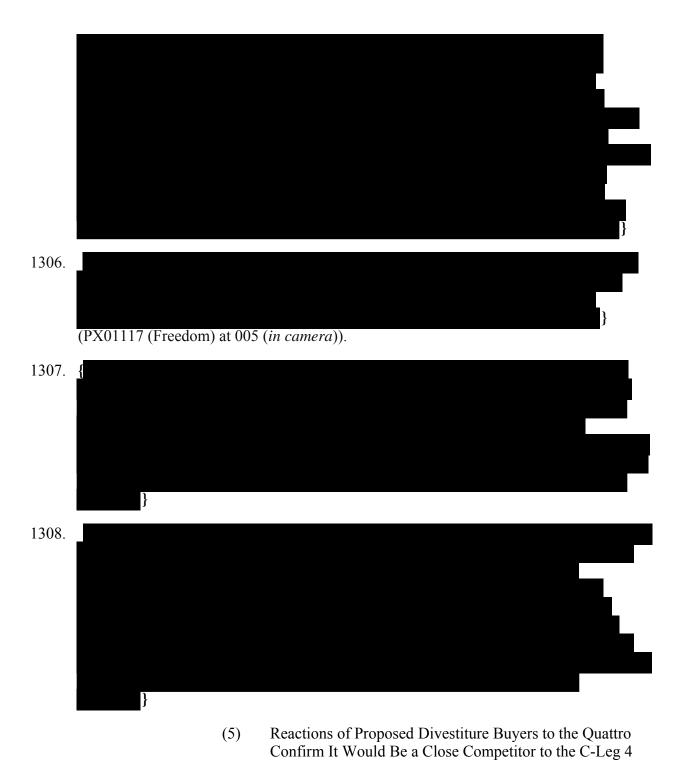








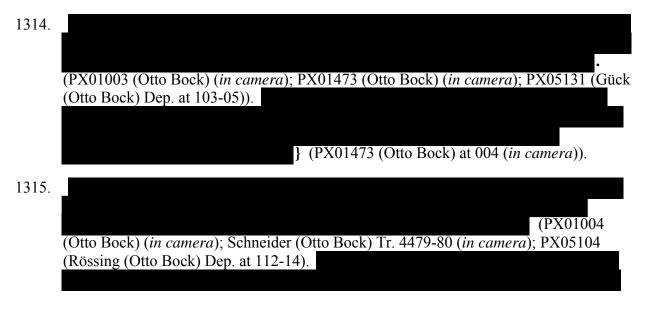






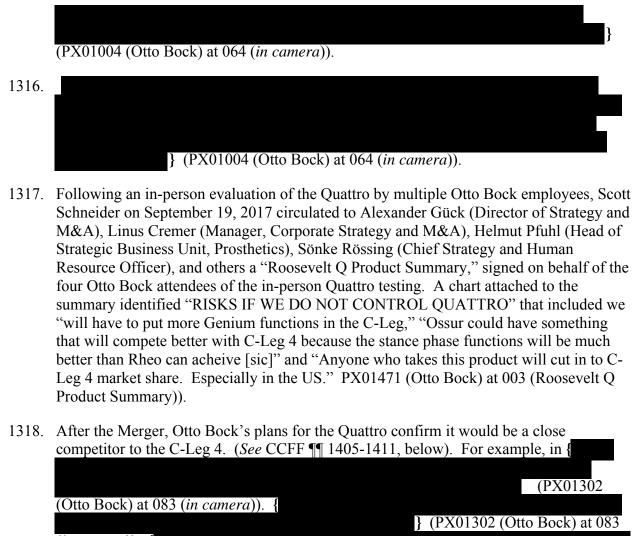
	}	
1310.	{	
		}
1311.		
		} (Mattear (Proteor Inc.) Tr.
1312.	5768-69 (in camera)).	
		(Mottoon (Drotoon Inc.)) Tr. 57(9 (0, 5794 95 (
	(6)	 Mattear (Proteor Inc.) Tr. 5768-69, 5784-85 (<i>in camera</i>)). Otto Bock's Due Diligence and Post-Merger Analysis of

- 6) Otto Bock's Due Diligence and Post-Merger Analysis of Quattro Confirm It Would Be a Close Competitor to the C-Leg 4
- 1313. In August 2017, Jon Hammack from Moelis wrote to David Smith, Freedom's then-CEO, "They've now seen how attractive our pipeline is. They know Quattro is a game changer. They know what it means if Ossur ends up with this." (PX01851 (Freedom) at 001).



} (PX05157

} (Swiggum (Otto



(in camera)). {

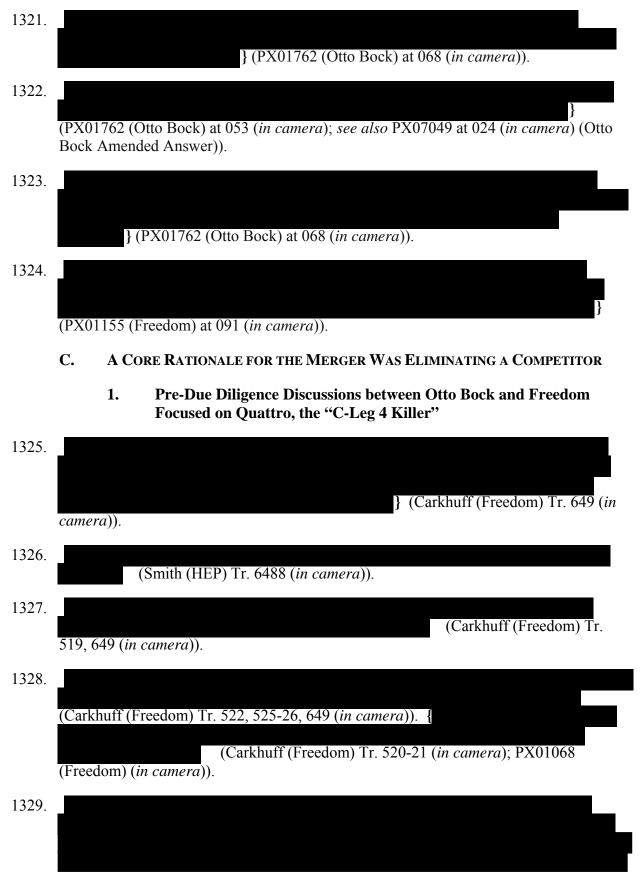
(Pfuhl) Dep. at 172). {

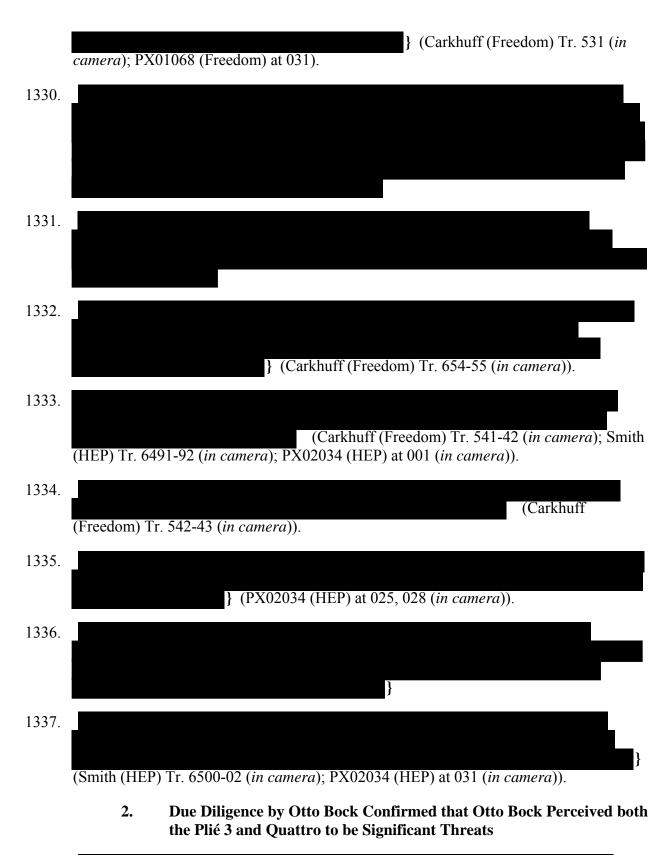
Bock) Tr. 3424) (*in camera*)).

- 2. Otto Bock's Next Generation C-Leg 5
- 1319. } (PX01892

(Otto Bock) at 006 (in camera)).

1320. Around February 2017, Otto Bock began its formal initiative to develop the C-Leg 5. (Schneider (Otto Bock) Tr. 4353-54; *see also* {



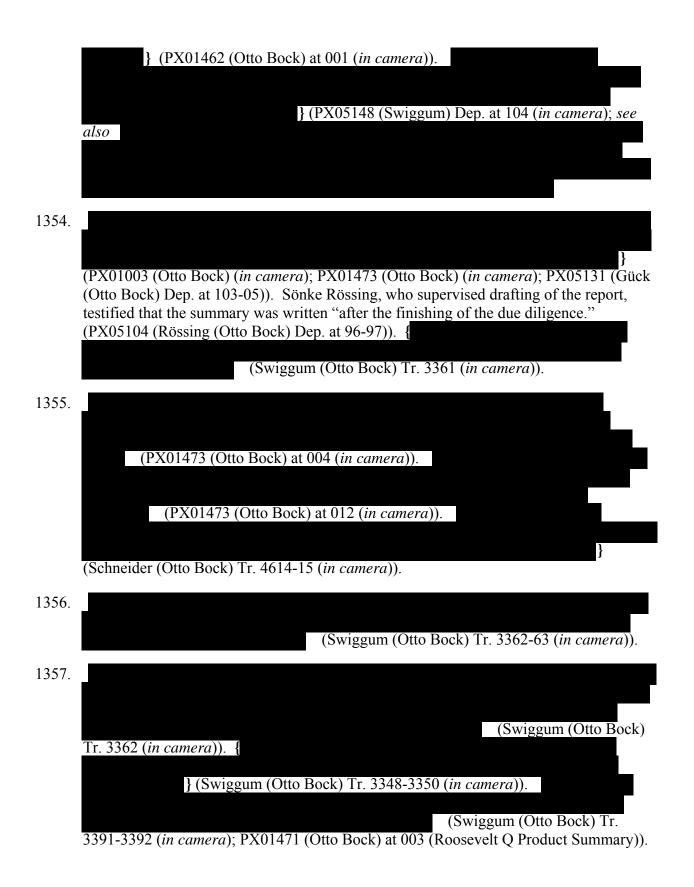


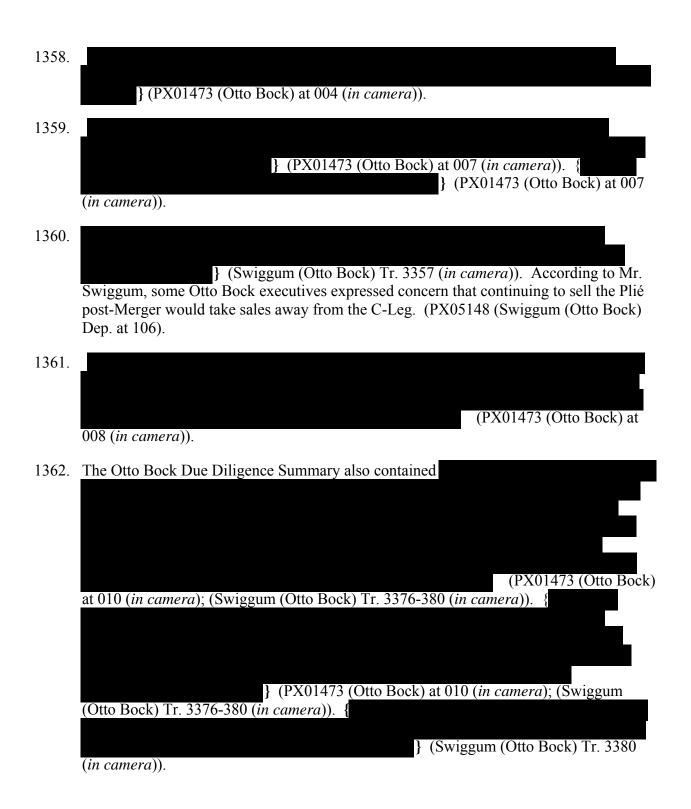
1338.

(Swiggum (Otto Bock) Tr. 3345 (*in camera*); PX05127 (Rössing (Otto Bock) Dep. at 118)).

1339. (Swiggum (Otto Bock) Tr. 3346-47 (in *camera*)). 1340. } (Swiggum (Otto Bock) Tr. 3347-48 (in camera)). 1341. Materials for this debrief were prepared by Mr. Gück and his team, and appear at PX01299. (PX01299 (Otto Bock) (in camera); (PX05131 (Gück (Otto Bock) Dep. at 83-84)). 1342. } (PX01299 (Otto Bock) at 006 (in camera); PX05131 (Gück (Otto Bock) Dep. at 85-86) (in camera)). 1343. (Swiggum (Otto Bock) Tr. 3348-49 (in camera)). 1344. { } (Swiggum (Otto Bock) Tr. 3349-50 (in camera)). 1345. } (Swiggum (Otto Bock) Tr. 3350 (in camera)). 1346. } (PX01465 (Otto Bock) at 2 (*in camera*)).

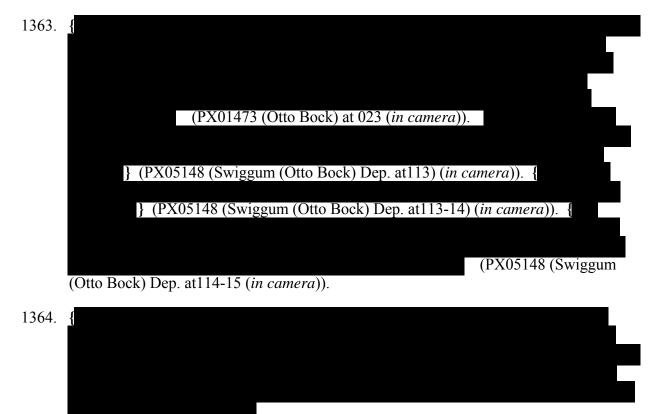
1347.	
	} (Swiggum (Otto Bock) Tr. 3354-55 (in camera)).
	a) <u>North America Due Diligence Report</u>
1348.	
	} (PX01091 (Otto Bock) (in camera); Schneider (Otto Bock) Tr. 4450-52 (in
	<i>camera</i>)). (Schneider (Otto Bock) Tr. 4583
	(in camera)).
1349.	
	(PX01091 (Otto Bock) at 002 (<i>in camera</i>)).
1350.	
	(PX01091 (Otto Bock) at 004 (<i>in camera</i>)).
	(Schneider
	(Otto Bock) Tr. 4453, 4583-84 (in camera)).
1351.	
	} (PX01091 (Otto Bock) at 012 (<i>in camera</i>)).
1352.	(in cumera)).
1552.	
	$(\mathbf{D}\mathbf{V}01001)(01) = \mathbf{D} = 1 + 021$
	(PX01091 (Otto Bock) at 024 (<i>in camera</i>)).
	b) <u>August Due Diligence Discussions</u>
1353.	



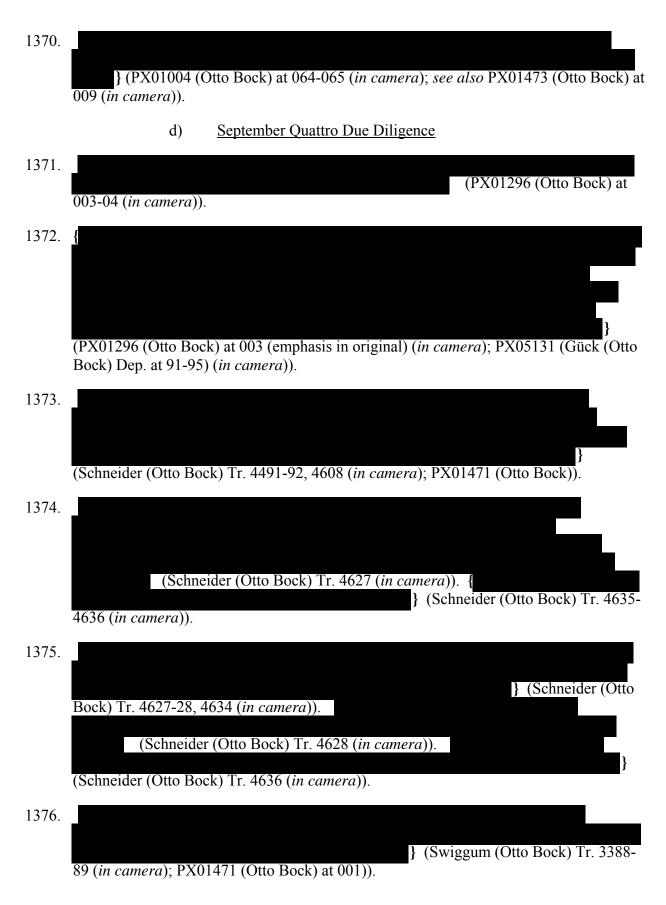


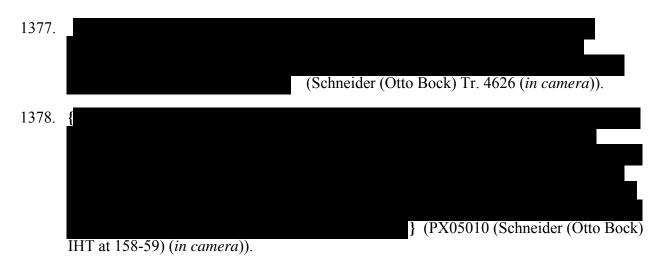


(PX01473 (Otto Bock) at 010 (in camera)).



c) Global Due Diligence Report 1365. } (PX01004 (Otto Bock) (in camera); Schneider (Otto Bock) Tr. 4479-80 (in camera); PX05104 (Rössing (Otto Bock) Dep. at 112-14). (Schneider (Otto Bock) Tr. 4461, 4591 (in camera)). 1366. { (PX01004 (Otto Bock) at 005 (in camera)). 1367. (PX01004 (Otto Bock) at 008 (*in camera*)). (Swiggum (Otto Bock) Tr. 3384 (in camera)). 1368. (PX01004 (Otto Bock) at 056 (in camera)). } (PX01004 (Otto Bock) at 008 (in camera)). 1369. } (PX01004 (Otto Bock) at 064 (*in camera*)). } (PX01004 (Otto Bock) at 064 (*in camera*)).



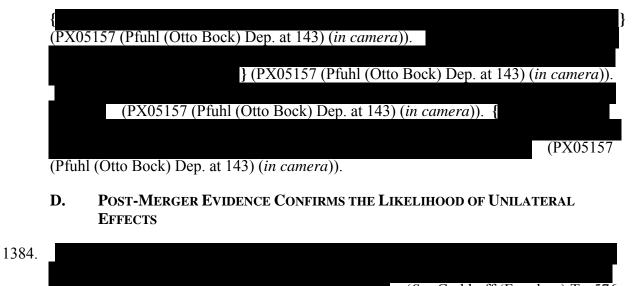


1379. Following the in-person evaluation of the Quattro, Scott Schneider on September 19, 2017 circulated to Alexander Gück (Director of Strategy and M&A), Linus Cremer (Manager, Corporate Strategy and M&A), Helmut Pfuhl (Head of Strategic Business Unit, Prosthetics), Sönke Rössing (Chief Strategy and Human Resource Officer), and others a "Roosevelt Q Product Summary," signed on behalf of the four Otto Bock

attendees of the in-person Quattro testing. (PX01471 (Otto Bock) at 001)).

- 1380. Mr. Schneider's summary concludes "Quick summary: The Quattro is better than we viewed in the Roosevelt videos. There are a few functions/features that are less than CLeg and a few that may be more than CLeg. As an aggregate of PROS and CONS, we believe the Quattro could be (we evaluated Alpha models still challenges to reach Beta) a CLeg contender but will not meet the Genium level." (PX01471 (Otto Bock) at 001).
- 1381. (Schneider (Otto Bock) Tr. 4638 (*in camera*); PX01471 (Otto Bock) at 003)). { } (Schneider (Otto Bock) Tr. 4638-4639 (*in camera*)). (Schneider (Otto Bock) Tr. 4638-39 (*in camera*)).
- 1382. The "PROS" column of the chart noted that the Quattro "Appears 'on par' with C-Leg 4 and a contender," has "[v]ery low noise", and has "[u]ser and CPO apps on Android and iOS." (PX01471 (Otto Bock) at 003). The "RISKS IF WE DO NOT CONTROL QUATTRO" included we "will have to put more Genium functions in the C-Leg," "Ossur could have something that will compete better with C-Leg 4 because the stance phase functions will be much better than Rheo can acheive [sic]" and "Anyone who takes this product will cut in to C-Leg 4 market share. Especially in the US." (PX01471 (Otto Bock) at 003).
- 1383.

} (PX01515 (Otto Bock) at 001 (*in camera*)).



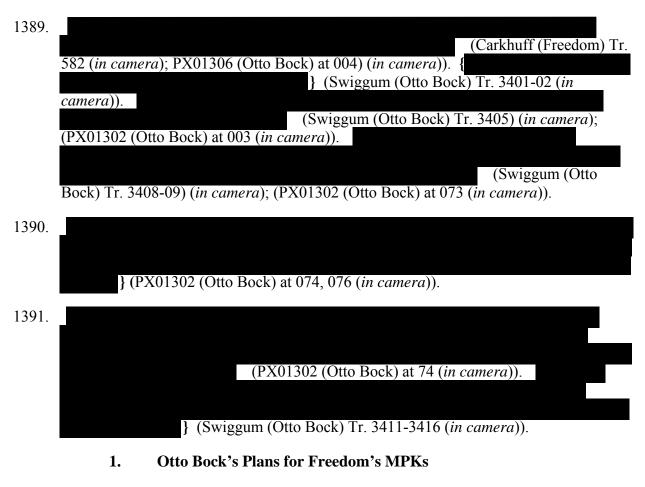
(*See* Carkhuff (Freedom) Tr. 576, 578-84 (*in camera*); PX01306 (Otto Bock) at 002, 004) (*in camera*)). { } (Carkhuff (Freedom) Tr. 576 (*in camera*); *see also* (PX01304 (Otto Bock) at 004 (Freedom Integration: Sales Workshop Meeting Minutes); PX01302 (Otto Bock) at 081-083 (*in camera*); (Swiggum (Otto Bock) Tr. 3398-3399 (*in camera*)).





002 (in camera); (Carkhuff (Freedom) Tr. 578-81 (in camera)).

1386.	(PX01306 (Otto Bock) at 002 (<i>in camera</i>); (Carkhuff (Freedom) Tr. 581-82) (<i>in camera</i>)).
1387.	(PX01306 (Otto Bock) at 002 (<i>in camera</i>); (Carkhuff (Freedom) Tr. 582 (<i>in camera</i>)).
1388.	} (PX01306 (Otto Bock) at 001 (<i>in camera</i>)).



- a) <u>Plié 3 plans</u>
- 1392. At the November 2017 meeting, Otto Bock executives discussed that, prior to the Merger, Freedom had been marketing the Plié 3 against the C-Leg 4 "[i]n a very concentrated way." (PX05157 (Pfuhl (Otto Bock) Dep. at 168)).
- 1393. During Dr. Pfuhl's November presentation, Otto Bock executives expressed concerns that continuing to sell the Plié post-Merger would take sales away from the C-Leg. (PX05148 (Swiggum (Otto Bock) Dep. at 106)).
- 1394.

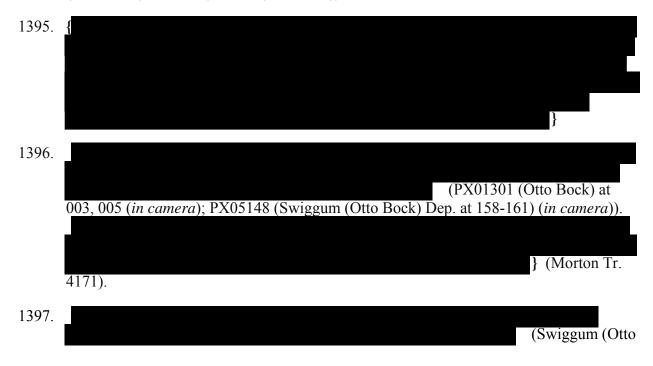
(PX01302 (Otto Bock) at 081 (*in camera*); PX05148 (Swiggum (Otto Bock) Dep. at 175-176)).

} (PX01302 (Otto Bock) at 081

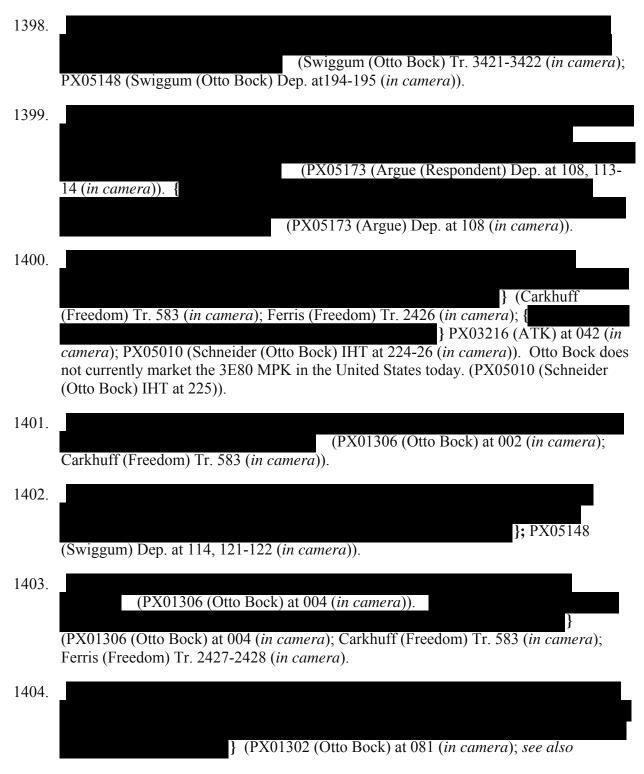
(in camera)).



(PX01302 (Otto Bock) at 081 (in camera))



Bock) Tr. 3421 (*in camera*)). Specifically, Matthew Swiggum, Otto Bock's CEO at the time, testified that, in the context of the dual brand strategy, he and other Otto Bock executives discussed adjusting the price of the Plié 3. (PX05148 Swiggum (Otto Bock) Dep. at 158-59; PX01301 (Otto Bock) at 003, 005 (*in camera*)).



PX05157 (Pfuhl (Otto Bock) Dep. at 168); PX05148 (Swiggum) Dep. at 193 (*in camera*)).

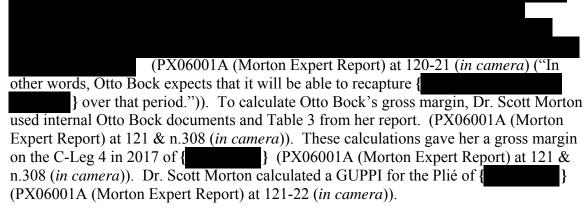
Quattro plans b) 1405. } (PX01301 (Otto Bock) at 003, 005 (in camera); PX05148 (Swiggum (Otto Bock) Dep. at 158-161) (in camera)). 1406. (Swiggum (Otto Bock) Tr. 3397-3398 (in camera); PX05163 (Stuch (Otto Bock) Dep. at 190 (in camera)); PX03215 (ATK) at 008 (in camera); PX01301 (Otto Bock) at 005 (in camera)). 1407. {**A** } (PX01302 (Otto Bock) at 083 (*in camera*)). { (PX01302 (Otto Bock) at 083 (*in camera*)). { } (PX05157 (Pfuhl) Dep. at 172). { } (Swiggum (Otto Bock) Tr. 3424) (in *camera*)). 1408. (Swiggum (Otto Bock) Tr. 3386-3387 (in camera)). (Swiggum (Otto Bock) Tr. 3387 (in camera)). 1409. (PX01306 (Otto Bock) at 004 (in camera)). 1410. } (Carkhuff (Freedom) Tr. 583-84 (in camera)). { (Swiggum (Otto Bock) Tr. 3402 (in camera)). (Swiggum (Otto Bock) Tr. 3402-*03) (in camera)).* 1411.

} (PX01306

(Otto Bock) at 004) (*in camera*); Swiggum (Otto Bock) Tr. 3404 (*in camera*); Carkhuff (Freedom) Tr. 584 (*in camera*)).

2. Dr. Scott Morton's GUPPI Analysis

- 1412. Complaint Counsel's expert, Dr. Fiona Scott Morton, conducted a Gross Upward Pricing Index ("GUPPI") analysis in this case. (PX06001A (Morton Expert Report) at 120-22). Dr. Morton's report explains that, "[a] GUPPI has two primary components—(1) the diversion rate between the product of one firm to the product of the merging partner; and (2) the margin on the product of its merging partner." (PX06001A (Morton Expert Report) at 120). She performed a separate GUPPI analysis on each product of the merging firms. (PX06001A (Morton Expert Report) at 120).
- 1413. Dr. Scott Morton calculated her GUPPI analysis for the Plié by multiplying the revenuebased diversion rate from the Plié 3 to the C-Leg 4 ("D_{PC}") by the percent margin on the C-Leg 4 ("M_C"). (PX06001A (Morton Expert Report) at 120).
- 1414. For the Plié, Dr. Scott Morton relied on {



- 1415. Dr. Morton concluded that, "a GUPPI of **{ accessed** } is associated with a strong incentive to increase the price of the Plié 3, and indicates likely harm to consumers from the merger." (PX06001A (Morton Expert Report) at 122 (*in camera*)).
 - **3.** Customers Have Testified about Their Concerns that the Transaction Will Deprive Them of the Benefit of Competition between Freedom and Otto Bock
- 1416. }
- 1417. Several customers testified that Otto Bock eliminated a significant competitor in the MPK market by acquiring Freedom. (*See, e.g.*, {
 PX05003 (Yates (Jonesboro) Dep. at 73-74, 80-81); PX05140 (Weott

(Orthotic Prosthetic Center) Dep. at 39-40); PX05151 (Patton (Prosthetic Solutions) Dep. at 122); (PX05145 (Ford (POA) Dep. at 70)).

- 1418. (PX01441 (Freedom) at 001 (*in camera*)).
 1419. (Hanger) Tr. 1435 (*in camera*)).
 1420. Curt Patton, the President and owner of Prosthetic Solutions, testified that he is concerned that Otto Bock's acquisition of Freedom will eliminate competition between
- concerned that Otto Bock's acquisition of Freedom will eliminate competition between the companies that has previously benefited Prosthetic Solutions. (PX05151 (Patton (Prosthetic Solutions) Dep. at 122)).
 - a) <u>Concern that Prices will Rise</u>
- 1421. Several customers testified that they believe prices of the Plié and C-Leg will rise because of the Merger. (PX05149 (Brandt (Ability P&O) Dep. at 94); PX05003 (Yates (Jonesboro) IHT at 73-74) (*in camera*); PX05145 (Ford (POA) Dep. at 72-73);

}; PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 39-40)).

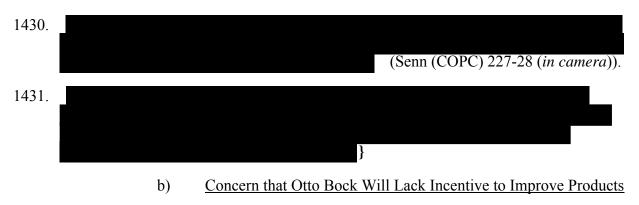
1422. Vinit Asar, CEO of Otto Bock and Freedom's largest customer, Hanger, testified that the Merger is "worrisome" because competition from Freedom had "made sure the other three [MPK' manufacturers] were being competitive." (PX05153B (Asar (Hanger) Dep. at 123-25)).

1423.			
	(PX05002 (Asar (Hanger) IHT at 58) (in camera)).		
1424.	40 (in camera) (discussing PX03205)).	(Asar (Hanger) Tr. 1439-	_
1425.	(PX05002 (Asar (Hanger) IHT at 52) (in camera)).		

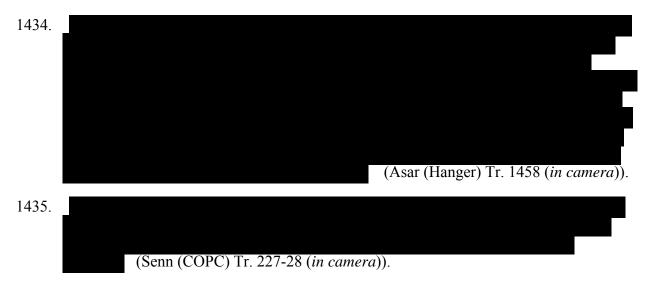
- 1426. Rob Yates, President and CEO of Jonesboro Prosthetic and Orthotic Laboratory, testified Otto Bock "certainly" could begin charging more for the Plié following the acquisition. (PX05003 (Yates (Jonesboro) IHT at 73-74)).
- 1427. Mark Ford, President and Managing Partner of Prosthetic & Orthotic Associates, testified that he believes the price for the Plié 3 would creep upwards under the ownership of Otto Bock and that he would lose his ability to pit Freedom as an independent entity against Otto Bock to receive better pricing. (PX05145 (Ford (POA) Dep. at 72-73)).
- 1428. Jeffrey Brandt from Ability Prosthetics and Orthotics testified that he is concerned "prices will start going back up" for the Plié and the C-Leg as a result of the Merger, and



1429. Keith Senn, President of Kentucky/Indiana Operations at the Center for Orthotic and Prosthetic Care, testified that he is "concerned about cost" given that "there's a significant difference between the cost of a Pli3 [sic] and a C-Leg 4." (PX05004 (Senn (COPC) IHT at 42-43)).



- 1432. (*See, e.g.*, Ford (POA) Tr. 1015-16; Senn (COPC) Tr. 227-28 (*in camera*); (Asar (Hanger) Tr. 1458 (*in camera*); PX05004 (Senn (COPC) IHT at 42-43)).
- 1433. Mark Ford, President and Managing Partner at Prosthetic and Orthotic Associates, testified that the "similar ideas and similar platforms" used by Freedom and Otto Bock for the Plié and C-Leg, respectively, causes him concern that the "inherent stronger competition" between the companies will be lost. Mr. Ford further testified that, with respect to Össur's Rheo, that MPK "is used by a lot of practices, but it's certainly viewed as a different product than the C-Leg or the Plié knee because of the platform, the functional platform that it's built on, so while they're both in the MPK category, there are differences there." (Ford (POA) Tr. 1015-16).



- 1436. Mr. Senn further testified that he is worried about the potential lack of "increased innovation, you know, new product lines, increased opportunity for our patients" post-Merger. (PX05004 (Senn (COPC) IHT at 42-43)).
 - c) <u>Concern that Merger Will Harm End Users</u>
- 1437. When prosthetic clinics receive lower prices for MPKs, customers testified that it increases the margin that the clinic receives on the device. (*See, e.g.*, Asar (Hanger) Tr. 1411; PX05108 (Yates (Jonesboro) Dep. at 74-75); PX05128 (Senn (COPC) Dep. at 34)).
- 1438. Prosthetic clinics testified that they use their increased margins to provide additional services to end users.

PX05128 (Senn (COPC) Dep. at 34)).

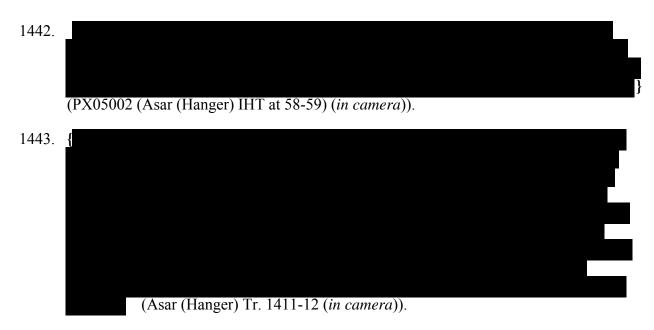
1439. For example, prosthetic clinics testified that they fund value-added services for patients with their additional profit. {

(PX05108 (Yates (Jonesboro) Dep. at

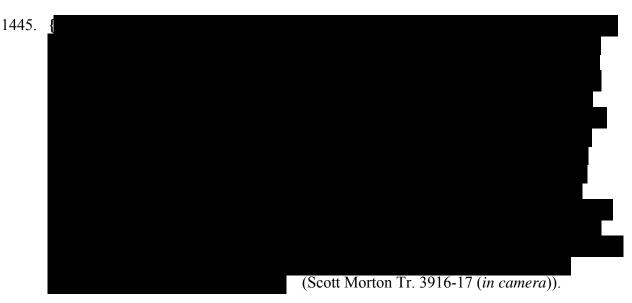
}.

75-76) (in camera)).

- 1440. } (Ford (POA) Tr. 1027-28 (*in camera*); PX05108 (Yates (Jonesboro) Dep. at 74-75); PX05128 (Senn (COPC) Dep. at 34)).
- 1441. Increased margins also translate to improved facilities for patients, according to prosthetic clinics who testified. {

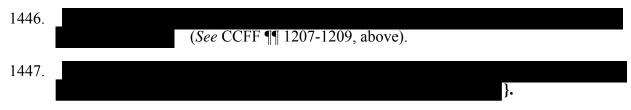


1444. In addition to price, Mark Ford of POA testified that "patients aren't going to benefit as much from new developments, new innovations and new support" after the Merger. (PX05145 (Ford (POA) Dep. at 71)).



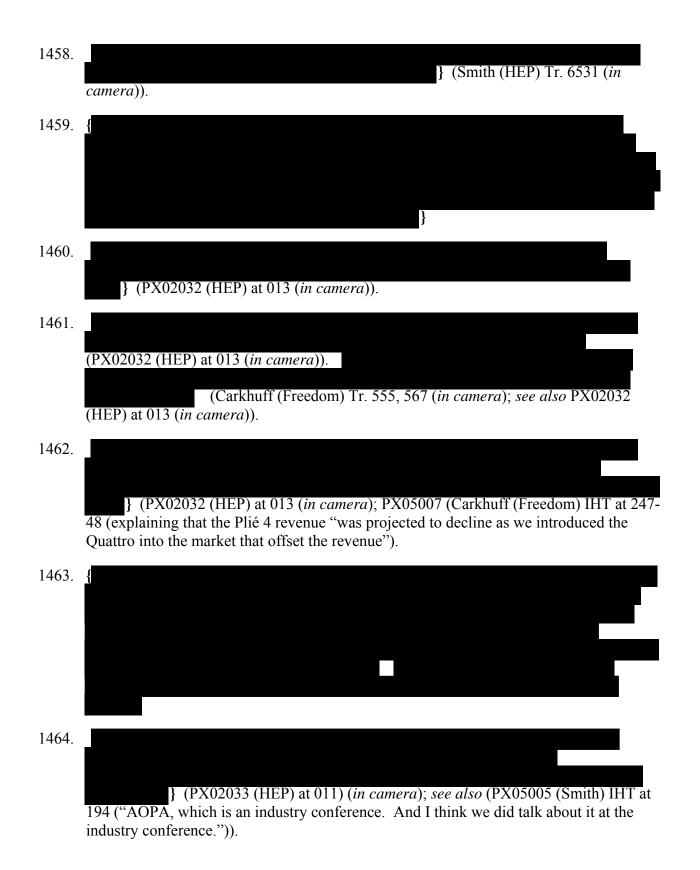
E. THE MERGER HAS ALREADY CAUSED HARM

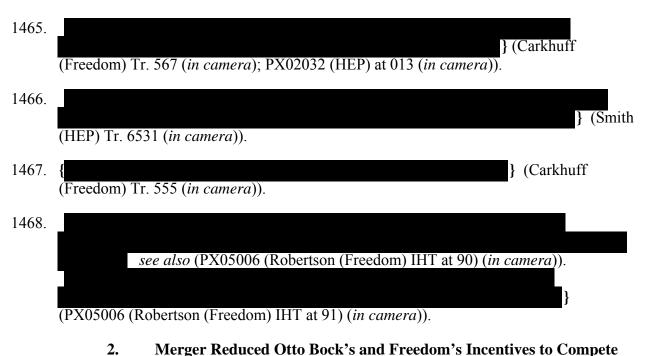
- 1. Product Delays
 - a) <u>Quattro Launch Delay from the Merger</u>



1448.	
	} (PX01117 (Freedom) at 014).
1449.	Robertson (Freedom) IHT at 39 (<i>in camera</i>))).
1450.	} (<i>See</i> CCFF ¶¶ 1290, 1294 above).
1451.	(PX05111 (Prince (Freedom) Dep. at 75 (in camera)).
1452.	According to Dr. Prince, the Quattro Project Manager and Technical Leader, while Quattro development has continued post-Merger, the Merger has "definitely slowed down the entire [Quattro] project." (PX05111 (Prince (Freedom) Dep. at 148)).
1453.	} (PX05115 (Robertson (Freedom) Dep. at 53) (<i>in camera</i>)).
1454.	(Carkhuff (Freedom) Tr. 731 (<i>in camera</i>); Prince (Freedom) Tr. 2796-97 (<i>in camera</i>)).
1455.	} (<i>See</i> CCFF ¶¶ 1228, 1229, above). b) <u>Plié 4 (Fast Fit) Delay</u>
1456.	(Carkhuff (Freedom) Tr. 396-397 (in camera)).
1457.	(PX05006 (Robertson (Freedom) IHT at 90) (<i>in camera</i>)). Specifically, the Plié 4 would have improved the "Ease of programming to speed up the programming of the product." (PX05005 (Smith) IHT at 66). (Smith (HEP) Tr. 6548 (<i>in camera</i>)).

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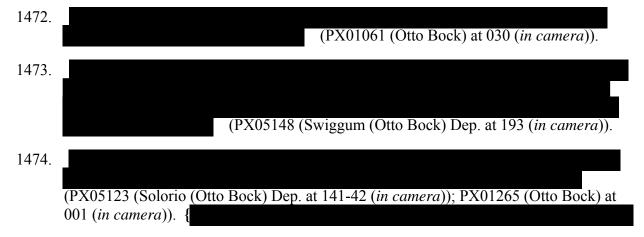


and Provided Respondent an Ability to Raise MPK Prices

- 1469. Dr. Helmut Pfuhl, Otto Bock's Head of Strategic Business Unit Prosthetics, explained that Freedom had previously marketed the Plié 3 "[i]n a very concentrated way" against Otto Bock's C-Leg 4. (PX05157 (Pfuhl (Otto Bock) Dep. at 168)).
- 1470. For example, just weeks before the Merger in September 2017, Otto Bock continued to compete aggressively against Freedom.

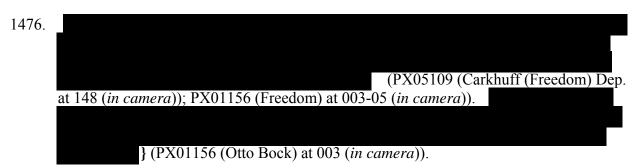
(PX01602 (Otto Bock) at 001 (in camera)).

1471. Immediately prior to the Merger, Otto Bock Executive Medical Director of North America, Andreas Kannenberg, recognized that acquiring Freedom would affect how Otto Bock competed. Dr. Kannenberg wrote to Milana Mileusnic on September 7, 2017 that, "There is something going on that I cannot yet talk about but that may force us to stop attacking the Plie." (PX01547 (Otto Bock) at 002).



(PX01265 (Otto Bock) at 001) (*in camera*)).

1475. On October 5, 2017, Matt Swiggum, Otto Bock's CEO at the time, wrote to Jeremy Mathews, Freedom's Senior VP of Sales and Marketing, to address a complaint from Kyra Velett Strupp, Florida Territory Manager from Freedom, regarding an Otto Bock sales representative making false Plie 3 claims. (PX01425 (Freedom) at 001-003). In response to this complaint, Mr. Swiggum wrote, "We are absolutely one company today and the target is not each other!" (PX05137 (Matthews (Freedom) Dep. at 234); PX01425 (Freedom) at 001). Mr. Mathews responds with, "as long as we are aligned in our messaging, we will get through this." (PX01425 (Freedom) at 001).



- 1477. David Reissfelder, the Freedom CEO put in place by Otto Bock after the Merger, testified that Matthew Swiggum (Otto Bock's CEO at the time of the Merger) and Andreas Schultz (Otto Bock's CFO), also expressed concern to him about perceived aggressive promotions and discounting on the Plié 3 after the Merger. Mr. Reissfelder testified that Mr. Swiggum and Mr. Schultz told him that "they felt like it was a lot of discounting" and "they thought that it wasn't something they would allow the OttoBock sales team to do, and therefore they recommended or they wanted us to stop doing it." (PX05138 (Reissfelder (Freedom) Dep. at 89-90)).
- 1478. Customers experienced negative consequences from the changed incenctives created by the Merger. For example, Mr. Endrikat of Empire Medical explained that his Freedom sales representative used to sell the Plié 3 by "selling against the C-Leg 4 mostly," but post-Merger, the sales representative informed Mr. Endrikat that "I'm now competing against my partner . . . it's a mental shift." According to Mr. Endrikat, his sales representative no longer "talk[ed] bad about" Otto Bock. (PX05116 (Endrikat (Empire) Dep. at 127-28)).
- 1479. Mark Ford, President and Managing Partner of Prosthetic and Orthotic Associates (POA), testified that Freedom previously offered a cooperative marketing arrangement to POA "[l]ast summer." (Ford (POA) Tr. 1014). The cooperative marketing arrangement would have benefited POA by leveraging manufacturers' "marketing dollars in our individual markets to benefit them as well as us." (Ford (POA) Tr. 1013). After the Merger, "everything got put on hold," and Mr. Ford has not heard anything from Freedom about the status of the cooperative marketing agreement. Ford (POA) Tr. 1014).

X. REMAINING COMPETITORS WILL NOT CONSTRAIN MERGER'S LIKELY ANTICOMPETITIVE EFFECTS

A. ÖSSUR

1. Össur's MPKs Rely On Functionally Different Technology Than Otto Bock's C-Leg 4 and Freedom's Plié

- 1480. Össur's Executive Vice President of R&D, Kim De Roy, testified that the company's MPKs use a unique and proprietary "magnetorheologic technology," which creates a magnetic field that builds a level of resistance to allow the knee to function. (De Roy (Össur) Tr. 3576-77); *see also* Blatchford (Endolite) Tr. 2148-49).
- 1481. The Össur Rheo MPK operates on a "very different platform" compared to the C-Leg 4 and the Plié 3, which both use "hydraulic technology" and are "more similar" to one another. (De Roy (Össur) Tr. 3591-93). Mr. De Roy of Össur testified that "patients will report that they feel . . . somewhat more stable when they're walking on a hydraulic unit because it is stiffer versus on a Rheo knee" (De Roy (Össur) Tr. 3592).
- 1482. Össur's Executive Vice President of R&D, Kim De Roy, testified that the Freedom Plié 3 is "more similar to the C-Leg 4" than the Össur Rheo because the Plié 3 and C-Leg 4 use hydraulic technology to provide resistance, while Össur's Rheo does not. (De Roy (Össur) Tr. 3592-93)
- 1483. } (See, e.g., Ford (POA) Tr. 950-51; Senn (COPC) Tr. 223-24 (in camera); PX05001 (Endrikat (Empire Medical), IHT at 21-23)).
- 1484. Mark Ford, President and CEO of POA, testified that the Össur Rheo is "viewed as a different product than the C-Leg or the Plié knee because of the platform, the functional platform that it's built on, so while they're both in the MPK category, there are differences there. So they are competition, the Rheo knee is competition for the C-Leg, but for many clinicians it's not as close a competition as the Plié is to the C-Leg." (Ford (POA) Tr. 1016).
- 1485. Mark Ford, President and CEO of POA, testified that compared to the Otto Bock C-Leg 4, the Össur Rheo MPK is "built on a different technology with magnetic fluids versus a hydraulic fluid system, and that changes the way the knee operates." (Ford (POA) Tr. 950). Moreover, Mr. Ford testified that compared to the Össur Rheo, Freedom's Plié 3 "is much more similarly designed to the C-Leg, does not use the magnetic fluid in the same way that the Össur knee does, and it's just the entire way that it operates is much more similar to the C-Leg than it is to the Rheo." (Ford (POA) Tr. 951).
- 1486. Jonathan Endrikat, the CEO of Empire Medical, testified that the population base that uses Össur's Rheo "isn't as broad" and it "takes a specific type of walker" to use the Össur's Rheo MPK. (PX05001 (Endrikat (Empire Medical) IHT at 21-22)).

1487.

(Senn (COPC) Tr. 223 (in camera)).

- 1488. Some clinics do not like the Össur Rheo in comparison to the Otto Bock and Freedom MPKs. (PX05128 (Senn (COPC) Dep. at 44) (testifying that "the practitioners do not like the Rheo knee and the the functions or the capability of that knee they do not feel compare to the Freedom and Ottobock knees at this time.")); PX05141 (Bright (North Bay) Dep. at 40-41)).
- 1489. Keith Senn, COPC's President of the Kentucky and Indiana offices, testified that COPC purchased fewer Rheo MPKs than Plié and C-Leg MPKs, from January 2017 to November 2017, because "the practitioners do not like the Rheo knee and the the functions or the capability of that knee they do not feel compare to the Freedom and Ottobock knees at this time." (PX05128 (Senn (COPC) Dep. at 44).
- 1490. Michael Bright, owner of North Bay Prosthetics and Orthotics, testified that North Bay has not trialed patients with the latest-version of the Rheo because "North Bay has not heard from anybody else in the industry a reason to, and after trialing a few times if something isn't working we're not willing to subject our patients to being guinea pigs of a manufacturer's product." (PX05141 (Bright (North Bay) Dep. at 41)).
- 1491. Michael Bright, owner of North Bay Prosthetics and Orthotics, testified in April 2018 that most patients who chose a different MPK after a trial fitting of the Rheo did so because "most just preferred the feel and function of either the Freedom Plie or the Otto Bock C-Leg." (PX05141 (Bright (North Bay) Dep. at 38)).

1492.		
		} (PX03103 (Ossur) at 007
	(in camera)).	
		(PX03103 (Össur) at 007 (in
	camera)).	
	2	Össun's MDK Tashnalagy Is Associated with Safety and Deliability

2. Össur's MPK Technology Is Associated with Safety and Reliability Concerns Among Clinic Customers

1493.		
	(PX01004 (Otto Bock) at 056) (<i>in camera</i>)).	
	} (PX01004 (Otto Bock) at 056) (<i>in camera</i>)).	

1494. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified similarly that the Össur Rheo knee "go[es] into a free swing when the battery was dead" while the Otto Bock microprocessor knees "have the safety of

locking up" if the battery dies or malfunctions. (PX05010 (Schneider (Otto Bock) IHT at 108-109)).

- 1495. Manar Ammouri, Freedom's Senior Product Manager, explained that Össur's Rheo knee causes a "safety concern" because "[w]hen the product goes into dead battery mode, the knee goes into free swing, which means it's loose, it's not stable." (PX05112 (Ammouri (Freedom) Dep. at 197-198)).
- 1496. Manar Ammouri, Freedom's Senior Product Manager, testified that "even when there is a dead battery, the Plié goes into stance for stability and safety." This feature is different from Össur Rheo, which advertises "a manual lock feature for when the battery dies," because a Plié user does not require "engag[ing] a manual lock." (PX05112 (Ammouri (Freedom) Dep. at 122)).
- 1497. Manar Ammouri, Freedom's Senior Product Manager, testified that the Rheo's lack of water resistance is a weakness for some patients. She explained, "[i]f their environment requires them to be near water, then I would say yes, it's a weakness." (PX05112 (Ammouri (Freedom) Dep. at 196-97)).
- 1498. Manar Ammouri, Freedom's Senior Product Manager, testified that the "Rheo 3 has a reputation of being boxy." (PX05112 (Ammouri (Freedom) Dep. at 198).
- 1499. In an email that Stephen Prince, Freedom's Quattro Project Leader, sent to Freedom Engineers Rob Glidden and Jonathan Byars on March 16, 2016, a set of notes under a header for "Marketing (Eric, Manar) – Input on size limitations" includes "I have read online forum posts saying the Rheo looks 'clunky and robotic', want to avoid this scenario…" (PX01123 (Freedom) at 001 (ellipsis in the original)).
- 1500. Freedom's Senior Product Manager, Manar Ammouri, testified in March 2018 that customers have told her that the weight of the Rheo is a weakness for the MPK. She elaborated that the customers told her "it's heavy or heavier" and testified that "[t]he heavier the product, the harder it is to decreases the number of patients you can put it on. Imagine a 90-pound female carrying around a five-pound device, that kind of eliminates her from using that product. You want to make sure you've got a light product that is usable on several patients or a spectrum of patients." (PX05112 (Ammouri (Freedom) Dep. at 197)).
- 1501. Third-party witnesses have testified about safety concerns with respect to the Össur Rheo knee. (PX05001 (Endrikat (Empire Medical) IHT at 21-22; PX05128 (Senn (COPC) Dep. at 82-83); PX05129 (Ell (Mid-Missouri) Dep. at 74).
- 1502. Mr. Sabolich, the owner and Clinical Director of Scott Sabolich Prosthetics and Research, testified that in February 2015 his clinic "had one of [their] patients fall on a Rheo Knee, and it broke literally in half." (Sabolich (Scott Sabolich Prosthetics and Research) Tr. 5889-90). After the incident, he explained that Össur "didn't want to pay the guy's \$1800 visit to the hospital and new glasses" (Sabolich (Scott Sabolich Prosthetics and Research) Tr. 5889-90).

- 1503. Jonathan Endrikat, CEO of Empire Medical, testified that the safety profile for the Freedom Plié is "more similar to the Ottobock C-Leg" than the Össur Rheo. (PX05001 (Endrikat (Empire Medical) IHT at 22-23)).
- 1504. Jonathan Endrikat, CEO of Empire Medical, stated that unlike the "safety mode" that occurs in the C-Leg and Plié when the battery runs out, the Össur Rheo goes into "free swing" that is unable to support the person's weight, resulting in "the perception being that it's not as safe because it goes into free swing." (PX05001 (Endrikat (Empire Medical), IHT at 21-22)).
- 1505. Likewise, Keith Senn, President of Kentucky/Indiana of COPC, testified that the company "steer[s]" patients to the safer MPKs from Freedom and Otto Bock, instead of the Össur Rheo, because "when the battery goes out on the Rheo, it goes into free swing phase, whereas the C-Leg goes into stiff mode phase . . . [when the Rheo] goes into free swing . . . that's increasing your risk of falls which is the whole purpose of the MPK." (PX05128 (Senn (COPC) Dep. at 82-83)).
- 1506. (Senn (COPC) Tr. 224 (*in camera*)).
- 1507. Jeffrey Brandt, the CEO of Ability Prosthetics and Orthotics, testified in April 2018 that "I personally don't feel like – you know, I feel like Össur has been a little absent on the microprocessor knee stage. Now, whether the Rheo XC is, you know, bringing a new – a whole other game to the town here – game to town. But their Rheo came out a long time ago and I feel like it was marginally adopted and just sort of – I didn't really hear about it after that for a long time." (PX05149 (Brandt (Ability Prosthetics and Orthotics) Dep. at 234)).
- 1508. In April 2018, Keith Watson, the President of Fourroux Prosthetics, testified, "[w]hen you go down a ramp [in Össur Rheos], they tend to click click click click click click. Because I think the signal, the electric pulse that is going to make the fluid a solid and then release and then make it a solid, from secondary feedback from patients, they can feel that. And it just feels unstable. Anytime anytime it brakes and release, brake, release, brake, release, it tends it has in my experience, it tends to make the patient not trust it." (PX05166 (Watson (Fourroux Prosthetics) Dep. at 142-143)).
- 1509. In April 2018, Michael Bright, owner of North Bay Prosthetics and Orthotics, testified his clinic does not purchase Össur's Rheo because they "[j]ust did not have good clinical outcomes when we last used it." (PX05141 (Bright (North Bay) Dep. at 201-202)).
- 1510. Mark Ford, President of Prosthetic and Orthotics Associates, testified that his clinic has only bought Freedom's Plié and Otto Bock's C-Leg in the last two years because of ["[p]atient preference and clinician preference in terms of what they think the patient is going to get out of the device." (Ford (POA) Tr. 954).

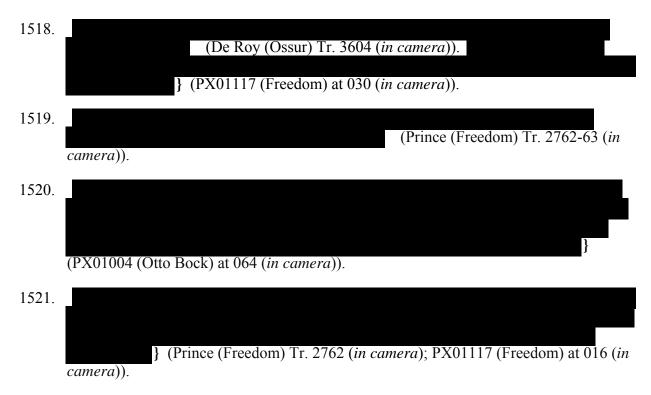
1511. Keith Senn of COPC testified that {

} (Senn (COPC) Tr. 224 (in camera)).

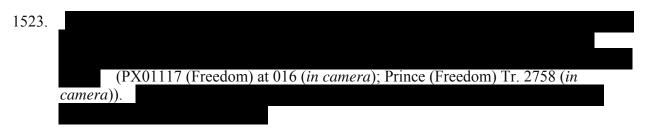
- 1512. Jeffrey Brandt, the CEO of Ability Prosthetics and Orthotics, testified in April 2018 that "I personally don't feel like – you know, I feel like Össur has been a little absent on the microprocessor knee stage. Now, whether the Rheo XC is, you know, bringing a new – a whole other game to the town here – game to town. But their Rheo came out a long time ago and I feel like it was marginally adopted and just sort of – I didn't' really hear about it after that for a long time." (PX05149 (Brandt (Ability Prosthetics and Orthotics) Dep. at 234)).
- 1513. Keith Watson, the President of Fourroux Prosthetics, testified in April 2018 that Össur's Rheo was "racheted" when his clinic fit the knee "several years" ago, which he attributes to its design and function. Mr. Watson explained, "When you go down a ramp, they tend to click click click click click. Because I think the signal, the electric pulse that is going to make the fluid a solid and then release and then make it a solid, from secondary feedback from patients, they can feel that. And it just feels unstable. Anytime anytime it brakes and release, brake, release, brake, release, it tends it has in my experience, it tends to make the patient not trust it." (PX05166 (Watson (Fourroux Prosthetics) Dep. at 142-143)).
- 1514. Robert Yates, the President and CEO of Jonesboro P&O Labs, also testified that "functional reliability" issues with early versions of the Rheo led to "disappointments" with the MPK. Mr. Yates explained, "It – instead of having a fluid motion, it would develop a chatter, so it didn't – it didn't move smoothly during stance phase, so we stopped using them. And then I think we had some, you know, service-related like power management issues." (PX05108 (Yates (Jonesboro P&O Labs) Dep. at 105).
- 1515. Michael Bright, owner of North Bay Prosthetics and Orthotics, testified in April 2018 that his clinic "[j]ust did not have good clinical outcomes" when it "last used" the Rheo. (PX05141 (Bright (North Bay) Dep. at 201-202)).
- 1516. Mark Ford, President of Prosthetic and Orthotics Associates, testified that his clinic only fit Freedom's Plié and Otto Bock's C-Leg on patients because ["[p]atient preference and clinician preference in terms of what they think the patient is going to get out of the device." (Ford (POA) Tr. 954).

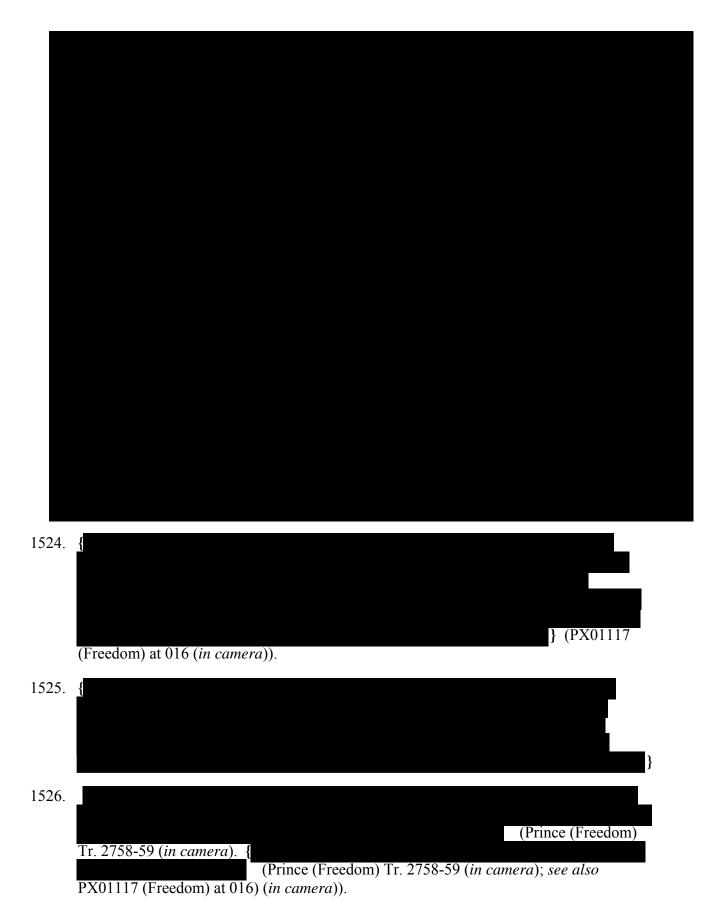
3. Freedom's Quattro Will Be Functionally Superior to, and Lower-Priced than, Össur's Rheo

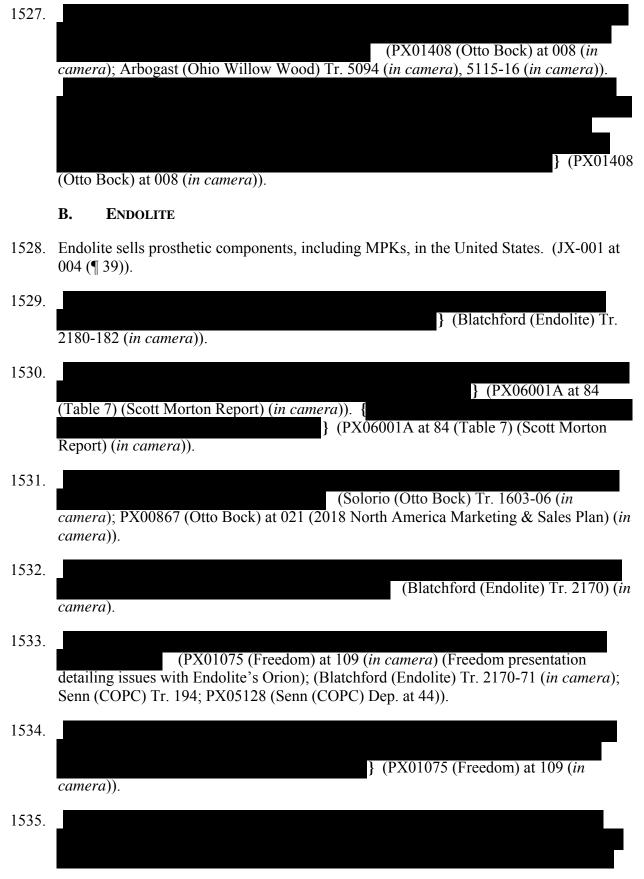
1517. During its due diligence of the acquisition of Freedom on or around September 19, 2017, after Otto Bock executives tested the Quattro in-person for several hours, they identified as "RISKS IF WE DO NOT CONTROL QUATTRO" that "Ossur could have something that will compete better with C-Leg 4 because the stance phase functions will be much better than Rheo can acheive [sic]" and "Anyone who takes this product will cut in to C-Leg 4 market share. Especially in the US." (PX01471 (Otto Bock) at 002).

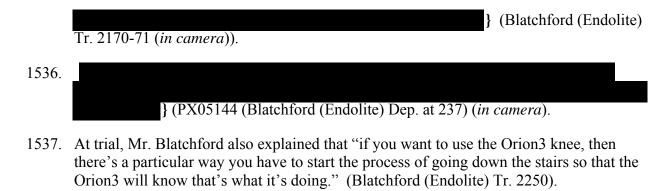


1522. Mr. De Roy, Össur's Executive Vice President of R&D, testified that the Rheo XC "includes a couple of features and functions that are not available in the Rheo Knee, such as the smooth transition from level ground walking to biking, it supports running, and it also supports up stairs walking as well as hindrance avoidance, so your obstacle avoidance. You're able to take a step over an obstacle with more stability and more safety." (PX05124 (De Roy (Össur) Dep. at 157-58). Össur prices the Rheo XC "approximately 9-10 thousand dollars more expansive" than the Rheo. Mr. De Roy testified that the Rheo XC's "two main competitors" are Otto Bock's Genium and X3. (De Roy (Össur) Tr. 3584).





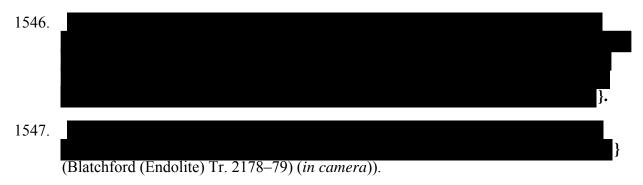




- 1538. } (RX-0607 (Endolite) at 009 (*in camera*)).
- 1539. Mr. Senn, President of Kentucky/Indiana Operations at COPC, testified that COPC "feel[s] that the quality of the Plié or back up to the C-Leg 4 is greater than the Endolite knee." (Senn (COPC) Tr. 194). He also previously testified, in March 2018, that COPC practitioners "do not feel the knee functions as well as the Freedom or Ottobock knees at this time." (PX05128 (Senn (COPC) Dep. at 44).
- 1540. Mr. Ford, President and Managing Partner of POA, testified that Endolite "to a lesser degree" is trying to get their company's business due to less service and support compared to the Otto Bock, Freedom, and Össur. (Ford (POA) Tr. 946, 956-957) (noting that Endolite is a "smaller company," that they "don't have as much support staff . . . don't have as large a sales force, they have far fewer clinicians . . . [and]so it makes it more challenging to get the support in a timely basis and with the level of support that we get from [Otto Bock, Freedom, and Össur]."
- 1541. (Blatchford (Endolite) Tr. 2170-171 (*in camera*)).
- 1542. Freedom's internal documents indicate that Endolite's Orion was not a major competitor. In particular, a Freedom regional sales manager noted that, despite Endolite's promotions, "the Orion is not a huge threat in my territory." (PX01700 (Freedom) at 001 (updating Freedom's Director of Field Sales and Clinical Training on Endolite promotion)).
- 1543. Mr. Senn of COPC testified that the company purchased only a few Endolite MPKs in 2017 because "the quality of the Plié or back up to the C-Leg 4 is greater than the Endolite knee." (Senn (COPC) Tr. 193-94).
- 1544. Jeff Sprinkle, the co-owner of Sprinkle Prosthetics, testified that he hasn't fit an Endolite Orion MPK on a patient in seven to eight years for "two reasons." He listed the reasons as "I didn't like the function of it. And the programming, for lack of a better word, seemed kind of Mickey Mouse, to me." He defined "Mickey Mouse" as "[w]ell,

basically, since I had never fit one, I called Endolite, the manufacturer, and we got on the phone. And you have to press certain buttons on the knee to get it to do certain things, have them walk. Then you press another button on the knee. There was no computer or hand-held laptop-type device to program it when I programmed the knee. It was basically from pressing buttons. And I just didn't like that way of - I didn't think that way was effective in programming a knee. It may have changed. But like I said, I don't fit that knee, so I don't know." (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 60-61)).

1545. In an internal Freedom document entitled "Competitor Info: Plie 3 vs. Orion3," Freedom identifies several advantages of the Plié over the Orion, including the weight, height, batteries, and water exposure. Freedom indicates the Plié 3 as weighing "2.7 lbs/1.2 kg" compared to "3.3 lbs/1.5 kg" for the Orion 3. The document also lists the height of the Plié 3 as 235 mm compared to "244 mm (plus 7-14 mm for proximal attachment)" for the Orion 3. (PX01973 (Freedom) at 001).



C. NABTESCO

1. Background on Nabtesco and Proteor Inc.

- 1548. Nabtesco does not sell its MPKs directly to prosthetic clinics in the United States. (PX03004 (Nabtesco) at 001) (explaining that Nabtesco has four distributors in the U.S.)).
- 1549. Previously, until September 2018, all of Nabtesco's sales in the United States were made through four distributors—Cascade Orthopedic Supply, Inc., Southern Prosthetic Supply, Inc. ("SPS"), PEL LLC, and Proteor, Inc. (PX03004 (Nabtesco) at 001; Mattear (Proteor Inc.) Tr. 5538-40, 5544-45).
- 1550. No one from Nabtesco testified at the trial or testified in a deposition. (Tr. 143-6895; JX002).
- 1551. Proteor Inc. (d/b/a Nabtesco & Proteor in USA) ("Proteor Inc.") is a distributor of prosthetic and orthotic products manufactured by Proteor France and prosthetic knees manufactured by Nabtesco Corporation. (Mattear (Proteor Inc.) Tr. 5520-22).
- 1552. Proteor Inc. was formed in 2016. (Mattear (Proteor Inc.) Tr. 5538).

- 1553. Proteor Inc. is "owned a hundred percent by Proteor France." (Mattear (Proteor Inc.) Tr. 5712). Nabtesco Corporation does not own Proteor Inc. (Mattear (Proteor Inc.) Tr. 5714). Proteor Inc. does not own Nabtesco Corporation. (Mattear (Proteor Inc.) Tr. 5714).
- 1554. Starting September 1, 2018, Proteor, Inc. became the exclusive distributor of Nabtesco's prosthetic knees in the United States. (Mattear (Proteor Inc.) Tr. 5521, 5525, 5546-547). As of September 1, 2018, all sales of Nabtesco's prosthetic knees in the United States go through Proteor Inc. (Mattear (Proteor Inc.) Tr. 5526).
- 1555. Proteor France "manufacture[s] prosthetic knees, prosthetic feet, orthotic joints, materials for prosthetics." (Mattear (Proteor Inc.) Tr. at 5519-520). Proteor France does not manufacture an MPK. (Mattear (Proteor Inc.) Tr. 5541).
- 1556. Proteor France is located in Dijon, France. Proteor France is a private, "family-owned company." (Mattear (Proteor Inc.) Tr. 5531-532).
- 1557. Proteor Inc. sells prosthetic products to prosthetic clinics and distributors including Southern Prosthetic Supply, Cascade Orthopedic Supply, and PEL Supply. (Mattear (Proteor Inc.) Tr. 5522-523, 5716).
- 1558. Proteor Inc. makes less money when it sells to a distributor than when it sells directly to a clinic. (Mattear (Proteor Inc.) Tr. 5716).
- 1559. As of September 19, 2018, Proteor Inc. employed seven sales team members and a business development manager. (Mattear (Proteor Inc.) Tr. 5527, 5563).
- 1560. No one at Proteor has any responsibility related to the research and development of MPKs at Nabtesco. (Mattear (Proteor Inc.) Tr. at 5717-718).
- 1561. } (Mattear (Proteor Inc.) Tr. 5646-647 (*in camera*)).
 - 2. Limited Sales of Nabtesco's MPKs

1562.		
		(PX06001A
	at 84 (Scott Morton Report) Table 7 (in camera)). {	
	} (PX06001A at 84 (Scott Mo	orton Report)
	Table 7 (<i>in camera</i>)).	

1563. Nabtesco currently manufactures and sells three MPK products—the Intelligent Knee, the Hybrid Knee, and the Allux. (Mattear (Proteor Inc.) Tr. 5534).

1564.	
	(PX03004 (Nabtesco) at 005).
1565.	} (Mattear (Proteor Inc.) Tr. 5721 (discussing PX03229) (Proteor Inc. Sales by Item Detail) (<i>in camera</i>)).
1566.	{ (PX03004 (Nabtesco) at 005; Mattear (Proteor Inc.) Tr. 5718).
	} (PX03004 (Nabtesco) at 005).
1567.	<pre>} (Mattear (Proteor Inc.) Tr. 5721 (discussing PX03229) (in camera)). {</pre>
1568.	(Mattear (Proteor Inc.) Tr. 5723 (discussing PX03229) (<i>in camera</i>)).
1569.	} (Mattear (Proteor) Tr. 5725 (<i>in camera</i>)).
1570.	
	} (Collins (Cascade) Tr. 3288-289 (<i>in camera</i>)).
1571.	Stephen Blatchford, the Executive Chairman of Endolite, testified at trial that the Allux has a "very limited presence" and Endolite doesn't "come across it very much at all." (Blatchford (Endolite) Tr. 2150-151). {
	(Blatchford (Endolite) Tr. 2163-164 (<i>in camera</i>)).
1572.	} (PX00867 (Otto Bock) at 021 (<i>in camera</i>); Solorio (Otto Bock) Tr. 1603-04 (<i>in camera</i>)).
1573.	
	PX01025 (Freedom) at 008 (<i>in camera</i>)).

3. Function and Design of Nabtesco's MPKs Prevent Them from Successfully Competing

- 1574. The microprocessor in Nabtesco's Hybrid MPK only controls the swing phase of a user's gait. (Mattear (Proteor Inc.) Tr. 5542). Nabtesco's Hybrid microprocessor knee manufactured by Nabtesco does not qualify for the MPK base L-Code, 5856. (PX05161 (Mattear (Proteor Inc.) Dep. at 49-50).
- 1575. { } } (Mattear (Proteor Inc.) 5738-739 (*in camera*)). { } (Mattear (Proteor Inc.) 5739-740 (*in camera*)). { } (Mattear (Proteor Inc.) 5739-740 (*in camera*)).
- 1576. Marketing material produced by Nabtesco Corporation lists a weight limit of 275 pounds. (Mattear (Proteor Inc.) Tr. 5607 (discussing RX-0345)).
- 1577.
 Inc.) Tr. 5731-32 (*in camera*)).
 (Mattear (Proteor Inc.) Tr. 5733 (*in camera*)).
 1578.
 (Mattear

(Proteor Inc.) Tr. 5738 (in camera)).

1579. Brad Mattear also testified that "[t]he most unique portion [of the Allux] being it's a fourbar MPK." (Mattear (Proteor Inc.) Tr. 5629).

((Mattear ((Proteor	Inc.)) Tr.	5731 ((in	camera))).

- 1580. According to Michael Oros, the President and CEO of Scheck & Siress, the Allux knee was designed for somebody with a very long residual" or more technically "a short floor to knee center height." Mr. Oros testified that the only time he's attempted to order an Allux was for a patient with a long residual limb characteristic. (Oros (Scheck & Siress) Tr. 4868-869).
- 1581. In the one instance he attempted to fit an Allux on a patient, Mr. Oros testified that he never received the MPK he ordered. (Oros (Scheck & Siress) Tr. 4868-869).

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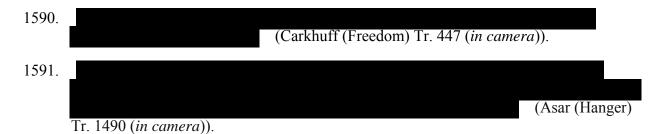
	(Mattear (Proteor Inc.) Tr. 5728 (<i>in camera</i>)). {
	(Mattear (Proteor Inc.) Tr. 5732 (<i>in camera</i>)).
1583.	
	(Mattear (Proteor Inc.) Tr. 5753 (<i>in camera</i>)).
1584.	
	} (Mattear (Proteor Inc.) Tr. 5753 (in camera)).
1585.	at Freedom, asked Lloyd Presswood, the Director of Field Sales and Clinical Training at Freedom, if there is "a clinical reason as to why a CP would choose a product like Allux versus P3? Other than price?" Mr. Presswood later responded that the Nabtesco Allux is a "piece of crap knee." (PX00811 (Freedom) at 001; <i>see also</i> Ferris (Freedom) Tr. 2356-358).
	} (PX05114 (Ferris (Freedom) Dep. at

91-92) (*in camera*)).

4. **Reputational Barriers for Nabtesco**

1586. Brad Mattear, General Manager of O&P at Proteor Inc., testified that he does not know why a patient or prosthetist might want to buy a knee like the Hybrid knee. (Mattear (Proteor Inc.) Tr. 5596).

1587.	
	} (Mattear (Proteor Inc.) Tr. 5744 (in
	camera)).
1588.	
	} (Mattear (Proteor) Tr. 5744-745 (in camera)).
1589.	
	(DX05152
	(PX05152 (Wise (Willow Wood) Dep. at 72)).

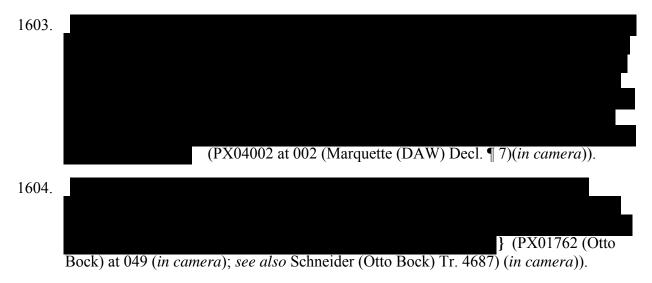


1592. Mr. Sabolich, the owner and Clinical Director of Scott Sabolich Prosthetics and Research, testified that his clinic hasn't fit an Allux MPK and characterized it as a "very janky knee." He explained, "We were introduced to [the Allux]. We had a practitioner who was very interested in using one, but it seemed – I hate to overuse the word 'janky,' but it was a very janky knee." (Sabolich (Scott Sabolich Prosthetic and Research) Tr. 5861, 5889).

5. Customers and Other Industry Participants Testified that Nabtesco Is Unable to Compete Successfully Against Freedom and Otto Bock

- 1593. Several clinic customers testified that they are not familiar with MPKs manufactured by Nabtesco. (*See, e.g.*, PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 61); PX05151 (Patton (Prosthetic Solutions) Dep. at 32); PX05149 (Brandt (Ability Prosthetics & Orthotics) Dep. at 241-42); PX05167 (Filippis (Wright & Filippis) Dep. at 115:12-17)).
- 1594. Jeff Sprinkle, the owner of Sprinkle Prosthetics, testified in April 2018 that he had never heard of Nabtesco as a manufacturer. (PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 61)).
- 1595. James Curtis Patton, III, the President and owner of Prosthetic Solutions, testified in April 2018 that he had seen the Allux MPK "at a show" but was not familiar with it. (PX05151 (Patton (Prosthetic Solutions) Dep. at 32)).
- 1596. Jeffrey Brandt, the CEO of Ability Prosthetics & Orthotics, testified in April 2018 that he was "vaguely" familiar with Nabtesco as a company and he did not know "a whole lot" but had "heard the name before." Mr. Brandt further testified that he didn't "really have any, like, experience with" the MPK knee sold by Nabtesco "or really even know anything about it." (PX05149 (Brandt (Ability) Dep. at 241-242)).
- 1597. Anthony Filippis, the CEO of Wright & Filippis, testified in April 2018 that he had never heard of the company Nabtesco or the Allux MPK. (PX05167 (Filippis (Wright & Filippis) Dep. at 115)).
- 1598. Keith Senn, the President of Kentucky/ Indiana Operations at the Center for Orthotic and Prosthetic Care, testified in July 2018 that COPC had not purchased any MPKs from Nabtesco in 2017 because he was not familiar with their MPK. He further elaborated that COPC did not have any plans to shift purchases of MPKs from Freedom to Nabtesco. (Senn (COPC) Tr. 194).

- 1599. Other clinic customers who had heard of MPKs manufactured by Nabtesco testified they would not fit a Nabtesco MPK on a patient because of difficulties with customer service or concerns about the reliability of the MPK. (*See, e.g.*, Ford (POA) Tr. 959; PX05141 (Bright (North Bay) Dep. at 87-88)).
- 1600. Michael Bright, the owner of North Bay Prosthetics, testified in April 2018 that North Bay had "tried to do a trial fit one time" on the Nabtesco Allux "and it didn't work, like the electronics didn't function, so we weren't even able to begin the trial because it didn't work, and that was our last attempt at it. It was something we did not – it's a lot cheaper, I believe, but it wasn't worth the risk of outcomes for us." (PX05141 (Bright (North Bay) Dep. at 87-88)).
- 1601. Mark Ford, the President of Prosthetics and Orthotics Associates, testified in August 2018 that POA has not purchased an MPK from Nabtesco. According to Mr. Ford, "[b]ecause they have a smaller sales and support staff, it's difficult for our clinicians to have knowledge about it." (Ford (POA) Tr. 959).
- 1602. Mark Ford also testified in August 2018 that Nabtesco's level of service and technical support is "not nearly to the degree that Össur or Otto Bock and Freedom have." (Ford (POA) Tr. 958).



D. DAW INDUSTRIES

1. Background on DAW Industries

- 1605. DAW Industries sells prosthetic components, including MPKs, in the United States. (JX001 at ¶ 40).
- 1606. DAW serves as a distributor of the MPKs it sells. A company named Teh Lin located in Taipei, Taiwan manufactures the MPKs that DAW distributes. (PX05146 (Marquette (DAW) Dep. at 15-17)).
- 1607. No one from DAW testified at the trial. (Tr. 143-6895).

1608. No one from The Lin testified at the trial or testified in a deposition. (Tr. 143-6895; JX002).

1609.	
	(Marquette (DAW) Decl. \P 7)(<i>in camera</i>)).
1610.	(DAW) Decl.) (<i>in camera</i>)).
1611.	Stephen Blatchford, the Executive Chairman of Endolite, testified at trial in August 2018 that he only had familiarity with DAW "[t]o a limited extent." Mr. Blatchford could not remember the name of any DAW MPKs, and testified that DAW's MPKs have "[v]ery little" presence in the United States. (Blatchford (Endolite) Tr. 2151).
1612.	
	(Blatchford (Endolite) Tr. 2164 (in camera)).
1613.	(PX00867 (Otto Bock) at 021 (2018 Prosthetics Roadmap to Success: North America Marketing & Sales Plan) (<i>in camera</i>); Solorio (Otto Bock) Tr. 1605 (<i>in camera</i>)).
	3. Clinic Customers Are Unfamiliar or Unwilling to Fit DAW MPKs
1614.	} (Senn (COPC) Tr. 191; Ell (Mid-Missouri) Tr. 1730-731; Sabolich (Scott Sabolich Prosthetic and Research) Tr. 5889; Oros (Scheck & Siress) Tr. 4811 (<i>in camera</i>); Ford (POA) Tr. 955; Brandt (Ability) Tr. 3763-764; Asar (Hanger) Tr. 1380-381 (<i>in camera</i>)).
1615.	<i>See, e.g.</i> , Ford (POA) Tr. 958; Ell (Mid-Missouri) Tr. 1736; Oros (Scheck & Siress) Tr. 4811 (<i>in camera</i>); Sabolich (Scott Sabolich Prosthetics and Research) Tr. 5891; PX05108 (Yates (Jonesboro) Dep. at 57-58, 64) (<i>in camera</i>); PX05149 (Brandt (Ability) Dep. at 243-44)).
1616.	(PX05108 (Yates (Jonesboro) Dep. at 57-58, 64) (<i>in camera</i>); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 64-65); PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 35-36)); PX05141 (Bright (North Bay) Dep. at 203); PX05151 (Patton (Prosthetic Solutions) Dep. at 116); PX05166 (Watson (Fourroux) Dep. at 173) (<i>in camera</i>); PX05167 (Filippis

2. DAW Has Minimal Sales in the United States

(Wright & Filippis) Dep. at 115-16); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 58-59)).

- 1617. Only one witness, who was deposed but did not appear at the trial, Curt Patton from Prosthetic Solutions, testified that his clinic had ever fit a DAW MPK. Prosthetic Solutions fit the DAW MPK "more than 10 years ago." (PX05151 (Patton (Prosthetic Solutions) Dep. at 116)).
- 1618. Robert Yates, the President and CEO of Jonesboro Prosthetic & Orthotic Laboratory, testified in March 2018 that he wasn't "familiar with DAW Industries' microprocessor knee. I don't know anything about it. I've never been impressed with DAW's products in general, so I'm not much interested in seeking that information." (PX05108 (Yates (Jonesboro) Dep. at 64)).
- 1619. (Asar (Hanger) Tr. 1395 (*in camera*)).
- 1620. For other clinic customers who had heard of the MPKs distributed by DAW, they testified that they would not fit a DAW MPK on a patient because of difficulties with customer service, interactions with sales representatives, or concerns about the reliability of the MPK. (*See, e.g.*, Ford (POA) Tr. 957-958; Ell (Mid-Missouri) Tr. 1736; PX05129 (Ell (Mid-Missouri) Dep. at 78); PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 35-36)).
- 1621. Mark Ford, President of Prosthetic and Orthotic Associates, testified that his "experience with DAW is very negative." Specifically, POA has "had struggles with them standing up with their warranties of their products. We've bought a limited number of products from them, and we struggle with timely shipping and we struggle with support of their warranties." (Ford (POA) Tr. 957-958).
- 1622. Mr. Ford added, DAW is "very aggressive with their telemarketing" and will make a call claiming "it's an emergency and get our clinicians to come out of the room with a patient and it's really a sales call. So our clinicians are not big fans of interacting with DAW." (Ford (POA) Tr. 958).
- 1623. Tracy Ell of Mid-Missouri O&P testified that DAW "has extremely rude and aggressive marketing principles." (Ell (Mid-Missouri) Tr. 1736).
- 1624. Mark Testerman, the Vice President of National and Key Accounts at Freedom, testified in August 2018 that he did not know the name of DAW's MPK. (Testerman (Freedom) Tr. 1264).
- 1625. Jeffrey Brandt, the CEO of Ability Prosthetics and Orthotics, testified in April 2018 that he was "not really" familiar with DAW's MPKs and no one at Ability well-versed in MPKs had mentioned them to him. Mr. Brandt explained that individuals at Ability would have brought DAW MPKs to his attention if they were on the caliber of the C-Leg, Plié, or the Rheo because "that's what they're supposed to do is just make sure they're

aware of clinical options out there for the patients." (PX05149 (Brandt (Ability) Dep. at 243-244)).

1626. Paul Weott, the owner of Orthotic Prosthetic Center, Inc., testified in March 2018 that he was "100 percent sure" his clinic had never fit a DAW MPK. He explained, "I don't know if I've ever seen one, and that's a – it's a personal thing. DAH (sic) is an odd company that markets very aggressively, and it tends to turn everybody off." Mr. Weott also testified that he "just never liked their products, and most of our practitioners – and I don't know if it's the area or what, but we just never have bought a lot of DAH (sic) products. They just never seemed to fit into our model." (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 35-36)).

XI. NEW ENTRY WOULD NOT BE TIMELY, LIKELY, OR SUFFICIENT TO CONSTRAIN THE MERGER'S ANTICOMPETITIVE EFFECTS

A. LAUNCH OF A NEW MPK WOULD NOT BE TIMELY

1. MPK Development Takes Several Years

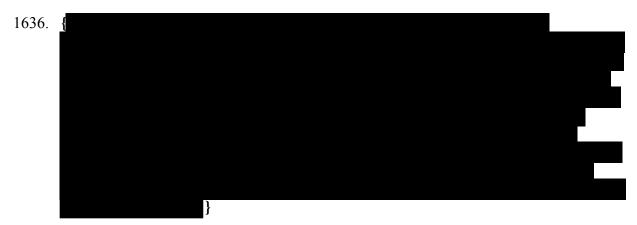
- a) Length of Time Required by Respondent to Develop its MPKs
 - (1) Otto Bock
- 1627. Otto Bock manufactures and markets the C-Leg 4, the fourth generation microprocessor knee for the C-Leg product line. {
- 1628. Andreas Eichler, Otto Bock's Head of the Prosthetics Lower Limb Mechatronic Systems business unit, acknowledged that "alterations on a microprocessor-guided knee can take up to two years, sometimes even three to four" and that "[o]ne could even say that the C-Leg 4 has been developed since 1997 up to today" with the introduction of the first C-Leg in 1997. (PX05133 (Eichler (Otto Bock)) Dep. at 114).
- 1629.
- 1630. According to Otto Bock, in addition to the time it takes to develop a microprocessor knee, a manufacturer of microprocessor knees would be required to develop a sales force, qualify for reimbursement, and undergo multiple phases of product testing, among other requirements, in order to successfully launch an MPK. (PX05133 (Eichler (Otto Bock) Dep. at 115-116).

- (2) Freedom
- 1631. Freedom manufactures and markets the Plié 3, the third generation microprocessor knee for the Plié product line. It took approximately three years for Freedom to develop the original Plié and a further three years to develop the second generation Plié 2. (Carkhuff (Freedom) Tr. 361-362; PX05007 (Carkhuff (Freedom) IHT at 155-56, 297-300)).
- 1632. Freedom's Chairman, Maynard Carkhuff, testified that it took approximately six years, from the development of the Plié 1 to the launch of the Plié 2, before Freedom had a product that could compete effectively in the MPK market, and a reputation to support it. (PX05007 (Carkhuff (Freedom) IHT at 299-300)).
- 1633. Freedom began the development of its fourth microprocessor knee, the Quattro, in the third quarter of 2015. (PX05007 (Carkhuff (Freedom) IHT at 245)).



- b) <u>Length of Time Required by Other Manufacturers to Develop</u> <u>MPKs</u>
- 1635. (Blatchford (Endolite) Tr. 2172-73 (*in camera*); De Roy (Ossur) Tr. 3613-14 (*in camera*)).





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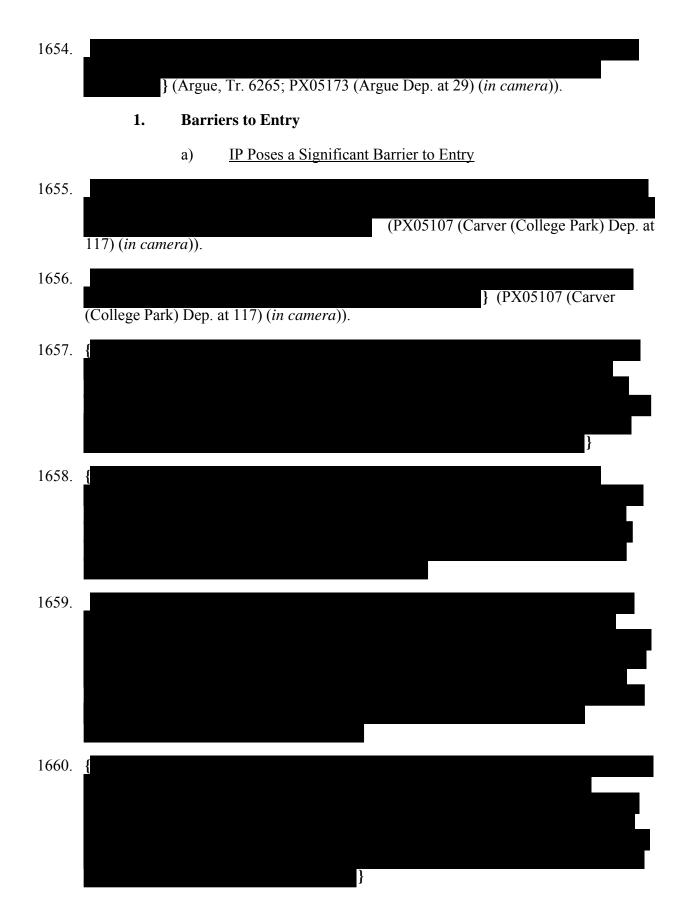
1637.	} (De Roy (Össur) Tr. 3617-18 (<i>in camera</i>)).
1638.	(De Roy (Ossur) Tr. 3624-25 (<i>in camera</i>)).
	(2) Endolite
1639.	} (Blatchford (Endolite) Tr. 2172).
1640.	} (Blatchford (Endolite) Tr. 2173 (in camera)).
1641.	
	(Blatchford (Endolite) Tr. 2174 (<i>in camera</i>)).
1642.	(PX04001

(Blatchford (Endolite) Decl. at \P 9) (*in camera*)).

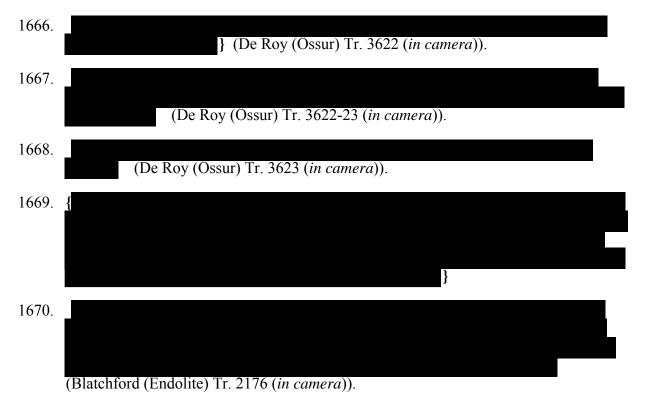
2. MPKs in Development Are Not on Track to Launch for Many Years

- 1643. Other prosthetic manufacturers and third parties interested in developing an MPK predict entry into the United States market will take at least another five years. (*See* PX04003 at 001 (Sun (BionicM), Decl.); PX05117 (Choi (ST&G) Dep. at 95)).
 - a) <u>BionicM's SuKnee</u>
- 1644. BionicM is a student-research team at the University of Tokyo that began a research project to develop an MPK, named the SuKnee, in approximately 2016. (PX04003 (Sun (BionicM) Decl. at ¶¶ 1-2)).

- 1645. As of March 2018, BionicM had not finished developing a prototype for the SuKnee. (PX04003 (Sun (BionicM) Decl. at ¶ 2)).
- 1646. The project leader for BionicM, Xiaojun Sun, does not expect to have a SuKnee ready for commercial use for several years. (PX04003 (Sun (BionicM) Decl. at ¶ 3)). Xiaojun Sun believes the "process required to begin selling the SuKnee in the United States would take a long time, maybe even more than a decade." (PX04003 (Sun (BionicM) Decl. at ¶ 3)).
 - b) <u>ST&G</u>
- 1647. ST&G is a seller of lower limb prosthetics, including mechanical knees, prosthetic feet, and prosthetic liners, and orthotics. (PX05117 (Choi (ST&G) Dep. at 15-17)). ST&G does not currently sell an MPK. (PX05117 (Choi (ST&G) Dep. at 27)).
- 1648. The president of ST&G, Glenn Choi, testified that the company began a development project for an MPK in approximately 2016. (PX05117 (Choi (ST&G) Dep. at 84)). The company's goal for the MPK development project is to provide an MPK with similar functions and benefits as other MPKs on the market at a more affordable price. (PX05117 (Choi (ST&G) Dep. at 92)).
- 1649. After starting the project in 2016, ST&G had not created a functioning prototype of an MPK as of March 2018. (PX05117 (Choi (ST&G) Dep. at 84)).
- 1650. Mr. Choi estimated, in March 2018, the company would finish building and testing a prototype within one or two years. (PX05117 (Choi (ST&G) Dep. at 86)). Once finished testing the prototype, Mr. Choi estimated the process for developing a commercial-scale production would take at least an additional six months. (PX05117 (Choi (ST&G) Dep. at 88)). ST&G would plan to perform field tests on the product after developing a commercial-scale production, which would require an additional six months. (PX05117 (Choi (ST&G) Dep. at 88)).
- 1651. ST&G would then plan to perform a "soft launch" outside of the country before beginning to sell the product in the United States. (PX05117 (Choi (ST&G) Dep. at 95)).
- 1652. Altogether, Mr. Choi believes the process would take "[a]t best, five years" as of March 2018 before ST&G could begin selling the MPK in the United States. (PX05117 (Choi (ST&G) Dep. at 95)).
- 1653. In order to compete as effectively as possible in the United States, Mr. Choi believes ST&G will need to spend an additional three years after the launch of the product to develop meaningful brand recognition in the United States. (PX05117 (Choi (ST&G) Dep. at 95)).
 - **B.** LAUNCH OF A NEW MPK IS NOT LIKELY



- 1661. Complaint Counsel's expert, Dr. Fiona Scott Morton, concluded that "[p]otential entrants seeking to develop a microprocessor knee in the United States are likely to encounter intellectual property barriers." (PX06001A at 145 (¶ 190) (Morton Expert Report)).
 - b) <u>Reputation and Brand are Critical</u>
- 1662. (*See, e.g.,* Blatchford (Endolite) Tr. 2176 (*in camera*); De Roy (Össur) Tr. 3622-24 (*in camera*); PX05007 (Carkhuff (Freedom) IHT at 296)).
- 1663. According to Freedom's Chairman, Maynard Carkhuff, "due to the prosthetists high reliance on the manufacturers of microprocessor knees, and any product in the prosthetic industry, the company's reputation for servicing, standing behind their products, quick turnaround times, being easy to do business with in tough times as well as good times, providing educational services, having high-quality products that can be relied on and that can service their patients well, and I think all of those and I'm sure many more are important." (PX05007 (Carkhuff (Freedom) IHT at 296).
- 1664. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified that "[b]rand and reputation is a very large consideration in the purchase of a prosthetic device") (PX05010 (Otto Bock) IHT at 58)).
- 1665. Freedom "experienced some reputational barriers to success" with the launch of the original Plié. (PX05007 (Carkhuff (Freedom) IHT at 297-298)).



- 1671. Freedom's Chairman, Maynard Carkhuff, testified that when Freedom launched its first-generation MPK in 2007, the Plié 1, its success was hindered by reputational barriers. (Carkhuff (Freedom) Tr. 361-362; PX05007 (Carkhuff (Freedom) IHT at 298)). It took about three years after the launch of the Plié 1 in 2007 for the company "to really gain credibility" and compete effectively in the market. (PX05007 (Carkhuff (Freedom) IHT at 297-300)).
- 1672. According to clinic customer testimony, reputation is also important to prosthetists when choosing an MPK to fit on a patient. (*See, e.g.*, PX05167 (Filippis (Wright & Filippis) Dep. at 112-13); PX05151 (Patton (Prosthetic Solutions) Dep. at 113-14); PX05141 (Bright (North Bay) Dep. at 211)).
- 1673. Michael Bright, a certified prosthetist and co-owner of North Bay Prosthetics and Orthotics, testified that he would like to see an MPK "on the market for a period of time . . . without having problems" before he would recommend it to patients. (PX05141 (Bright (North Bay) Dep. at 211)). Mr. Bright also testified that he would not purchase an MPK "right away" from a manufacturer who had never sold one. (PX05141 (Bright (North Bay) Dep. at 226).
- 1674. Glenn Choi, President of ST&G, testified that his company will need to spend an additional three years after the launch of its in-development MPK to establish meaningful brand recognition in the United States. (PX05117 (Choi (ST&G) Dep. at 95)).

1675.				
	(Collins (Cascad	le) Tr. 3291-92 ((in camera)).	

c) <u>Development of an Extensive Sales and Clinical Force is</u> <u>Necessary</u>

1676. A direct sales model is important to the effective sale of MPKs in the United States. (De Roy (Össur) Tr. 3573 (a direct sales force is "absolutely necessary" to sell MPKs to U.S. clinics); PX05007 (Carkhuff (Freedom) IHT at 136 (agreeing that any manufacturer who wants to sell MPKs effectively in the U.S. has to have a sales force to interact with prosthetists and patients)); PX05148 (Swiggum (Otto Bock) Dep. at 32-33); PX05009 (De Roy (Össur) IHT at 18)).

1677.

	1 (PY05144 (Blatchford
	} (PX05144 (Blatchford
(Endolite) Den at 215) (in camera))	
(Endolite) Dep. at 215) (in camera)).	

- 1678. As Freedom's Vice President of National and Key Accounts, Mark Testerman, testified, "[t]here's no doubt that a direct sales force is important in driving Plié 3 sales for Freedom Innovations". (Testerman (Freedom) Tr. 1125-26).
- 1679. As of the trial, Freedom had 14 regional sales managers. (Testerman (Freedom) Tr. 1114-15).
- 1680. Aside from SPS, a distributor owned by Hanger, Freedom sells its MPKs direct to customers in the United States. (PX05118 (Testerman (Freedom) Dep. at 41); PX05005 (Smith (HEP) IHT at 159)).
- 1681. This is similar to other MPK manufacturers. For example, Otto Bock sells 100 percent of its MPKs directly. (PX05148 (Swiggum (Otto Bock) Dep. at 38)).
- 1682. Otto Bock has four sales regions in the United States, with six to eight sales representatives per region that report to a regional sales manager. Otto Bock's sales representatives sell the entire suite of Otto Bock's prosthetic products. (Solorio (Otto Bock) Tr. 1638-39).
- 1683. Endolite has 15 sales representatives located across the United States. Like Otto Bock, Endolite's "sales representatives sell the whole product range." (Blatchford (Endolite) Tr. 2127-29).
- 1684. Össur has approximately 50 sales representatives "spread around the U.S." (De Roy (Össur) Tr. 3568). Össur only sells its MPKs directly "because they are more complicated to fit. They require more education. There's programming to those knees. And to ensure proper outcomes we decided to do that ourselves." (De Roy (Össur) Tr. 3570).
- 1685. Selling MPKs directly has contributed to Otto Bock and Freedom's success in the MPK market. (PX05163 (Stuch (Otto Bock) Dep. at 45-48); PX05007 (Carkhuff (Freedom) Dep. at 132-134)).
- 1686. As Vinit Asar, President and CEO of Hanger, testified, "[i]t would be very difficult to work with" an MPK manufacturer who does not have a direct sales force. (PX05153B (Asar (Hanger) Dep. at 65)). {



 1687. In-person meetings between sales representatives and customers help facilitate sales. (Blatchford (Endolite) Tr. 2129-30; PX05137 (Matthews (Freedom) Dep. at 113-115); PX05151 (Patton (Prosthetic Solutions) Dep. at 109-10, 115); PX05168 (Sprinkle (Sprinkle Prosthetics) Dep. at 68)).

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- 1688. Otto Bock's National Sales Director Walter Governor explained in an e-mail on Freedom's "Keys to Success," "if we are not in front of our customers asking for their business, our competition is." (PX01326 (Otto Bock) at 001).
- 1689. Otto Bock's sales representatives visit Hanger's clinics more than 2,000 times per year. (PX05148 (Swiggum (Otto Bock) Dep. at 58-59)).
- 1690. For Freedom, building relationships with customers "help[s] sell Freedom products, drive revenue, drive profitability, short and long term." (Testerman (Freedom) Tr. 1101-02). In particular, building relationships with customers is "a component of trying to protect Plié 3 sales." (Testerman (Freedom) Tr. 1102).
- 1691. Freedom's sales managers visit clinic customers multiple times to build relationships and make sales. According to Mark Testerman, Freedom's Vice President of National and Key Accounts, "[i]f a Freedom Innovations RSM [Regional Sales Manager] spends more time in a given location, whether it's a key account or across any channel, they have a greater likelihood of building a relationship, as we discussed earlier, gaining access to a trial, and getting that prosthetist and the patient to trial a Freedom product." (Testerman (Freedom) Tr. 1121-23).



- 1694. MPKs are highly technical products. (*See, e.g.,* PX05109 (Carkhuff (Freedom) Dep. at 111); PX05163 (Stuch (Otto Bock) Dep. at 45-48); PX05159 (Arbogast (Willow Wood) Dep. at 137-38); PX05141 (Bright (North Bay) Dep. at 223)).
- 1695. A direct sales force must be knowledgeable about MPK products. (PX05010 (Schneider (Otto Bock) IHT at 40)).
- 1696. Direct sales representatives typically have better knowledge of MPKs than distributors, which has led some manufacturers to rely more on their direct sales representatives than distributors. (De Roy (Össur) Tr. 35702-3573; PX05141 (Bright (North Bay) Dep. at 190-91223); PX05162 (Ruhl (Otto Bock) Dep. at 183-84); see also (Blatchford (Endolite) Tr. 2132-2133)) (Endolite's Executive Chairman, Stephen Blatchford, testifying at trial that Endolite switched to using its own sales force about ten years ago and how, as a

result, Endolite's sales tripled and its customer relationships improved)). Otto Bock, for example, sells 100 percent of its MPKs directly. (PX05148 (Swiggum (Otto Bock) Dep. at38-39)).

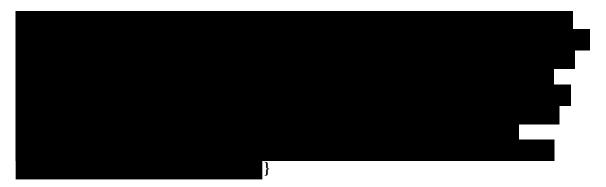
- 1697. Sales representatives educate customers on MPKs. (PX05167 (Filippis (Wright & Filippis) Dep. at 99-100); PX05009 (De Roy (Össur) Dep. at 17); PX05130 (Governor (Otto Bock) Dep. at 61-62); PX05004 (Senn (COPC) IHT at 22-23)). Rob Yates, President and CEO of Jonesboro P&O Laboratory testified that the role of sales reps "tends to be one of support and education." "They provide education to use, sometimes directly. Sometimes it's in the form of bringing in a clinical specialist to provide education to our clinical staff." (PX05108 (Yates (Jonesboro) Dep. at 30-31).
- 1698. Freedom's Vice President of National and Key Accounts, Mark Testerman, testified about the importance of educating customers on your products. According to Mr. Testerman, "if you can educate a practitioner on the functionality of our product, they can see it, it only makes sense that they perhaps would might want to try that product. And if they try the product, it may be something that they'd want to purchase for that particular their next patient". (Testerman (Freedom) Tr. 1110-11).
- 1699. Mr. Testerman testified that Freedom offers continuing education classes for prosthetists, which provide Continuing Education Unit ("CEU") credits to the practitioners and, "at the same time they can learn about Freedom products . . . [I]t's definitely a good, solid, aggressive strategy to try to differentiate ourselves from the competition." (Testerman (Freedom) Tr. 1107-08).
- 1700. Sales representatives keep customers informed of the latest technological developments of MPKs. (Testerman (Freedom) Tr. 1117-19; PX05148 (Swiggum (Otto Bock) Dep. at 32-33); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 68-69); Blatchford (Endolite) Tr. 2130-31; PX05145 (Ford (POA) Dep. at 34-36); PX05007 (Carkhuff (Freedom) IHT at 132-133); *see also*Lustomers

appreciate learning about improvements to the MPK products. (PX05141 (Bright (North Bay) Dep. at 223); PX05007 (Carkhuff (Freedom) Dep. at 132-133)).

- 1701. According to Mark Ford, President of Prosthetic and Orthotic Associates, information on product updates and software changes comes from a manufacturer's sales representatives and clinical educators. He testified that such information "is very helpful because it's going to optimize the performance of those components for that specific patient". (Ford (POA) Tr. 960-61).
- 1702. According to Mr. Ford, oftentimes "the local sales rep becomes the first point of contact" when his clinic has a technical question about a product. (Ford (POA) Tr. 962-63).
- 1703. The assistance provided by direct sales representatives includes providing a demo knee to customers so that their patients can trial the MPK. (Testerman (Freedom) Tr. 1121). "[I]f a Freedom rep can get that trial and it's a successful trial, because the prosthetist

sees the joy in the patient in their functionality from that particular trial, it will definitely help in the sale." (Testerman (Freedom) Tr. 1122-23).

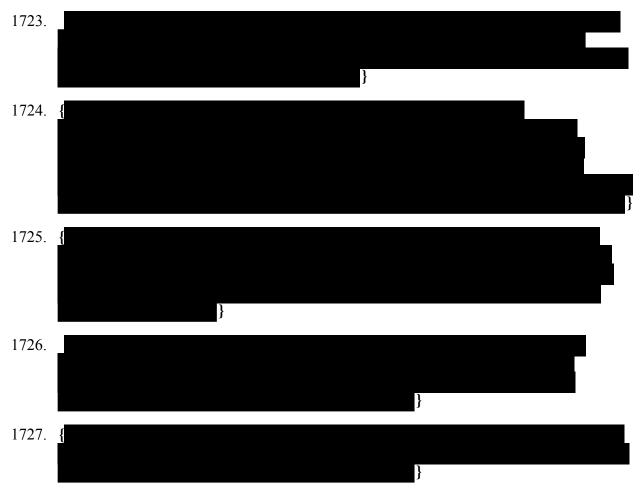
- 1704. Sales representatives and clinical staff also assist prosthetists with fittings of MPKs. (Testerman (Freedom) Tr. 1118-19; Blatchford (Endolite) Tr. 2131; De Roy (Össur) Tr. 3539; PX05148 (Swiggum (Otto Bock) Dep. at 33-34); PX05114 (Ferris (Freedom) Dep. at 138); PX05130 (Governor (Otto Bock) Dep. at 60-61); PX05009 (De Roy (Össur) IHT at 17); PX05151 (Patton (Prosthetic Solutions) Dep. at 92-93)).
- 1705. MPK manufacturers, including Otto Bock, Freedom, and Össur assist customers in obtaining reimbursement for MPKs. (Testerman (Freedom) Tr. 1113-14; De Roy (Össur) Tr. 3538; PX05148 (Swiggum (Otto Bock) Dep. at 34-36); (Ford (POA) Tr. 970-72).
- 1706. If MPK manufacturers did not have a direct sales force, it would lead to fewer MPK sales. (De Roy (Össur) Tr. 3573; Testerman (Freedom) Tr. 1125-26; PX05163 (Stuch (Otto Bock) Dep. at 45-48); PX05148 (Swiggum (Otto Bock) Dep. at 38-39); PX05137 (Matthews (Freedom) Dep. at 124-125)).
- 1707. Complaint Counsel's expert, Fiona Scott Morton, concluded that "to compete effectively in the United States, prosthetic manufacturers must have established sales and support presences in the United States, as clinics require assistance with fitting, service, and repair of microprocessor prosthetic knees." (PX06001A at 70 (¶90) (Morton Expert Report)).
- 1708. Freedom employs a clinical team of prosthetists that "conduct educational courses on how to adjust Plié to each individual patient's needs," as well as meet directly with prosthetists, provide training to sales staff, and going out into the field to help prosthetists and amputees use the Plié effectively. (PX05109 (Carkhuff (Freedom) Dep. at 19-20)).
- 1709. One of the responsibilities of Freedom's clinical team is "to take phone calls from clinicians who are fitting Plié" to try to diagnose issues and, at times, to visit the customer directly to help resolve issues. (PX05109 (Carkhuff (Freedom) Dep. at 22-23)).
- 1710. Clinical education by Freedom's clinical prosthetists is "an important method of promoting and educating customers on the benefits [of the Plié 3]. And if they believe those benefits, then it can be converted to trial and hopefully usage of the product." (PX05109 (Carkhuff (Freedom) Dep. at 23-24)).
- 1711. Freedom's Vice President of National and Key Accounts, Mark Testerman, testified that he believed Freedom's MPK sales would be negatively impacted if the company did not provide sales representatives and clinical prosthetists to provide troubleshooting services to their customers. (PX05118 (Testerman (Freedom) Dep. at 51-53)).
- 1712. Mr. Testerman testified that if Freedom did not provide troubleshooting and fitting services, "it could affect Plié 3 sales." (Testerman (Freedom) Tr. 1118-1120).
- 1713.



1714. Mark Ford, the President and CEO of Prosthetic & Orthotic Associates, testified that the MPK manufacturers' clinical teams are "very important" because when POA clinicians "need help, they need it quickly, and they're looking for experience, so that's where being able to get that is very helpful for our clinicians." (Ford (POA) Tr. 964)).



2. Failed Attempts by Other Prosthetic Companies Highlight the Difficulty of Developing an MPK



3. Best Positioned Theoretical Entrants in Prosthetic Industry Have No Plans to Enter

1728. Companies in the industry operating in adjacent markets such as mechanical knee manufacturers, foot manufacturers, and clinic operators testified that they have no current plans to develop and sell an MPK. For example, TruLife, a manufacturer of mechanical knees, does not currently have plans to develop or distribute an MPK. (PX05136 (Knudsen (TruLife) Dep. at 60, 115-16).



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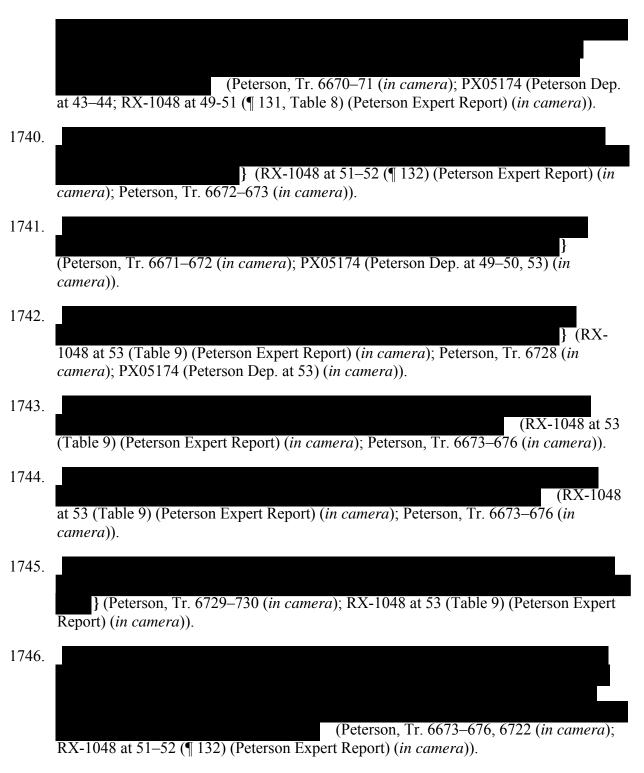
XII. RESPONDENT'S ASSERTED EFFICIENCIES DO NOT REBUT PRESUMPTION OF COMPETITIVE HARM

- 1733. Complaint Counsel's expert witness, Ms. Christine Hammer, concluded that Respondent has not demonstrated that the Merger would produce any cognizable efficiencies. Even assuming that Respondent's claimed efficiencies are cognizable, Ms. Hammer concludes that Respondent has failed to establish that MPK customers would benefit from the claimed efficiencies or that the Respondent's claimed cognizable efficiencies would outweigh the anticompetitive harm resulting from the Merger. (Hammer Tr. 2880, 2898-99; PX06002 at 056, 062 (¶¶ 144, 163) (Hammer Expert Report)).
- 1734. The Merger Guidelines outline the framework within which to assess Respondent's claimed efficiencies. (PX08040 at 032-34 (§ 10) (Merger Guidelines)). Efficiencies are deemed "cognizable" if they are "merger-specific," "have been verified[,] and do not arise from anticompetitive reductions in output or service." (PX08040 at 033 (§ 10) (Merger Guidelines)). Respondent has the burden to "substantiate efficiency claims so that the Agencies can verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific." (PX08040 at 033 (§ 10) (Merger Guidelines)).

A. **Respondent's Claimed Efficiencies**

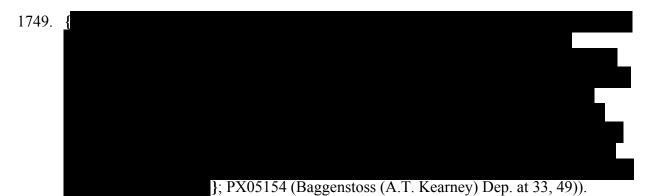
- 1735. Respondent relies on James R. Peterson, its efficiencies expert, to quantify its claimed cost-savings efficiencies. (RX1048 at 3 (¶¶ 1, 14) (Peterson Expert Report)).
- 1736. } (Peterson, Tr. 6668–672 (*in camera*); PX03185 (AT Kearney) at 004-079 (*in camera*)).
- 1737. The Integration Team, made up of personnel from Otto Bock, Freedom, and A.T. Kearney, conducted work on potential cost-savings synergies from the Merger. (PX05127 (Röessing (Otto Bock) Dep. at 50–51); PX05154 (Baggenstoss (A.T. Kearney) Dep. at 27, 33)).





- B. RESPONDENT'S CLAIMED EFFICIENCIES ARE NOT COGNIZABLE
 - 1. Respondent's Claimed Efficiencies are Not Verifiable

- 1747. The Merger Guidelines state "[e]fficiency claims will not be considered if they are vague, speculative, or otherwise cannot be verified by reasonable means." (PX08040 at 033 (§ 10) (Merger Guidelines)).
 - a) <u>Respondent's Claimed Efficiencies Are Speculative</u>
- 1748. In mid- December 2017, the Integration Team stopped all work to evaluate any potential efficiencies or cost savings from the Merger. (PX05127 (Röessing (Otto Bock) Dep. at 36–37; PX05154 (Baggenstoss (A.T. Kearney) Dep. at 26) (testifying that A.T. Kearney stopped performing all work relating to Otto Bock's acquisition of Freedom in "mid-December"); PX05170 (Schneider (Otto Bock) Dep. at 22-23)). At that point, work relating to identifying synergies opportunities was "all early stage" and "incomplete." (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 27, 33)).

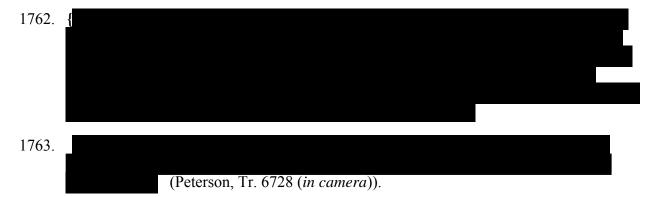


- 1750. With respect to the first Hardness Level—identifying an opportunity—the integration team identified synergy opportunities relating to sales, manufacturing facilities, back office, procurement, European organization, and manufacturing process. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 53–54)).
- 1751. When asked which of the identified synergy opportunities progressed to the second Hardness Level—setting a synergy target—Dr. Baggenstoss responded, "None of them. They were initial estimates on the opportunity, but a proper target setting was not done by mid-December." (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 54)).
- 1752. None of the identified synergy opportunities progressed to the second Hardness Level of setting a synergy target because Otto Bock "did not come to that stage where this made sense." (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 54-55)).
- 1753. The second Hardness Level—setting a synergy target—involves typically the CFO offering a "top down" cost savings target, followed by a "bottom-up assessment" by the integration team, which can lead to readjusting the target. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 54–55)).
- 1754. Ms. Christine Hammer, Complaint Counsel's Efficiencies Expert, concluded that the lack of definitive synergy targets indicates that the potential efficiencies identified are preliminary and speculative. (Hammer Tr. 2898; PX06002 at 062 (¶ 163) (Hammer Expert Report)).

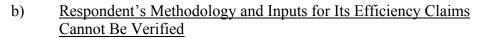
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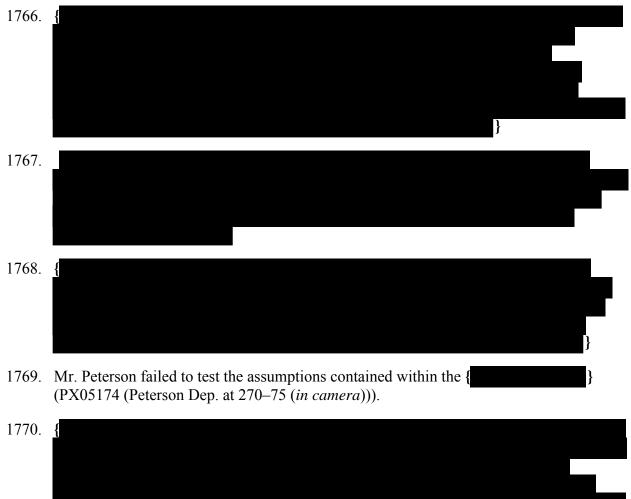
(Peterson, Tr. 6720 (*in camera*); PX05154 (Baggenstoss (A.T. Kearney) Dep. at 54)). Mr. Peterson's conclusion is not credible given Dr. Baggenstoss's testimony, as the integration project lead. (PX05127 (Röessing (Otto Bock) Dep. at 34, 50–51)).

- 1756. Furthermore, when the Integration Team stopped all work to evaluate any potential efficiencies or cost savings from the Merger in mid-December 2017, it also stopped all other work related to integration planning for the Merger. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 26–29)).
- 1757. When integration work stopped, "integration plans were either not started or in [a] very early stage." (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 27)).
- 1758. Mr. David Reissfelder, Freedom's CEO, stated, "in the U.S., I don't believe there were any decisions really made at any point about, you know, honestly, any aspect of the integration." (PX05138 (Reissfelder (Freedom) Dep. at 125)).
- 1759. Due to the lack of decisions with respect to integration, Otto Bock had not yet determined integration plans related to the synergy opportunities it had identified, including manufacturing footprint, logistics, back-office in the United States, and the R&D organization. PX05154 (Baggenstoss (A.T. Kearney) Dep. at 29-30, 55-57)). As a result, Dr. Baggenstoss testified that cost savings estimates from identified synergy opportunities in manufacturing footprint, logistics, back office, and R&D could be affected. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 54–57)).
- 1760. In December 2017, with respect to the cost savings that Otto Bock expects to realize from the Merger, Scott Schneider, Otto Bock's Vice President of Medical Affairs, Government Affairs, and Business Development, testified, "I don't believe we have a set number that we'd be able to tell you." (PX05010 (Schneider (Otto Bock) IHT at 152)).
- 1761. Furthermore, Dr. Röessing, Otto Bock's Chief Strategy and Human Resources Officer, the Otto Bock executive responsible for designing the Freedom integration plan, could not identify any document indicating potential cost savings generated by Otto Bock's acquisition of Freedom. (PX05127 (Röessing (Otto Bock) Dep. at 37–38)).



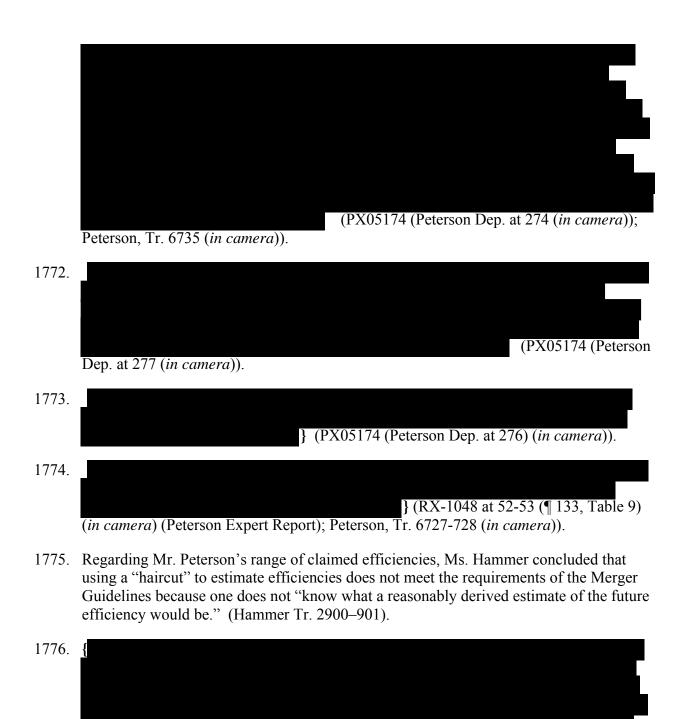
- 1764. Apart from relying on Mr. James Peterson's expert report, Dr. Argue did not conduct any separate analysis of cost savings that might result from the Merger. (Argue, Tr. 6259; PX05173 (Argue Dep. at 30)).
- 1765. Dr. Argue did not perform any independent assessment to verify the cost savings estimate that Mr. Peterson included in his report. (Argue, Tr. 6259; PX05173 (Argue Dep. at 30)).











} (PX05174 (Peterson Dep. at 280) (*in camera*)).

(Hammer Tr. 2913 (in

camera)).

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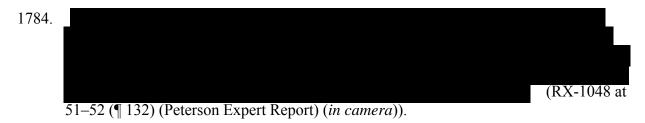
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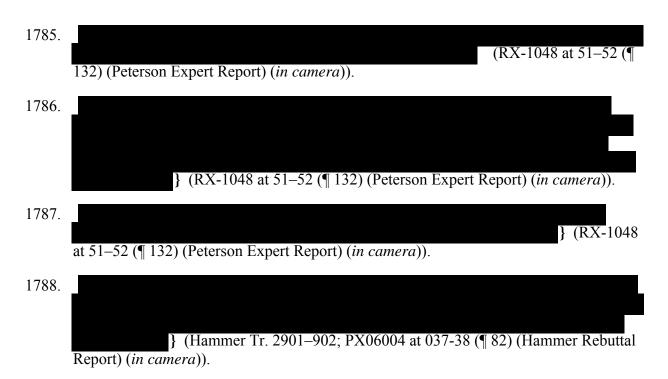
(RX-1048 at 45–53 (¶¶ 120–135) (*in camera*) (Peterson Expert Report); PX05174 (Peterson Dep. at 71)).

- 1779. Mr. Peterson testified that his expert report did not include the calculation he used to determine the claimed cost-savings efficiencies from gross margin improvements, as derived from the {PX05174 (Peterson Dep. at 71) (*in camera*)).
- 1780. { } (PX06004 at 035 (¶ 76) (Hammer Rebuttal Report) (*in camera*).
- 1782. Dr. Argue did not do any independent assessment to verify the cost savings estimate that Mr. Peterson included in his expert report. (Argue, Tr. 6259; PX05173 (Argue Dep. at 30)).

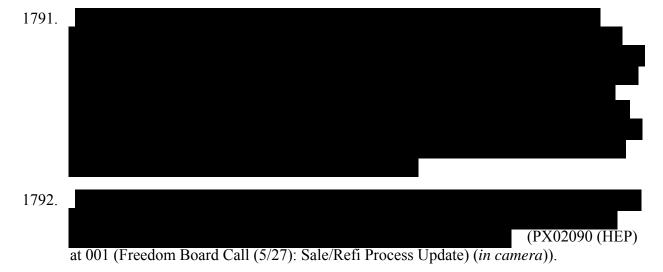
2. Respondent's Claimed Efficiencies are Not Merger Specific

- 1783. Merger-specific efficiencies are those "likely to be accomplished with the proposed merger and unlikely to be accomplished in the absence of either the proposed merger and or another means having comparable anticompetitive effects." (PX08040 at 033 (§ 10) (Merger Guidelines)). Moreover, efficiencies are not merger-specific if they "could be attained by practical alternatives that mitigate competitive concerns, such as divestiture or licensing." (PX08040 at 033 n.13 (§ 10) (Merger Guidelines)).
 - a) <u>Respondent's Claimed Efficiencies Could Be Achieved through</u> <u>Independent Cost-Saving Initiatives</u>





- 1789. Ms. Hammer concluded that Mr. Peterson did not demonstrate that the claimed efficiencies are merger-specific because Mr. Peterson did not provide "any ordinary-course documents or really anything that would help one obtain some certainty that indeed [a claimed efficiency] is likely to be merger-specific." (Hammer Tr. 2901; *see also* PX06004 at 036 (¶ 78) (Hammer Rebuttal Report)).
- 1790. Dr. Argue did not do any independent assessment to determine whether the cost savings Mr. Peterson cites in his report are merger specific. (Argue, Tr. 6259; PX05173 (Argue Dep. at 30)).
 - b) <u>Respondent's Claimed Efficiencies Could Be Achieved through</u> <u>Other, Less Anticompetitive Transactions</u>



1793.	(Smith (HEP) Dep. at 53–54 (<i>in camera</i>)).
1794.	} (PX06004 at 037 (¶ 82) (Hammer Rebuttal Report) (<i>in camera</i>)).
1795.	(Peterson, Tr. 6739 (<i>in camera</i>); PX05174 (Peterson Dep. at 278) (<i>in camera</i>)). { } (Peterson, Tr. 6739 (<i>in camera</i>)).
1796.	} (RX-1048 at 51–52 (¶ 132) (Peterson Expert Report) (<i>in camera</i>)). } (RX-1048 at 51–52 (¶ 132) (Peterson Expert Report) (<i>in camera</i>)).
1797.	Mr. Peterson failed to consider alternative ways that the claimed efficiencies could be

- 1797. Mr. Peterson failed to consider alternative ways that the claimed efficiencies could be accomplished absent the Merger. (Hammer Tr. 2902; PX06004 at 036 (¶ 78) (Hammer Rebuttal Report)).
 - C. THERE IS NO EVIDENCE SHOWING RESPONDENT'S CLAIMED EFFICIENCIES WILL BE PASSED ON TO CUSTOMERS
 - 1. There is No Evidence Showing Respondent's Claimed Cost Savings Will Be Passed on to Customers

1798.	
	} (Peterson, Tr. 6749 (in camera)).
1799.	
	} (PX05174 (Peterson Dep. at 284 (<i>in camera</i>)); Peterson, Tr. 6746–749 (<i>in camera</i>)).
1800.	
	((Peterson, Tr. 6746-749 (<i>in camera</i>)); PX05174 (Peterson Dep. at 281–283 (<i>in camera</i>)); PX06004 at 038 (¶ 84) (Hammer Rebuttal Report)).

- 1801. Dr. Argue, Respondent's expert, testified that he did not analyze whether any of the claimed efficiencies identified by Mr. Peterson, Respondent's other expert, would be passed through to customers. (Argue, Tr. 6259; PX05173 (Argue Dep. at 35–36)).
- 1802. Dr. Argue did not perform any assessment to determine whether the efficiencies Mr. Peterson calculates in his report would result in lower prices for MPK customers. (Argue, Tr. 6259-260; PX05173 (Argue Dep. at 35–36).
- 1803. } (RX-1048 at 45–53 (¶ 120–135) (Peterson Expert Report) (*in camera*)).
- 1804. Because Mr. Peterson did not specify what portion of any claimed efficiencies are fixed versus marginal costs, Mr. Peterson failed to show what portion of the claimed efficiencies would be more likely to be passed on to consumers. (Hammer Tr. 2904; PX06004 at 039 (¶ 87) (Hammer Rebuttal Report)).
- 1805. }

(PX01302 (Otto Bock) at 081 (*in camera*)).

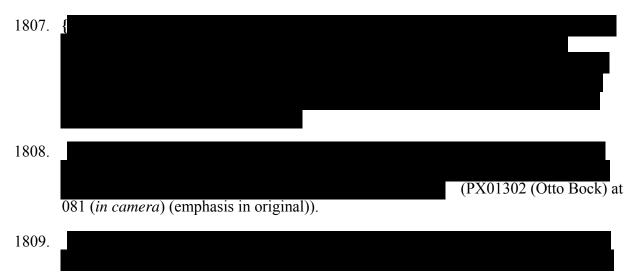
- 2. There is No Evidence Showing Respondent's Claimed Efficiencies regarding Repositioning the Plié Will Benefit Customers
- 1806. Dr. Argue, Respondent's expert witness, claims that Otto Bock's repositioning of the Plié 3 offers procompetitive benefits to customers. (RX-1049 at 83 (¶ 177) (Argue Expert Report)). {

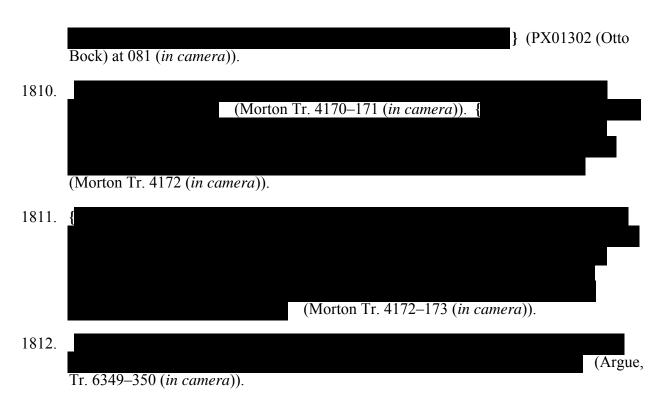
 } (RX-1049 at 83–84 (¶ 179))

 (Argue Expert Report) (*in camera*).

 (RX-1049 at 83-84 (¶ 179) (Argue))

Expert Report) (in camera)).





- 1813. There is no evidence in the record regarding any benefit to consumers of the 3E80. (Tr. 143-6895; JX002).
- 1814. Dr. Argue testified that he did not perform any assessment to determine whether the efficiencies Mr. Peterson estimated in Peterson's expert report would be passed on as lower prices for MPK customers. (Argue, Tr. 6259-60; PX05173 (Argue Dep. at 35-36)).
- 1815. } (Argue, Tr. 6359 (*in camera*); PX05173

(Argue Dep. at 43 (*in camera*)).

XIII. RESPONDENT HAS FAILED TO MEET ITS BURDEN TO SHOW FREEDOM WAS A FAILING FIRM AT THE TIME OF THE MERGER

- 1816. Ms. Christine Hammer, Complaint Counsel's expert, concluded that Freedom was not a failing firm because it did not meet any of the three requirements for a "failing firm" under the Merger Guidelines when the Merger occurred, in September 2017. (PX06002 at 006 (¶ 9) (Hammer Expert Report)).
- 1817. In order to assert successfully a failing firm defense, according to the Merger Guidelines Respondent must demonstrate 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. (PX08040 at 035 (§ 11) (Merger Guidelines)).

1818. The Merger Guidelines state that, "Any offer to purchase the assets of the failing firm for a price above liquidation value of those assets will be regarded as a reasonable alternative offer. Liquidation value is the highest value the assets could command for use outside the relevant market." (PX08040 at 035 n.16 (§ 11) (Merger Guidelines)).

A. FREEDOM'S FINANCIAL CONDITION PRIOR TO THE MERGER

1. Financial Condition Prior to April 2016

1819.		
		} (PX03008 (Madison
	Capital) at 005 (in camera)). {	
		} (PX03008 (Madison Capital) at
	006 (<i>in camera</i>)).	

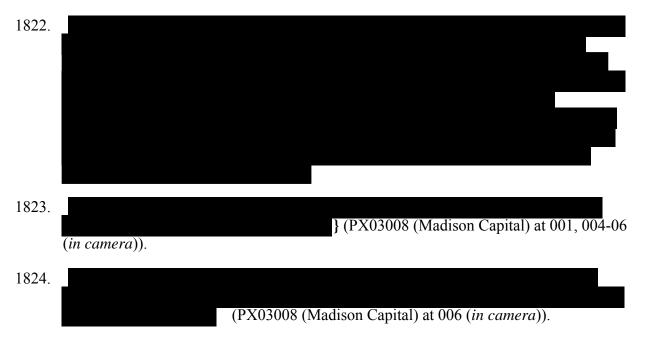
1820. Later that year, in the fourth quarter of 2015, Otto Bock released its C-Leg 4 MPK, which negatively impacted Freedom's MPK sales. (*See* CCFF ¶¶ 1056-1073, above). For example, {

(PX03008 (Madison Capital) at 005 (in camera)).

} (PX03008 (Madison

1821. Freedom also delayed the launch of its Kinnex microprocessor ankle, from the end of 2015 to the third quarter of 2016. {

Capital) at 005 (in camera)).



1825. David Smith became Freedom's Chairman and CEO on April 1, 2016. (Smith (HEP) Tr. 6408).

2. **Changes Implemented by CEO David Smith**

- a) 1826. } (PX02034 (HEP) at 049 (in camera)). 1827. (Smith (HEP) Tr. 6511 (in camera)).
- 1828. In June 2016, David Smith hired Jeremy Matthews (Freedom's current senior VP of sales and marketing) as VP of domestic sales, to "lead the sales team for the U.S. and to help marketing." (PX05137 (Matthews (Freedom) Dep. at 13)).
- 1829. { }
- 1830. Maynard Carkhuff's role also changed from CEO to Chief Innovation Officer. (Carkhuff (Freedom) Tr. 291–292).
- 1831. } (PX02034 (HEP) at 049 (*in camera*)).
 - b) Plié 3 Improvements
- 1832. } (Smith (HEP) Tr. 6537, 6543 (in camera)).
- 1833. Specifically, in 2016, Freedom put initiatives in place to improve the quality of the Plié 3. (Kim (Freedom) Tr. 2515; see also (PX02034 (HEP) at 049 (in camera) ({



Changes in Personnel

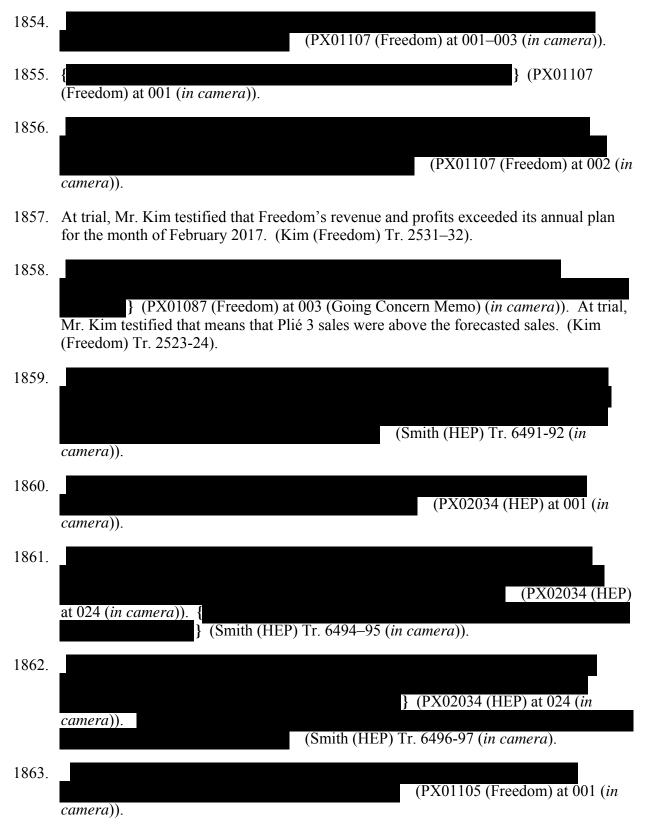
	(PX05137 (Mathews (Freedom) Dep. at 205-06) (in camera)).
1835.	
	<pre>} (PX05115 (Robertson (Freedom) Dep. at 101-02 (in camera)). {</pre>
1836.	(PX05137 (Mathews
1837.	(Freedom) Dep. at 196) (<i>in camera</i>)).
1838.	} (PX05137 (Mathews
	 (Freedom) Dep. at 196) (<i>in camera</i>)). c) <u>David Smith's Strategic Plan</u>
1839.	(PX01014 (Freedom) (<i>in camera</i>)).
1840.	(PX03009 (Madison Capital) at 002 (<i>in camera</i>)).
1841.	(PX03009 (Madison Capital) at 002 (<i>in camera</i>)).

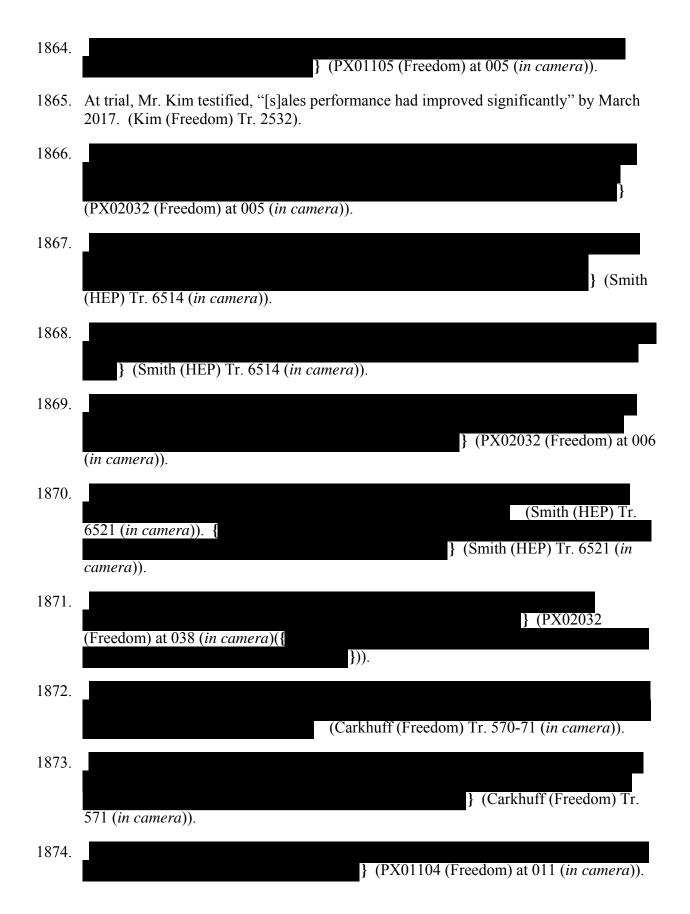
- 1842. Christine Hammer, Complaint Counsel's expert witness, stated, "In my opinion, the 2017 Strategic Plan provided a sound roadmap for Freedom to address its declining revenues and profits, which had caused the liquidity constraints that it faced." (PX06002 at 014 (¶ 28) (Hammer Expert Report)). Furthermore, Christine Hammer stated, "Freedom appears to be a company that had temporarily experienced financial difficulties but had successfully implemented the changes required for it to succeed in the future." (PX06002 at 028 (¶ 70) (Hammer Expert Report)).
- 1843.

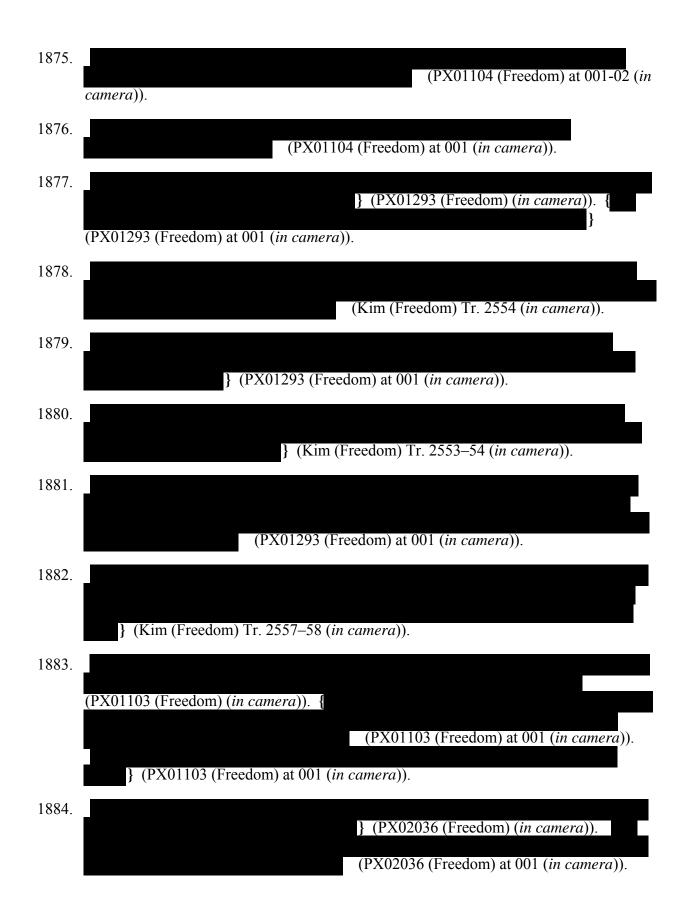
} (Smith (HEP) Tr. 6487–88 (*in camera*)).

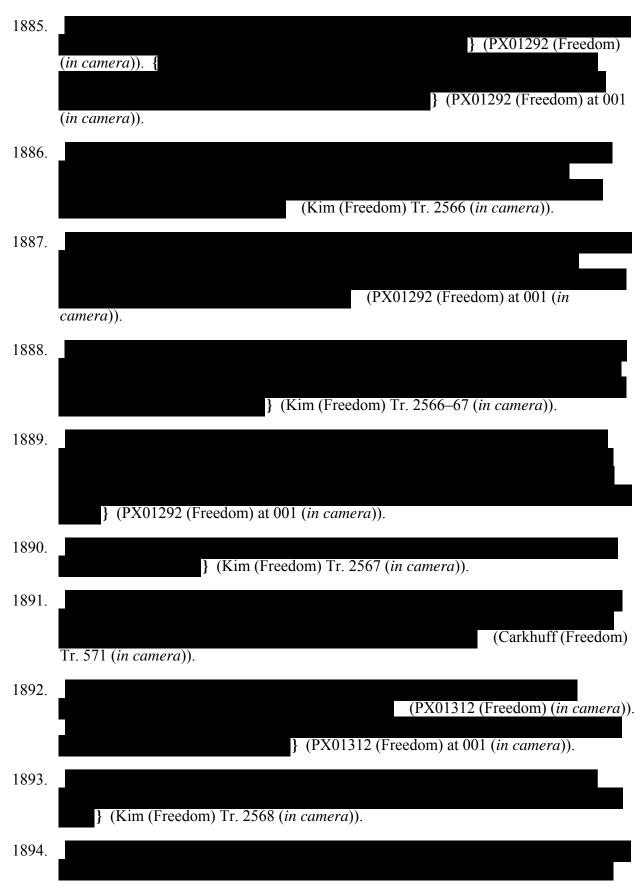
1844.		(Smith (HEP) Tr. 6489 (<i>in camera</i>)).
1845.	6489 (in can	(Smith (HEP) Tr.
1846.	(HEP) Tr. 64	(Smith
	3.	Freedom's Financial Turnaround
		a) <u>Late 2016 Inflection Point</u>
1847.		
		} (PX01109 (Freedom) at 001 (<i>in camera</i>)).
1848.		Kim testified that in December 2016, Freedom's revenues and profit annual financial plan. (Kim (Freedom) Tr. 2530
1849.		
		} (PX02034 (HEP) at 050 (<i>in camera</i>)).
1850.		
	(Going Cond	} (PX01087 (Freedom) at 003 cern Memo) (<i>in camera</i>)).
	(0	b) <u>Freedom Financial Performance in 2017</u>
1851.		
	008 (in came	(PX01108 (Freedom) at 001,
1852.		<i>((10))</i> .
1052.	(PX01108 /	Freedom) at 008 (<i>in camera</i>)).
	(1 201100 (1	

1853. At trial, Mr. Kim testified that Freedom's revenue and profits exceeded its annual plan for the month of January 2017. (Kim (Freedom) Tr. 2531–32).

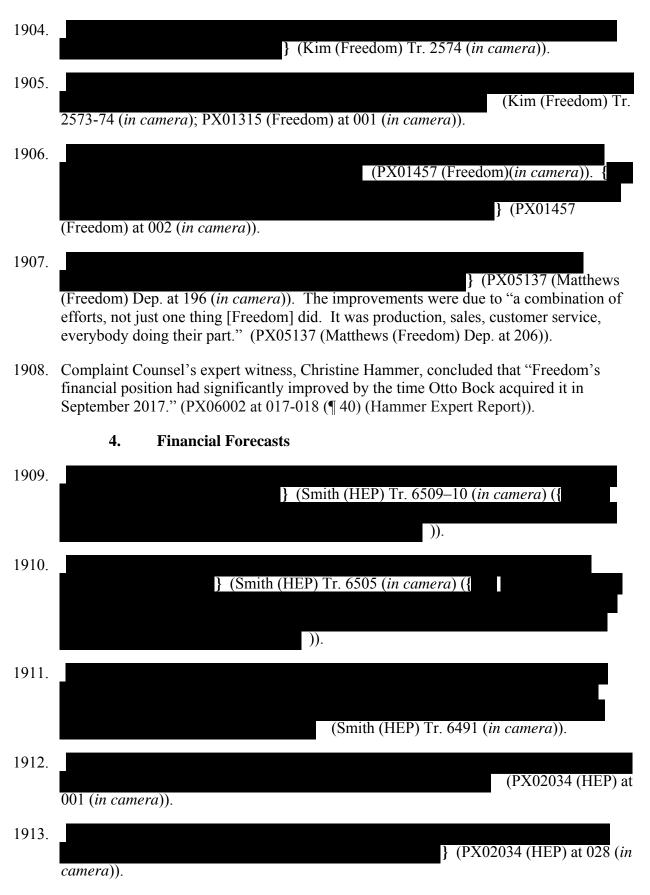


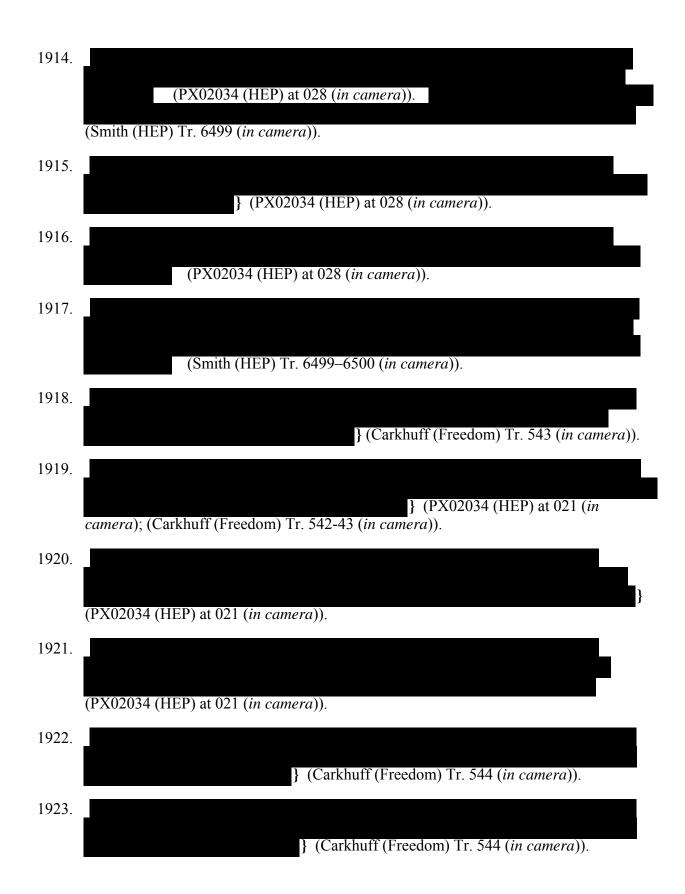


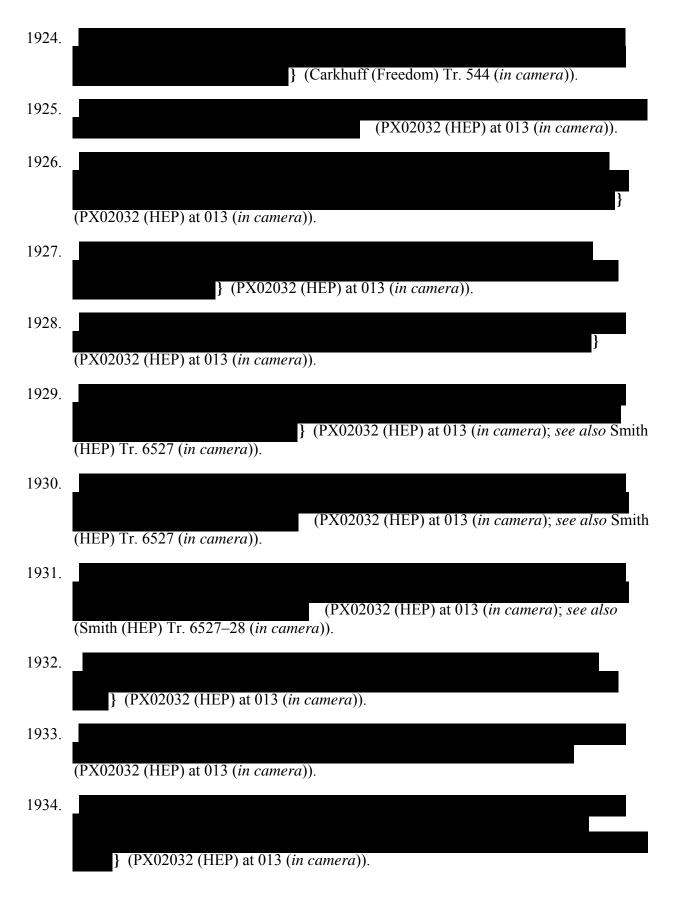


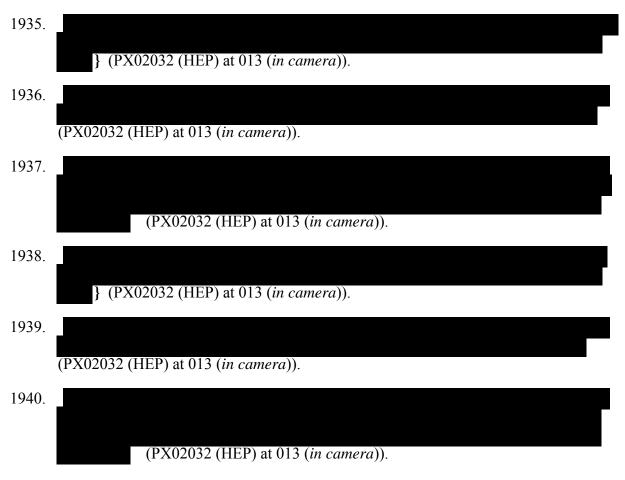


	(PX01312 (Freedom) at 001 (<i>in camera</i>)).
1895.	} (Kim (Freedom) Tr. 2569 (in camera)).
1896.	(PX01313 (Freedom)(<i>in</i> <i>camera</i>)). (PX01313 (Freedom) at 002 (<i>in camera</i>)).
1897.	} (Kim (Freedom) Tr. 2570 (<i>in camera</i>)).
1898.	} (PX01313 (Freedom) at 002 (<i>in camera</i>)).
1899.	(Freedom) Tr. 2571 (<i>in camera</i>)).
1900.	(HEP)(<i>in camera</i>)).
	(<i>in camera</i>)). { (<i>in camera</i>)). { (<i>PX02028</i> (HEP) at 001 (<i>in camera</i>)).
1901.	} PX02028 (HEP) at 003 (<i>in camera</i>)).
1902.	(HEP) at 003 (<i>in camera</i>)).
1903.	(PX01315 (Freedom)(<i>in camera</i>)). { } (PX01315 (Freedom) at 001 (<i>in camera</i>)).

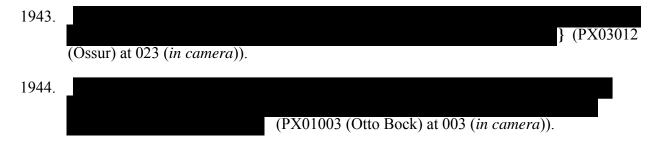








- 1941. On July 15, 2017, David Smith, Freedom's former Chairman and CEO, sent an email to Jon Hammack, Managing Director of Moelis, which included business points for Rolf Classon, a Freedom board member, to deliver to Professor Hans George N\u00e4der, of Otto Bock. (PX02010 (HEP) at 001). One of the business points David Smith instructed to be delivered to Professor N\u00e4der was that "our pipeline is the best it's ever been in the history of [the] company. That investment will be harvested over the next several years. Quattro MPK is a crown jewel. . . ." (PX02010 (HEP) at 001).
- 1942. On August 17, 2017, Jon Hammack, managing director of Moelis, emailed Rolf Classon, a Freedom board member about Freedom's negotiations with Otto Bock, which stated, "They've now seen how attractive our pipeline is. They know Quattro is a game changer. They know what it means if Ossur ends up with this." (PX01851 (Freedom) at 001).



B. RESPONDENT HAS NOT DEMONSTRATED THAT FREEDOM WOULD HAVE BEEN UNABLE TO MEET ITS FINANCIAL OBLIGATIONS IN THE NEAR FUTURE

1945. Christine Hammer, Complaint Counsel's expert witness, concluded, "at the time of its acquisition by Otto Bock, in September 2017, Freedom would have been able to meet its financial obligations in the near future." (PX06002 at 008 (¶ 17) (Hammer Expert Report)).

1. The Clean Independent Audit of Freedom's 2016 Financial Statements is Inconsistent with an Inability to Meet Near-Term Financial Obligations

- 1946. Prior to Freedom's acquisition by Otto Bock, it was Freedom's regular practice to retain independent auditors to conduct an annual audit of Freedom's financial statements. (Kim (Freedom) Tr. 2494–95).
- 1947. Independent auditors typically would audit Freedom's financial statements in mid-February or mid-March of each year. (Kim (Freedom) Tr. 2497).
- 1948. At the end of the audit process, Freedom's independent auditor would provide a report on Freedom's financial statements. (Kim (Freedom) Tr. 2500–01).
- 1949. The independent auditors report would include an opinion on whether the financial statements present fairly the financial position of Freedom, in accordance with Generally Accepted Accounting Principles ("GAAP"). (Kim (Freedom) Tr. 2501).
- 1950. According to Complaint Counsel's expert witness, Christine Hammer, "[u]nder Generally Accepted Accounting Principles ('GAAP'), "continuation of an entity as a going concern is presumed as the basis for financial reporting unless and until the entity's liquidation becomes imminent." (PX06002 at 024 (¶ 59) (Hammer Expert Report)).
- 1951. According to Ms. Hammer, under GAAP, "[i]n connection with preparing financial statements for each annual and interim reporting period, an entity's management shall evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable)." (PX06002 at 024 (¶ 60) (Hammer Expert Report)).
- 1952. According to Ms. Hammer, under GAAP, "[o]rdinarily, conditions or events that raise substantial doubt about an entity's ability to continue as a going concern relate to the entity's ability to meet its obligations as they become due. Accordingly, management's evaluation of an entity's ability to continue as a going concern ordinarily is based on conditions and events that are relevant to an entity's ability to meet its obligations as they become due within one year after the date that the financial statements are issued." (PX06002 at 024-025 (¶ 61) (Hammer Expert Report)).

- 1953. Lee Kim, Freedom's CFO, is a certified public accountant, licensed in California. (Kim (Freedom) Tr. 2495–96).
- 1954. Lee Kim, Freedom's CFO testified that the term "going concern" refers to an entity that "has the financial capability to operate for the long term." (Kim (Freedom) Tr. 2502).
- 1955. Lee Kim, Freedom's CFO, was responsible for managing the independent audit process while it was ongoing each year. (Kim (Freedom) Tr. 2497).
- 1956. Lee Kim, Freedom's CFO, was responsible for interacting with the financial auditors that were retained by Freedom for its annual audits. (Kim (Freedom) Tr. 2495).
- 1957. Lee Kim, Freedom's CFO, would try to be truthful in his communications with Freedom's financial auditors. (Kim (Freedom) Tr. 2495).
- 1958. Lee Kim, Freedom's CFO, would provide financial information to the independent auditors they would request for the audit. (Kim (Freedom) Tr. 2497).
- 1959. Lee Kim, Freedom's CFO, testified that he has an obligation to provide outside auditors with information that is free from material misstatements. (Kim (Freedom) Tr. 2500).
- 1960. Prior to Otto Bock's acquisition of Freedom, the last independent audit of Freedom's financial statements was completed in March 2017. (Kim (Freedom) Tr. 2501).
- 1961. The March 2017 independent audit was of Freedom's 2016 financial statements. (Kim (Freedom) Tr. 2501).
- 1962. Squire & Company ("Squire") conducted the March 2017 independent audit of Freedom's 2016 financial statements. (Kim (Freedom) Tr. 2501).
- 1963. During the course of the audit Squire conducted in March 2017, Lee Kim, Freedom's CFO, provided Squire with information regarding the financial state of Freedom. (Kim (Freedom) Tr. 2502).
- 1964. During the course of the audit Squire conducted in March 2017, Lee Kim, Freedom's CFO, strived to be truthful in his communications with Squire. (Kim (Freedom) Tr. 2502).

a) <u>Going Concern Memo</u>

- 1965. During the audit Squire conducted in March 2017, Squire informed Lee Kim, Freedom's CFO, that it was considering including a paragraph in its audit opinion expressing doubt about Freedom's ability to continue as a going concern. (Kim (Freedom) Tr. 2502-03).
- 1966. At trial, Lee Kim, Freedom's CFO, testified that during the March 2017 audit, Squire requested that Mr. Kim draft "a memorandum addressing the various accounting requirements in the guidance with respect to financial reporting regarding going concern." (Kim (Freedom) Tr. 2503).

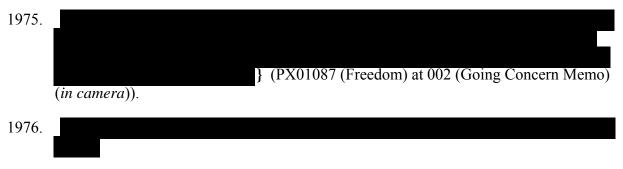
- 1967. Lee Kim, Freedom's CFO, had an understanding of the potential impact that the information conveyed in the memo could have on Squire's audit opinion. (Kim (Freedom) Tr. 2504).
- 1968. Lee Kim, Freedom's CFO, drafted and provided Squire with the memorandum that it requested. (Kim (Freedom) Tr. 2504).
- 1969. } (PX01087 (Freedom) at 001–

004 (email with Going Concern Memo) (in camera)).

- 1970. At trial, Lee Kim, Freedom's CFO, confirmed that the attachment, "Going concern memo, 2016.doc," was the memo he wrote regarding the factors that could affect the evaluation of Freedom as a going concern within the context of the March 2017 audit. (Kim (Freedom) Tr. 2505–06).
- 1971. At trial, Lee Kim, Freedom's CFO, confirmed that he provided the Going Concern Memo to Squire during the March 2017 audit. (Kim (Freedom) Tr. 2510).
- 1972. At trial, Lee Kim, Freedom's CFO, testified that he drafted the Going Concern Memo in March 2017. (Kim (Freedom) Tr. 2510).
- 1973. (PX01087 (Freedom) at 001 (email with Going Concern Memo) (*in camera*)). { (PX01087 (Freedom) at 001 (email with Going Concern Memo) (*in camera*)). At trial, Lee Kim, Freedom's CFO, confirmed that

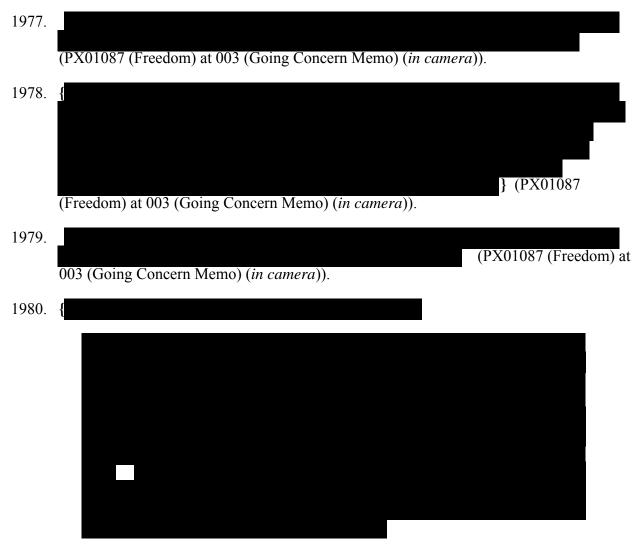
the "opinion" he referenced was the opinion of Squire & Company with respect to its audit of Freedom's 2016 financial statements. (Kim (Freedom) Tr. 2507).

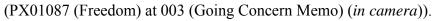
1974. At trial, Lee Kim, Freedom's CFO, testified that Squire ultimately removed the going concern modification it had been considering including in its opinion, meaning that Squire's report did not include information about issues relating to Freedom's ability to continue as a going concern. (Kim (Freedom) Tr. 2508). Mr. Kim testified that Squire's "opinion did not include that information." (Kim (Freedom) Tr. 2508).



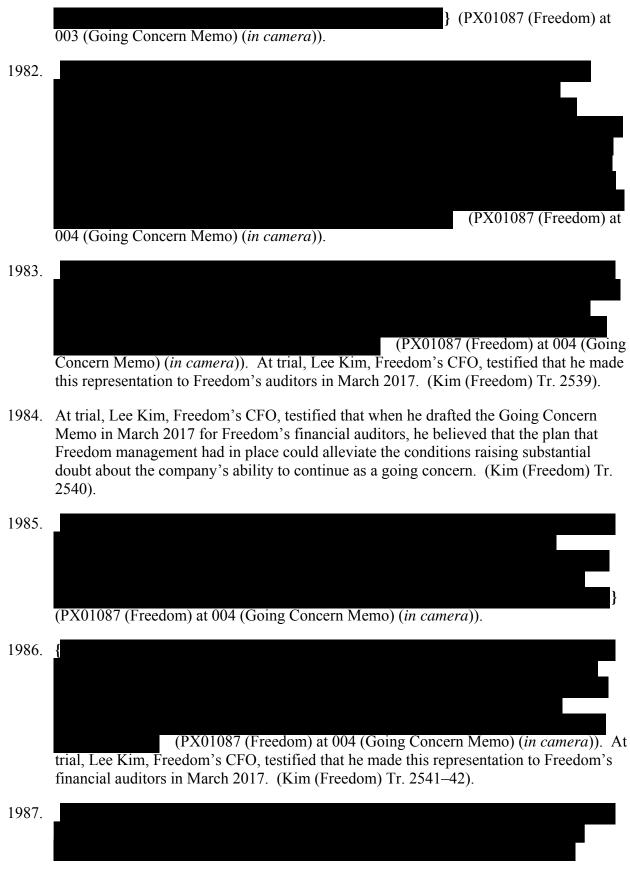


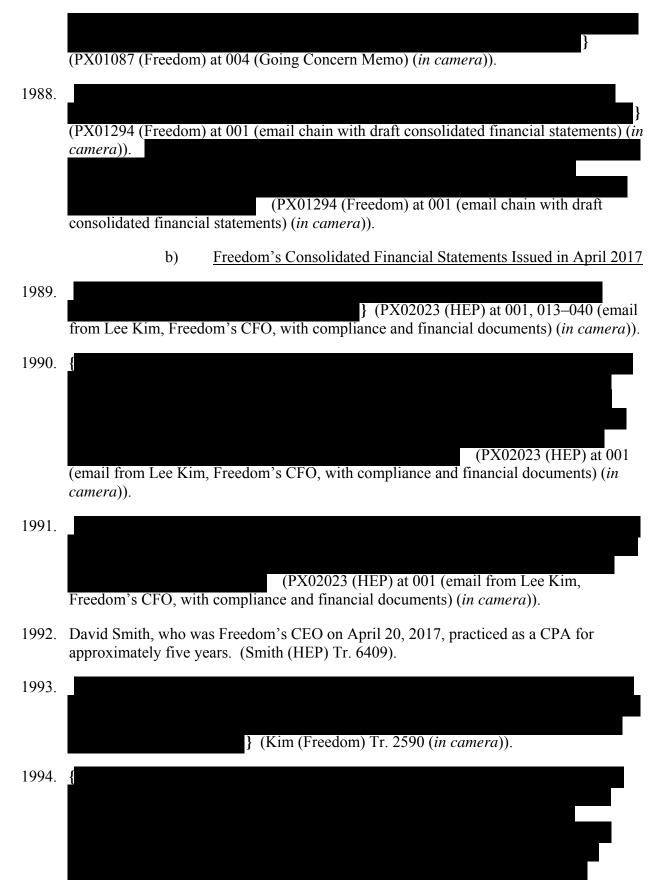
(PX01087 (Freedom) at 002–003 (Going Concern Memo) (in camera)).



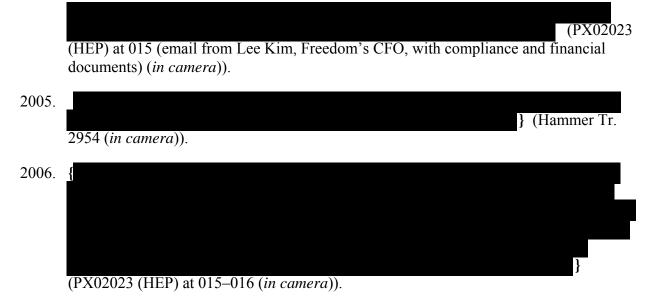








	} (PX02023 (HEP) at 002 ((email from Lee Kim, Freedom's CFO, with compliance and financial documents) (<i>in camera</i>)).
1995.	} (Kim (Freedom) Tr. 2591 (in camera)).
1996.	(Kim (Freedom) Tr. 2591 (in camera)).
1997.	(PX02023 (HEP) at 021–022 (email from Lee Kim, Freedom's CFO, with compliance and financial documents) (<i>in camera</i>)).
1998.	{ (Kim (Freedom) Tr. 2592 (<i>in camera</i>)).
1999.	Tr. 2592 (<i>in camera</i>)).
2000.	{ } (PX02023 (HEP) at 021–022 (email from Lee Kim, Freedom's CFO, with compliance and financial documents) (<i>in camera</i>)).
2001.	} (PX02023 (HEP) at 022 (email from Lee Kim, Freedom's CFO, with compliance and financial documents) (<i>in camera</i>)).
2002.	(PX02023 (HEP) at 021–022 (email from Lee Kim, Freedom's CFO, with compliance and financial documents) (<i>in camera</i>)).
2003.	} (PX02023 (HEP) at 015–016 (email from Lee Kim, Freedom's CFO, with compliance and financial documents) (<i>in camera</i>)).
2004.	



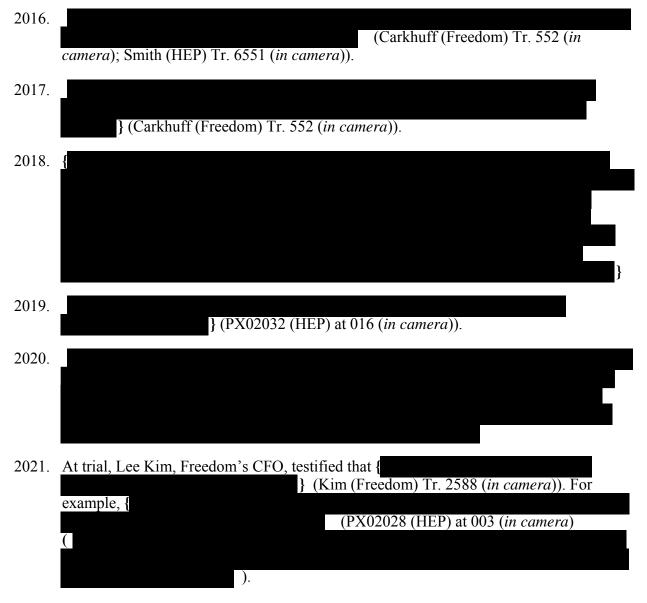
- 2007. No one from Squire & Company, which, on April 6, 2017, submitted its Independent Auditor's Report of Freedom's Consolidated Financial Statements for Years Ended December 31, 2016 and 2015, testified at trial. (Hearing Tr. 143-6895).
- 2008. No one from Squire & Company, which, on April 6, 2017, submitted its Independent Auditor's Report of Freedom's Consolidated Financial Statements for Years Ended December 31, 2016 and 2015, testified at a deposition. (JX002).
- 2009. There is no testimony in the record from Squire & Company that Freedom's audited Consolidated Financial Statements for Years Ended December 31, 2016 and 2015 are not accurate. (Tr. 143-6895; JX002).
- 2010. Squire & Company, which, on April 6, 2017, submitted its Independent Auditor's Report of Freedom's Consolidated Financial Statements for Years Ended December 31, 2016 and 2015, did not produce any documents in In the Matter of Otto Bock HealthCare North America, Inc., Docket No. 9378, before the Federal Trade Commission. (JX002).
- 2011. There are no documents in the record from Squire & Company stating that Freedom's audited Consolidated Financial Statements for Years Ended December 31, 2016 and 2015 are not accurate. (JX002).
- 2012. Christine Hammer, Complaint Counsel's expert witness, concluded,

(PX06002 at 028 (¶ 69) (Hammer Expert Report) (in

camera)).

2. Freedom's Actions were Inconsistent with an Inability to Meet Near Term Financial Obligations

- 2013. In preparing Freedom's audited Consolidated Financial Statements for Years Ended December 31, 2016 and 2015, Freedom never employed a liquidation method of accounting. (Kim (Freedom) Tr. 2548).
- 2014. At trial, Lee Kim, Freedom's CFO, testified that Freedom never employed a liquidation method of accounting because Freedom was not going to be liquidated. (Kim (Freedom) Tr. 2548).
- 2015. At trial, Lee Kim, Freedom's CFO, testified that Freedom never undertook any efforts to value what its various assets could be sold for through liquidation. (Kim (Freedom) Tr. 2548).



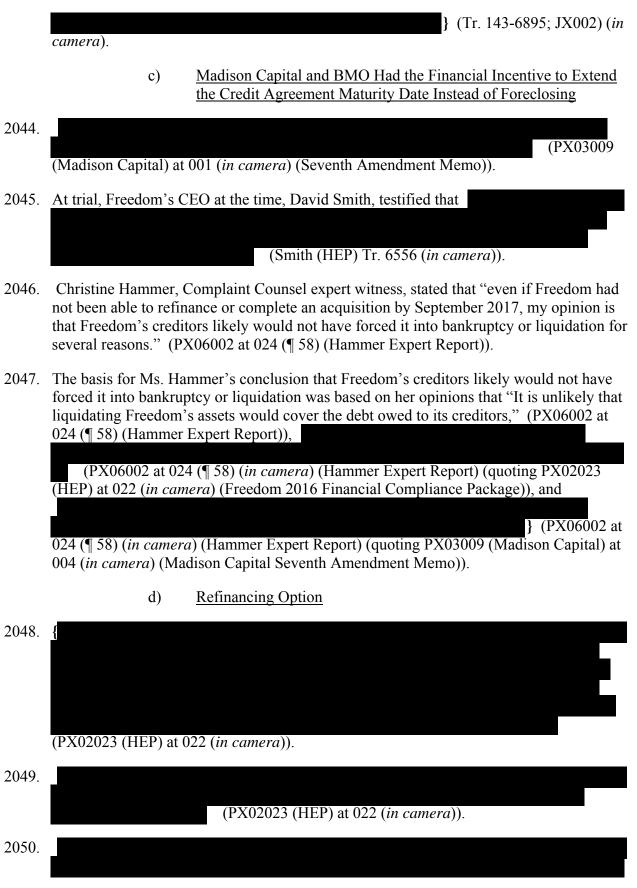
2022. On December 1, 2017, David Smith, Freedom's CEO at the time, testified that Freedom had fairly recently extended the leases for its Irvine, California and Gunnison, Utah facilities for three years each. (PX05005 (Smith (HEP) IHT at 001, 214-15)).

2023. At trial, Lee Kim, Freedom's CFO, testified { (Kim (Freedom) Tr. 2588 (in camera)). 2024. At trial, Lee Kim, Freedom's CFO, testified that { } (Kim (Freedom) Tr. 2588 (*in camera*)). { } (PX05126 (Kim (Freedom) Dep. at 160). { (PX05126 (Kim (Freedom) Dep. at 160). 2025. } (PX02032 (HEP) at 013 (in camera)). 2026. Christine Hammer, Complaint Counsel's expert witness, stated, "In my experience, Freedom's continued investment in its product development pipeline and plans for business expansion are not consistent with a company that is close to imminent failure or in decline." (PX06002 at 018-019 (¶ 43) (Hammer Expert Report)). 3. Freedom Has Not Demonstrated that Absent the Merger, Its Creditors Likely Would Have Forced It into Bankruptcy or Liquidation Freedom's Lenders Previously Extended the Repayment Date a) Instead of Foreclosing 2027. (RX-0826 (Freedom) (in camera)(Credit Agreement)). 2028. .} (RX-0826 (Freedom) at 28 (*in camera*) (Credit Agreement)). 2029. } (PX03009 (Madison Capital) at 001 (in camera) (Seventh Amendment Memo)). 2030. (Kim (Freedom) Tr. 2602-04 (in camera)). 2031. PX01677 (Freedom) (in camera) (Seventh Amendment to Credit Agreement)). 2032. (PX01677 (Freedom) at 002 (*in camera*) (Seventh Amendment to Credit Agreement)).

- 2033. PX01677 (Freedom) at 012 (*in camera*) (Seventh Amendment to Credit Agreement)).
 2034. PX01677 (Freedom) at 013 (*in camera*) (Seventh Amendment to Credit Agreement)).
 2035. PX01087 (Freedom) at 003 (*in camera*) (Going Concern Memo)).
 2036. At trial, Lee Kim, Freedom's CFO testified that there were eight amendments to
- 2036. At trial, Lee Kim, Freedom's CFO testified that there were eight amendments to Freedom's Credit Agreement with Madison Capital and BMO. (Kim (Freedom) Tr. 2528).
 - b) <u>Respondent Submitted No Testimony or Documents from</u> Freedom's Lenders Showing that They Would Have Foreclosed
- 2037. No one from Madison Capital Financial, one of Freedom's lenders, testified at trial. (Tr. 143-6895).
- 2038. No one from Madison Capital Financial, one of Freedom's lenders, testified at a deposition. (JX002).

camera)).

- 2041. No one from Bank of Montreal ("BMO"), one of Freedom's lenders, testified at trial. (Tr. 143-6895).
- 2042. No one from BMO, one of Freedom's lenders, testified at a deposition. (JX002).
- 2043. No one from BMO, one of Freedom's lenders, testified {

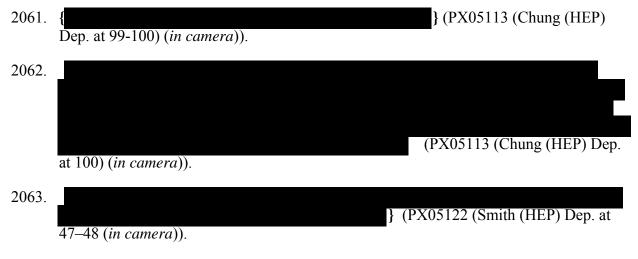


	{PX02023 (HEP) at 022 (<i>in camera</i>)).
2051.	(PX02093 (HEP) (<i>in camera</i>)).
	(<i>in camera</i>)).
2052.	} (PX02093 (HEP) (in camera)).
2053.	(Moelis) (<i>in camera</i>)).
2054.	(PX03087 (Parker Hannifin) at 001) (<i>in camera</i>)).
2055.	} (PX03087 (Parker Hannifin) at 001) (<i>in camera</i>)).
2056.	(PX05125 (Dorotheou (Parker Hannifin) Dep. at 112-113 (<i>in camera</i>)).
2057.	(PX03087 (Parker Hannifin) at 001) (<i>in camera</i>)).
2058.	(PX02100 (HEP) at 002 (<i>in camera</i>)).
2059.	

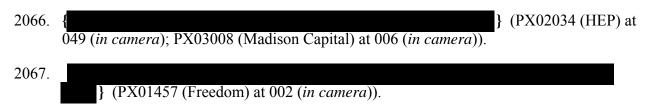
(PX05125 (Dorotheou (Parker Hannifin) Dep. at 111) (in camera)).

2060. Complaint Counsel's expert, Christine Hammer, concluded that "if Freedom had made good faith efforts to explore extending its existing credit agreement with Madison Capital and refinancing BMO's share of the maturing credit facility with either new equity or debt sources, Freedom could have been successful in obtaining additional financing." (PX06002 at 22 (¶ 51) (Hammer Expert Report)).Complaint Counsel's expert, Christine Hammer, concluded that although refinancing arrangements may not have been as favorable to Freedom's equity investors as the sale to Otto Bock, they "would likely have been pursued" in lieu of bankruptcy or liquidation. (PX06002 at 023 (¶ 57) (Hammer Expert Report)).

C. REORGANIZATION UNDER CHAPTER 11 WAS NOT SERIOUSLY CONSIDERED



- 2064. Christine Hammer, Complaint Counsel's expert witness, concluded, "Given that Freedom's reorganization efforts were proving to be successful outside of Chapter 11, there is no reason to believe, barring new evidence produced to the record, that Freedom could not have reorganized successfully in Chapter 11 or implemented a successful reorganization plan." (PX06002 at 031 (¶ 75) (Hammer Expert Report)).
- 2065. Ms. Hammer identified multiple factors related to a company's ability to reorganize successfully under Chapter 11 bankruptcy, including an increase in sales, reduction of costs, reduction of personnel, and change in top management. (PX06002 at 031 (¶ 75) (Hammer Expert Report)). Ms. Hammer concluded that "Despite not having entered into Chapter 11 bankruptcy, many of the actions taken by Freedom to reorganize its business prior to the Otto Bock acquisition echo the reorganization variables examined within the Chapter 11 literature." (PX06002 at 031 (¶ 75) (Hammer Expert Report)).



} (PX06004 at

- 2068. Freedom executed a restructuring plan to reduce its "expense run rate" which is Freedom's "total monthly expenses." (Kim (Freedom) Tr. 2515-16; PX01087 (Freedom) at 003 (Going Concern Memo) (*in camera*)). Mr. Kim testified, this restructuring "reduced the expense run rate." (Kim (Freedom) Tr. 2516).

024 (¶ 50) (*in camera*) (Hammer Rebuttal Report)).

2071. In her Rebuttal Report, Christine Hammer, Complaint Counsel's expert, stated, "Further Freedom's cash situation would not appear unusual in a Chapter 11 context. Often cash is made available through DIP financing, which provides the reorganizing company with the cash it needs to successfully reorganize." (PX06004 at 024 (¶ 51) (Hammer Rebuttal Report)).

D. FREEDOM DID NOT MAKE GOOD-FAITH EFFORTS TO ELICIT REASONABLE ALTERNATIVE OFFERS

- 2072. The Merger Guidelines state that, in order to qualify as a failing firm, the company must have 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 sever danger to competition" than the Merger at issue. (PX08040 at 035 (§ 11) (Merger Guidelines)).
- 2073. The Merger Guidelines state, "[a]ny offer to purchase the assets of the failing firm for a price above the liquidation value of those assets will be regarded as a reasonable alternative offer. Liquidation value is the highest value the assets could command for use outside the relevant market." (PX08040 at 035 n.16 (§ 11) (Merger Guidelines)).
- 2074. Christine Hammer, Complaint Counsel's expert witness, concluded, "Freedom's sales process did not amount to a good-faith effort to elicit reasonable alternative offers." (PX06002 at 032 (¶ 78) (Hammer Expert Report)).
 - 1. Freedom's Sales Process Focused on Otto Bock to the Exclusion of Other Less Anticompetitive Options
 - a) <u>Freedom's Sales Process Focused on Otto Bock to the Exclusion</u> Other Less Anticompetitive Strategic Buyers

2075.	(Carkhuff (Freedom) Tr. 649 (<i>in camera</i>)).
2076.	(Parker Hannifin) at 001–002 (<i>in camera</i>)). (PX03096 (Parker Hannifin) at 001 (<i>in camera</i>)). { (PX03096 (Parker Hannifin) at 001 (<i>in camera</i>)). {
2077.	(Carkhuff (Freedom) Tr. 519, 649 (<i>in camera</i>)) { (Carkhuff (Freedom) Dep. at 46) (<i>in camera</i>)).
2078.	(Carkhuff (Freedom) Tr. 522, 525-26, 649 (<i>in camera</i>)). { } (Carkhuff (Freedom) Tr. 520-21 (<i>in camera</i>); PX01068 (Freedom) (<i>in camera</i>)).
2079.	(PX05122 (Smith (HEP) Dep. at 24-27) (<i>in camera</i>)).

- 2080. Jon Hammack, Managing Director at Moelis, testified that Moelis knew about the discussions with Otto Bock in the fall of 2016, but did not play a role in them. (PX05110 (Hammack (Moelis) Dep. at 14)).
- 2081. Jon Hammack, Managing Director at Moelis, testified that in the October 2016 timeframe, Moelis was not asked to provide any assistance with selling the Freedom business. (PX05110 (Hammack (Moelis) Dep. at 19-20)).
- 2082. Jon Hammack, Managing Director at Moelis, testified that in the October 2016 timeframe, Moelis had not been asked to conduct any outreach to potential acquirers. (PX05110 (Hammack (Moelis) Dep. at 19-20)).

2083. Jon Hammack, Managing Director at Moelis, testified that in the October 2016 timeframe, Moelis had not been asked to reach out to any possible refinance partners. (PX05110 (Hammack (Moelis) Dep. at 19-20)).

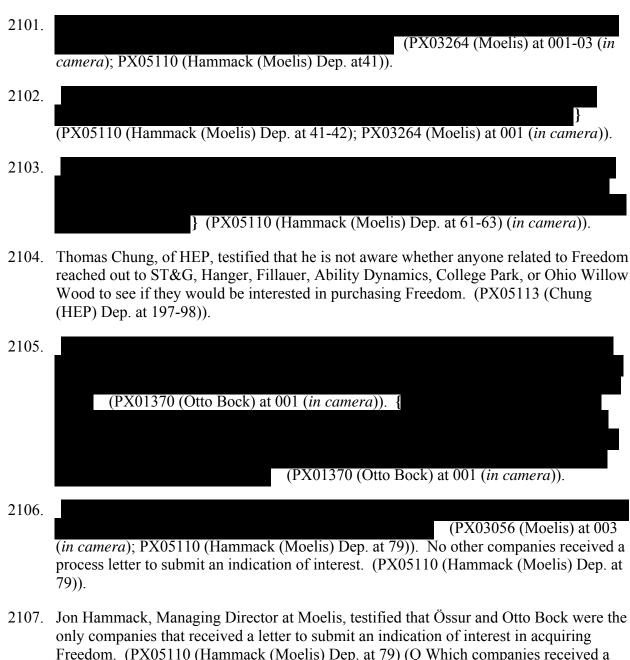


(PX03092 (Parker Hannifin) at 001 (in camera)).

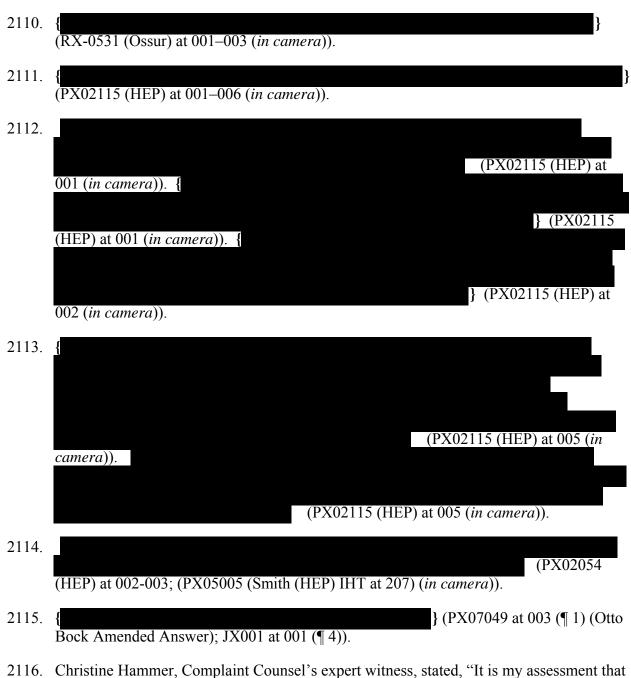
(PX03092 (Parker Hannifin) at 001 (in camera)).

- 2085. On November 27, 2016 Professor Has Georg Näder, primary owner of Ottobock HealthCare GmbH, emailed David Smith, the CEO of Freedom at the time, stating, "we are too busy with M&A and year end rally to start any work before January-I tried to squeeze our project in but my team is overloaded-I am still very much positive-that we may find a winwin sweet spot-lets catch up [in] January." (PX02059 (HEP) at 001, 002).
- 2086. On November 28, 2016, Maynard Carkhuff, Freedom's Chairman, emailed Achilleas Dorotheou, a Freedom board member, stating, "[o]n a confidential basis, yesterday I received a note from Hans Georg Näder advising that Freedom continues as a top priority, however, they are focusing on wrapping up two prosthetic acquisitions before year-end." (PX01111 (Freedom) at 001).
- 2087. Jon Hammack, Managing Director at Moelis, testified that at no time in 2016 was Moelis asked by Freedom to identify potential acquirers for the business. (Hammack (Moelis) Tr. 6081).
- 2088. Jon Hammack, Managing Director at Moelis, testified that at no time in 2016 was Moelis asked by Freedom to conduct any outreach to potential acquirers for the business. (Hammack (Moelis) Tr. 6081).
- 2089. Jon Hammack, Managing Director at Moelis, testified that at no time in 2016 was Moelis asked by Freedom to reach out to any possible refinancing partners. (Hammack (Moelis) Tr. 6082).
- 2090.
 (PX03009 (Madison Capital Funding) at 002 (*in camera*)).
 2091.

	{PX03002 (Moelis) at 002 (<i>in camera</i>)).
2092.	(Moelis) at 002 (<i>in camera</i>)).
2093.	(Carkhuff (Freedom) Tr. 541-42 (<i>in camera</i>); Smith (HEP) Tr. 6491-92 (<i>in camera</i>); PX02034 (HEP) at 001 (<i>in camera</i>)).
2094.	} (Carkhuff (Freedom) Tr. 542-43 (<i>in camera</i>)).
2095.	(PX02034 (HEP) at 001 (<i>in</i> camera)).
2096.	{ } (PX02088 (HEP) at 001; PX03084 (Parker Hannifin) at 001 (<i>in camera</i>)).
2097.	In an April 6, 2017 email, Thomas Chung, of HEP, summarized the Freedom board of directors meeting on April 6, 2017. (PX02088 (HEP) at 001–002.) Freedom's board of directors authorized Moelis to tell Otto Bock that, "there is no need to submit an offer at \$60M." (PX02088 (HEP) at 001).
2098.	(PX05110 (Hammack (Moelis) Dep. at 47); PX02089 (HEP) at 001 (<i>in camera</i>); PX05125 (Dorotheou (Parker Hannifin) at 67) (<i>in camera</i>)).
2099.	Christine Hammer, Complaint Counsel's expert witness, concluded that nothing in the record shows "that Freedom pursued similar discussions with any potential acquirer other than Otto Bock before April 2017." (PX06002 at 34-35 (¶ 92) (Hammer Expert Report)).
2100.	 b) Freedom's Sales Process Focused on a Sale of the Company Rather than Refinancing } (PX03136 (Moelis) at 002 (<i>in camera</i>)).



- Freedom. (PX05110 (Hammack (Moelis) Dep. at 79) (Q Which companies received a process letter to submit an indication of interest? A Ossur and Ottobock. Q Anyone else? A No.).
- 2108. (Carkhuff (Freedom) Tr. 660-61 (*in camera*)). { } PX03102 (Össur) (Project Roosevelt – Non-Binding Proposal) (*in camera*); (De Roy (Össur) Tr. 3606-07 (*in camera*)).
- 2109. In August 2017, Moelis requested that Otto Bock and Össur submit their second-round bids. (PX03239 (Moelis) at 007-10; PX03238 (Moelis) at 008-11).

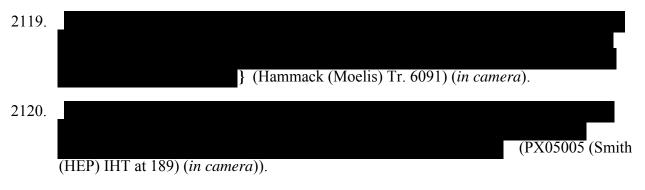


- 2116. Christine Hammer, Complaint Counsel's expert witness, stated, "It is my assessment that by focusing primarily on a strategic sale, Freedom precluded the opportunity to refinance its existing credit facility with debt and/or equity." (PX06002 at 044 (¶ 109) (Hammer Expert Report)).
- 2117. Christine Hammer, Complaint Counsel's expert witness, stated, "Freedom still had potential financing options available when it was acquired by Otto Bock in September 2017, but it did not fully explore them because it prioritized a sale of its business to Otto Bock instead." (PX06002 at 046 (¶ 113) (Hammer Expert Report)).
- 2118. Christine Hammer, Complaint Counsel's expert witness, concluded, "Freedom's shareholders' financial incentives led them to prefer a strategic sale to Otto Bock instead

of pursuing possible refinancing options." (PX06002 at 046 (¶ 114) (Hammer Expert Report)).

2. Freedom's Sales Process Precluded Likely Additional Reasonable Alternative Offers

a) <u>Freedom Limited its Sales Process Limited to Bidders Able to Pay</u> <u>More than \$75M</u>



- b) <u>Freedom Failed to Contact Interested Bidders</u>
- 2121. Christine Hammer, Complaint Counsel's expert witness, concluded that, "Freedom's sale process excluded numerous companies operating within the prosthetics industry that may have made reasonable alternative offers and that Freedom certainly did not make unsuccessful good-faith efforts to elicit such offers." (PX06002 at 043 (¶ 105) (Hammer Expert Report)).

Nabtesco

(1)

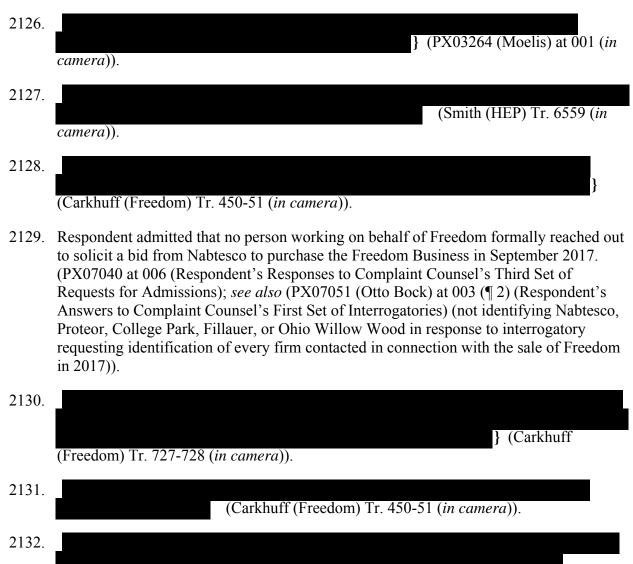
2122. (PX02033 (HEP) at 001–021 (*in camera*)).
(PX02033 (HEP) at 021 (*in camera*)).
2123.

} (Smith (HEP) Tr. 6551 (*in camera*); PX02033 (HEP) at 001–021 (*in camera*)).

- 2124. On September 7, 2017, Maynard Carkhuff, Freedom's Chairman, sent David Smith, then Freedom's CEO, an email that stated "Do you have time for a brief call. I was just approached by Nabtesco regarding their interest in acquiring Freedom." (PX01288 (Freedom) at 002).
- 2125.

} (Smith (HEP) Tr. 6561–62 (*in camera*)). Mr. Smith

informed Mr. Carkhuff that Freedom already had "several good offers in hand." (PX01288 (Freedom) at 001-02). Mr. Smith informed a Freedom board member that Freedom could validate Nabtesco's interest if the current "process falls apart." (PX01288 (Freedom) at 001).



(Carkhuff (Freedom) Tr. 450-51 (in camera)).

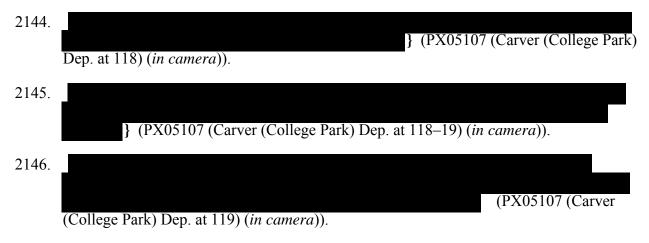
- 2133. } (Carkhuff (Freedom) Tr. 451 (*in camera*)).
- 2134. At trial, Jon Hammack, Managing Director at Moelis, Freedom's investment bank, testified that Moelis did not contact Nabtesco regarding a potential transaction with Freedom. (Hammack (Moelis) Tr. 6093).

	(2) Proteor
2135.	(PX02033 (HEP) at 001–002 (<i>in camera</i>)). } (PX02033 (HEP) at 021 (<i>in</i>
	<i>camera</i>)).
2136.	(Smith (HEP) Tr. 6551; PX02033 (HEP) at 021 (<i>in camera</i>)).
2137.	
	(PX03264 (Moelis) at 001 (<i>in camera</i>)).
2138.	(Smith (HEP) Tr. 6557 (in
	camera)).
2139.	At trial, Jon Hammack, Managing Director at Moelis, Freedom's investment bank, testified that Moelis did not contact Proteor Inc. regarding a potential transaction with Freedom. (Hammack (Moelis) Tr. 6093–94; <i>see also</i> (PX07051 (Otto Bock) at 003 (¶ 2) (Respondent's Answers to Complaint Counsel's First Set of Interrogatories) (not identifying Nabtesco, Proteor, College Park, Fillauer, or Ohio Willow Wood in response to interrogatory requesting identification of every firm contacted in connection with the sale of Freedom in 2017)).
2140.	
	(Mattear (Proteor) Tr. 5761-62 (in camera))
	(3) College Park
2141.	
	} (PX02033 (HEP)
	at 001–021 (<i>in camera</i>)).
	} (PX02033 (HEP) at 021 (<i>in camera</i>)).
2142.	(PX03264 (Moelis) at 001

(in camera)).

2143. At trial, Jon Hammack, Managing Director at Moelis, Freedom's investment bank, testified that Moelis did not contact College Park regarding a potential transaction with

Freedom. (Hammack (Moelis) Tr. 6093; *see also* (PX07051 (Otto Bock) at 003 (\P 2) (Respondent's Answers to Complaint Counsel's First Set of Interrogatories) (not identifying Nabtesco, Proteor, College Park, Fillauer, or Ohio Willow Wood in response to interrogatory requesting identification of every firm contacted in connection with the sale of Freedom in 2017)).



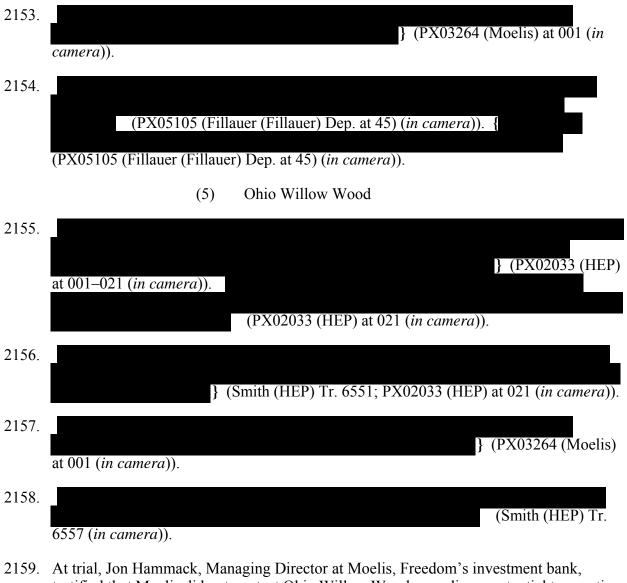
2147. Freedom's CEO at the time, David Smith, testified that reaching out to College Park, or another small competitor, would be "the worst thing to do" because it "would have alerted a small competitor that [Freedom] was being sold" and would waste time with "a partner that couldn't buy us." (PX05122 (Smith (HEP) Dep. at 174-75)).

Fillauer

(4)

- 2148.] (PX02033 (HEP) at 001–021 (*in camera*)).
 2149. (Smith (HEP) Tr. 6551; PX02033 (HEP) at 021 (*in camera*)).
 2150. (Smith (HEP) Tr. 6556 (*in camera*)).
- 2151. At the deposition of David Smith, Freedom's CEO at the time, on March 22, 2018, when asked if he reached out to Fillauer as part of the Freedom sales process, Smith responded, "Philaur? [sic] No. I don't even know who they are." (PX05122 (Smith (HEP) Dep. at 86)).
- 2152. At trial, Jon Hammack, Managing Director at Moelis, Freedom's investment bank, testified that Moelis did not contact Fillauer regarding a potential transaction with

Freedom. (Hammack (Moelis) Tr. 6094; *see also* (PX07051 (Otto Bock) at 003 (\P 2) (Respondent's Answers to Complaint Counsel's First Set of Interrogatories) (not identifying Nabtesco, Proteor, College Park, Fillauer, or Ohio Willow Wood in response to interrogatory requesting identification of every firm contacted in connection with the sale of Freedom in 2017)).



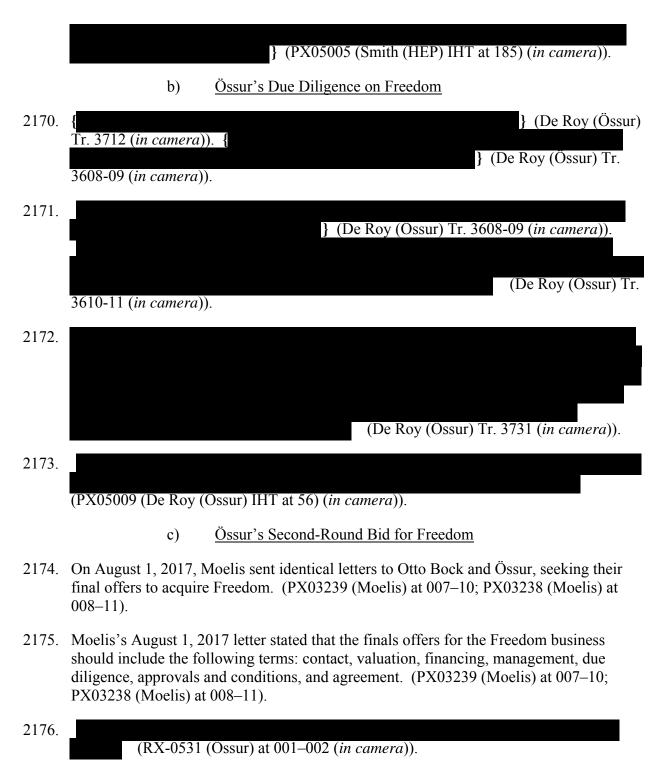
2159. At trial, Jon Hammack, Managing Director at Moelis, Freedom's investment bank, testified that Moelis did not contact Ohio Willow Wood regarding a potential transaction with Freedom. (Hammack (Moelis) Tr. 6094; *see also* (PX07051 (Otto Bock) at 003 (¶ 2) (Respondent's Answers to Complaint Counsel's First Set of Interrogatories) (not identifying Nabtesco, Proteor, College Park, Fillauer, or Ohio Willow Wood in response to interrogatory requesting identification of every firm contacted in connection with the sale of Freedom in 2017)).

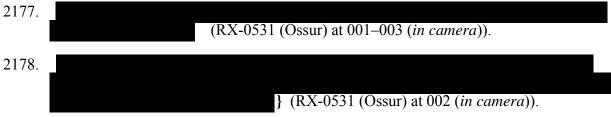


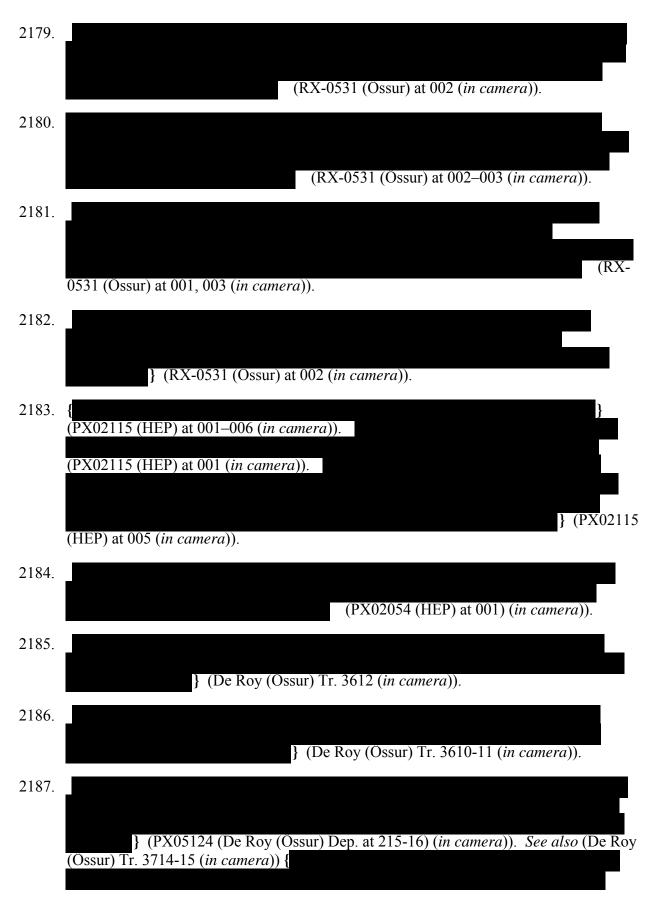
	5080 (in camera)). { } (An	bogast (Ohio Willow Wood) Tr. 5080-81 (in camera)).
2161.) (i ii	
	Tr. 5087 (in camera)).	} (Arbogast (Ohio Willow Wood)
2162.	11. 5087 (in camera)).	
	camera)).	} (Carkhuff (Freedom) Tr. 728 (in
2163.	{ Willow Wood) Tr. 5081 (in cam	} (Arbogast (Ohio

E. FREEDOM HAD A REASONABLE ALTERNATIVE OFFER FROM ÖSSUR

- 2164. The Merger Guidelines explain, "[a]ny offer to purchase the assets of the failing firm for a price above the liquidation value of those assets will be regarded as a reasonable alternative offer. Liquidation value is the highest value the assets could command for use outside the relevant market." (PX08040 at 035 n.16 (§ 11) (Merger Guidelines)).
- 2165. Christine Hammer, Complaint Counsel's expert, concluded, "Further, despite its flawed sales process, I have seen no evidence to show that a { bid Össur submitted to acquire Freedom would not qualify as a reasonable alternative offer." (PX06002 at 32 (¶ 79) (*in camera*) (Hammer Expert Report)).
 - 1. Össur's Bids
 - a) <u>Össur's Initial Bid for Freedom</u>
- 2166. [) PX03102 (Ossur) (Project Roosevelt – Non-Binding Proposal) (*in camera*); (De Roy (Ossur) Tr. 3606-07 (*in camera*)).
 2167. [) (De Roy (Ossur) Tr. 3606 (*in camera*)).
 2168. {] (PX05005 (Smith (HEP) IHT at 183-84)); (De Roy (Ossur) Tr. 3709-10 (*in camera*)).
 2169. [) (PX05005 (Smith (HEP) IHT at 184-86) (*in camera*)). {]









(De Roy (Ossur) Tr. 3612 (in camera)).

- 2189. In a September 8, 2017 email sent to Maynard Carkhuff, Freedom's Chairman, David Smith, Freedom's CEO at the time, described Freedom as having "several good offers in hand." (PX01288 (Freedom) at 001).
- 2190. { (RX-

- 2191. With respect to his opinion on whether Össur's offer to acquire Freedom was a "reasonable alternative offer," James Peterson, Respondent's Expert Witness, testified, "I did not make an opinion or report within the context of the Merger Guidelines if [Össur's offer] met the liquidation threshold and the noncompetition threshold." (PX05174 (Peterson Dep. at 126–27)). Further, with respect to whether Mr. Peterson had offered an opinion that Össur's offer to acquire Freedom was not a reasonable alternative offer, Mr. Peterson testified, "I did not offer that specific statement in my report." (PX05174 (Peterson (Respondent) Dep. at 127)).
- 2192.

} (PX05122 (Smith (HEP) Dep. at 181 (*in camera*))).

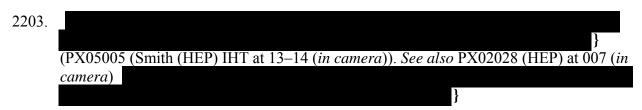
2193. Respondent's expert witness, James Peterson, testified that he is not aware of testimony or documents in the record that indicate that Össur intended to discontinue selling Freedom's microprocessor knee products in the United States. (PX05174 (Peterson Dep. at 133))

2. Liquidation Value of Freedom

a) <u>No Ordinary Course Estimate of Liquidation Value Was</u> <u>Performed</u>

^{0536 (}Ossur) at 001 (*in camera*)).

- 2194. (Carkhuff (Freedom) Tr. 552 (*in camera*)).
- 2195. Lee Kim, Freedom's CFO, testified that in preparing its own financial statements, Freedom never employed a liquidation method of accounting. (Kim (Freedom) Tr. 2548).
- 2196. (Smith (HEP) Tr. 6551 (*in camera*)).
- 2197.} (PX07028 (HEP) at 002 (Response to Specification No. 1) (*in camera*)).
- 2198. Jon Hammack, Managing Director of Moelis, Freedom's investment bank, testified that Freedom never asked Moelis to assist in calculating a liquidation value of Freedom. (PX05110 (Hammack (Moelis) Dep. at 200)).
- 2199. Jon Hammack, Managing Director of Moelis, Freedom's investment bank, testified that HEP never asked Moelis to assist in calculating a liquidation value of Freedom. (PX05110 (Hammack (Moelis) Dep. at 200).
 - b) <u>Respondent's Experts Did Not Estimate Liquidation Value</u>
- 2200. Respondent's expert witness, James Peterson, did not perform a liquidation analysis of Freedom's business. (RX-1048 at 0044 (Peterson Expert Report) ("While I did not perform a liquidation analysis)).
- 2201. At trial, Respondent's expert witness, James Peterson, testified, "I did not calculate a point estimate of the liquidation value of Freedom." (Peterson, Tr. 6691).
- 2202. (Argue, Tr. 6373 (*in camera*)).
 - c) <u>Evidence Indicates Freedom's Liquidation Value Is Substantially</u> <u>below Össur's Bid</u>
 - (1) CEO David Smith's Estimate of Liquidation Value



2204. (Smith (HEP) Tr. 6556 (*in camera*)).

- 2205. In response to whether Chapter 7 bankruptcy was discussed, David Smith, Freedom's CEO at the time, testified "[W]hen you look at those economics of what you're going to pull in, you're not going to pay the debtors back. Could you sell your IP for something? You're not going to pay your banks back." (PX05122 (Smith (HEP) Dep. at 50)).
- 2206. David Smith, Freedom's CEO at the time, testified that if Freedom would have entered bankruptcy under Chapter 7 (liquidation bankruptcy), "work in process is worthless." (PX05122 (Smith (HEP) Dep. at 50)).
- 2207. David Smith, Freedom's CEO at the time, testified that if Freedom would have entered bankruptcy under Chapter 7 (liquidation bankruptcy), "raw materials, you could probably sell 60 cents on the dollar back to your original vendor." (PX05122 (Smith (HEP) Dep. at 50)).
- 2208. David Smith, Freedom's CEO at the time, testified that if Freedom would have entered bankruptcy under Chapter 7 (liquidation bankruptcy), "finished goods, you could probably auction, but the problem is a lot of your finished goods are, you know, you got 9,000 size, you know, 11s, when you need, you know, 9,000 size 8s kind of thing. So, are you going to get 40, 50, 60 percent on the dollar?" (PX05122 (Smith (HEP) Dep. at 50)).
- 2209. (PX02028 (Freedom) at 006 (*in camera*)).
 2210. } (PX05122 (Smith (HEP) Dep. at 190 (*in camera*))).
- 2211. David Smith, Freedom's CEO at the time, testified that if Freedom would have entered bankruptcy under Chapter 7 (liquidation bankruptcy), "[t]he receivables, you could factor the receivables and collect those." (PX05122 (Smith (HEP) Dep. at 50)).
 - (2) Complaint Counsel's Expert's Estimate of Upper Bound of Freedom's Liquidation Value

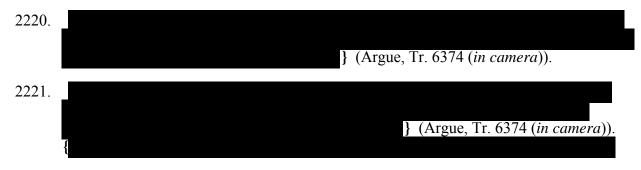
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2212. Christine Hammer, Complaint Counsel's expert witness, did not offer an opinion on Freedom's exact liquidation value. (PX06002 at 046 (¶ 124) (Hammer Expert Report)). *See also* Hammer Tr. 2979–80 (*in camera*) {

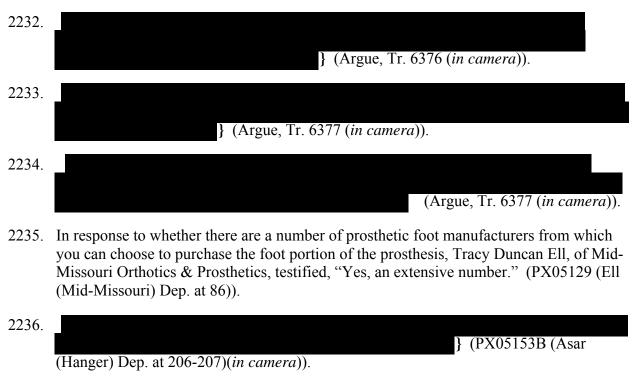
2213. Christine Hammer, Complaint Counsel's expert witness, used the book value of Freedom's tangible assets and fair value of Freedom's intangible assets to establish an upper boundary for the liquidation value. (PX06002 at 053 (¶ 142) (Hammer Expert Report)). *See also* Hammer Tr. 2980 (*in camera*) {

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	(Hammer Expert Report) (<i>in camera</i>)).	} (PX06002 at 053 (¶ 142)
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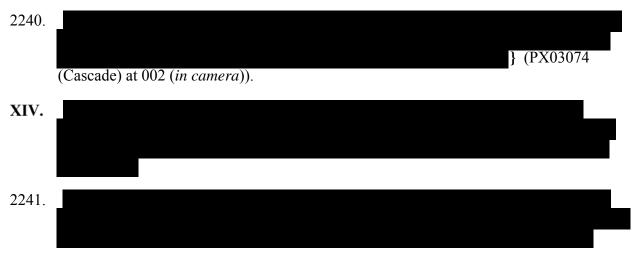
- 2218. Christine Hammer, Complaint Counsel's expert witness, stated, "nothing suggests that Össur's bid does not qualify as a reasonable alternative offer, as defined by the Merger Guidelines." (PX06002 at 045 (¶ 119) (Hammer Expert Report)).
- 2219. Ms. Hammer opined, "Because Össur submitted its bid as part of the sale process of Freedom as a going concern, instead of an asset liquidation sale, I find it unlikely that the liquidation value of the Freedom assets would be greater than Össur's bid." (PX06002 at 046 (¶ 122) (Hammer Expert Report)).
 - **3.** Respondent Did Not Establish the Competitive Impact of an Össur Acquisition of Freedom
 - a) <u>Respondent's Expert Did Not Perform Critical Aspects of a</u> <u>Competitive Analysis of an Össur-Freedom Transaction</u>

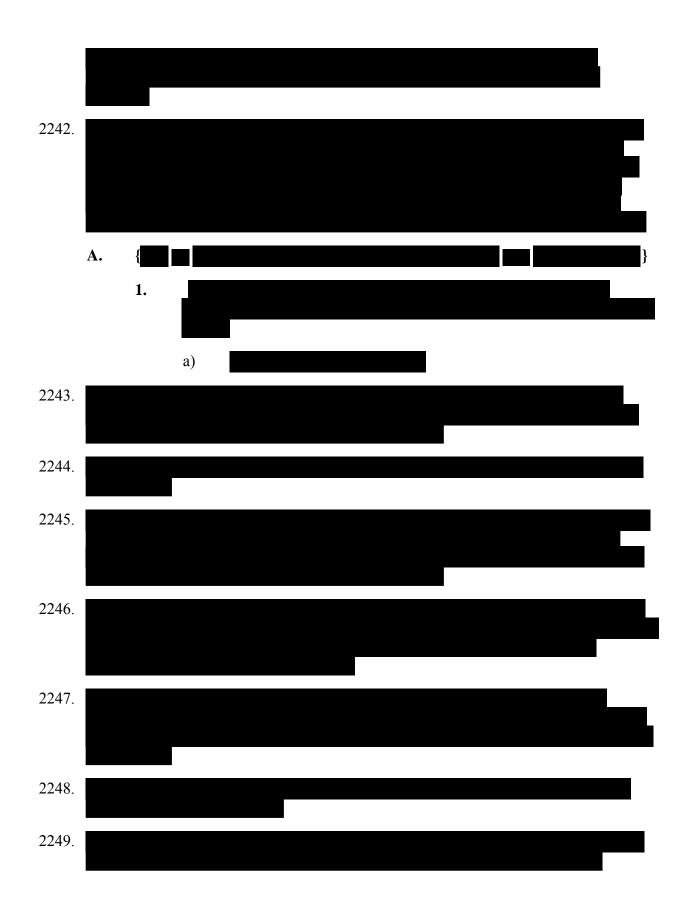


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		b)	Respondent's Expert's Market Shar for a K3 Foot Market Are Unreliab Record	
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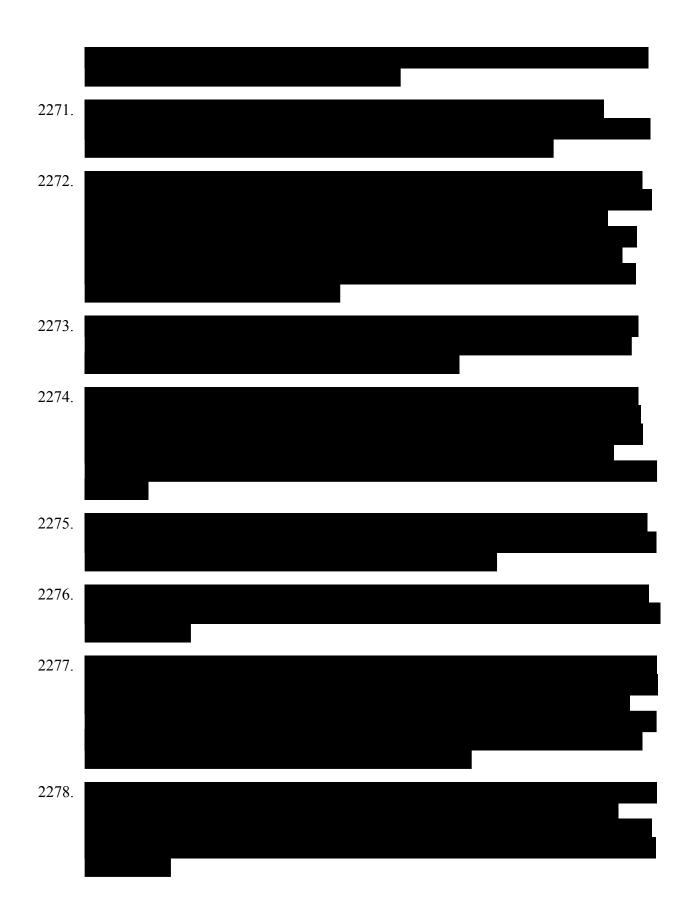
- 2237. (Arbogast (Ohio Willow Wood) Tr. 5191-92 (*in camera*)). { } (Arbogast (Ohio Willow Wood) Tr. 5192 (*in camera*)).
- 2238. Kim Peter Viviane De Roy, Össur's executive vice president of R&D, testified "There's quite a few more" prosthetic foot manufacturers in the United States compared to MPK manufacturers, even when only considering manufacturers of K3 and K4 feet. (De Roy (Össur) Tr. 3587). De Roy estimated that there are between seven and nine foot producers. (De Roy (Össur) Tr. 3589).
- 2239. Keith Watson, of Fourroux Prosthetics, testified, "we see tons of different feet." (PX05166 (Watson (Fourroux) Dep. at 124)).



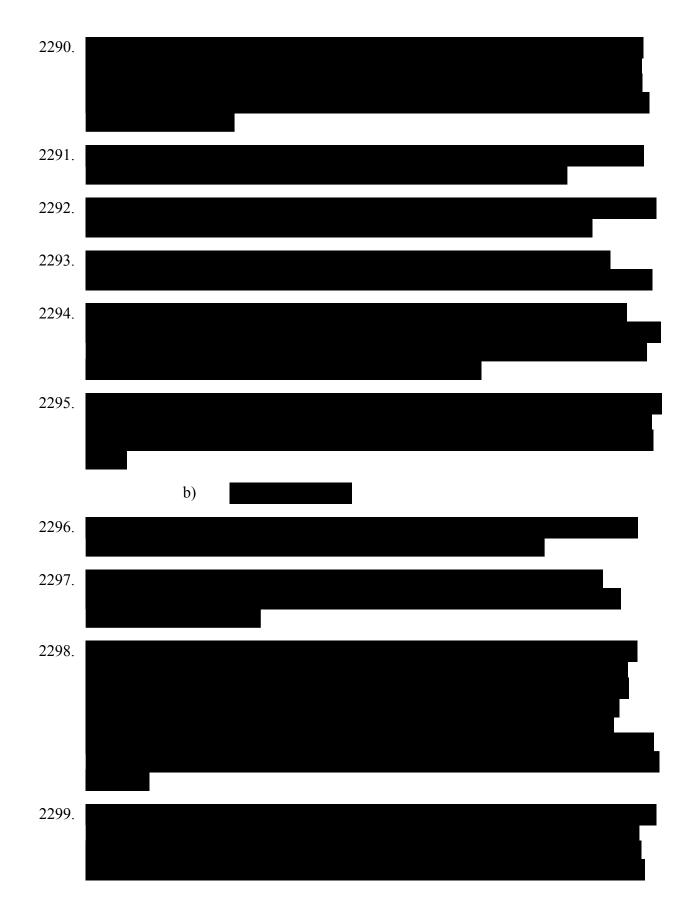


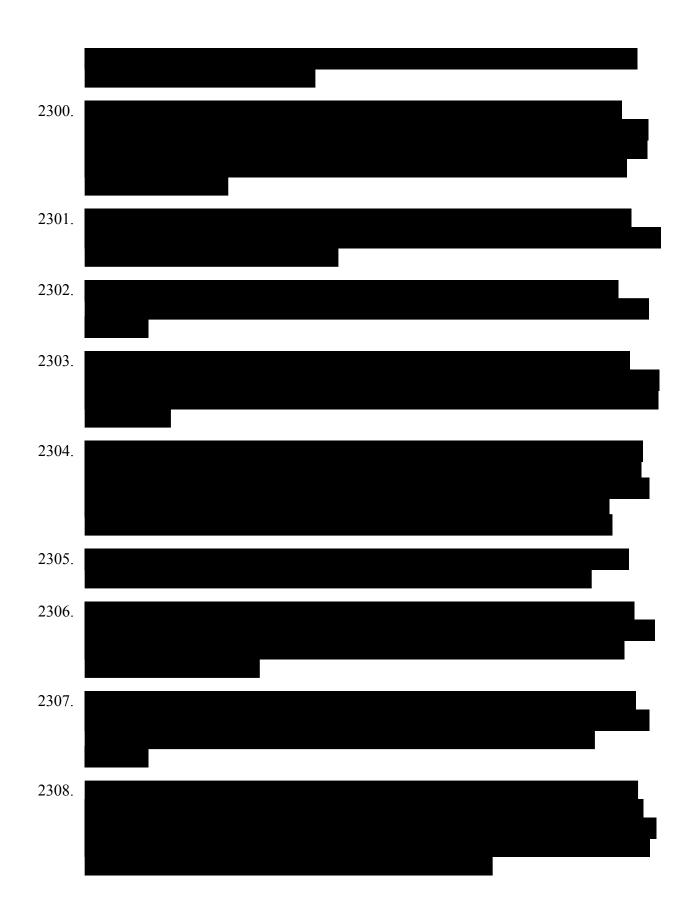


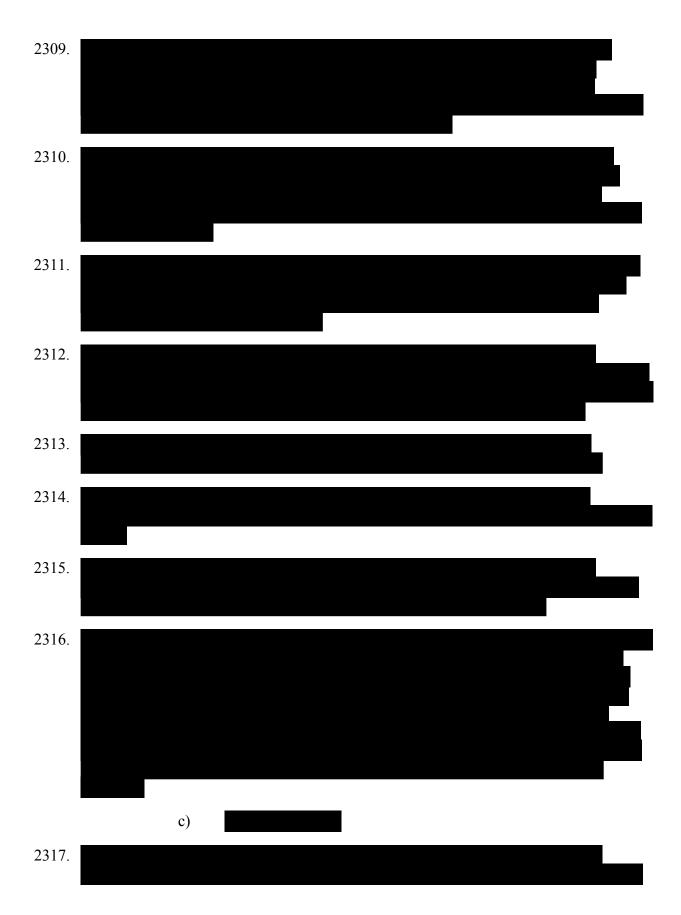




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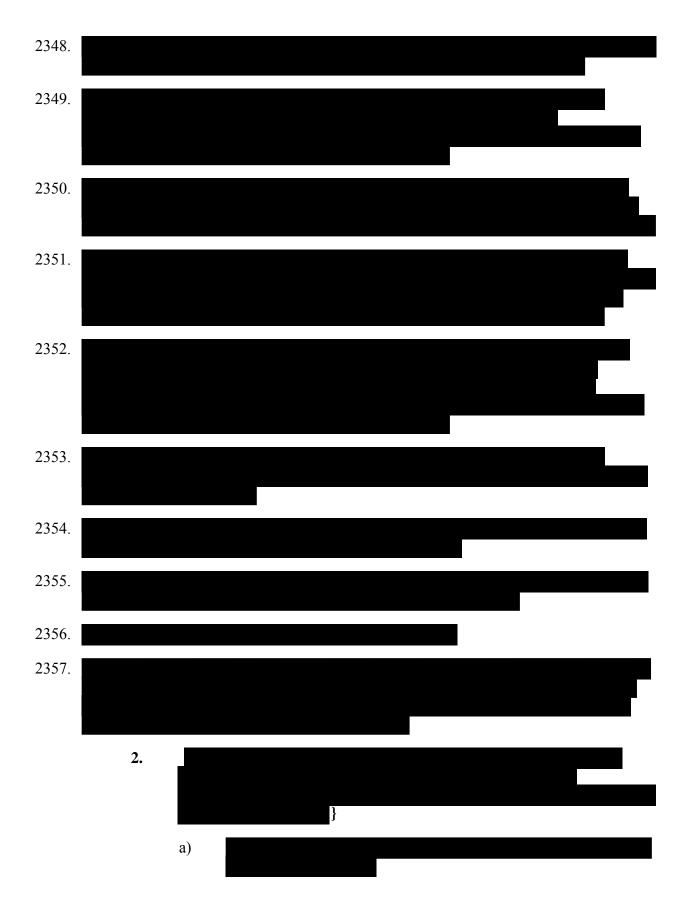


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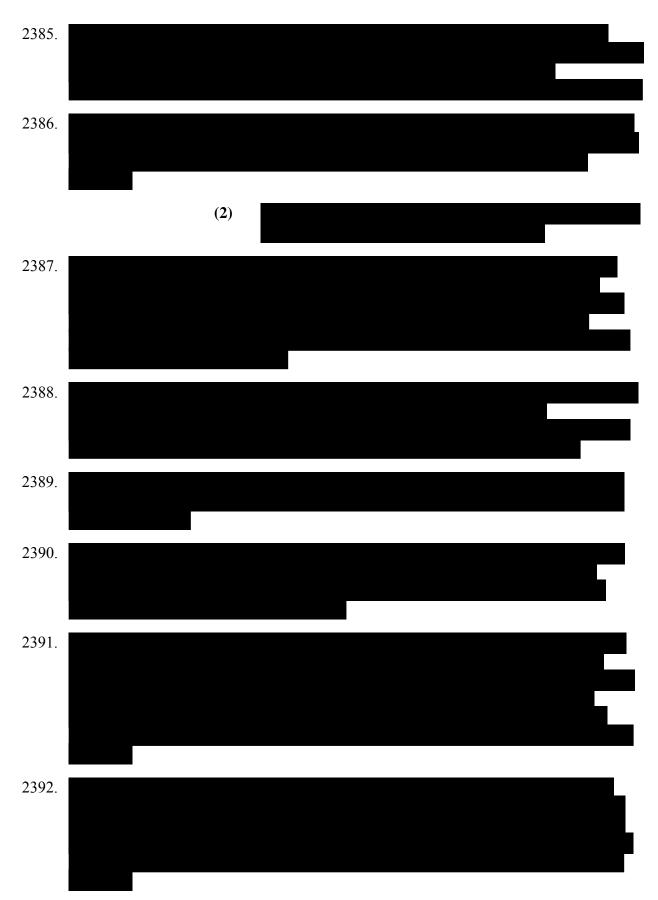






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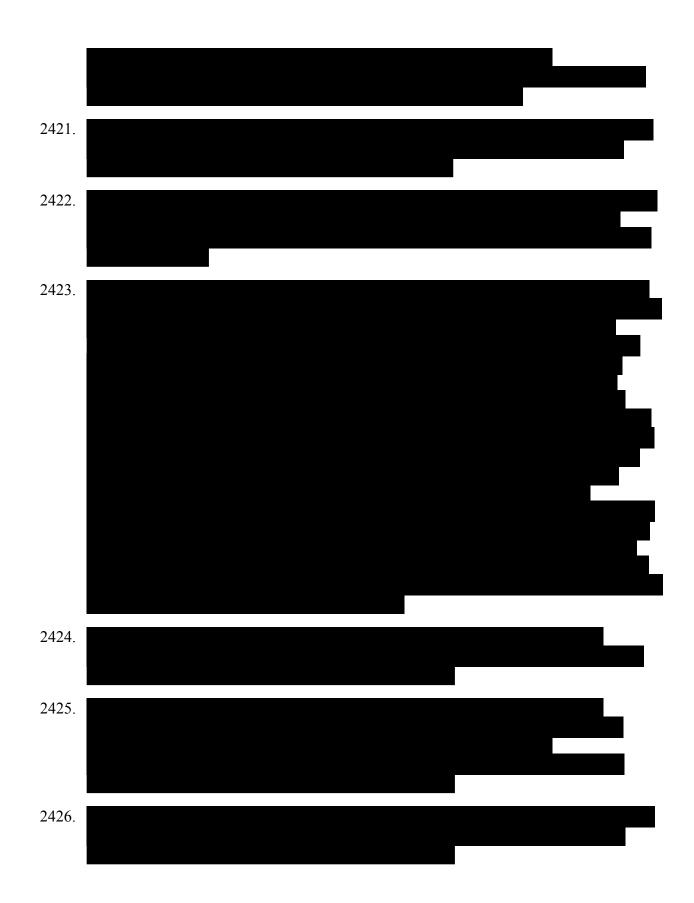


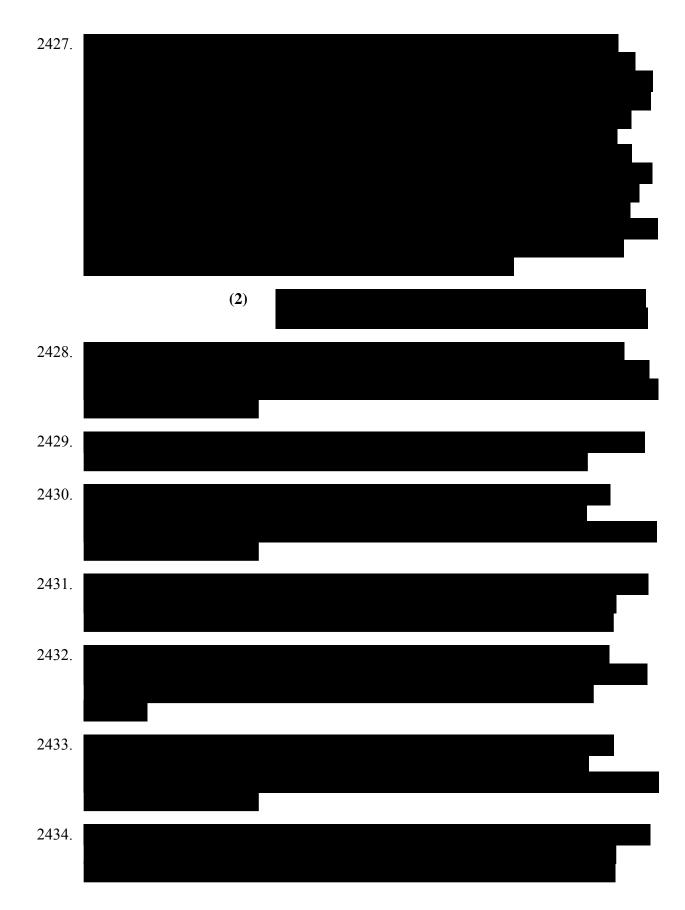


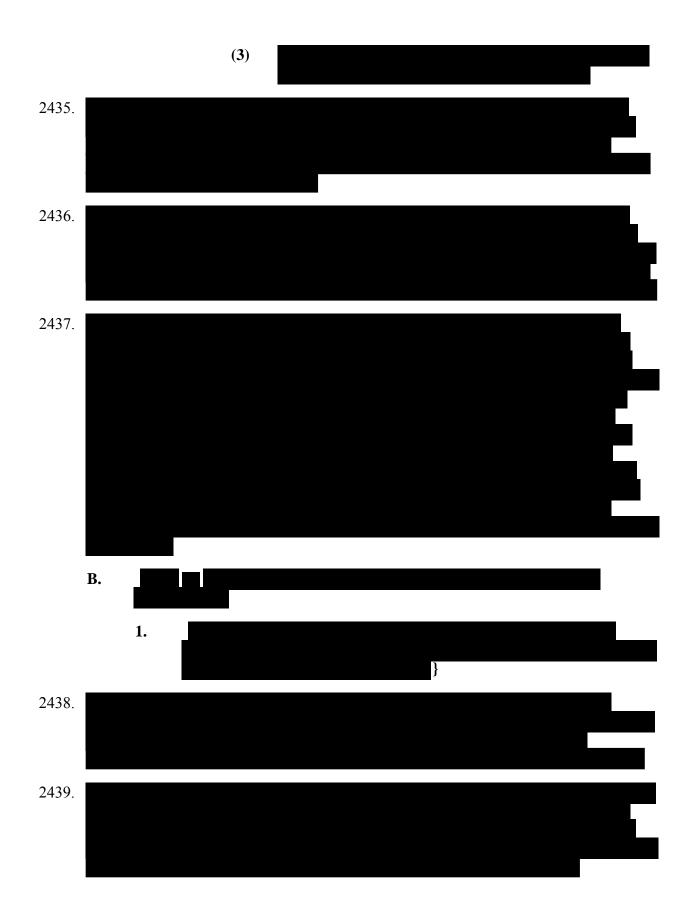






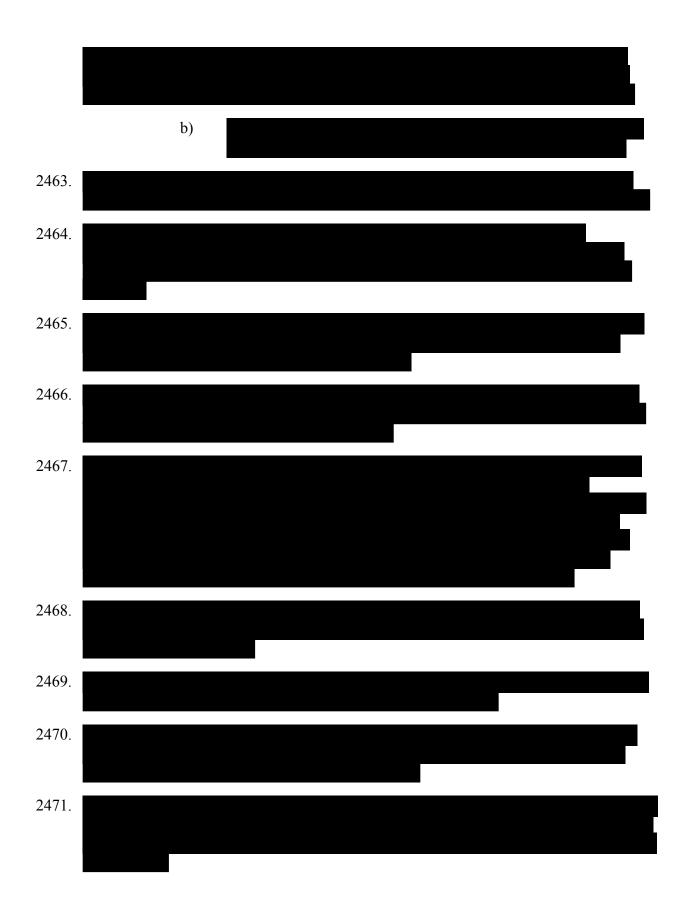


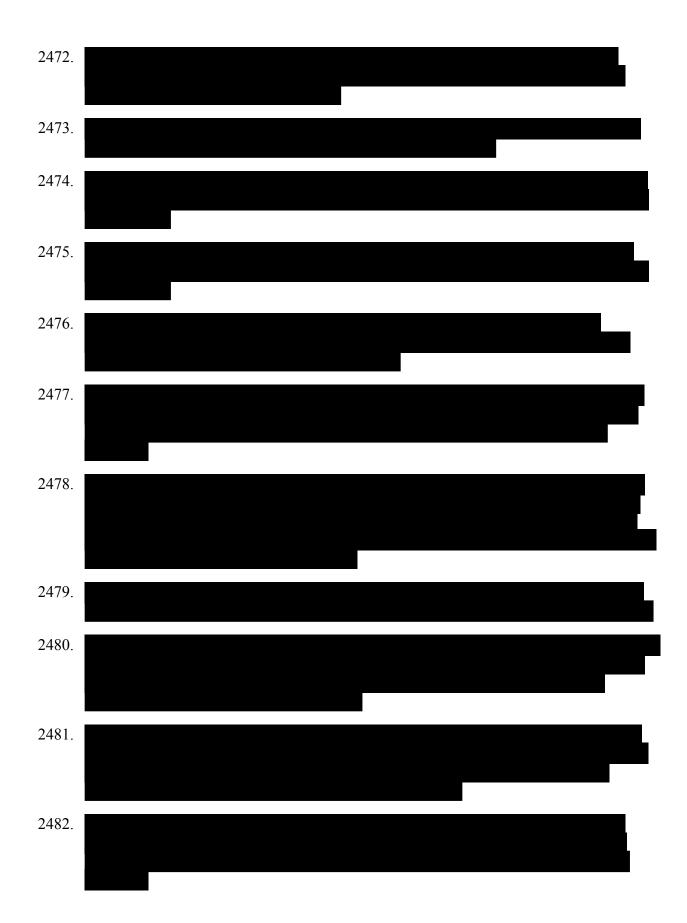


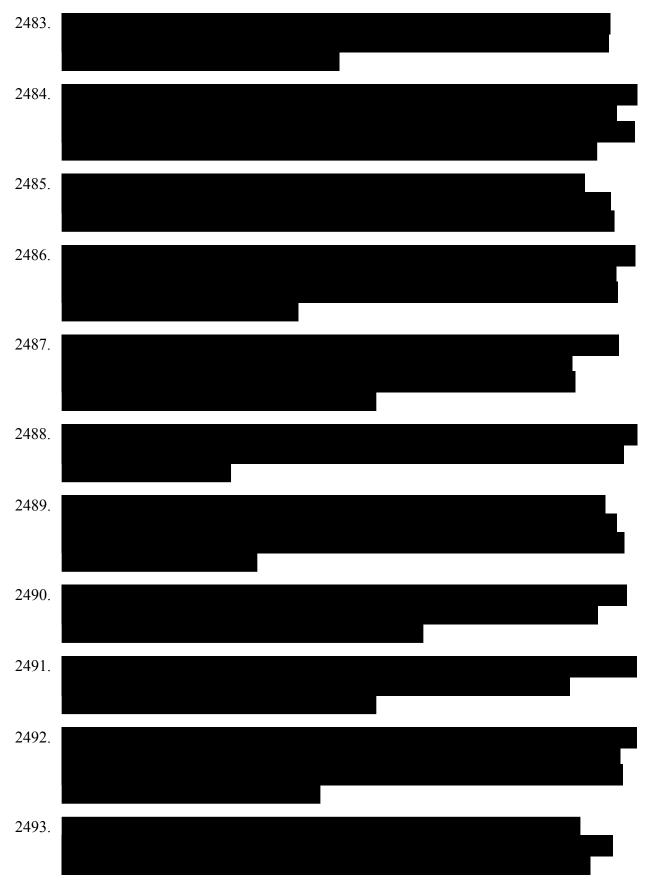


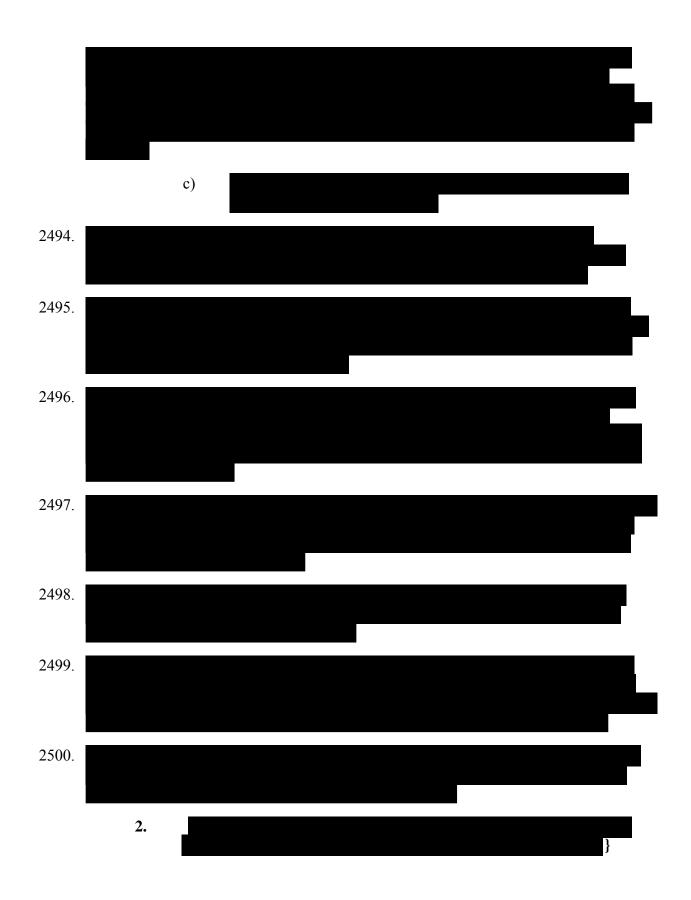


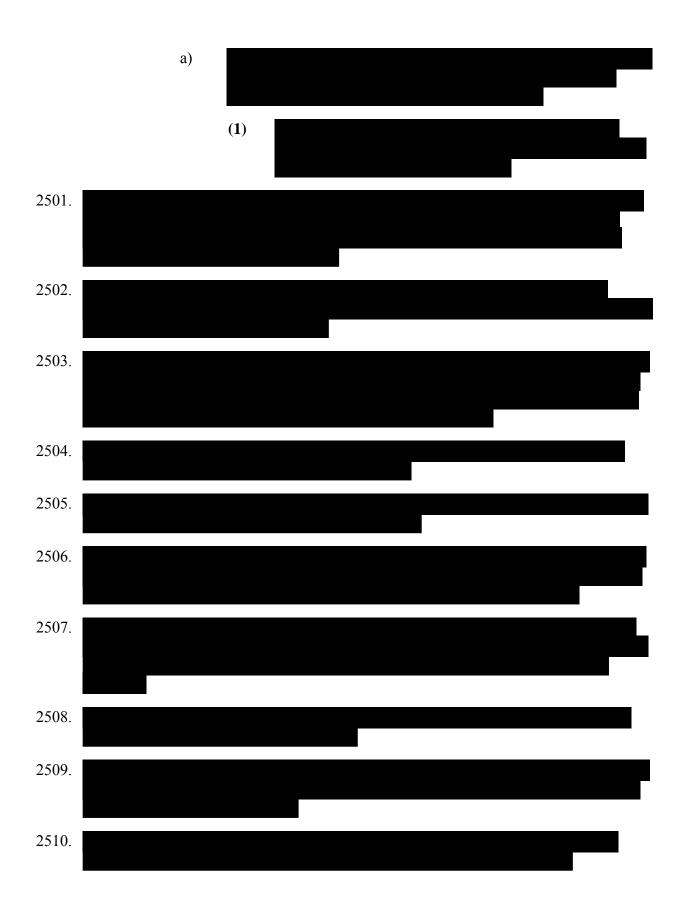




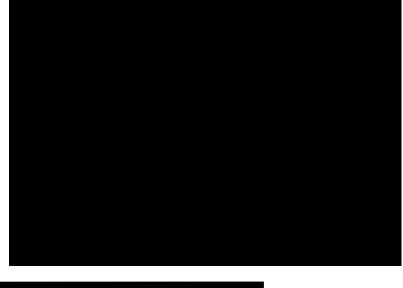


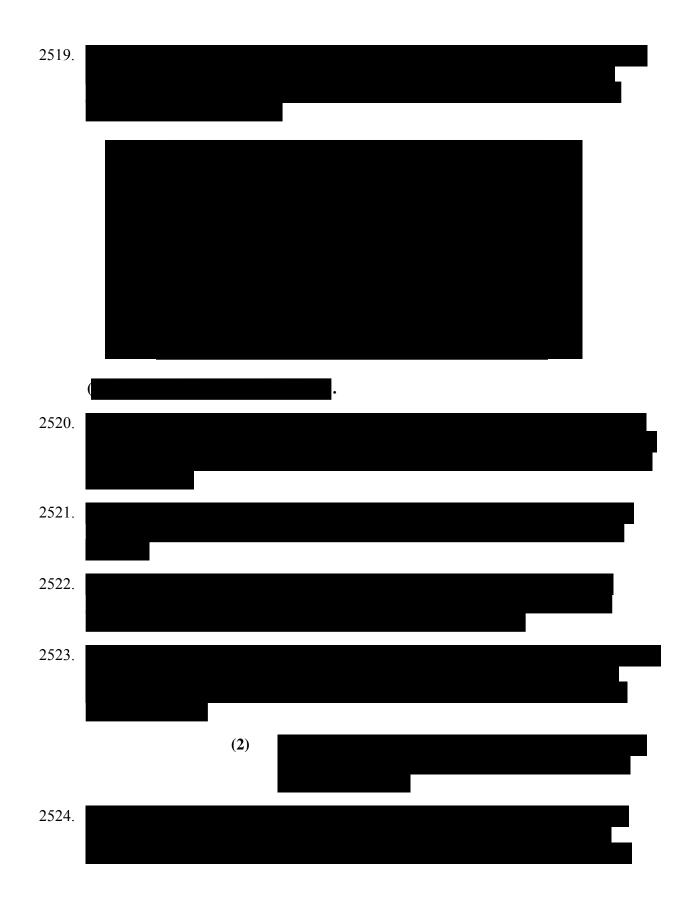


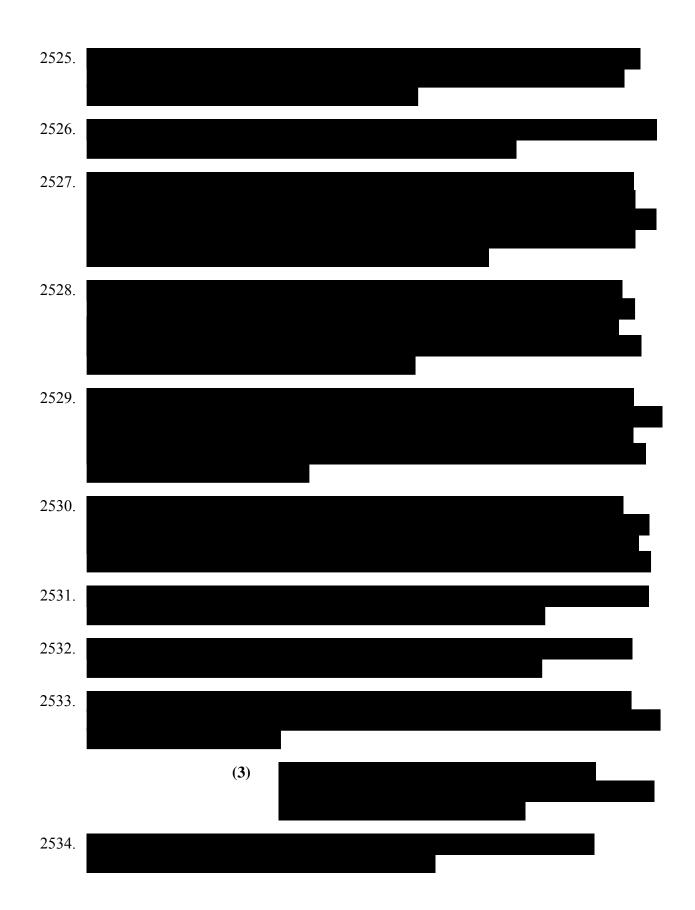


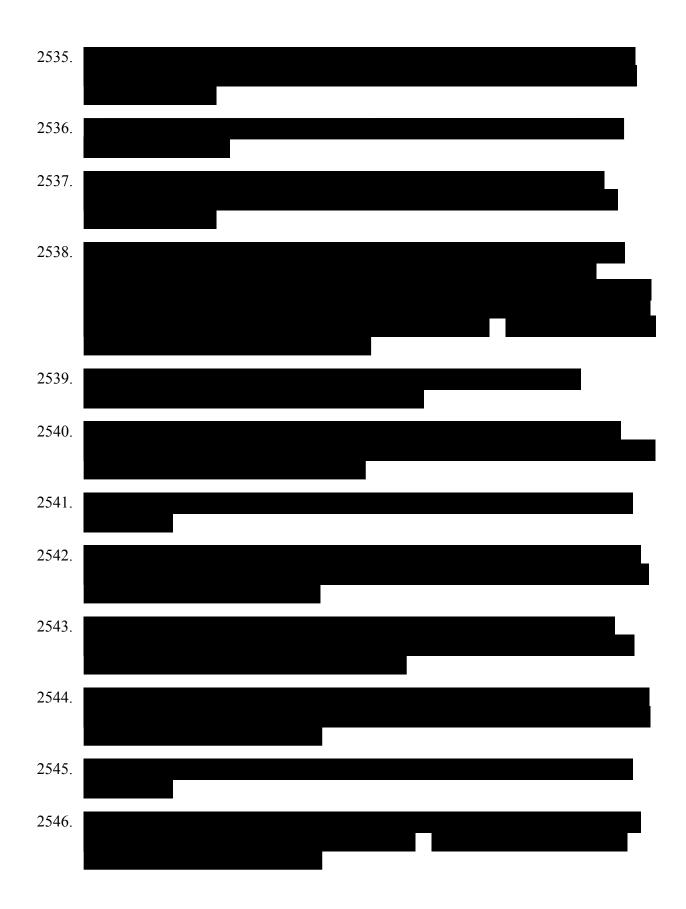




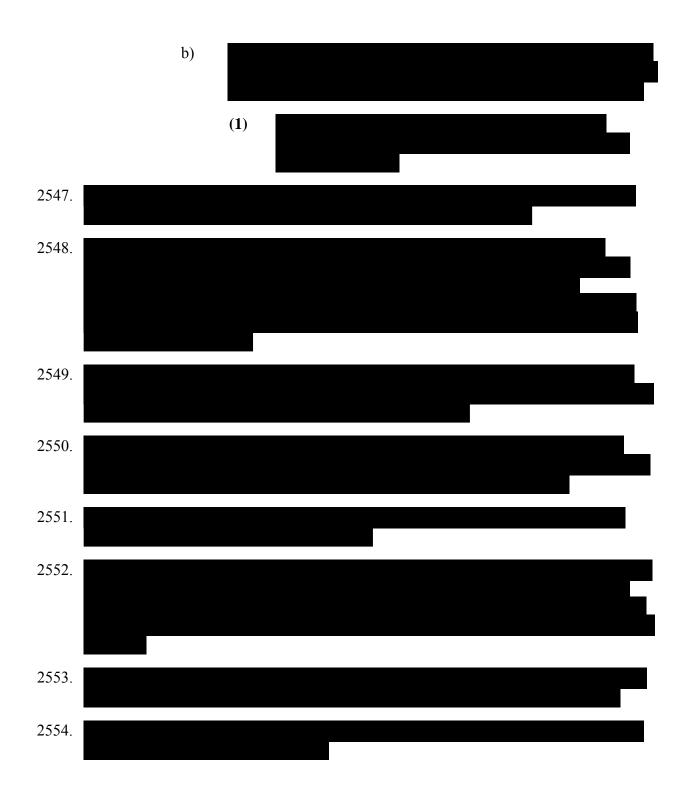




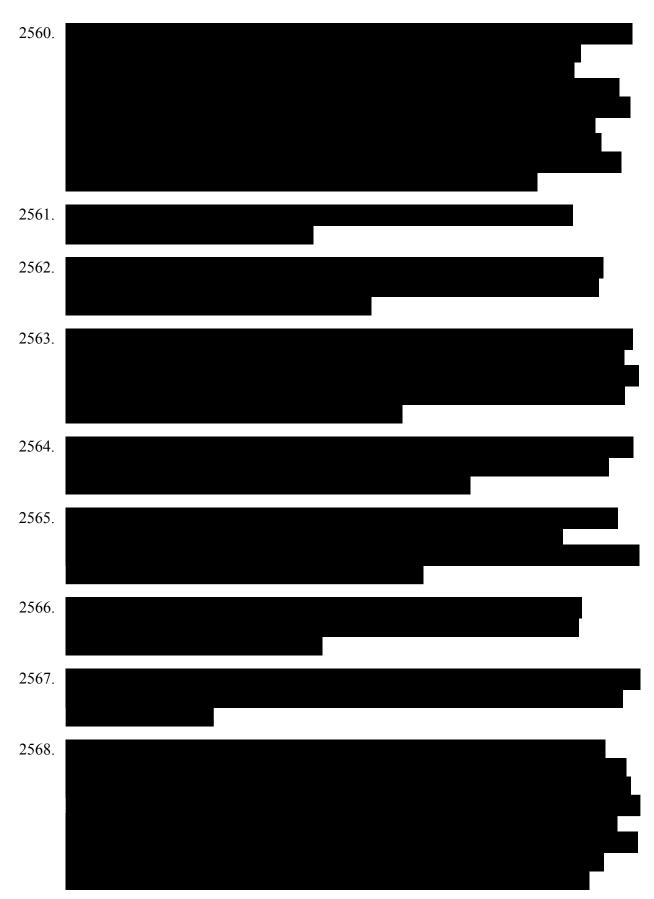




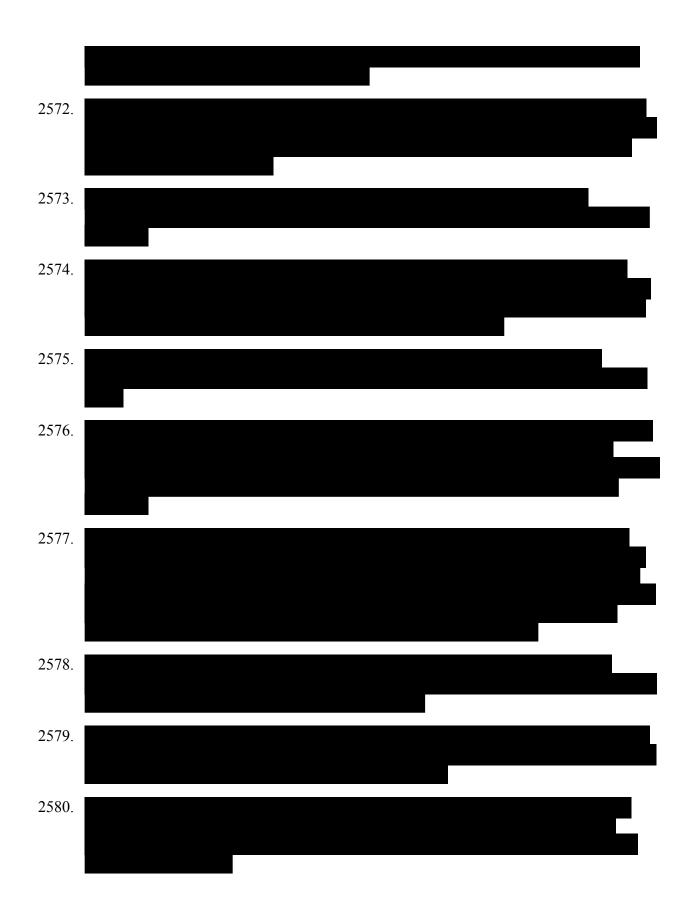
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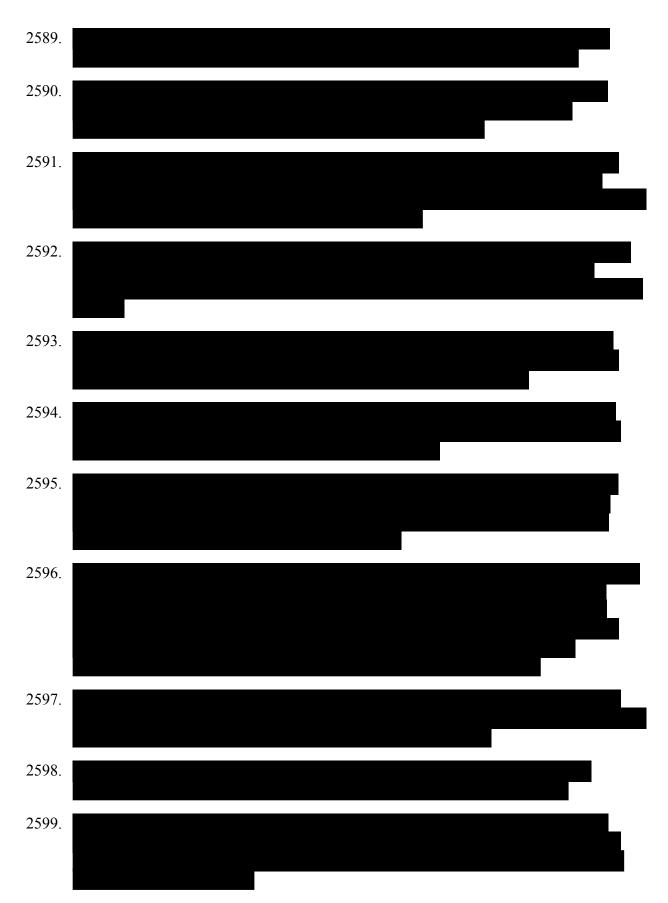


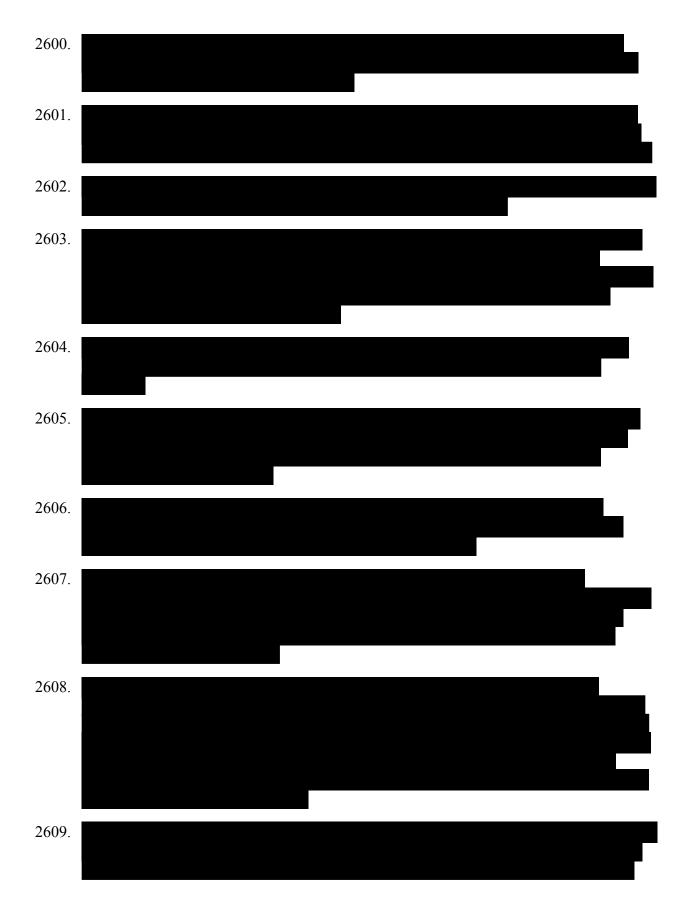


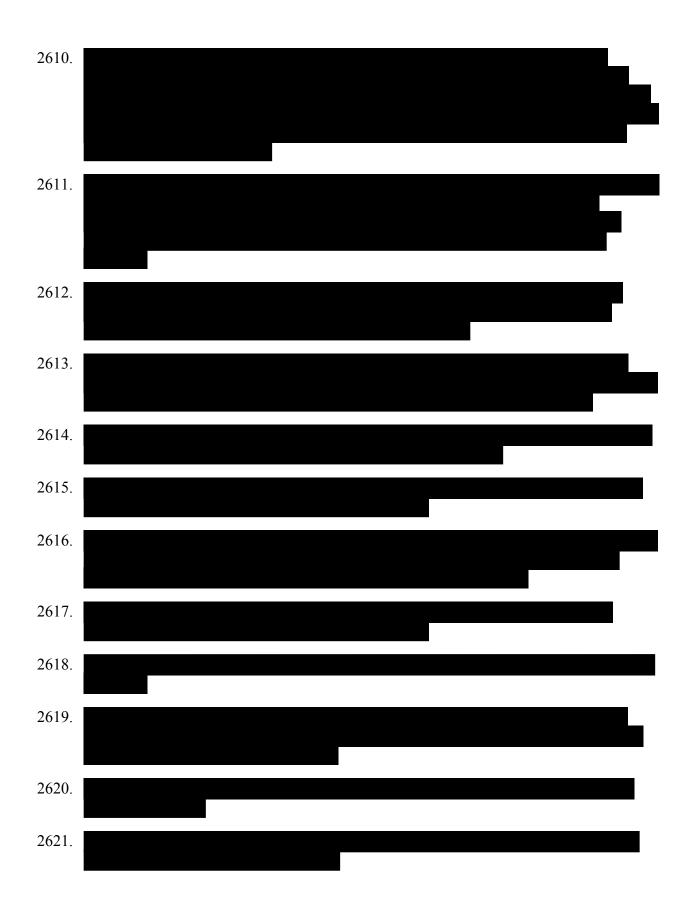


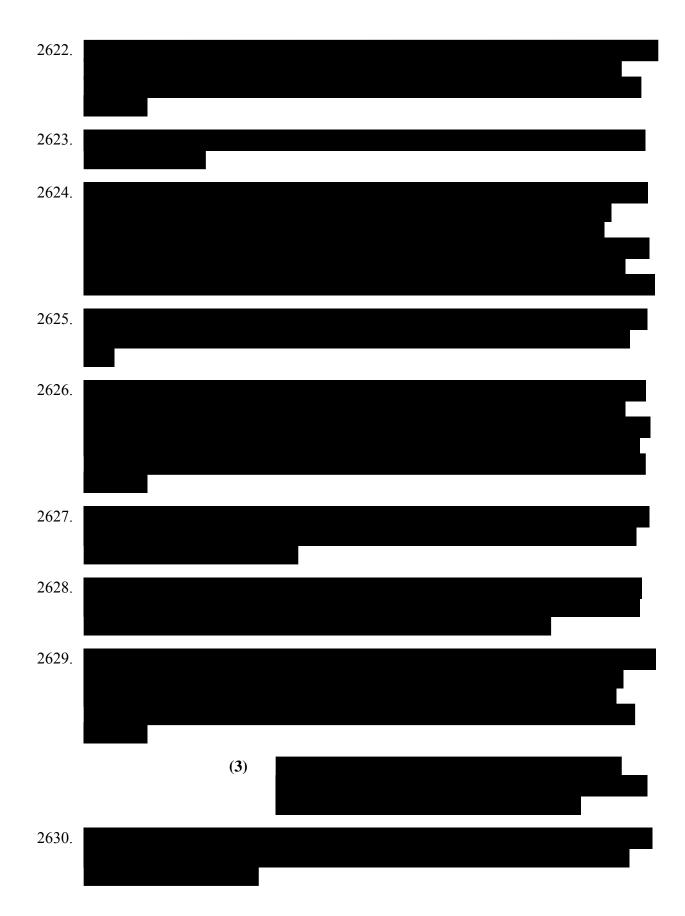


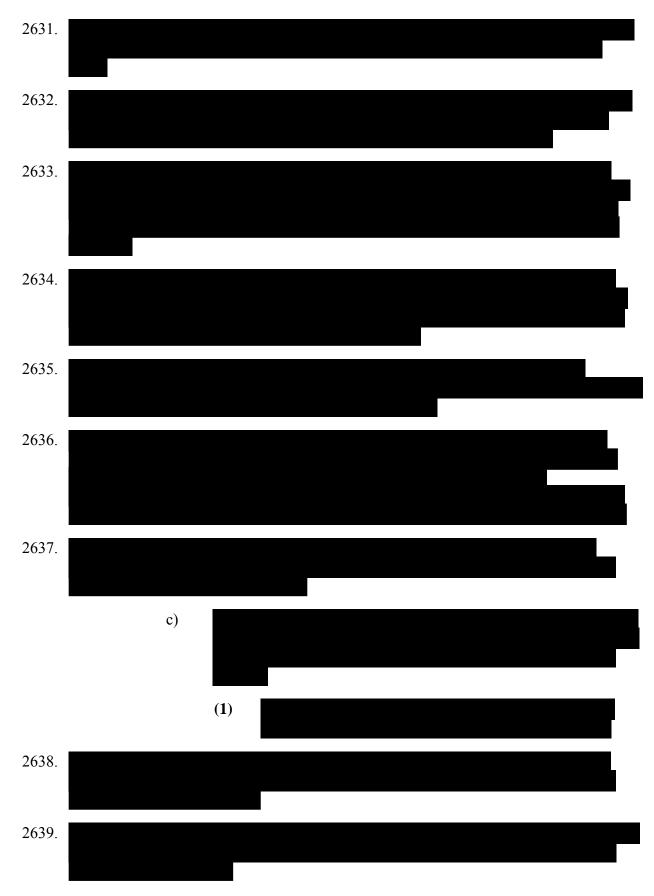






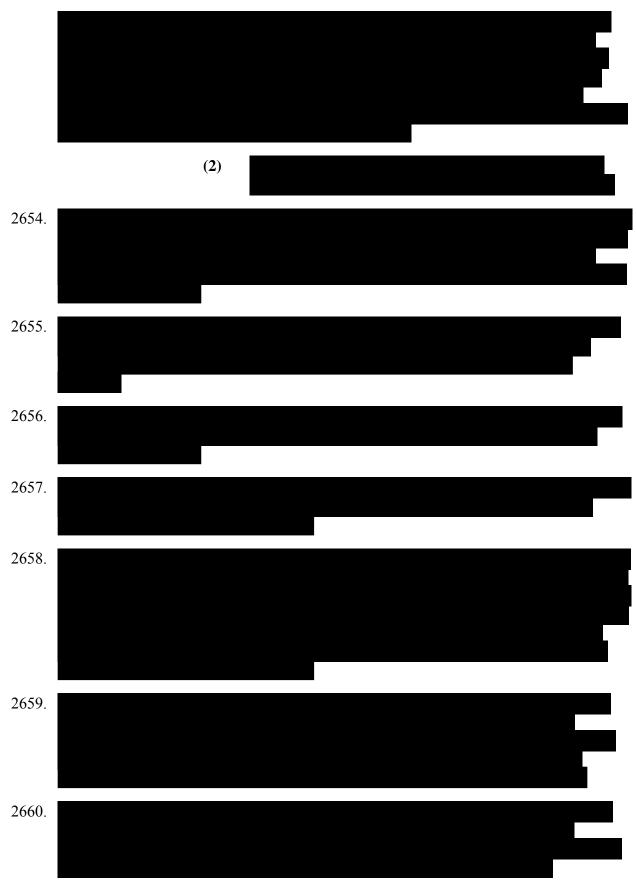




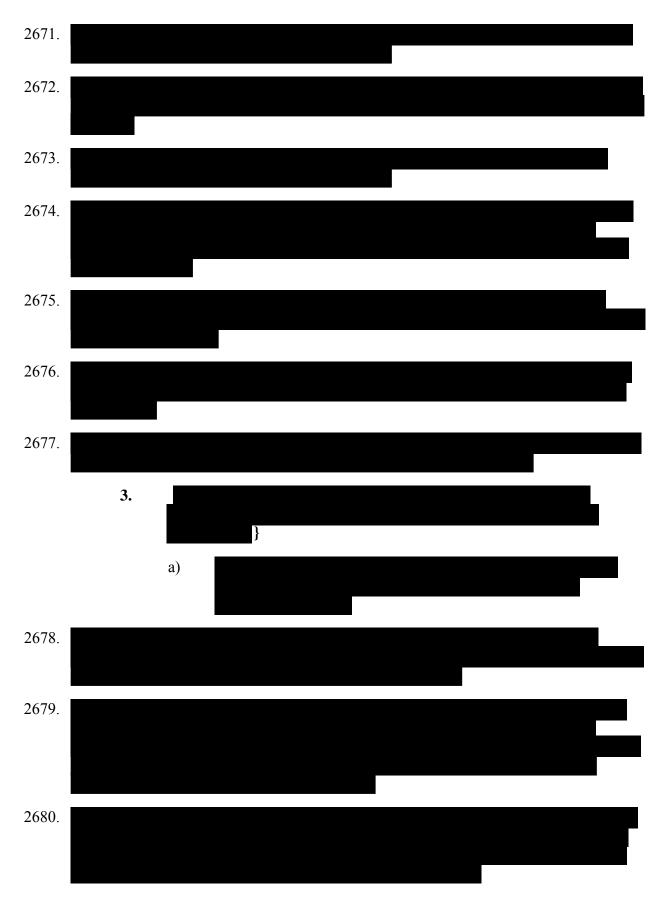


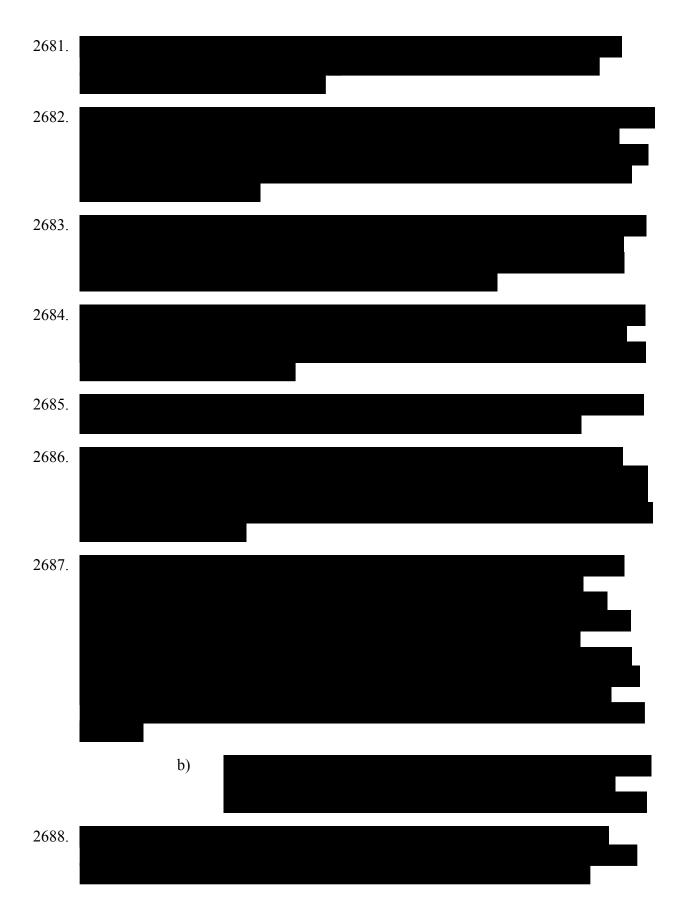
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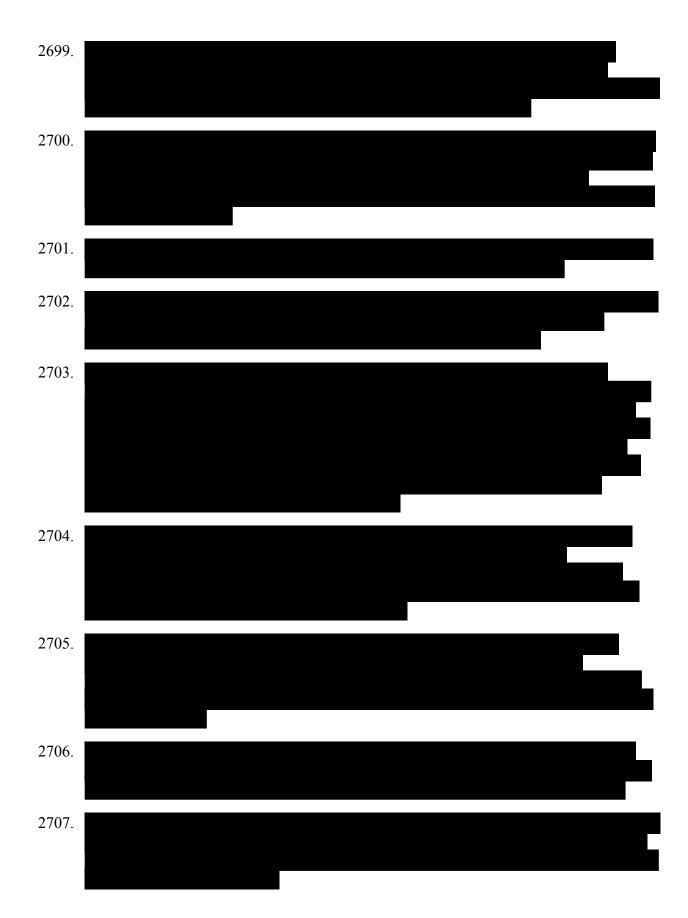


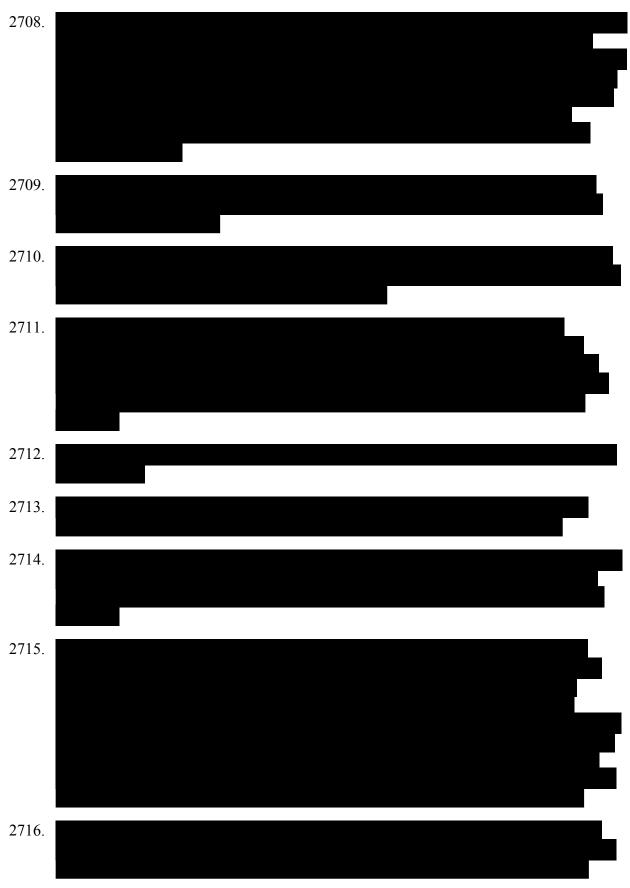


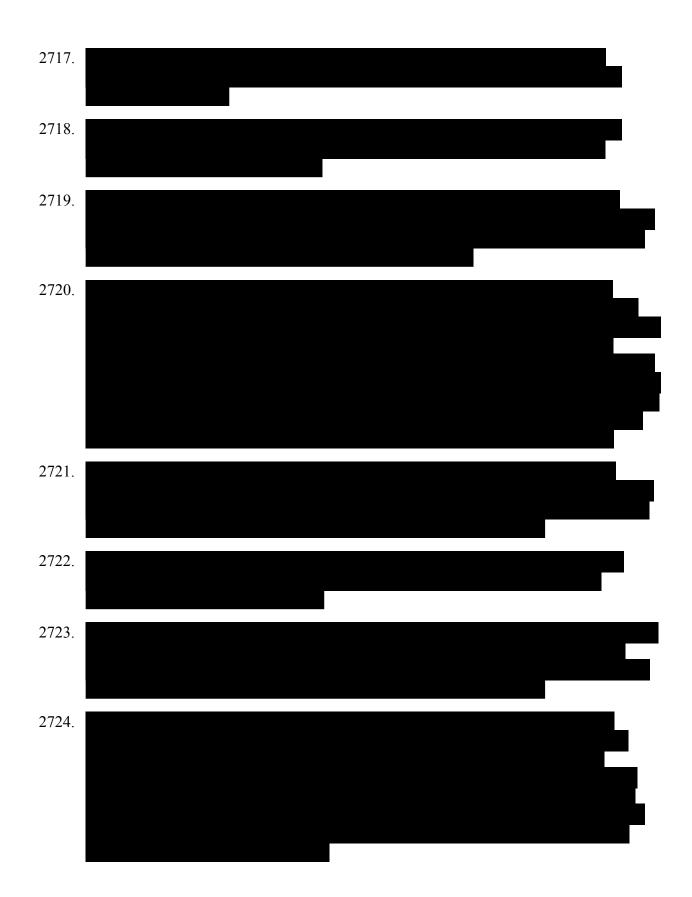




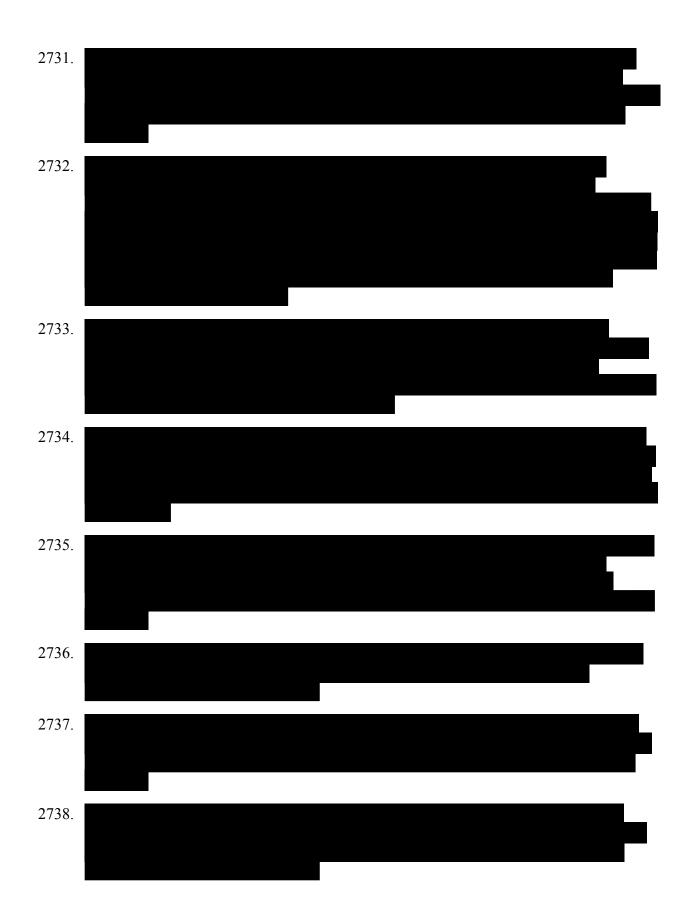
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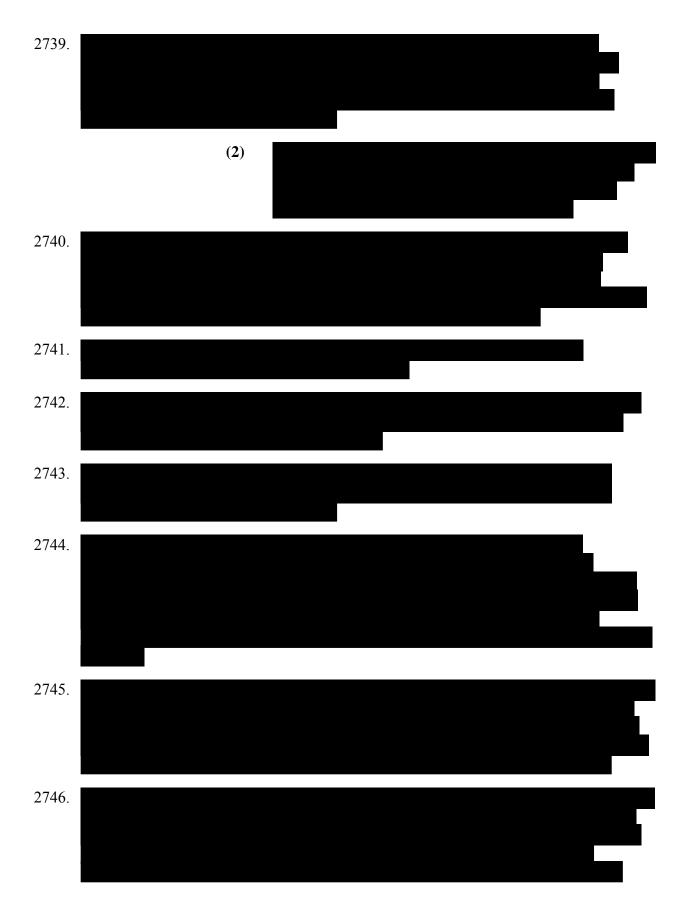


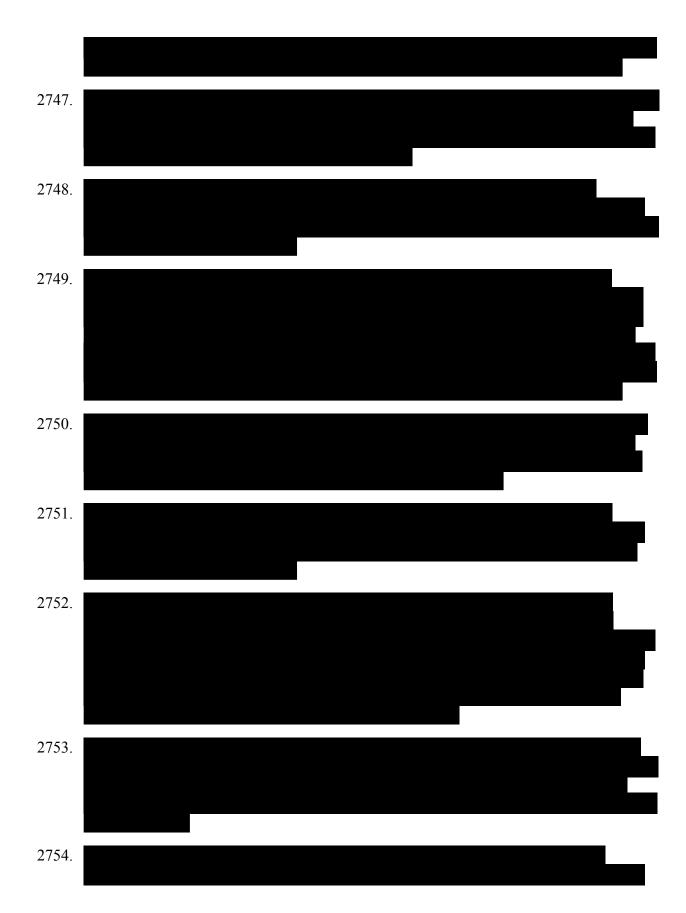


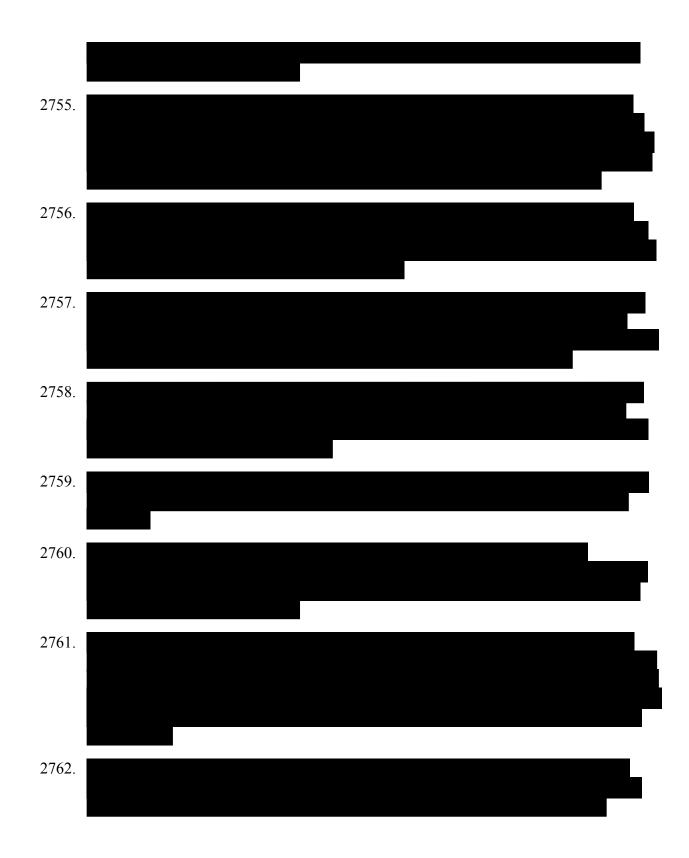


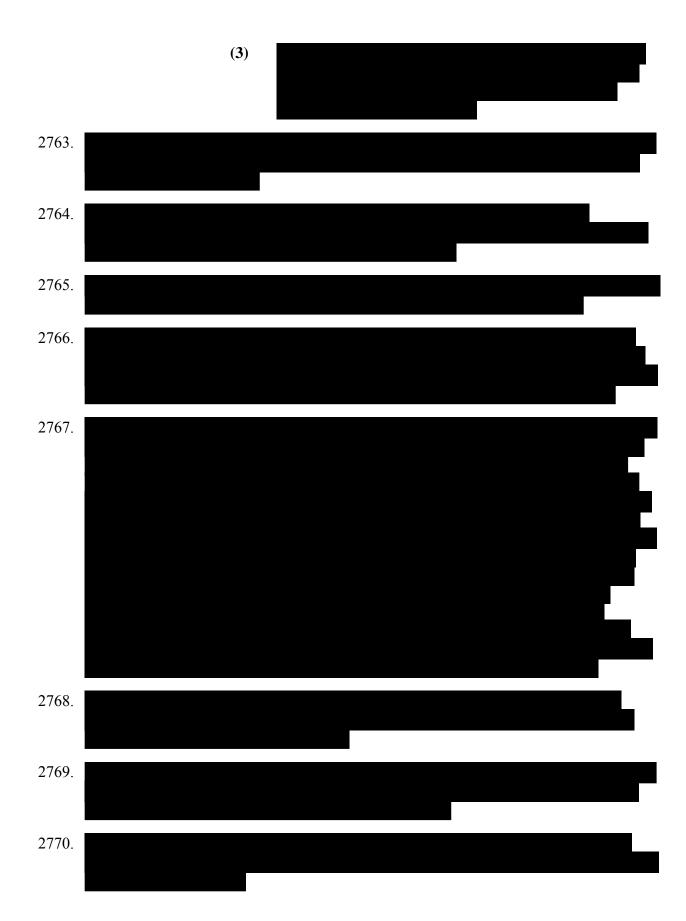


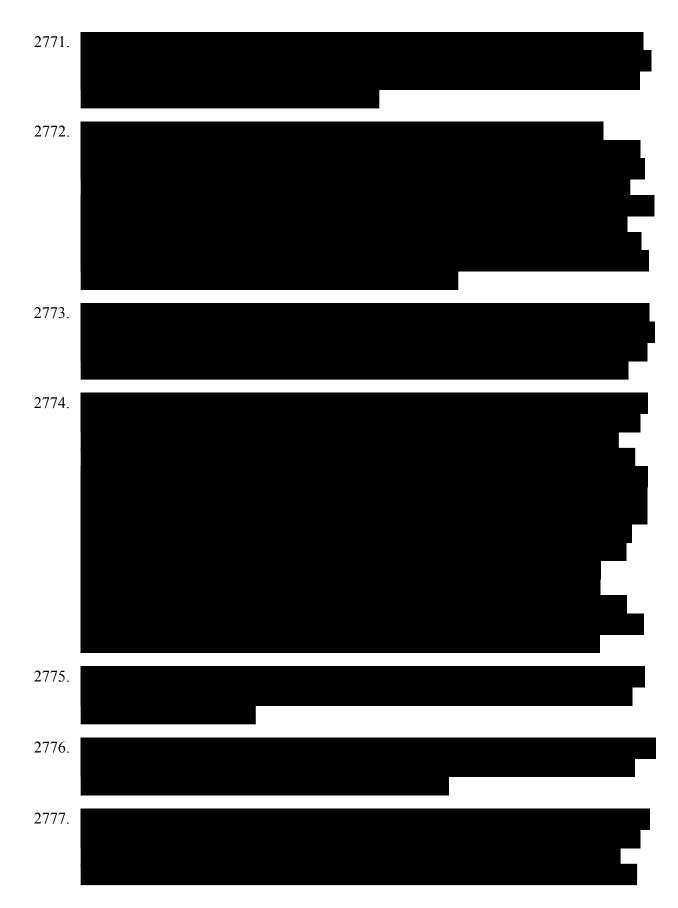


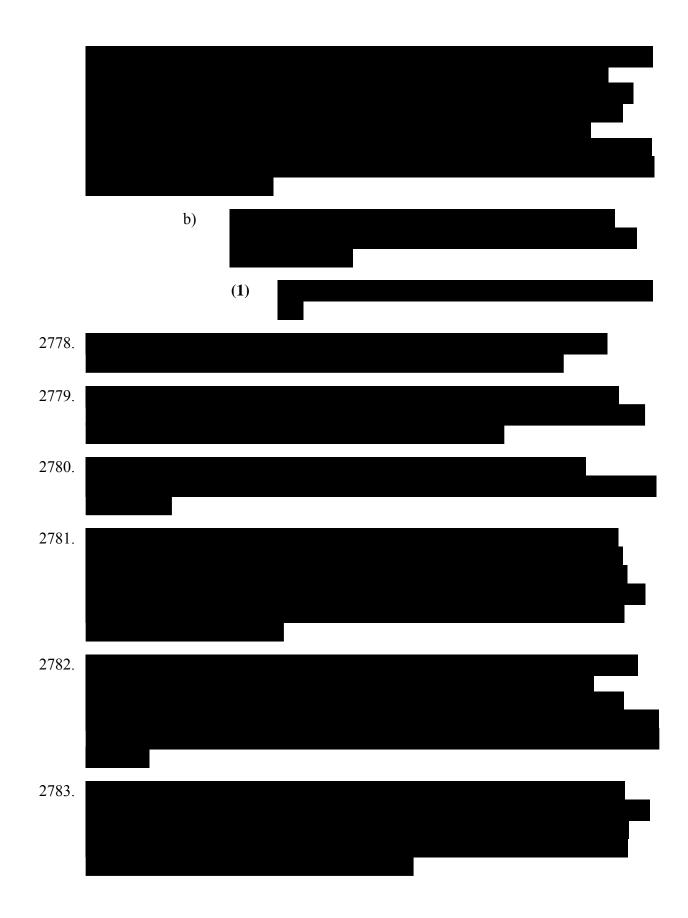


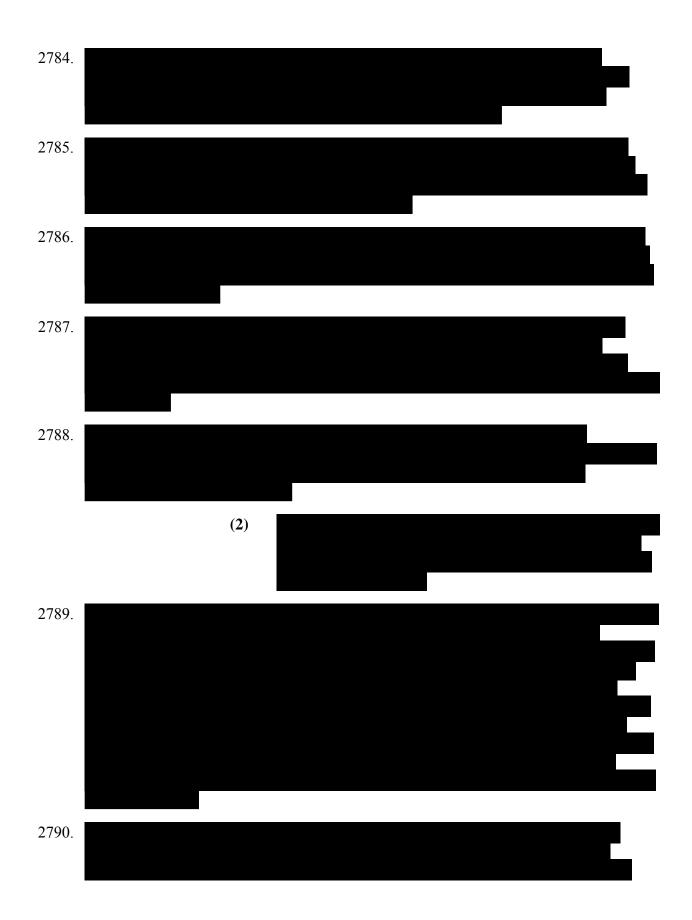


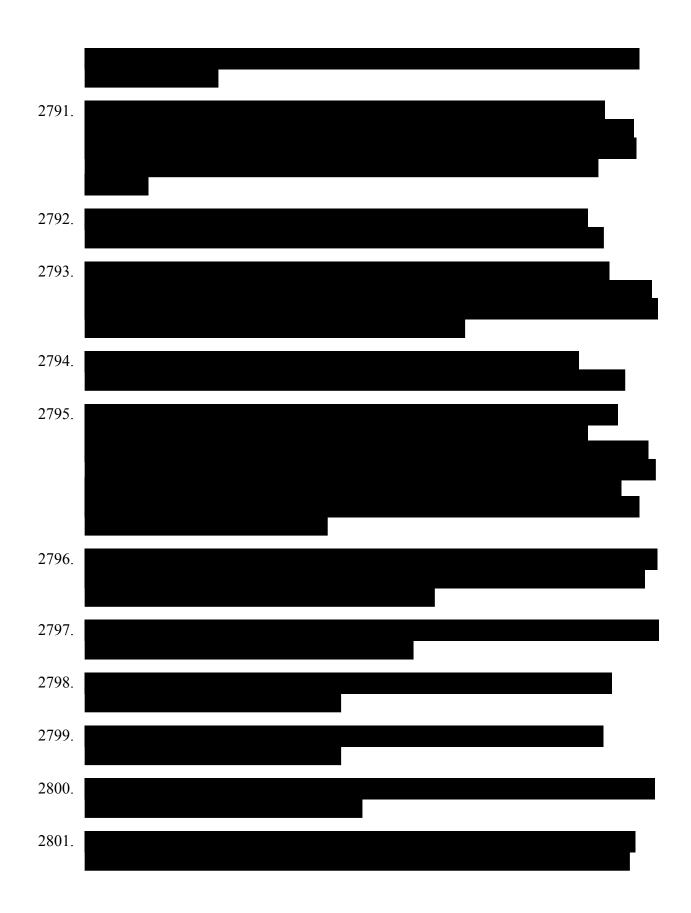






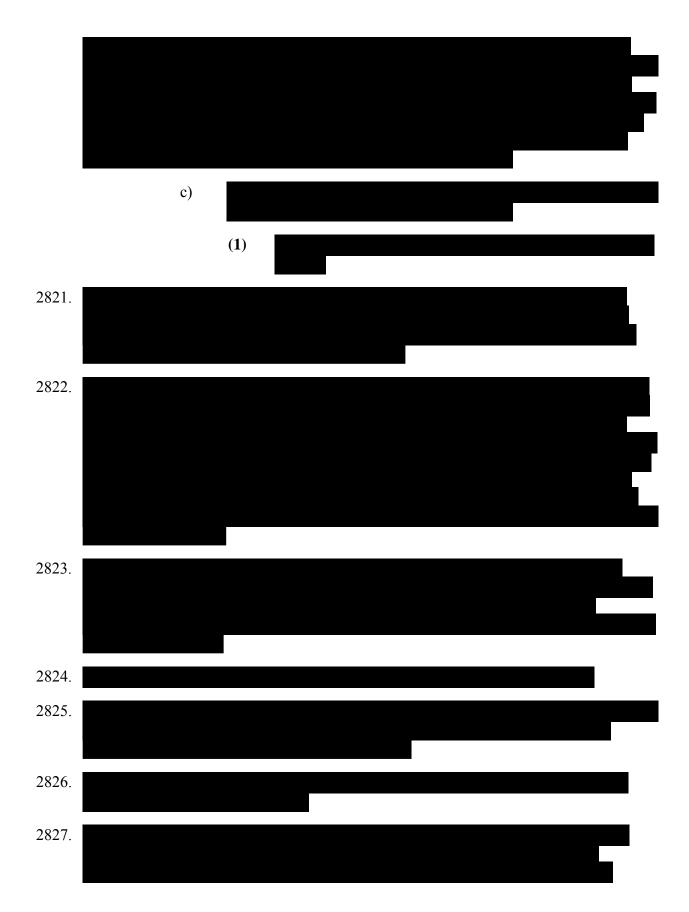


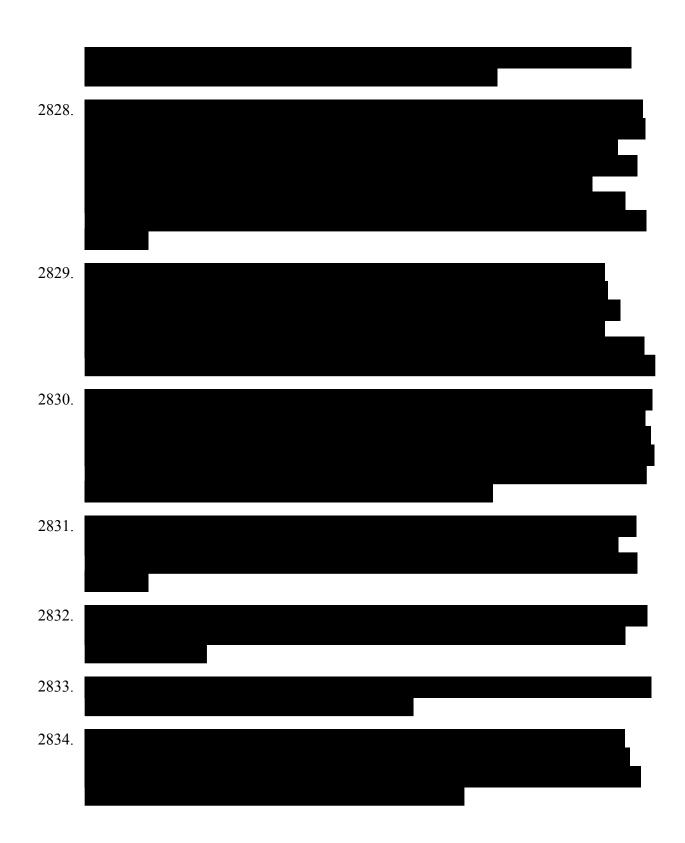




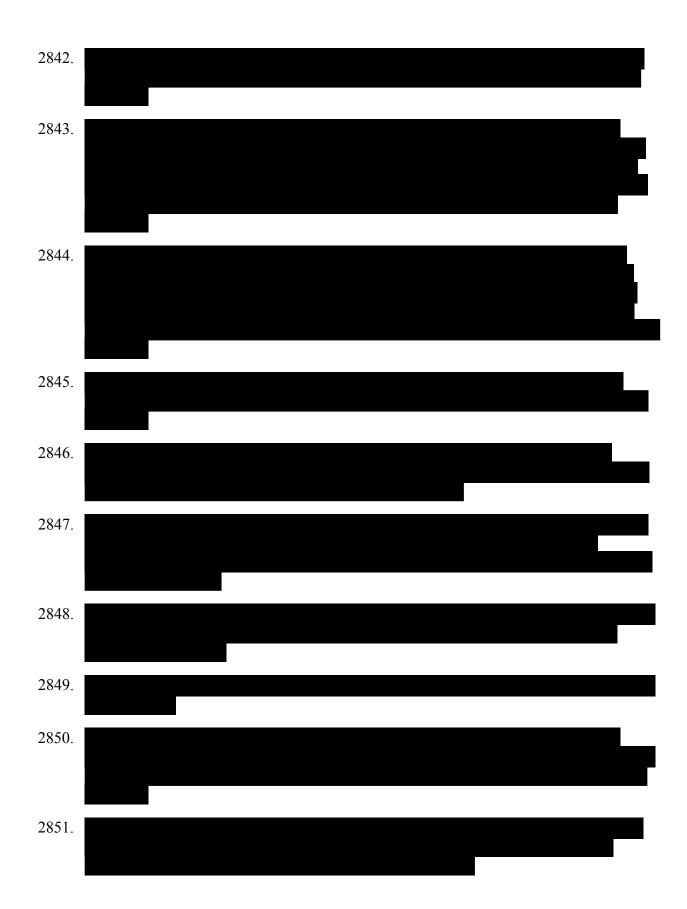


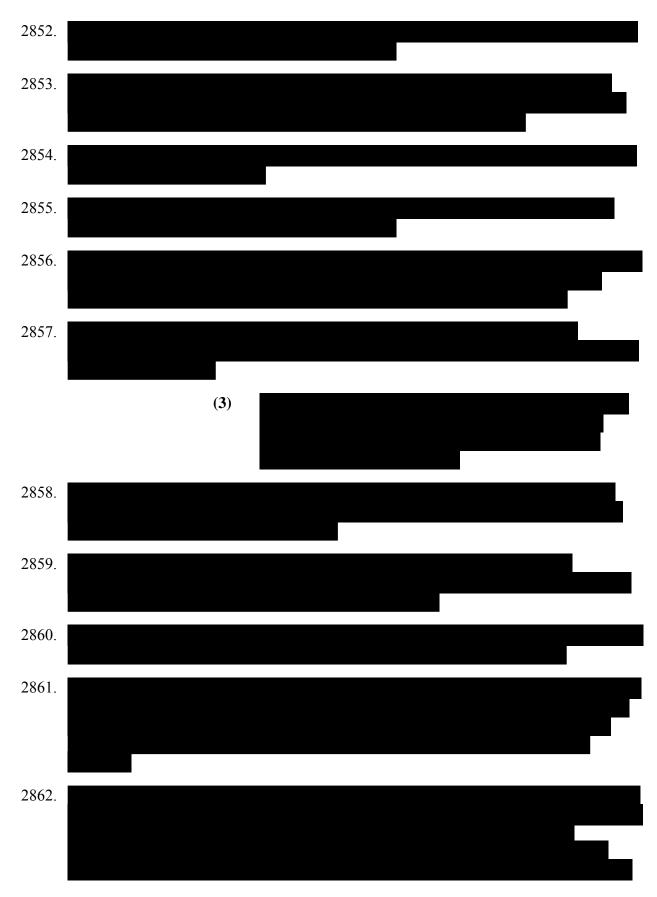




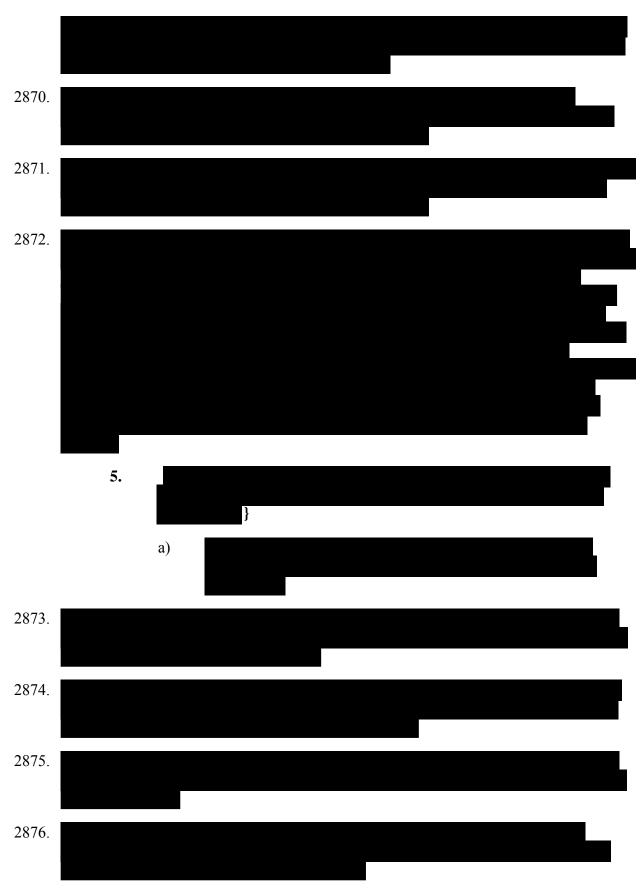


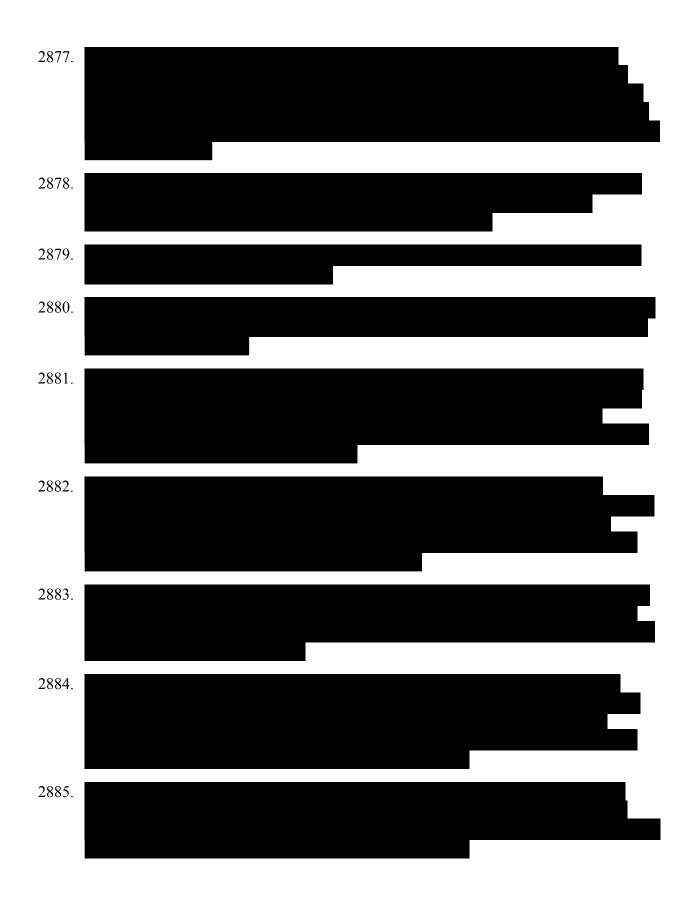






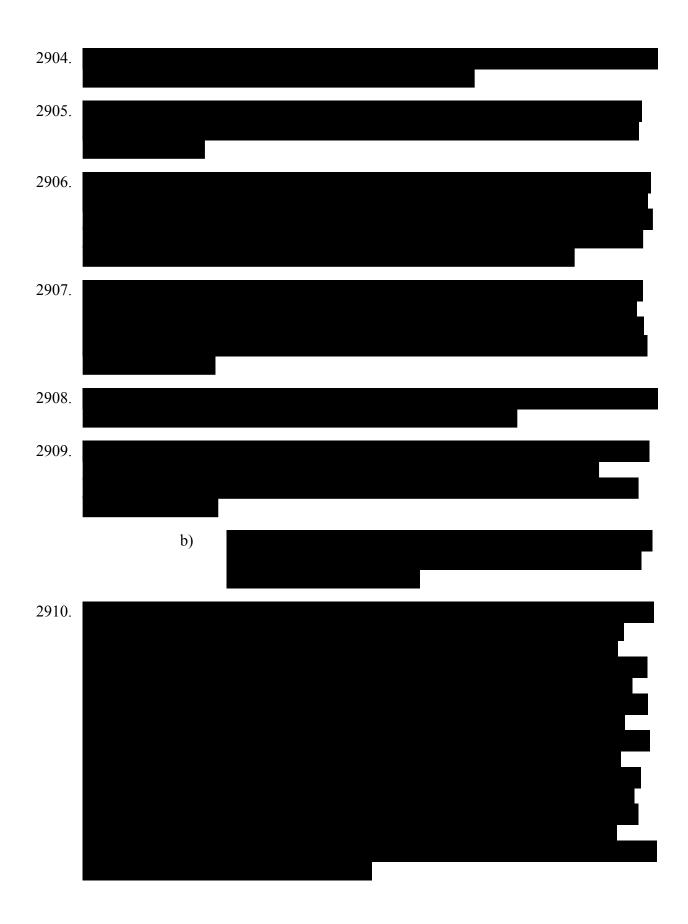


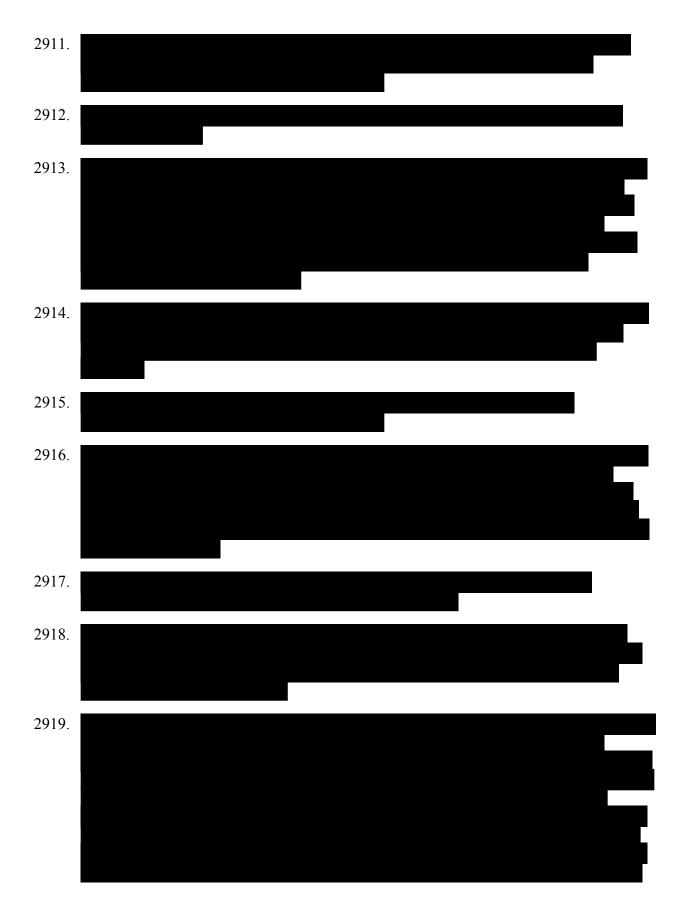




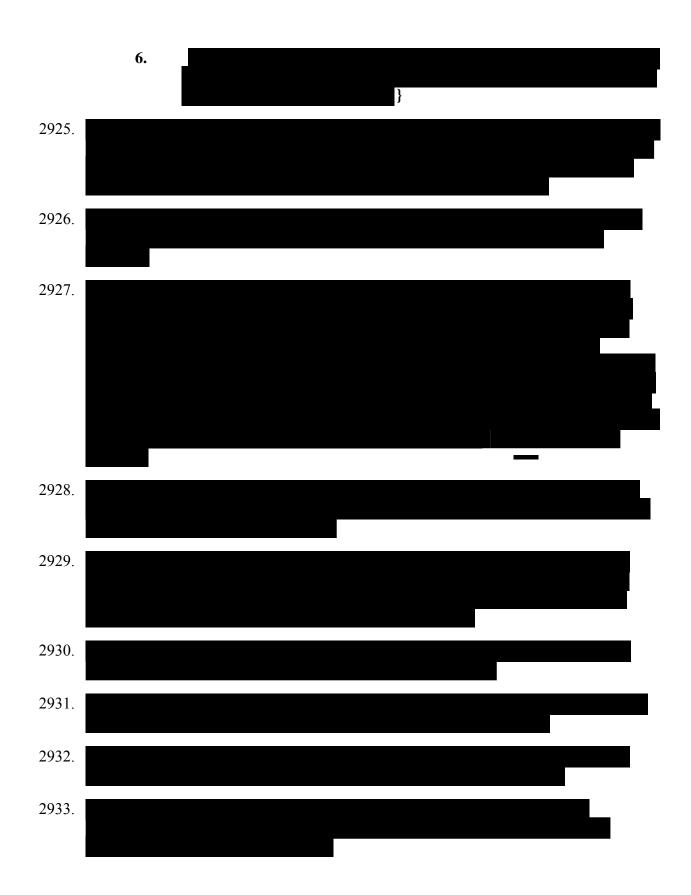














XV. RESPONDENT'S EXPERTS FAIL TO REBUT PRESUMPTION THAT THE ACQUISITION IS ILLEGAL

A. FLAWS IN DR. ARGUE'S ANALYSIS

1. Dr. Argue's Critical Loss Analysis is Flawed

- 2936. } (RX-1049 at 021-023 (§ IV.C) (Argue Expert Report) (*in camera*); (PX05173 (Argue) Dep. at 180)).
- 2937. One assumption of Dr. Argue's symmetrical critical loss test was that every MPK has the same margin. (PX05173 (Argue) Dep. at 176)).
- 2938. Dr. Argue testified that Otto Bock's and Freedom's MPKs have different average sales prices and different margins. (Argue Tr. 6285).
- 2939. Dr. Argue testified that MPKs are differentiated products. (Argue Tr. 6285).
- 2940. According to the Merger Guidelines, "Critical loss analysis asks whether imposing at least a SSNIP on one or more products in a candidate market would raise or lower the hypothetical monopolist's profits." (PX08040 at 015 (§ 4.1.3) (Merger Guidelines)).
- 2941. Dr. Argue's critical loss analysis tested the effect of a price increase on all MPKs. (Argue, Tr. 6285-86). Dr. Argue did not model the effect of a SSNIP on just one product in the candidate market. (Argue Tr. 6288-89).
- 2942. According to the Merger Guidelines, critical loss analysis involves an analysis of whether "the predicted loss is less than the critical loss." (PX08040 at 015 (§ 4.1.3) (Merger Guidelines)). "The 'critical loss' is defined as the number of lost unit sales that would leave profits unchanged." (PX08040 at 015 (§ 4.1.3) (Merger Guidelines)). "The 'predicted loss' is defined as the number of unit sales that the hypothetical monopolist is predicted to lose due to the price increase." (PX08040 at 015 (§ 4.1.3) (Merger Guidelines)).

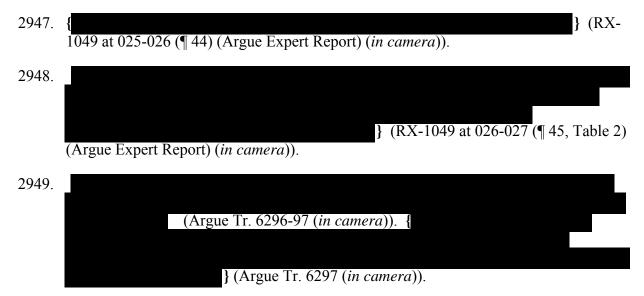
(Argue Tr. 6291 (in camera)).

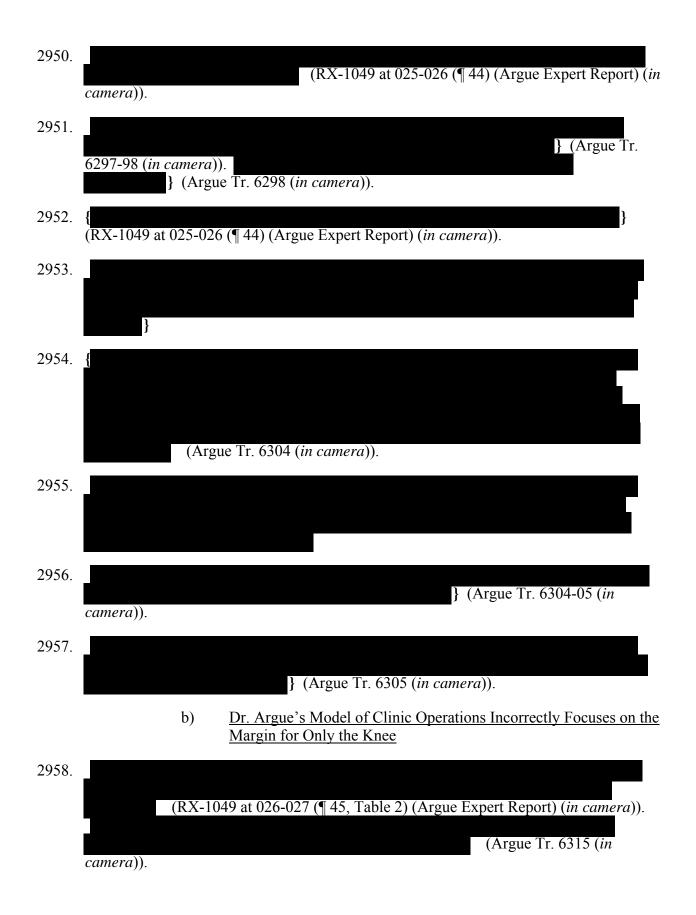
2944. Dr. Scott Morton concluded that Dr. Argue did not perform a complete critical loss analysis because Dr. Argue did not calculate a predicted loss to compare to his critical loss estimate. (PX06003 at 011 (¶ 17) (Morton Rebuttal Report)).

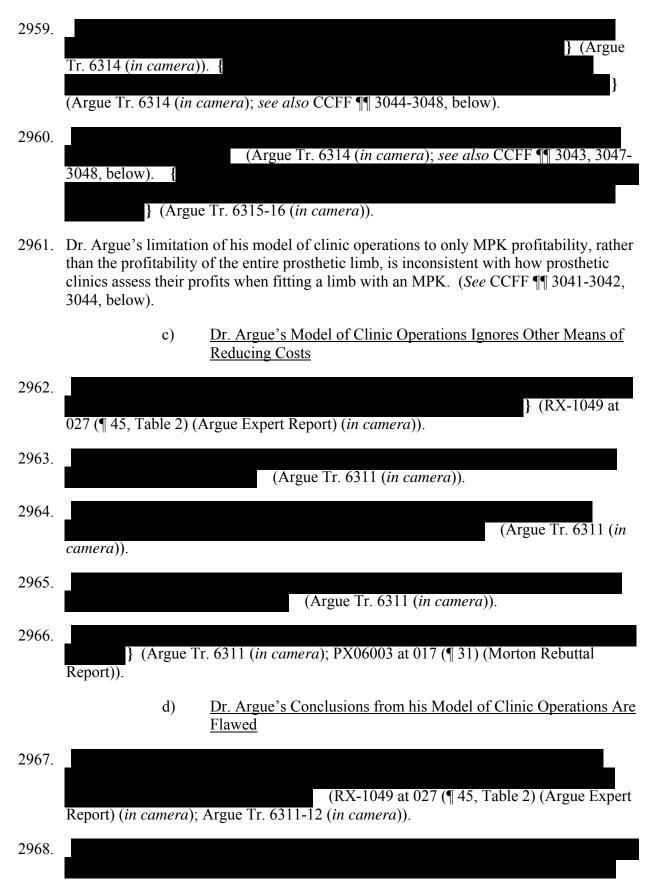
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	(Morton Rebuttal Report) (in camera)). {	} (PX06003 at 011-012 (¶¶ 18-21)
	Report) (in camera)).	} (PX06003 at 012 (¶ 21) (Morton Rebuttal
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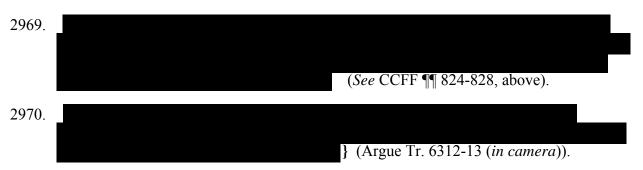
- 2. Dr. Argue's Model of Clinic Operations Is Flawed and Based on Inaccurate Assumptions
- 2946. Dr. Argue "constructed a model of clinic operations" to address the question of "whether a 5% increase in the price of MPKs would actually make MPKs unprofitable for clinics and thus compel them to switch some patients from MPKs to non-MPKs." (RX-1049 at 025 (¶ 43) (Argue Report)).
 - a) Dr. Argue's Model of Clinic Operations Is based on Unreliable Assumptions and Data







(RX-1049 at 027 (¶ 45, Table 2) (Argue Report) (*in camera*); Argue Tr. 6312 (*in camera*)).



- 2971. Dr. Scott Morton concluded that Dr. Argue's model is inherently flawed as he does not consider the profitability of the clinic if it switched patients with private insurance to alternative microprocessor knees. (PX06003 at 015-16 (¶ 28) (Morton Rebuttal Report)).
- 2972. (PX06003 at 015-017 (¶¶ 28-30,

 Table 1) (Morton Rebuttal Report) (in camera)).

- 3. Dr. Argue's Claim that MPKs Create Significant Reimbursement Risks to Clinics Is Flawed
 - a) <u>Existence of RAC Audits is Irrelevant to Analysis of the Likely</u> <u>Competitive Effects of the Merger</u>
 - (1) RAC Audits Existed Prior to the Merger
- 2973. Medicare and other payers conduct Recovery Audit Contractor ("RAC") audits. (Schneider (Otto Bock) Tr. 4744; Senn (POA) Tr. 210;; Ell (Mid-Missouri O&P) Tr. 1749-50; see also {



- 2974. During a RAC audit, the payer reviews a patient file from a prosthetic clinic associated with a particular insurance reimbursement claim. (PX05139 (Schneider (Otto Bock) Dep. at 82); Senn (COPC) Tr. 210). If the patient's file does not contain the proper documentation, the payer may recoup the insurance reimbursement payment to the prosthetic clinic for that claim. (PX05139 (Schneider (Otto Bock) Dep. at 82–84); Senn (COPC) Tr. 210).
- 2975.
- 2976. RAC audits started to intensify in the prosthetic industry around 2011 and 2012. (Schneider (Otto Bock) Tr. 4745; PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at

25); Ford (POA) Tr. 973 (testifying that RAC audits came to the prosthetic industry in 2012)).

- 2977. RAC audits existed before the Merger and have continued after the Merger. (Carkhuff (Freedom) Tr. 717). The Merger has not changed anything about the way payers conduct RAC audits. (Carkhuff (Freedom) Tr. 717-18).
- 2978. Before the Merger, the presence of RAC audits existed for every sale that Freedom has made. (Carkhuff (Freedom) Tr. 718).
- 2979. In response to the advent of RAC audits, prosthetic clinics "found ways to create better documentation and feel more secure about their billing practices." (PX05107 (Carver (College Park Industries) Dep. at 210–212)).
- 2980. Maynard Carkhuff, Chairman of Freedom, testified that since 2012, prosthetic clinics have improved their ability to document and receive reimbursement for MPKs, to varying degrees. (Carkhuff (Freedom) Tr. 717).
- 2981. Prosthetic and Orthotic Associates ("POA") has a 27-step procedure used to avoid exposure to RAC audits. (Ford (POA) Tr. 973). Before POA submits a reimbursement claim, "you have to have all 27 boxes checked." (Ford (POA) Tr. 975). POA has never failed a RAC audit. (Ford (POA) Tr. 977).



- 2985. In response to a June 2017 inquiry from Freedom's Vice President of Marketing and Product Development, Eric Ferris, Hanger relayed that it did not anticipate any reduction in MPK sales (or increase in mechanical knee sales) in response to an expansion of CMS "L5856 Prepayment Authorization Review[s]". Hanger noted that it is "confident in their documentation and will continue to submit MPKs based on patient requirements." (RX-0441 (Freedom) at 2).
- 2986. In order to protect against RAC audits, Keith Senn, the President and COO of COPC of Kentucky, testified that his clinic maintains records of practitioner and physician's notes,

patient's measurements (i.e. height, weight, etc.), prescriptions, and records detailing the fitting process. (Senn (COPC) Tr. 211-12).

2987. MPK manufacturers have also begun offering services to prosthetic clinics to assist them in responding to RAC audits. (Schneider (Otto Bock) Tr. 4746; De Roy (Össur) Tr. 3561–62).

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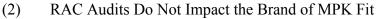
(Asar (Hanger) Tr. 1368–69 (in camera)).

- 2989. Otto Bock provides a service to its customers where Otto Bock looks at claims to ensure the claims would meet the requirements of a payer's protocols and procedures. (Schneider (Otto Bock) Tr. 4746).
- 2990. Otto Bock's Scott Schneider, Vice President of Government, Medical Affairs, and Future Development, testified that he "believe[s] that our service helps reduce the number of deficiencies within a claim to have a clean claim," which would help with a RAC audit. (PX05139 (Schneider (Otto Bock) Dep. at 95-96).
- 2991. Otto Bock also conducts webinars open to any clinic customer on different reimbursement topics, including claim submittals, coding and reimbursement. (Schneider (Otto Bock) Tr. 4746). The webinars have information to help customers understand reimbursement deficiencies and what they can do going forward to reduce those deficiencies. (Schneider (Otto Bock) Tr. 4746).
- 2992. Beginning around 2012, Össur began to "educate and help the customers build a stronger patient file and provide the necessary information to ensure that if you do put the patient on a microprocessor device or advanced foot device that you had the right motivation and that you would not be at risk of having to refund or repay that later in the process." (De Roy (Össur) Tr. 3561–62).
- 2993. Össur created a "step-by-step guide to a successful claim" for its Rheo MPK. The guide contains information about the proper procedure and documentation for insurance reimbursement claims of an MPK. (PX03242 (Össur) at 001–015).
- 2994. Prosthetic clinics have not reduced their purchases of MPKs in response to RAC audits. (Ford (POA) Tr. 976–77; Senn (COPC) Tr. 212; Ell (Mid-Missouri) Tr. 1749–50; Brandt (Ability) Tr. 3768; PX05141 (Bright (North Bay Prosthetics) Dep. at 177); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 26); PX05166 (Watson (Fourroux Prosthetics) Dep. at 182)).
- 2995. Mark Ford, President and Managing Partner of Prosthetic and Orthotic Associates, testified that the concern of RAC audits does not cause POA to shift patients from MPKs to mechanical knees. (Ford (POA) Tr. 976–77).

- 2996. Keith Senn, President of the Kentucky and Indiana operations for COPC, testified that COPC has not instructed its prosthetic clinics to avoid fitting any specific MPKs due to the risk of a RAC audit. (Senn (COPC) Tr. 212).
- 2997. Jeffrey Brandt, CEO of Ability Prosthetics and Orthotics, testified that the risk of a RAC audit has not affected the number of MPKs, including Freedom Pliés, that Ability Prosthetics & Orthotics ("Ability") fits on patients. (Brandt (Ability) Tr. 3768).
- 2998. Mr. Brandt expects "an uptick in the number of RAC audits in the future." (PX05149 (Brandt (Ability) Dep. at 256–57)). Despite the anticipated uptick in RAC audits, Mr. Brandt testified that Ability would not fit fewer MPKs, including Pliés, as a result, because "our documentation process around rationale and justification for an MPK is sound, clinically sound." (PX05149 (Brandt (Ability) Dep. at 257)).
- 2999. Michael Bright, a certified prosthetist and owner of North Bay Prosthetics, testified that North Bay has not stopped fitting MPKs in response to RAC audits. (PX05141 (Bright (North Bay Prosthetics) Dep. at 177)). If an MPK was medically appropriate for a patient, Mr. Bright would not fit the patient with a mechanical knee just for fear of a RAC audit. (PX05141 (Bright (North Bay) Dep. at 177–178)).
- 3000. Jim Weber, President and CEO of Prosthetic & Orthotic Care ("P&O Care"), testified that RAC audits have not had an "impact from P&O Care's perspective on the purchase of [prosthetic] components. It was an impact on the clinical documentation, the procedure by which we would submit a claim." (PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 26)).
- 3001. Keith Watson, President of Fourroux Prosthetics, testified that "Fourroux contends that [RAC audit] impacts on its clinics and clinical assessments regarding prosthetic devices containing microprocessor controlled knees or mechanical knees has been negligible." (PX05166 (Watson (Fourroux Prosthetics) Dep. at 182)).
- 3002. Tracy Ell, owner and Chief Prosthetist of Mid-Missouri Orthotics and Prosthetics, testified that RAC audits have not limited Mid-Missouri from fitting MPKs because "the process that we go through in having the proper documentation in place prior to submissions [of claims to Medicare or payers] is vital to the approval and acceptance" of those claims. (Ell (Mid-Missouri) Tr. 1749–50).
- 3003. Scott Sabolich, owner and Clinical Director of Scott Sabolich Prosthetics and Research, LLC, testified that, "[i]f you're choosing a mechanical K3 knee over a microprocessor K3 knee based solely on the fact that you could get audited and shut your business down, you're making an immoral decision based on your clinical connotations of ethics that shouldn't be made. You should make the best decision for the patient." (PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 219-220)).
- 3004. Despite the increase of RAC audits in the past five to six years, Orthotic and Prosthetic Centers has increased the number of MPKs it has fit on patients each year. (PX05140 (Weott (Orthotic and Prosthetic Centers) Dep. at 121–122)).

- 3005. When RAC audits became more common, Wright & Filippis did not change its "clinical determinations on patients." (PX05167 (Filippis (Wright & Filippis) Dep. at 81)). The percentage of MPKs that Wright & Filippis fit "changed hardly at all over a three year period." (PX05167 (Filippis (Wright & Filippis) Dep. at 81)).
- 3006. MPK manufacturers have not observed a substantial decline in the MPK business due to RAC audits. For example, Kim De Roy, Össur's Executive Vice President of R&D, testified that "I don't believe there's any substantial impact . . . from RAC audits on the [MPK] business today." (De Roy (Össur) Tr. 3567).
- 3007. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified that he did not even know how many RAC audits were conducted in the United States in 2016 or 2017, including how many RAC audits were conducted on MPKs. (Schneider (Otto Bock) Tr. 4744-45). He also did not know what percentage of RAC audits on MPK reimbursements resulted in finding a deficiency. (Schneider (Otto Bock) Tr. 4745).





- 3010. RAC audits also have not impacted the brand of MPK that customers purchase. (*See*, *e.g.*, Senn (COPC) Tr. 213; PX05129 (Ell (Mid-Missouri) Dep. at 161); Brandt (Ability) Tr. 3768).
- 3011. Keith Senn, President of the Kentucky and Indiana operations for Center for Orthotic and Prosthetic Care, testified that he has not found particular brands of MPKs to present a higher risk during a RAC audit than others. (Senn (COPC) Tr. 212-13).
- 3012. Tracy Ell, owner and Chief Prosthetist of Mid-Missouri Orthotics and Prosthetics, similarly testified that he is not aware of certain MPKs presenting a higher risk of a RAC audit. (PX05129 (Ell (Mid-Missouri) Dep. at 161)).
- 3013. Jeffrey M. Brandt, CEO of Ability Prosthetics and Orthotics, testified that the threat of RAC audits has not affected the number of Freedom Plié MPKs that Ability fits on its patients. (Brandt (Ability) Tr. 3768).
 - b) <u>PDAC Verification Is Irrelevant to Analysis of the Merger's Likely</u> <u>Competitive Effects</u>

- (1) PDAC Verification of Prosthetic Devices Is Not Required
- 3014. Payers use the "L-Code system" to determine the amount of reimbursement they provide to clinics for the provision of an above-the-knee prosthesis on a patient. (PX05118 (Testerman (Freedom) Dep. at 84-85); PX05135 (Weber (Prosthetic & Orthotic Care) Dep. at 37-38); PX05108 (Yates (Jonesboro P&O Lab) Dep. at 34-35).
- 3015. Prosthetic manufacturers typically recommend L-codes for their prosthetic devices to assist clinic customers in the reimbursement process. (PX05158 (Swain (Ability Dynamics) Dep. at 100; PX05139 (Schneider (Otto Bock) Dep. at 27-28); see also Kannenberg (Otto Bock) Tr. 1999-2000 (discussing the L-codes that manufactures recommend for various MPKs); PX08023 (Otto Bock) (listing recommended L Codes for each of Otto Bock's MPKs); PX08020 (Otto Bock) at 001 (Otto Bock C-Leg website, including "Suggested HCPCS Coding")).
- 3016.

}. (Solorio (Otto Bock) Tr. 1623 (*in camera*); PX05139 (Schneider (Otto Bock) Dep. at 27-28); PX05165 (Sanders (United) Dep. at 75)).

- 3017. Noridian Healthcare Solutions, LLC has served as the PDAC contractor for CMS for "approaching 10 years now." (Sanders (United) Tr. 5383-84). PDAC receives, evaluates, and processes coding verification applications for CMS. (PX05165 (Sanders (United) Dep. at 28, 75-76)).
- 3018. Otto Bock's Executive Medical Director, Dr. Andreas Kannenberg, testified that "[t]he verifications of codes by PDAC are always product specific." Therefore, PDAC approval for one prosthetic device like an MPK will not apply to other competing MPKs. (PX05150 (Kannenberg (Otto Bock) Dep. at 112-13)).
- 3019. With respect to MPKs, only Otto Bock's C-Leg and Compact and Össur's Rheo and Power Knee have received PDAC verification. (Schneider (Otto Bock) Tr. 4381-82; PX05139 (Schneider (Otto Bock) Dep. at 30-31); De Roy (Össur) Tr. 3646-47).
- 3020. { (Schneider (Otto Bock) Tr. 4381-82; 4747-48 (*in camera*); PX05150 (Kannenberg (Otto Bock) Dep. at 111).
- 3021. Despite releasing the Rheo in 2004, Össur only received PDAC verification for the MPK in December 2017. (De Roy (Össur) Tr. 3613, 3646-47).
- 3022. Endolite has not obtained PDAC verification for the Orion. (PX05144 (Blatchford (Endolite) Dep. at 20, 73); Kannenberg (Otto Bock) Tr. 2001).
- 3023. PDAC verification is only directly applicable to reimbursement under Medicare. (PX05114 (Ferris (Freedom) Dep. at 161-62); PX05158 (Swain (Ability Dynamics) Dep. at 100-01) ("The PDAC approved coding only applies to Medicare claims.")).



- 3026. Freedom's 2015 Plié 3 Fact Sheet, in a section entitled "Ottobock Claims vs Reality," addresses head on Otto Bock's marketing tactic criticizing the Plié for its lack of PDAC approval by stating that "PDAC is not required for reimbursement." (PX08008 (Freedom) at 001).
- 3027. Otto Bock executives concurred that PDAC is not required for prosthetic devices. Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, testified that MPKs are not required to have PDAC verification, and that manufacturers of MPKs can market their devices without PDAC verification. (Schneider (Otto Bock) Tr. 4747) {

Executive Medical Director Andreas Kannenberg also testified that, "there is no obligation of manufacturers to seek verification of coding recommendations by PDAC." (Kannenberg (Otto Bock) Tr. 1970).



- (2) Freedom Plié's PDAC Status Has Not, and Will Not Inhibit Competition between the Plié and C-Leg
- 3029. Freedom recommends that customers seek reimbursement for the Plié under L-Code 5856, for microprocessor swing and stance knees. (*See* CCFF ¶¶ 3067-3069, below).
- 3030. The Plié is reimbursed as a swing and stance MPK, under L-Code 5856. (*See* CCFF ¶¶ 3070, 3072, 3074-3075, below)
- 3031. Jack Sanders, Senior Clinical Program Consultant at United Healthcare, testified that United is agnostic to the manufacturer of a particular prosthetic device. (PX05165 (Sanders (United) Dep. at 104)). Mr. Sanders testified that the lack of PDAC verification

has not stopped United from reimbursing for the Plié. (Sanders (United) Tr. 5496) (*in camera*)).

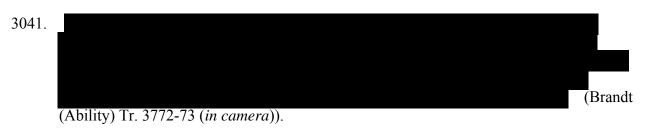
- 3032. Freedom's clinic customers do not view a lack of PDAC verification to be a bar to seeking reimbursement for the Plié. (PX05141 (Bright (North Bay Prosthetics) Dep. at 174); Oros (Scheck & Siress) Tr. 4877-78; PX05116 (Endrikat (Empire Medical) Dep. at 195)).
- 3033. Michael Bright, a certified prosthetist and owner of North Bay Prosthetics, testified that North Bay continues to fit Pliés regardless of its PDAC approval status. (PX05141 (Bright (North Bay) Dep. at 174.) Mr. Bright further testified that a product's lack of PDAC approval does not affect the risk of a RAC audit. (PX05141 (Bright (North Bay) Dep. at 178)).

3034.	3609-010 (<i>in camera</i>)).	} (De Roy (Ossur) Tr.
3035.		
	camera)).	} (Scott Morton Tr. 4247-48) (<i>in</i>

4. Dr. Argue's Claim that Reimbursement Would Prevent an MPK Price Increase is Flawed

- 3036. The amount of reimbursement provided by an insurer, including Medicare, to a clinic is typically called an "allowable" or a "fee." (*See, e.g.*, PX05010 (Schneider (Otto Bock) IHT at 80)).
- 3037. The difference between the acquisition cost of an MPK and the overall reimbursement allowable goes to the clinic or prosthetist. (PX05124 (De Roy (Össur) Dep. at 135-136)).
- 3038. This reimbursement amount "reflects the time spent in assembling the device and the time spent teaching the patients" as well as time spent by the prosthetist "following up on care with the patient." (PX05124 (De Roy (Össur) Dep. at 135-136)). Kim De Roy, Executive Vice President of R&D at Össur, testified that "there's fair margins" for the prosthetists to "fulfill the requirements of fitting, teaching, and then follow-up" at the current reimbursement levels. (PX05124 (De Roy (Össur) Dep. at 136)).
- 3039. Insurers, including Medicare, do not tie the amount of reimbursement to the prices charged by manufacturers for prosthetic devices. (Carkhuff (Freedom) Tr. 596-97; PX05165 (Sanders (United) Dep. at33-34) ("Q. And does the reimbursement that United provides to its vendor clinics for fitting a United beneficiary with a microprocessor knee vary in any way based on the clinic vendor's acquisition cost for the knee? A. No."))

3040. Instead, a clinic "gets paid not by brand or by product selected but by function of the product." (PX05010 (Schneider (Otto Bock) IHT at 84); see also Kannenberg (Otto Bock) Tr. 1872; PX05117 (Choi (ST&G) Dep. at 47-49); PX05165 (Sanders (United) Dep. at33-34)).

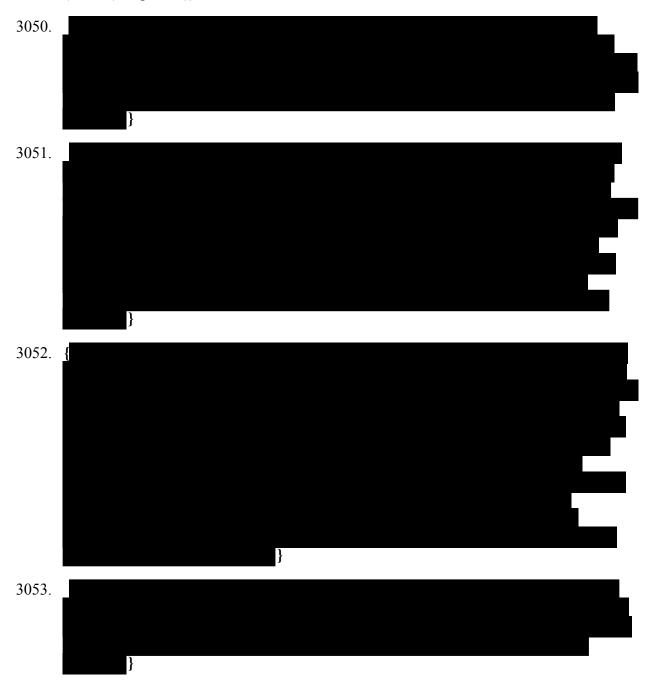


3042.

(Brandt (Ability) Tr. 3773 (in camera)).

- 3043. Michael Bright, owner of North Bay Prosthetics & Orthotics, testified that his clinic makes a profit on all of the combined components that are part of the lower limb prosthetic. (PX05141 (Bright (North Bay) Dep. at 178-179)).
- 3044. Tracy Ell, owner and Chief Prosthetist of Mid-Missouri Orthotics and Prosthetics, considers the margin from the "entire above-the-knee prosthetic" that he bills for, not just the MPK. (Ell (Mid-Missouri O&P) Tr. 1815).
- 3045. In fitting a MPK, "it typically comes with other components that make up a leg" and the "reimbursement associated with the entire leg would be greater than the amounts" for the MPK itself. (Carkhuff (Freedom) Tr. 378).
- 3046. } (Senn (COPC) Tr. 275-76) (*in camera*).
- 3047. Paul Weott, owner of Orthotic and Prosthetic Centers, testified that when he fits an above-the-knee amputee with a prosthetic, he earns margin on the foot, the "socket and the liners," as well as the knee. (PX05140 (Weott (Orthotic Prosthetic Center) Dep. at 44-45)).
- 3048. According to Scott Sabolich, owner and Clinical Director of Scott Sabolich Prosthetics and Research, a "typical K3 definitive, above-the-knee, Medicare allowable is around 40,000, \$45,000" so the co-pay for a patient for an MPK or mechanical knee "doesn't move the needle as much as the entire cost of the leg." (PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 190)). However, the knee is the single most profitable component, followed by the foot. (PX05132 (Sabolich (Scott Sabolich Prosthetics) Dep. at 238)).

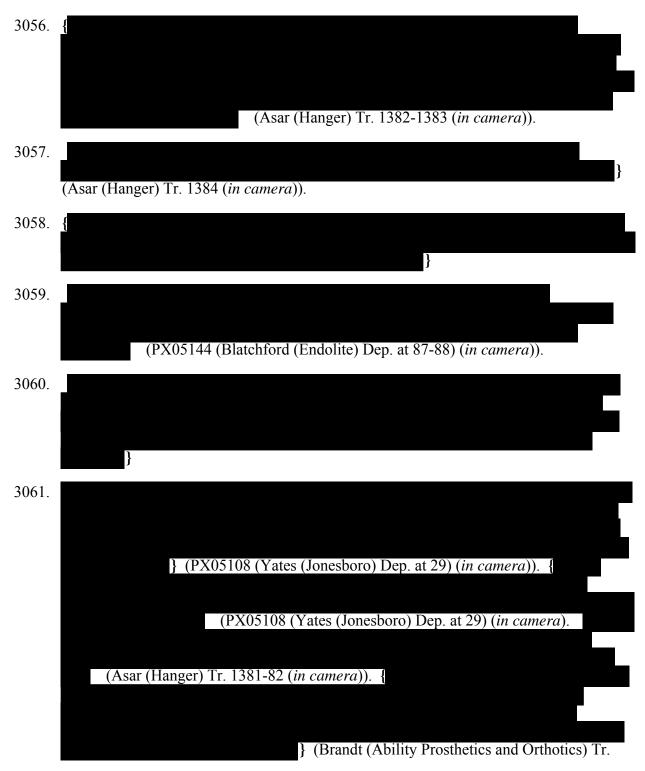
3049. The "total allowables" for the "C-Leg (Current), Orion, Rheo, and Plie" are "roughly" \$28,000. (PX05010 (Schneider (Otto Bock) IHT at 80); *see also* PX05007 (Carkhuff (Freedom) IHT at 112 (discussing PX01023 (Freedom) at 003) (*in camera*)). Reimbursement for a C-Leg 4 is the same as a Plié 3, from either Medicare or a private insurer. (*See, e.g.*, PX05007 (Carkhuff (Freedom) IHT at 112-113); PX05165 (Sanders (United) Dep. at33)).

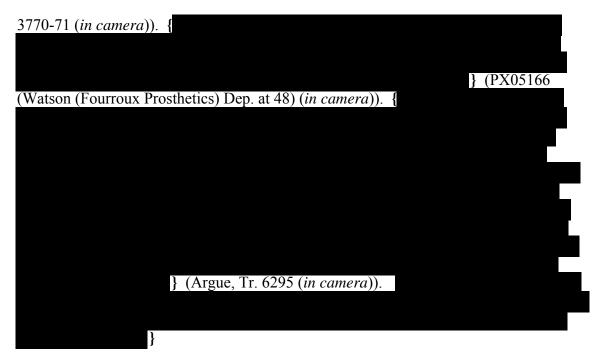


3054. Current reimbursement rates are such that fitting an MPK would remain profitable even were the price of MPKs to increase. Kim De Roy, Executive Vice President of R&D of

Össur, testified that there is "room" for Össur to raise the price of its MPK with the current reimbursement rates. (PX05124 (De Roy (Össur) Dep. at 138-139)).

3055. The reimbursement amount for prosthetic components is usually double the amount that prosthetists pay for the component. (PX05010 (Schneider) IHT at 64)).





5. Dr. Argue's Claim that Plié 3 Does Not Compete Closely with C-Leg 4 due to Alleged Functional Differences Is Contradicted by the Record



- 3063. Freedom's Plié 3 and Otto Bock's C-Leg have been direct competitors and viewed by Respondent and customers as close substitutes for each other for several years. (*See* CCFF ¶¶ 1028-1139, above).
- 3064. Freedom considers the Plié to be an MPK with swing and stance functionality. (Carkhuff (Freedom) Tr. 350-51; Ferris (Freedom) Tr. 2351; PX05111 (Prince (Freedom) Dep. at 94-97) (*in camera*); PX05114 (Ferris (Freedom) Dep. at 141) ("We do actually have swing and stance functionality in our knee."); PX05114 (Ferris (Freedom) Dep. at 159); PX01022 (Freedom) at 063 ("The MPC knee market consists of two major categories: (a) Stance only knees (L-5858) and (b) Swing & Stance knee (L-5856).... Products under the Swing & Stance category are: C-Leg from Otto Bock, Rheo from Ossur, Orion from Endolite, and Plié 2.0 from Freedom Innovations."); PX01214 (Freedom) at 025, 035; PX01686 (Freedom) at 011).

3065. The Plié is marketed by Freedom as a swing and stance MPK. (Carkhuff (Freedom) Tr. 350-51; Schneider (Otto Bock) Tr. 4729-30, 4732;
350-51; Schneider (Otto Bock) at 007; PX01847 (Freedom) at 004).

- 3066. In a Plié 3 marketing document, titled "Plié 3 Microprocessor Knee Fact Sheet" Freedom compared the "Plié 3 vs C-Leg4" noting that "[b]oth Plié 3 and C-Leg 4 have swing and stance control." (PX01214 (Freedom) at 030 (chart comparing "Ottobock Claims vs Reality)).
- 3067. Freedom recommends that customers seek reimbursement for the Plié under L-Code 5856, which is for microprocessor swing and stance knees. (Kannenberg (Otto Bock) Tr. 2000; Carkhuff (Freedom) Tr. 350;

; PX05137 (Matthews (Freedom) Dep. at 154); PX01214 (Freedom) at 025; PX01732 (Otto Bock) at 002, 007; ; PX07008 (Otto Bock) at 004).

- 3068. (Schneider (Otto Bock) IHT at 184)). 2060
- 3069. 3070. }
- 3071. (PX07008 at 004 (¶
 9) (Respondent's Confidential Responses to Complaint Counsel's First Set of Requests for Admissions) (*in camera*)).
- 3072. The Plié is reimbursed as a swing and stance MPK, under L-Code 5856. (Carkhuff (Freedom) Tr. 350, 714-15; Kannenberg (Otto Bock) Tr. 1969-70, 2000; Schneider (Otto Bock) Tr. 4728; Ell (Mid-Missouri) Tr. 1732; {

}; PX05150 (Kannenberg (Otto Bock) Dep. at 76); PX05163 (Stuch (Otto Bock) Dep. at 189); PX05108 (Yates (Jonesboro) Dep. at 195-96); PX05144 (Blatchford (Endolite) Dep. at 64-65); PX01880 (Otto Bock) at 001 (noting, with regard to the Rheo, Orion, and Plié, that "these other standard MPKs are billed with the same codes as the C-Leg"); {

3073. Market participants consider the Plié to be an MPK. { }; PX05117 (Choi (ST&G) Dep. at 124-26); PX05124 (De Roy

}.

(Össur) Dep. at 147-49); PX05144 (Blatchford (Endolite) Dep. at 74); PX05146 (Marquette (DAW) Dep. at 57)).

- 3074. Specifically, prosthetists consider the Plié to be an MPK because they receive reimbursement for the Plié under L-Code 5856. (Schneider (Otto Bock) Tr. 4727-28;
 {
 {
 {
 {
 PX05128 (Senn (COPC) Dep. at 76); PX05129 (Ell (Mid-Missouri) Dep. at 64); PX05145 (Ford (POA) Dep. at 142)).
- 3075. _____}
- 3076. Mid-Missouri Orthotics & Prosthetics uses the same L codes for the C-Leg 4 as it does for the Plié 3 when seeking reimbursement and has received reimbursement for both MPKs using those L codes. (Ell (Mid-Missouri) Tr. 1732).

3077.	camera)).	} (PX01023 (Freedom) at 003 (in
3078.		
		(PX01062 (Otto Bock) at 004 (<i>in camera</i>)).
3079.		} (RX-1049 at 52 (¶
	101) (Argue Expert Report) (in camera)).	

- 3080. United Healthcare reimburses clinics the same amount for Otto Bock's C-Leg 4 and Freedom's Plié 3. (PX05165 (Sanders (United Healthcare) Dep. at 33)).
- 3081. Eric Ferris, Freedom's Vice President of Marketing, Customer Service, and Product Development, testified that Otto Bock salespeople were telling customers that the Plié does not offer swing and stance control, but the Plié does in fact have swing and stance control. (Ferris (Freedom) Tr. 2351 (Q: But the Plié does in fact have swing and stance control, doesn't it? A: I believe so. Again, according to my engineers, yes.).
- 3082. (Arbogast (Ohio Willow Wood) Tr. 5110 (*in camera*)).
- 3083. Prosthetists consider the Plié to offer comparable functionality to the C-Leg and other swing and stance MPKs. (PX05108 (Yates (Jonesboro) Dep. at 64-65) (*in camera*) ("In my experience, for most users, the C-Leg is functionally similar to the Plié."); PX05128 (Senn (COPC) Dep. at 82); PX05129 (Ell (Mid-Missouri) Dep. at 21-22, 63-64)).

- 3084. } (Asar (Hanger) Tr. 1380–81 (*in camera*)).
- 3085. Mark Ford, President and Managing Partner of Prosthetic & Orthotic Associates, testified, "C-Leg and the Plié knees are our clinicians' preference" for MPKs. (Ford (POA) Tr. 937).
- 3086. Freedom considers other swing and stance MPKs to be the Plié's primary competition. (*See, e.g.*, PX05112 (Ammouri (Freedom) Dep. at 109); PX05114 (Ferris (Freedom) Dep. at 30); PX05114 (Ferris (Freedom) Dep. at 145); PX05118 (Testerman (Freedom) Dep. at 27-28); {
- 3087. According to Freedom's Vice President of National and Key Accounts, Mark Testerman, "[Freedom's] main competitors that I would see in key accounts would be Ossur, Endolite, Otto Bock. Those are the primary three that we compete with." (PX05118 (Testerman (Freedom) Dep. at 27-28)).
- 3088. Otto Bock identifies the Plié, along with other swing and stance MPKs, to be the competitors to the C-Leg. {

}

}; PX01732 (Otto Bock) at 002; PX01742 (Otto Bock) at 008 (identifying the Rheo 3, Plié 3, and Orion 2 as "Primary Competitors"); PX01868 (Otto Bock) at 002; { }; PX01874 (Otto Bock) at 005).

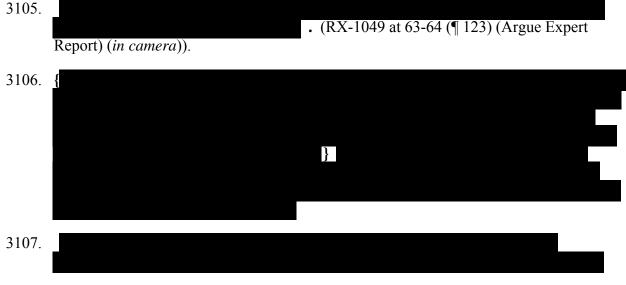
6. Dr. Argue's Power Buyer Analysis is Flawed and Contradicted by the Record

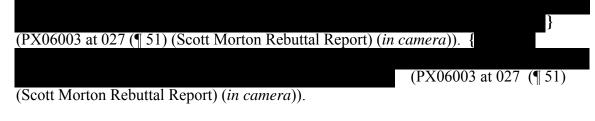
- 3089. According to the Merger Guidelines, "[n]ormally, a merger that eliminates a supplier whose presence contributed significantly to a buyer's negotiating leverage will harm that buyer." (PX08040 at 030 (§ 8) (Merger Guidelines)).
- 3090. Maynard Carkhuff, Freedom's Chairman, testified that the ability of Hanger to negotiate lower MPK prices turns in part on whether Hanger could credibly threaten to switch to another MPK, such as the C-Leg 4. Mr. Carkhuff agreed that if Hanger's threat to switch to another MPK such as the C-Leg 4 were credible, Hanger may use that to negotiate lower prices from Freedom for the Plié 3. (PX05007 (Carkhuff (Freedom) IHT at 122) ("Q. And so in negotiations with Freedom, Hanger may be able to negotiate a lower price based on that bargaining leverage, right? A. Yes. Q. And the ability of Hanger to negotiate lower prices turns in part on whether it could credibly threaten to switch to another microprocessor knee some portion of its sales to say, like, C-Leg 4, right? A. Yes. Q. And so if that threat is credible, they may use that to negotiate lower prices from Freedom for the Plié 3, right? A. Right.")).





- 3101. In the event that the combined firm raises prices, Hanger's CEO testified that Hanger "would be forced to absorb the price increase." (PX05002 (Asar (Hanger) IHT at 52) (*in camera*)).
- 3102. According to Mr. Asar, "it's going to be hard for Hanger, a Hanger Clinic, our patient care segment, to switch that much volume from one manufacturer to the other, especially from Otto Bock." (Asar (Hanger) Tr. 1447 (*in camera*)).
- 3103. As such, Mr. Asar believes that the Merger is "worrisome" and that the "price flexibility" Hanger experienced pre-Merger "may go away from the marketplace for us at Hanger." (PX05153B (Asar (Hanger) Dep. at 123-125 (*in camera*)); PX05002 (Asar (Hanger) IHT at 58) (*in camera*)).
- 3104. Respondent Expert, Dr. Argue, concluded that adverse competitive effects are unlikely to occur because Hanger, as the largest operator of orthotic and prosthetic clinics in the United States, serves as a "powerful buyer" and has the ability to constrain any increase in prices by the combined Otto Bock and Freedom. (RX-1049 at 61 (¶ 122) (Argue Expert Report)).





- 3108. According to the Merger Guidelines, "even if some powerful buyers could protect themselves, the Agencies also consider whether market power can be exercised against other buyers." (PX08040 at 030 (§ 8) (Merger Guidelines)).
- 3109. {
 (Carkhuff (Freedom) Tr. 695 (*in camera*)).
 3110.
 - } (Solorio (Otto Bock) Tr. 1626-27 (in camera)).

7. Dr. Argue Does Not Present an Entry Analysis

- 3111. Respondent Expert, Dr. Argue, admits that Section 9 of the Merger Guidelines relates to entry. (Argue (Respondent) Tr. 6261).
- 3112. Argue (Respondent) Dep. at 25). (Argue (Respondent) Dep. at 25).
- 3113. } (Argue, Tr. 6263 (*in camera*); PX05173 (Argue (Respondent) Dep. at 26)).
- 3114. Respondent Expert, Dr. Argue, did not perform any analysis of how long it would take a firm without a microprocessor knee to develop a microprocessor knee. (Argue (Respondent) Tr. 6265-66; PX05173 (Argue (Respondent) Dep. at 26)).
- 3115. Dr. Argue's Report does not contain any analysis of how much it would cost a firm without a microprocessor knee to develop a microprocessor knee. (Argue, Tr. 6266; PX05173 (Argue (Respondent) Dep. at 26-27)).
- 3116. Respondent Expert, Dr. Argue, did not perform any analysis of whether anyone beyond current microprocessor knee manufacturers have microprocessor knees in development. (Argue, Tr. 6266; PX05173 (Argue (Respondent) Dep. at 27)).
- 3117. Dr. Argue did not perform any analysis of the intellectual property held by Otto Bock related to its microprocessor knees. (Argue, Tr. 6266; PX05173 (Argue (Respondent) Dep. at 27-28)).

- 3118. Respondent Expert, Dr. Argue, did not perform any analysis specific to the intellectual property held by Freedom for its microprocessor knees. (Argue, Tr. 6266; PX05173 (Argue (Respondent) Dep. at 28)).
- 3119. Dr. Argue's Report does not contain any analysis of failed microprocessor knee development efforts by other manufacturers. (Argue, Tr. 6266; PX05173 (Argue (Respondent) Dep. at 28)).

8. Dr. Argue Does Not Present an Efficiencies Analysis

- 3120. Apart from relying on the expert report of Respondent efficiencies expert, Mr. James Peterson, Respondent's other expert, Dr. Argue did not conduct any separate analysis of cost savings from the Merger. (Argue, Tr. 6259; PX05173 (Argue (Respondent) Dep. at 30)).
- 3121. Respondent Expert, Dr. Argue, did not perform any independent assessment to verify the cost savings estimate that Mr. Peterson calculated in his report. (Argue, Tr. 6259; PX05173 (Argue (Respondent) Dep. at 30-31)).
- 3122. Dr. Argue did not perform any independent assessment to determine whether the cost savings Mr. Peterson cites in his report are merger-specific. (Argue, Tr. 6259; PX05173 (Argue (Respondent) Dep. at 31)).
- 3123. Respondent Expert, Dr. Argue, did not perform any assessment to determine whether the efficiencies that Mr. Peterson estimates in his report would be passed on to MPK customers. (Argue, Tr. 6259; PX05173 (Argue (Respondent) Dep. at 35)).
- 3124. Dr. Argue did not perform any assessment to determine whether the efficiencies Mr. Peterson calculates in his report would result in lower prices for MPK customers. (Argue, Tr. 6259-60; PX05173 (Argue (Respondent) Dep. at 35-36)).

B. FLAWS IN MR. JAMES PETERSON'S ANALYSIS

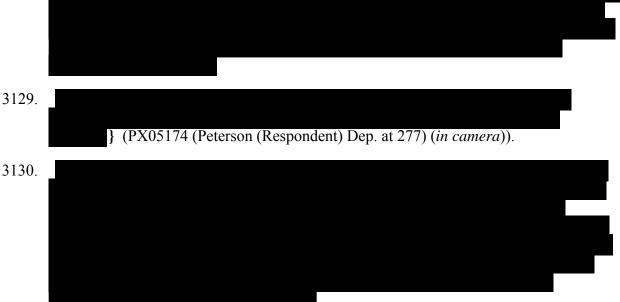
1. Mr. Peterson's Efficiencies Analysis Is Flawed

- 3125. The efficiencies analysis of Respondent's expert witness, James Peterson, relies on speculative cost-savings estimates and are not verifiable. (*See* CCFF ¶¶ 1748-1782, above).
- 3126. (*See* CCFF ¶¶ 1748-1782, above).
- 3127. {

But Dr. Baggenstoss, the A.T. Kearney executive responsible for the Integration Team, testified that synergy opportunities were "all early stage" at the time work stopped. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 27); PX05127 (Röessing

(Otto Bock) Dep. at 34, 50–51) (noting that Dr. Baggenstoss was the "project lead" of the Integration Team)).

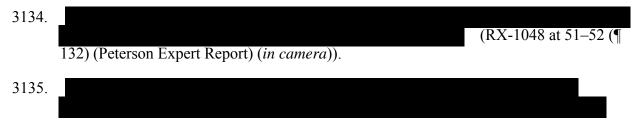
3128. Dr. Baggenstoss of A.T. Kearney was the integration project lead. (PX05127 (Röessing (Otto Bock) Dep. at 34, 50–51)). {



3131. Regarding Mr. Peterson's range of claimed efficiencies, Ms. Hammer, Complaint Counsel's efficiencies expert, concluded that using a "haircut" to estimate efficiencies does not meet the requirements of the Merger Guidelines because one does not "know what a reasonably derived estimate of the future efficiency would be." (Hammer Tr. 2900–901).



3133. Mr. Peterson's efficiencies analysis did not analyze the extent to which the claimed efficiencies could be achieved through independent cost-savings initiatives nor did it take into account practical alternatives (e.g., divestiture or licensing) that could mitigate competitive concerns. (*See* CCFF ¶¶ 1784-1797, above).



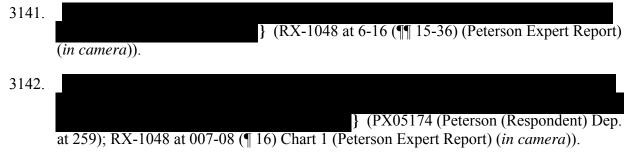
(Peterson Tr. 6738-39 (*in camera*); *see also* (PX05174 (Peterson (Respondent) Dep. at 278) (*in camera*).

3136. Ms. Hammer, Complaint Counsel's efficiencies expert, concluded that the claimed efficiencies were not demonstrated to be merger-specific, as Mr. Peterson failed to assess whether or not the alleged efficiencies could result from Freedom implementing non-proprietary best practices. (Hammer Tr. 2901–902; PX06004 at 036 (¶ 78) (Hammer Rebuttal Report)).

3137.			
		(Hammar Tr. 2001: see also \mathbf{P} V06004 at 027.28 (\mathbf{P} 22) (Hammar Baby	1tto1
	Report)).	(Hammer Tr. 2901; <i>see also</i> PX06004 at 037-38 (¶ 82) (Hammer Rebu	illai

3138.
(Peterson Tr. 6749 (*in camera*)).
3139.
{ (RX-1048 at 45–53 (¶ 120–135) (Peterson

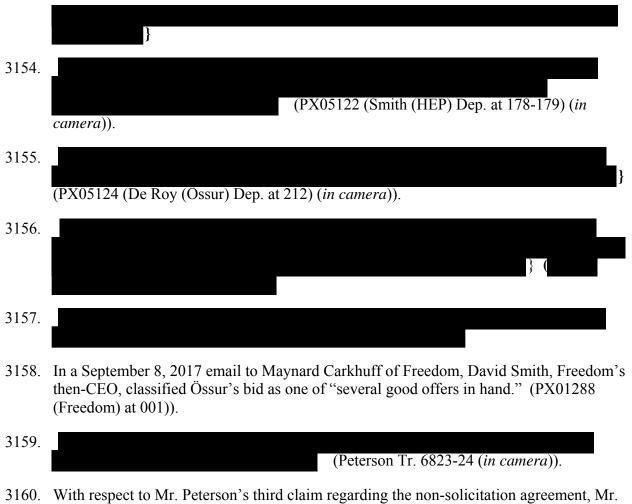
- 3140. Complaint Counsel expert, Ms. Hammer, concluded that because Mr. Peterson did not specify what portion of any claimed efficiencies are fixed versus marginal costs, he failed to show what portion of the claimed efficiencies would be more likely to be passed on to consumers. (Hammer Tr. 2904; PX06004 at 039 (¶ 87) (Hammer Rebuttal Report)).
 - 2. Mr. Peterson's Failing Firm Analysis is Flawed
 - a) <u>Mr. Peterson Focused on Freedom's Financial History Prior to the</u> 2017 Turnaround



b) <u>Mr. Peterson Does Not Calculate a Liquidation Value</u>

Expert Report) (in camera)).

- 3143. The Merger Guidelines define a "reasonable alternative offer" as "[a]ny offer to purchase the assets of the failing firm for a price above the liquidation value of those assets[.]" (PX08040 at 035 n.16 (§ 11) (Merger Guidelines)).
- 3144. Mr. Peterson, Respondent's expert, agreed that under the Merger Guidelines, a reasonable alternative offer is any offer to purchase the assets of the failing firm for a price above the liquidation value of those assets. (Peterson, Tr. 6690–91).
- 3145. Mr. Peterson's expert report did not contain a liquidation analysis of Freedom's business. (RX-1048 at 044 (¶ 115) (Peterson Expert Report)).
- 3146. At trial, Mr. Peterson, Respondent's expert witness, testified, "I did not calculate a point estimate of the liquidation value of Freedom." (Peterson Tr. 6691).
- Mr. Peterson did not calculate the liquidation value of Freedom's inventory. (Peterson Tr. 6691-92).
- 3148. Mr. Peterson did not calculate the liquidation value of Freedom's accounts receivable. (Peterson Tr. 6692).
- 3149. Mr. Peterson did not calculate the liquidation value of Freedom's property, plants or equipment. (Peterson Tr. 6692).
- 3150. Mr. Peterson did not calculate the liquidation value of any of Freedom's tangible assets. (Peterson Tr. 6692).
- 3151. Mr. Peterson did not calculate the liquidation value of any of Freedom's intangible assets. (Peterson Tr. 6693).
 - c) <u>Mr. Peterson's Argument that Össur's Bid was Insincere is</u> <u>Contradicted by the Record</u>
- 3152. } (Peterson Tr. 6653 (*in camera*)).
- 3153. In his deposition, Mr. Peterson stated that he had not offered an opinion on whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have an opinion as to whether { was a reasonable alternative offer; in particular, Mr. Peterson did not have



- Hammack of Moelis testified at his deposition that Freedom "didn't withhold any people from [Össur], but initially, at the beginning, we withheld some information that [Össur] said they didn't want to get because it was sensitive around certain product categories."
 (PX05110 (Hammack (Moelis) Dep. at 86-87)). Overall, Mr. Hammack could not "recall there being significant differences" in the information that Otto Bock and Össur received during the due diligence process. (PX05110 (Hammack (Moelis) Dep. at 91-92).
- 3161. } (Peterson Tr. 6825-26 (*in camera*); PX05174 (Peterson (Respondent) Dep. at 108 (*in camera*))).
 d) <u>Mr. Peterson's Argument that Freedom's Revenue Gains Were</u> <u>Unsustainable is Contradicted by the Record</u>
 3162. (Peterson, Tr. 6619, 6622) (*in camera*).
 3163.
 - } (Smith, Tr. 6574) (*in camera*).

XVI. WITNESS BACKGROUNDS

A. LAY WITNESSES WHO TESTIFIED AT TRIAL

1. Complaint Counsel's Witnesses

a) <u>Respondent's Executives</u>

Maynard Carkhuff

- 3164. Maynard Carkhuff is Chairman of Freedom. This is a senior strategic position within Freedom. His current Chairman position does not refer to Freedom's board of directors. (Carkhuff (Freedom) Tr. 290).
- 3165. At the time of the Merger, Mr. Carkhuff was on Freedom's board of directors. (Carkhuff (Freedom) Tr. 291).
- 3166. Mr. Carkhuff joined Freedom in 2005 as President of the company. In 2012, Mr. Carkhuff became CEO and President, and was the top executive of the Company with responsibility for all aspects of the company's operations. In 2015, Mr. Carkhuff became Chairman of the board of directors. (Carkhuff (Freedom) Tr. 291-294).
- 3167. Subsequently, in April 2016, Mr. Carkhuff became Vice Chairman and Chief Innovation Officer at Freedom. As Chief Innovation Officer, he focused on strategic issues at Freedom, chaired the technology committee, and collaborated the with Chairman of Freedom's board and CEO on potential acquisitions and new product development efforts. (Carkhuff (Freedom) Tr. 292, 296).
- 3168. Mr. Carkhuff then entered into his current role as Chairman in October 2017. (Carkhuff (Freedom) Tr. 292).
- 3169. Mr. Carkhuff is also manager for the Hold Separate agreement between the FTC and Otto Bock. (Carkhuff (Freedom) Tr. 290-291).
- 3170. Prior to the Merger, Mr. Carkhuff sat on Freedom's Product Approval Committee ("PAC"). PAC approves all new products that Freedom launches. Mr. Carkhuff sat on committee when Freedom was evaluating its new Quattro MPK. (Carkhuff (Freedom) Tr. 296-298).

<u>Eric Ferris</u>

- 3171. Eric Ferris has been the Vice President of Marketing, Customer Service and Product Development at Freedom since February 2018. (Ferris (Freedom) Tr. 2299). From July 2015 through February 2018, he was the Director of Marketing and Customer Service. (Ferris (Freedom) Tr. 2298).
- 3172. Mr. Ferris is a member of Freedom's Operating Committee, which is responsible for the overall management of Freedom, Freedom's Executive Committee, which deals with

urgent issue, Freedom's Product Approval Committee, which approves the product development phases for the overall organization and particular development projects, and the IP committee, which reviews patent proposals. (Ferris (Freedom) Tr. 2299-300).

3173. Mr. Ferris's responsibilities include marketing Freedom's products, promoting the products, messaging, competitive assessments, pricing, education, and strategy regarding messaging for sales into the different sales channels. (Ferris (Freedom) Tr. 2303-05).

Dr. Andreas Kannenberg

- 3174. Dr. Andreas Kannenberg is Executive Medical Director for Otto Bock HealthCare North America. He has been in that position since 2013. (Kannenberg (Otto Bock) Tr. 1819). As Executive Medical Director, Dr. Kannenberg's responsibilities include clinical research and education, and reimbursement. (Kannenberg (Otto Bock) Tr. 1824).
- 3175. Prior to joining Otto Bock, Dr. Kannenberg received his M.D. and Ph.D. from Humboldt University in Berlin, Germany. (Kannenberg (Otto Bock) Tr. 1820).
- 3176. Dr. Kannenberg joined Otto Bock as Director of Medical Affairs. In this role, Dr. Kannenberg provided education and training to prosthetists and orthotists, including education about the evidence supporting the use of Otto Bock products. (Kannenberg (Otto Bock) Tr. 1821-22).
- 3177. In 2003, Dr. Kannenberg established Otto Bock's clinical research department, which grew from a one-person department to a group of 20 Otto Bock employees. (Kannenberg (Otto Bock) Tr. 1821). This department gathers existing evidence and develops new evidence to convince payers to reimburse for Otto Bock products. It also organizes and supervises clinical research related to Otto Bock's products. (Kannenberg (Otto Bock) Tr. 1821-22).

Lee Kim

- 3178. Lee Kim is the Chief Financial Officer of Freedom and has been since he started working at Freedom in February of 2008. (Kim (Freedom) Tr. 2492). Mr. Kim continues to hold the position of Chief Financial Officer following Freedom's acquisition by Otto Bock. (Kim (Freedom) Tr. 2492).
- 3179. Mr. Kim is licensed as a Certified Public Accountant in California. (Kim (Freedom) Tr. 2495-96).
- 3180. As the Chief Financial Officer of Freedom, Mr. Kim reported directly to the CEO of Freedom. (Kim (Freedom) Tr. 2493).
- 3181. As CFO of Freedom, Mr. Kim is the executive responsible for managing Freedom's accounting operations and preparing the company's financial statements. (Kim (Freedom) Tr. 2493). Mr. Kim established internal controls to ensure Freedom reported financial statements that were materially correct. (Kim (Freedom) Tr. 2493). Mr. Kim also prepared the company's financial forecasts. (Kim (Freedom) Tr. 2494).

- 3182. Mr. Kim reported financial statements that he prepared and the financial forecasts he developed to Freedom's board of directors. (Kim (Freedom) Tr. 2494).
- 3183. Mr. Kim was the Freedom executive with the ultimate authority for ensuring the accuracy of Freedom financial statements. (Kim (Freedom) Tr. 2494).
- 3184. Lee Kim is a Certified Public Accountant licensed in California and is familiar with the Financial Accounting Standards Board Codification. (Kim (Freedom) Tr. 2495-96).
- 3185. Mr. Kim was responsible for engaging outside accountants to conduct the annual audit of Freedom's financial statements and was the executive responsible for managing the audit process while it was ongoing each year. (Kim (Freedom) Tr. 2497). Mr. Kim testified that he "had overall responsibility for the audit" process. (Kim (Freedom) Tr. 2498). Mr. Kim acknowledged that as a member of Freedom's management team he had an obligation to provide outside auditors with information free from material misstatement. (Kim (Freedom) Tr. 2500).
- 3186. Following Freedom's acquisition by Otto Bock, Mr. Kim continues to be the executive overseeing the annual audit process for Freedom. (Kim (Freedom) Tr. 2500).

Dr. Stephen Prince

- 3187. Dr. Stephen Prince is currently the Quattro Project Manager and Technical Leader at Freedom. He began working at Freedom in June 2012 and became Project Manager in 2015. (Prince (Freedom) Tr. 2672-73).
- 3188. Dr. Prince received his bachelor's degree, master's degree, and Ph.D. in mechanical engineering from UCLA in 2007, 2009, and 2011, respectively. (Prince (Freedom) Tr. 2672-73).
- 3189. Dr. Prince was one of the two mechanical engineers who developed Freedom's Kinnex. (Prince (Freedom) Tr. 2674).
- 3190. As the Quattro Project Manager and Technical Leader, Dr. Prince manages both the core team, "a cross-functional team within Freedom," and the R&D team at Freedom working on the Quattro project. (Prince (Freedom) Tr. 2675). The R&D team is comprised of approximately ten engineers at any given time, including mechanical engineers, software engineers, and firmware engineers. (Prince (Freedom) Tr. 2676). The core team is comprised of "clinical representative, marketing, purchasing, finance, [and] quality[.]" (Prince (Freedom) Tr. 2679).
- 3191. As the Quattro Project Manager and Technical Leader, Dr. Prince holds daily status meetings with the R&D team responsible for the Quattro. (Prince (Freedom) Tr. 2678-79). Dr. Prince also hosts a weekly meeting with the core team for the Quattro project in order to review milestones for the project. (Prince (Freedom) Tr. 2679).
- 3192. Dr. Prince also helps lead the internal Project Approval Committee ("PAC") for the Quattro project. His responsibilities include "prepar[ing] the documentation and

present[ing] the majority of that material." (Prince (Freedom) Tr. 2681). The PAC consists of Freedom's CEO, CFO, Vice President of Marketing, Vice President of R&D, and Senior Director of Quality. (Prince (Freedom) Tr. 2680-81). The PAC must approve each of the six phases in the Product Development Process ("PDP") in order for the project to progress. (Prince (Freedom) Tr. 2681).

3193.

(Prince (Freedom) Tr. 2683 (*in camera*)). John Robertson testified that Dr. Prince was the team leader for the Quattro project when it was initiated. (PX05006 (Robertson (Freedom) IHT at 19)).

3194. (PX05115 (Robertson (Freedom) Dep. at 179-80) (*in camera*)).

<u>Cali Solorio</u>

- 3195. Cali Solorio has been the Senior Prosthetics Marketing Manager at Otto Bock since March 2017. (Solorio (Otto Bock) Tr. 1575). In this role, Ms. Solorio manages Otto Bock's MPK products through their life cycles in the North American market. Solorio (Otto Bock) Tr. 1575). She leads Otto Bock's prosthetic marketing team. (Solorio (Otto Bock) Tr. 1577). She leads the strategic direction of Otto Bock's marketing initiatives as it relates to Otto Bock's prosthetic products, including pricing, advertising promotions and product promotions. (Solorio (Otto Bock) Tr. 1578-79).
- 3196. Ms. Solorio joined Otto Bock in December of 2014 as a marketing manager generalist and held that position until July 2015. (Solorio (Otto Bock) Tr. 1574). From July 2015 to March 2017, Ms. Solorio was market manager for microprocessor knees. (Solorio (Otto Bock) Tr. 1574). In this position, Ms. Solorio was involved in the marketing strategy, advertising, product pricing and promotions, and educating the sales team regarding prosthetic knees. (Solorio (Otto Bock) Tr. 1577-78).
- 3197. Ms. Solorio assisted with the launch of Otto Bock's C-Leg 4 in April 2015 and took responsibility for the product in July of 2017. (Solorio (Otto Bock) Tr. 1576).
- 3198. Sales representatives and market managers report to Ms. Solorio whenever they see competitors running promotions, including promotions involving competing MPKs. (Solorio (Otto Bock) Tr. 1580).

Matthew Swiggum

- 3199. Matthew Swiggum joined Otto Bock in 1997 as a sales representative. He held various roles in the company for almost 21 years. (Swiggum (Otto Bock) Tr. 3315-17).
- 3200. Mr. Swiggum became Regional President and CEO of Otto Bock HealthCare North America in September 2016. He was in that position at the time of the Merger and was personally involved in meetings regarding the integration of Freedom after it was acquired by Otto Bock. (Swiggum (Otto Bock) Tr. 3309-10).

- 3201. As Regional President and CEO, Mr. Swiggum was responsible for maintaining and generating a sustainable profit for Otto Bock and for all customer-facing responsibilities. (Swiggum (Otto Bock) Tr. 3317).
- 3202. Mr. Swiggum was also involved in analyzing Freedom's Plié 3 business after Otto Bock's acquisition of Freedom. (Swiggum (Otto Bock) Tr. 3343).
- 3203. Mr. Swiggum's employment with Otto Bock was terminated on February 22, 2018. (Swiggum (Otto Bock) Tr. 3313-3314).
- 3204. Mr. Swiggum currently receives \$30,000 per month from Otto Bock. (Swiggum (Otto Bock) Tr. 3311). This arrangement will continue until about April 2019, and provides that Mr. Swiggum may provide Otto Bock with consulting services. (Swiggum (Otto Bock) Tr. 3312).

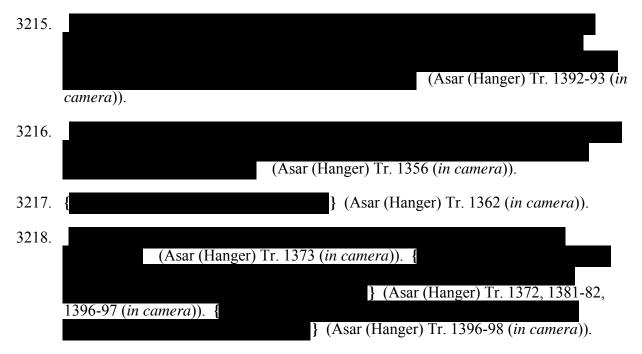
<u>Mark Testerman</u>

- 3205. Mark Testerman is Freedom's Vice President of National and Key Accounts, a position he has held since February 2014. (Testerman (Freedom) Tr. 1073). Key accounts are the top 50 domestic customers based on volume of products sold. (Testerman (Freedom) Tr. 1073). Mr. Testerman builds relationships with these key accounts and works with them on contracting and pricing. (Testerman (Freedom) Tr. 1079).
- 3206. The majority of Mr. Testerman's time is spent "maintaining and nursing existing key accounts" with some time devoted to "identifying new key accounts." (Testerman (Freedom) Tr. 1182).
- 3207. Mr. Testerman updates the marketing and clinical teams on specific key accounts during weekly conference calls. (Testerman (Freedom) Tr. 1088).
- 3208. Prior to becoming Vice President of National and Key Accounts, Mr. Testerman was Freedom's Vice President of Domestic Sales from October 2010 through February 2014. (Testerman (Freedom) Tr. 1072-73). In that role, Mr. Testerman managed the sales team and implemented Salesforce.com at the company. (Testerman (Freedom) Tr. 1075). He was also involved in new product launches and worked with the marketing, operating and finance business units at Freedom. (Testerman (Freedom) Tr. 1078).
 - b) <u>Third Party Witnesses</u>

Vinit Asar

- 3209. Vinit Asar is President and Chief Executive Officer of Hanger, Incorporated ("Hanger") and a board member of Hanger's executive board. (Asar (Hanger) Tr. 1308).
- 3210. As President and CEO, Mr. Asar is responsible for the operational and strategic sides of the business. (Asar (Hanger) Tr. 1310).

- 3211. Prior to his current position, Mr. Asar was Chief Growth Officer at Hanger from December 2009 until 2011 and Chief Operating Officer from 2011-2012. (Asar (Hanger) Tr. 1310-11). As Chief Growth Officer, Mr. Asar was responsible for business development opportunities. (Asar (Hanger) Tr. 1311). As Chief Operating Officer, Mr. Asar maintained his Chief Growth Officer duties and was responsible for some additional business in the products and services segment. (Asar (Hanger) Tr. 1311).
- 3212. Mr. Asar is familiar with the prosthetic fitting process. (Asar (Hanger) Tr. 1321). He visits between 60 and 80 clinics a year. (Asar (Hanger) Tr. 1312). During a clinic visit, Mr. Asar generally spends time with the clinicians, and "in some cases will sit with a patient while the clinician is fitting the patient" (Asar (Hanger) Tr. 1323). He talks with clinicians about the technology and what types of fittings they are doing. (Asar (Hanger) Tr. 1324).
- 3213. Hanger's annual educational fair, which includes education related to MPKs, is "tremendously helpful" for Mr. Asar's role as CEO. (Asar (Hanger) Tr. 1327) Otto Bock, Freedom, Össur and Endolite have booths at the annual educational fair. (Asar (Hanger) Tr. 1328).
- 3214. Mr. Asar is familiar with MPKs and mechanical knees from his visits to Hanger's clinics, where he sees patients wearing both types of prosthetic knees. (Asar (Hanger) Tr. 1335). Mr. Asar is familiar with MPKs and mechanical knees from monthly business reviews. (Asar (Hanger) Tr. 1335). During Hanger's annual educational fair, he sits in sessions, which have allowed him to understand the differences between MPKs and mechanical knees. (Asar (Hanger) Tr. 1335).



3219. Hanger provides healthcare services for orthotic and prosthetic patients in 44 states and Washington, D.C. (Asar (Hanger) Tr. 1307).

- 3220. Approximately 80% of Hanger's revenues (about \$850 million) come from its patient care segment, which includes patient care clinics across the country. (Asar (Hanger) Tr. 1307-08). This segment fits mechanical and microprocessor prosthetic knees. (Asar (Hanger) Tr. 1309). There are about 700 full-time Hanger clinics and 120 part-time satellite clinics in the United States. (Asar (Hanger) Tr. 1312). The clinics employ about 1500 orthotist-prosthetists. (Asar (Hanger) Tr. 1313).
- 3221. The products and services division at Hanger is called Southern Prosthetic Supply, or SPS. (Asar (Hanger) Tr. 1319). SPS distributes orthotic and prosthetic devices from manufacturers to independent clinics outside of Hanger. (Asar (Hanger) Tr. 1319). SPS has a sales force but it does not assist in fittings. (Asar (Hanger) Tr. 1320). SPS has five distribution centers in the United States. (Asar (Hanger) Tr. 1320-21).
- 3222. (Asar (Hanger) Tr. 1373 (*in camera*)).

Brian Stephen Blatchford

- 3223. Brian Stephen Blatchford is Executive Chairman of Charles, A Blatchford & Sons Limited, (Endolite), a family-owned business in the United Kingdom. (Blatchford (Endolite) Tr. 2089, 2091). He owns just under a quarter of the shares of the company. (Blatchford (Endolite) Tr. 2090-91).
- 3224. As Executive Chairman, Mr. Blatchford looks at the strategic direction of Endolite, manages the board of directors and is responsible for the strategic direction of developing products. (Blatchford (Endolite) Tr. 2091).
- 3225. Prior to becoming Executive Chairman, Mr. Blatchford was CEO of Endolite from January 1, 1986 to March 31, 2015. (Blatchford (Endolite) Tr. 2094). As CEO, Mr. Blatchford ensured Endolite met its overall plan, managed the management team, and was responsible for each area of operation of the company. (Blatchford (Endolite) Tr. 2094).

Jeffrey Brandt

- 3226. Jeffrey Brandt is CEO of Ability Prosthetics and Orthotics ("Ability"). (Brandt (Ability) Tr. 3742). He has worked at Ability since 2004, when he founded it. (Brandt (Ability) Tr. 3743).
- 3227. Mr. Brandt is a certified prosthetist. (Brandt (Ability) Tr. 3743). He received that certification after completing Northwestern University's orthotic-prosthetic residency program, completing two one-year residencies, and passing the board examinations. (Brandt (Ability) Tr. 3744).
- 3228. Mr. Brandt acted as a certified prosthetist at Ability from 2004 through 2012, during which time he "generally" made the decision of which type of knee to fit on above-the-knee amputees. (Brandt (Ability) Tr. 3751).

- 3229. As CEO, Mr. Brandt is currently involved in business development and with AOPA. (Brandt (Ability) Tr. 3756). He also has "ultimate responsibility with respect to the profitability" of Ability. (Brandt (Ability) Tr. 3757).
- 3230. Ability operates ten facilities across Maryland, Pennsylvania and North Carolina where prosthetists and orthotists "evaluate, design, fit the device that's prescribed and then provide ongoing follow-up care and maintenance for that patient over the course of the lifetime of the device." (Brandt (Ability) Tr. 3742-43).
- 3231. Ability has "roughly 43" employees, 18 of whom are certified prosthetists. (Brandt (Ability) Tr. 3743).

William Carver, III

- 3232. William Carver, III is President and Chief Operating Officer of College Park Industries ("College Park"), a prosthetic manufacturer. (Carver, (College Park) Tr. 2003). Prior to his current position, Mr. Carver was the Director of Operations and the Operations Manager. (Carver, (College Park) Tr. 2003-04).
- 3233. While Director of Operations, Mr. Carver was responsible for quality, shipping and receiving, returns, toolmaking, machining, and some of the manufacturing and engineering departments. (Carver, (College Park) Tr. 2004).
- 3234. As Chief Operating Officer and President, Mr. Carver is currently in charge of the strategy, business plan, vision and public image of College Park. (Carver, (College Park) Tr. 2005-07). The executive team reports to him. (Carver, (College Park) Tr. 2006).
- 3235. College Park manufactures and sells prosthetic feet for K1, K2 and K3 users, some mechanical knees, liners, endo components, and upper limb products such as myoelectric elbows, mechanical elbows, shoulder joints, electrodes, mechanical fingers and hands. (Carver (College Park) Tr. 2003). College Park's only knee is the Guardian knee which is a "safety knee" for K2 users. (Carver (College Park) Tr. 2012). College Park is developing the Capital hydraulic knee for K3 users. (Carver (College Park) Tr. 81-82).
- 3236. College Park has three manufacturing facilities in Boston, Massachusetts, Warren, Michigan and Mount Clemens, Michigan. (Carver, (College Park) Tr. 2010).
- 3237. Founded in 1986, College Park has approximately 130 employees. (Carver, (College Park) Tr. 2011).

Jeffrey Collins

- 3238. Jeffrey Collins is President of Cascade Orthopedic Supply and its Canadian subsidiary, OrtoPed ULC. (Collins (Cascade) Tr. 3270).
- 3239. "Cascade is a wholesale distributor of medical supplies and equipment, specifically serving certified prosthetists and orthotists in the United States. (Collins (Cascade) Tr.

3271).

(Collins (Cascade) Tr. 3288 (in camera)).

3240. As President, Mr. Collins leads Cascade's directors and oversees the business. (Collins (Cascade) Tr. 3271).

Tracy Ell

- 3241. Tracey Ell is the owner and Chief Prosthetist at Mid-Missouri Orthotics and Prosthetics ("Mid-Missouri O&P"). (Ell (Mid-Missouri O&P) Tr. 1659). He has had that position for 18 years. (Ell (Mid-Missouri O&P) Tr. 1659).
- 3242. As owner of Mid-Missouri O&P, Mr. Ell coordinates referral sources, coordinates the fabrication facilities, supervises residents, fits orthotics and approves L codes prior to submissions for authorization of insurance. (Ell (Mid-Missouri O&P) Tr. 1662). As Chief Prosthetists at Mid-Missouri O&P, Mr. Ell supervises the majority of all prosthetic fittings, coordinates resident training and fabrication. (Ell (Mid-Missouri O&P) Tr. 1662-63).
- 3243. Mr. Ell became a certified prosthetist in 1998 after obtaining a bachelor's from Truman State University, being trained at Northwestern University's medical school program in prosthetics and sitting for the national certification exam. (Ell (Mid-Missouri O&P) Tr. 1664-66). Mr. Ell also obtained a certification as a fitter in orthotics. (Ell (Mid-Missouri O&P) Tr. 1667).
- 3244. In addition to his positions at Mid-Missouri O&P, Mr. Ell does prosthetic claims review for the State of Missouri, educates prosthetic residents at the University of Missouri at their biweekly clinics and engages in resident education with the Veteran's Administration. (Ell (Mid-Missouri O&P) Tr. 1672-73).
- 3245. Mid-Missouri O&P was founded by Mr. Ell and his partner, Shawn Bright in 2000. (Ell (Mid-Missouri O&P) Tr. 1660). It has four clinics located in Columbia, Missouri, Jefferson City, Missouri, Rolla, Missouri and O'Fallon, Missouri. (Ell (Mid-Missouri O&P) Tr. 1660-61).
- 3246. Mid-Missouri O&P employs three certified prosthetists and one prosthetic resident. (Ell (Mid-Missouri O&P) Tr. 1661). These prosthetists fit between 30-50 mechanical knees each year and 10-20 MPKs each year. (Ell (Mid-Missouri O&P) Tr. 1676).

Mark Ford

3247. Mark Ford is President and Managing Partner of Prosthetic and Orthotic Associates ("POA"), a full-service orthotic and prosthetic patient care practice. (Ford (POA) Tr. 902). Mr. Ford has held this position since June of 2016. (Ford (POA) Tr. 902). As President and Managing Partner of POA, Mr. Ford oversees all the business operations and facilities, negotiates with manufacturer, and manages the partner team of the company and the profitability of the business. (Ford (POA) Tr. 902, 904-05).

- 3248. POA has three full-time clinics in Middletown, New York, Kingston, New York, and Poughkeepsie, New York and one part-time clinic in Mahwah, New Jersey. (Ford (POA) Tr. 905-06). POA employs 22 people. (Ford (POA) Tr. 906). Nine of them are prosthetists. (Ford (POA) Tr. 917).
- 3249. Mr. Ford has "almost twenty years of experience" in the prosthetics industry. (Ford (POA) Tr. 918). Mr. Ford testified that he has held positions "where [he] needed to understand the product lines that prosthetists work with, and in order to understand how our products work best for them, [he] needed to understand the process, so [he has] been in hundreds if not thousands of prosthetic facilities in the last twenty years in 21 different countries." (Ford (POA) Tr. 918-19).
- 3250. Prior to his work at POA, Mr. Ford was the marketing manager and then director of marketing at Ohio Willow Wood, director of marketing and VP of Operations for North America at Touch Bionics, and Director of Business Development and then Chief Business Development Officer and later President of OPIE Choice Network at O&P Digital Technologies. (Ford (POA) Tr. 907-910).
- 3251. Mr. Ford is "personally involved" in negotiations with prosthetic manufacturers and is responsible for managing the profitability of the POA business. (Ford (POA) Tr. 904-05).
- 3252. Mr. Ford has "daily interaction" with POA prosthetists, as well as weekly "work in progress" calls that include discussions about "what's going on with [each] patient, what do we see is the activity level of this patient, what do we see that the patient is wanting to be able to do, what is the initial evaluation that the clinician has done with that patient, [and] what do they anticipate the treatment plan to become." (Ford (POA) Tr. 920-21, 923-24).
- 3253. Mr. Ford has discussions with POA clinicians related to MPKs, including "the features and benefits of each of those different MPK systems that are out there, how those features and benefits are valuable to different types of patients." (Ford (POA) Tr. 924-25).
- 3254. Mr. Ford is generally familiar with the Otto Bock C-Leg 4 and Freedom Plié 3 "through their marketing, through attending their seminars at national meetings, through discussions with [POA] clinicians, [and] through their website." (Ford (POA) Tr. 948). Moreover, Mr. Ford personally attends the MPK manufacturer training sessions, in particular from Otto Bock, Freedom, and Össur. (Ford (POA) Tr. 948-49).

Dr. Kenton Kaufman

- 3255. Dr. Kenton Kaufman is the W. Wendel Hall, Jr. Musculoskeletal Research Professor, a professor of biomedical engineering, Director of the Motion Analysis Laboratory and is on staff as a consultant in orthopedic surgery, physiology and biomedical engineering departments at the Mayo Clinic. (Kaufman (Mayo) Tr. 808). In those roles, Dr. Kaufman is involved in research, clinical care and education. (Kaufman (Mayo) Tr. 809).
- 3256. Additionally, Dr. Kaufman is on the editorial board for Prosthetics and Orthotics International, the official journal of the International Society for Prosthetics and Orthotics

and the editorial board for Gait and Posture, the official journal of the Gait and Clinical Movement Analysis Society. (Kaufman (Mayo) Tr. 816). He is on the advisory board for the National Center for Medical Rehabilitation Research at NIH and the medical advisory board for Prosthetics 202, an initiative with the American Orthotic and Prosthetic Association. (Kaufman (Mayo) Tr. 816).

- 3257. As Director of the Motion Analysis Laboratory at the Mayo Clinic, Dr. Kaufman is responsible for the operation, the quality of data, the final recommendations, the operations and the financial aspects of the laboratory. (Kaufman (Mayo) Tr. 812-13). He is also the principal investigator for most of the projects the laboratory takes on. (Kaufman (Mayo) Tr. 813).
- 3258. Dr. Kaufman has published 250 peer-reviewed journal articles to date, of which, 11 involve prosthetic microprocessor knees in the last decade. (Kaufman (Mayo) Tr. 818-19).
- 3259. The Mayo Clinic, based in Rochester, Minnesota, is a nonprofit academic medical center that provides clinical care, research and education. (Kaufman (Mayo) Tr. 807). The clinic treats approximately 1.3 million patients each year and physicians from the clinic publish about 700,000 articles each year. (Kaufman (Mayo) Tr. 807).
- 3260. Dr. Kaufman received his Bachelor's and Master's degrees from South Dakota State University, and a Ph.D from North Dakota State University. (Kaufman (Mayo) Tr. 809).
- 3261. Before moving to the Mayo Clinic, Dr. Kaufman was the director of orthopedic research at the Children's Hospital in San Diego for seven years. (Kaufman (Mayo) Tr. 810).

Lieutenant Colonel Dr. Benjamin Kyle Potter

- 3262. Dr. Benjamin Kyle Potter works at Walter Reed National Military Medical Center in Bethesda, Maryland, as the Chief of the Department of Orthopedics and the Chief Orthopedic Surgeon for the Amputee Patient Care Program. (Potter (Walter Reed) Tr. 744).
- 3263. Dr. Potter has been Chief Orthopedic Surgeon for 10 years. In his role, he "personally perform[s] and/or supervise[s] the vast majority of the amputation surgery that goes on within the Department of Orthopedics and . . . tend[s] to follow the vast majority of the persons with limb loss recovery at Walter Reed once they become outpatients in the postsurgical setting." (Potter (Walter Reed) Tr. 744-735)
- 3264. Prior to his employment at Walter Reed, Dr. Potter received his Bachelor of Science from the United States Military Academy at West Point in 1997. He received his Doctorate of Medicine from the University of Chicago in 2001, and he did his orthopedic surgery residence at Walter Reed, graduating in 2007. (Potter (Walter Reed) Tr. 752).
- 3265. Dr. Potter also served in the United States Army, where he was eventually promoted to Lieutenant Colonel. He was deployed to Afghanistan twice in 2011 and 2016. (Potter (Walter Reed) Tr. 752-753).

3266. During his career, Dr. Potter performed over 100 amputations and has been involved in approximately 500. (Potter (Walter Reed) Tr. 754-755)

Kim De Roy

- 3267. Kim De Roy has been the Executive Vice President of Research and Development at Össur hf (Össur) since November of 2017. (De Roy (Össur) Tr. 3525-28). He was Vice President of Global Marketing, Prosthetics, for five years beginning in 2012, and Vice President of Sales, Prosthetics, Americas for four and a half years beginning in 2013. (De Roy (Össur) Tr. 3528). He has worked in other positions at Össur since 2002. (De Roy (Össur) Tr. 3534).
- 3268. As Vice President of Sales, Prosthetics, Americas, Mr. De Roy was "responsible to oversee all sales-created activities for prosthetics in the Americas market" including MPKs and K3 mechanical knees. (De Roy (Össur) Tr. 3528-29). As Vice President of Global Marketing, Prosthetics, Mr. De Roy "oversaw the global activities in marketing for prosthetics." (De Roy (Össur) Tr. 3529).
- 3269. Mr. De Roy has personal experience with orthotics because he is a below the knee amputee. (De Roy (Össur) Tr. 3534). His academic background in orthotics includes a Bachelor's degree with prosthetics and orthotics and a Master's degree with physical therapy and rehabilitation. (De Roy (Össur) Tr. 3536).
- 3270. Headquartered in Iceland, Reykjavik, Össur manufactures a broad range of lower and upper limb prosthetics. (De Roy (Össur) Tr. 3537). Össur's U.S. headquarters is in Foothill Ranch, California. (De Roy (Össur) Tr. 3537). Össur employs "about 300-400" people in the United States. (De Roy (Össur) Tr. 3538).



Keith Senn

- 3272. Keith Senn is the President of the Kentucky and Indiana operations of the Center for Orthotic and Prosthetic Care ("COPC"). (Senn (COPC) Tr. 149). Mr. Senn began working at COPC in January 1997 as its Chief Financial Officer. (Senn (COPC) Tr. 149-150).
- 3273. COPC is an orthotic and prosthetic clinic that provides "customer and off-the-shelf orthotic and prosthetic services to patients." COPC began operating with one clinic in Louisville, Kentucky in January 1997. (Senn (COPC) Tr. 149-150). Currently, COPC operates 25 clinics located in Kentucky, Indiana, North Carolina, New York, and

Pennsylvania, including 8 clinic locations in Kentucky and Indiana. (Senn (COPC) Tr. 151-152, 157).

- 3274. COPC has 120 employees, including approximately 50 employees who serve as either certified prosthetists, orthotists, or both. In its Indiana and Kentucky offices, COPC employs 15 clinical prosthetists and fits lower-limb prosthetics at each location. (Senn (COPC) Tr. 157-158).
- 3275. As CFO, Mr. Senn helped develop COPC as a new business by overseeing its "financial side, human resources, payroll, purchasing, accounts payable, contracting, setting up offices, [and] setting up procedures." (Senn (COPC) Tr. 150). These responsibilities included establishing guidelines for insurance reimbursement and compliance, as well as establishing a process for purchasing and accounts receivable. (Senn (COPC) Tr. 150-151).
- 3276. Mr. Senn's current role as the President of COPC's Kentucky and Indiana operations involves overseeing the various departments within COPC and the day-to-day operation of the company. (Senn (COPC) Tr. 151).
- 3277. As President, Mr. Senn helps create policy manuals to establish set procedures for patient care across the clinics in the Kentucky and Indiana regions. (Senn (COPC) Tr. 151-152). These policy manuals include a "purchasing guideline" listing preferred products for patients based on feedback from prosthetists across COPC's clinics. (Senn (COPC) Tr. 154-155). Mr. Senn also assists in the creation of bi-weekly "work in progress" reports to monitor the progress of COPC patients as they progress through their treatment and insurance reimbursement. (Senn (COPC) Tr. 165-166).
- 3278. Four employees in the Kentucky and Indiana region report directly to Mr. Senn, including the general manager, accounts receivable manager, and marketing staff. (Senn (COPC) Tr. 157-158). The general manager is a certified prosthetist who oversees the other prosthetists employed at COPC's clinics in the region. (Senn (COPC) Tr. 152-153). Mr. Senn speaks with the general manager of COPC's Kentucky and Indiana regions about staffing issues, the operations at its facilities, patient care, and other concerns about the day-to-day operations of the company. (Senn (COPC) Tr. 157-158).
- 3279. In his roles at COPC, Mr. Senn directly interacts with patients to assist with payment and insurance issues as they arise. (Senn (COPC) Tr. 154). Mr. Senn previously interacted daily with patients during their visits and prosthetists when his office was located in a COPC clinic. (Senn (COPC) Tr. 152-153, 161).
- 3280. Mr. Senn also meets with sales representatives from MPK manufacturers to discuss products, outreach to COPC's prosthetists regarding training on devices, and other issues involving the sale of MPK products. (Senn (COPC) Tr. 161-162).

2. **Respondent's Witnesses**

a) <u>Respondent's Executives</u>

Scott Schneider

3281. Scott Schneider is Otto Bock's Vice President of Government, Medical Affairs and Future Development. (Schneider (Otto Bock) Tr. 4260).

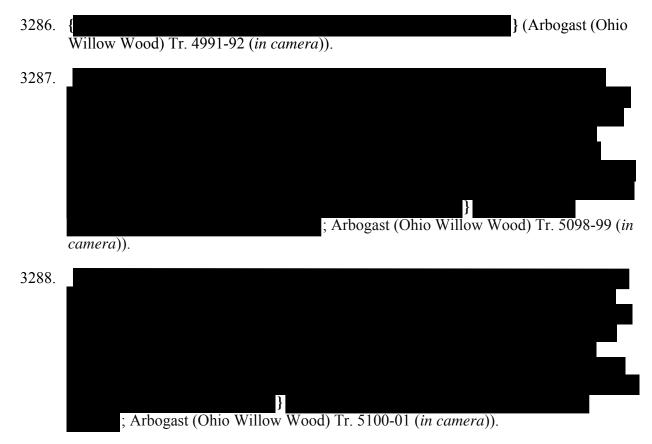
David Smith

- 3282. David Smith was CEO of Freedom from April 1, 2016 to September 2017. (Smith (HEP) Tr. 6408).
- 3283. Mr. Smith's employment at Freedom ended in September 2017, around the time of the Merger. (Smith (HEP) Tr. 6407).

3284.				(Smith (HEP)	Tr. 6518
	(in camera)).		(Smith (HEP) Tr. 6519 (in camera))		
		b)	Lay Witnesses		

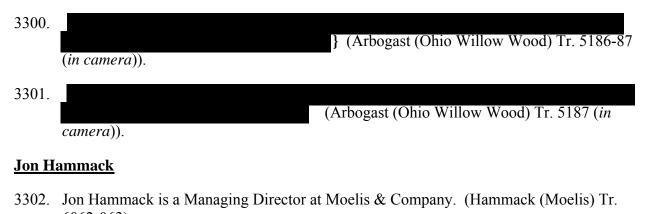
Ryan Arbogast

3285. Ryan Arbogast is majority owner and CEO of Ohio Willow Wood Company. (Arbogast (Willow Wood) Tr. 4929).



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3289.	} ; Arbogast
2200	(Ohio Willow Wood) Tr. 5100 (in camera)).
3290.	; Arbogast (Ohio Willow Wood) Tr. 5101 (<i>in camera</i>)).
3291.	
	; Arbogast (Ohio Willow Wood) Tr. 5101 (<i>in camera</i>)).
3292.	
	; Arbogast (Ohio Willow Wood) Tr. 5101-02 (<i>in camera</i>)).
3293.	} (Arbogast (Ohio Willow Wood) Tr. 5103-04 (<i>in camera</i>); PX03021 (Ohio Willow Wood) (<i>in camera</i>)).
3294.	(PX05159 (Arbogast (Ohio Willow Wood) Dep. at 150) (in camera)).
3295.	(PX05159 (Arbogast (Ohio Willow Wood) Dep. at 33-34) (<i>in camera</i>)).
3296.	(Arbogast (Ohio Willow Wood) Tr. 5091 (in camera)).
3297.	
	(Arbogast (Ohio Willow Wood) Tr. 5090-91 (<i>in camera</i>)).
3298.	
	(Arbogast (Ohio Willow Wood) Tr. 5009) (in camera)).
3299.	(Arbogast (Ohio Willow
	Wood) Tr. 5187 (<i>in camera</i>)).



- 6062-063). 2202 Mr. Hammaak tastified that he was the lead at Meelis managing the client relationship
- 3303. Mr. Hammack testified that he was the lead at Moelis managing the client relationship with Freedom. (Hammack (Moelis) Tr. 6064).
- 3304. Mr. Hammack testified that Moelis was formally engaged by Freedom in May 2017. (Hammack (Moelis) Tr. 6063). Moelis served as Freedom's financial advisor in exploring the sale of the company. (Hammack (Moelis) Tr. 6065). Moelis also advised Freedom on potential refinancing alternatives. (Hammack (Moelis) Tr. 6065). [
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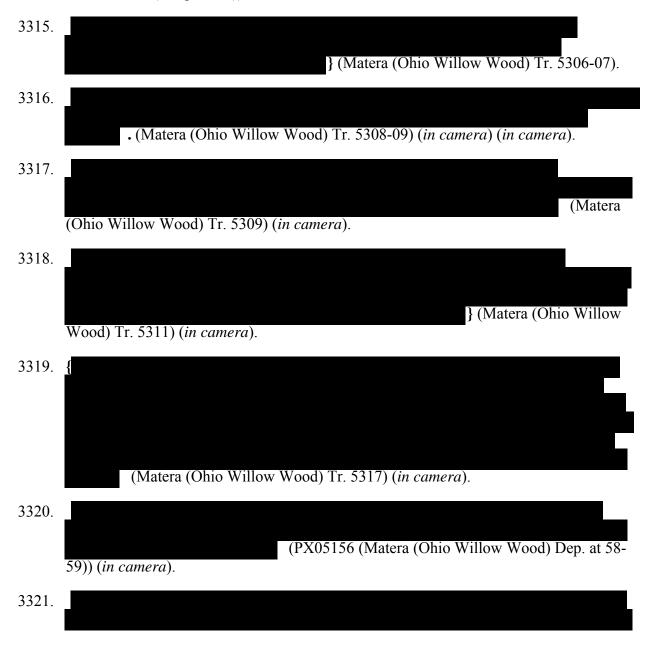
(Hammack

(Moelis) Tr. 6085-86) (*in camera*). Mr. Hammack, along with others at Moelis, also had responsibility for contacting potential refinancing partners on behalf of Freedom. (Hammack (Moelis) Tr. 6071).

John Matera

- 3306. John Matera is Chief Operating Officer of Ohio Willow Wood Company. (Matera (Ohio Willow Wood) Tr. 5224-25).
- 3307. Mr. Matera joined Ohio Willow Wood in October 2012 as Senior Director of Operations. (Matera (Ohio Willow Wood) Tr. 5296). Mr. Matera's title changed approximately five years ago but his responsibilities have not changed. (Matera (Ohio Willow Wood) Tr. 5296).
- 3308. Ohio Willow Wood is the first prosthetics company that Mr. Matera has worked for in his career. (Matera (Ohio Willow Wood) Tr. 5296). Mr. Matera has approximately six years of experience in the prosthetics industry. (Matera (Ohio Willow Wood) Tr. 5296).
- 3309. Mr. Matera has no prior experience with microprocessor knees. (Matera (Ohio Willow Wood) Tr. 5296).
- 3310. Mr. Matera has no prior experience in the assembly or manufacture of microprocessor knees. (Matera (Ohio Willow Wood) Tr. 5296).

- 3311. Mr. Matera has no experience troubleshooting issues arising during the development of a microprocessor knee. (Matera (Ohio Willow Wood) Tr. 5296-297).
- 3312. Mr. Matera has no experience in handling repairs of microprocessor knees. (Matera (Ohio Willow Wood) Tr. 5297).
- 3313. During his time at Ohio Willow Wood, Mr. Matera has not been involved in any acquisitions. (Matera (Ohio Willow Wood) Tr. 5305).
- 3314. In his deposition, Mr. Matera testified that his experience involving relocation of assets during his never involved a transition services agreement (PX05156 (Matera (Ohio Willow Wood) Dep. at 41)).



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	(Ohio Willow Wood) Tr. 5322) (<i>in camera</i>).
3322.	{ (Ohio Willow Wood) Tr. 5324) (<i>in camera</i>).
3323.	
	(Matera (Ohio Willow Wood) Tr. 5326-27) (<i>in camera</i>).
3324.	(Ohio Willow Wood) Tr. 5349) (<i>in camera</i>).
3325.	} (Matera (Ohio Willow Wood) Tr. 5361-62) (<i>in camera</i>).

Bradley Mattear

- 3326. Bradley Mattear Vice President of Orthotics at Proteor, Inc. (d/b/a Proteor and Nabtesco USA). (Mattear (Proteor Inc.) Tr. 5710). At the time of his deposition in April 2018, he was the Managing Director USA of Proteor Inc. (Mattear (Proteor, Inc.) Tr. 5518-19).
- 3327. Proteor Inc. is a distributor of prosthetic goods manufactured by Proteor Holdings ("Proteor France") and Nabtesco Corporation. (Mattear (Proteor Inc.) Tr. 5713-14). Nabtesco Corporation is located in Kobe, Japan. (Mattear (Proteor Inc.) Tr. 5714).
- 3328. At the time of his deposition, in April 2018, Proteor Inc. operated a single location in Muskego, Wisconsin and employed five employees including Mr. Mattear. (Mattear (Proteor Inc.) Tr. 5712-13).
- 3329. Proteor Inc. has moved from Muskego, Wisconsin to Tempe, Arizona. (Mattear (Proteor Inc.) Tr. 5519). Mr. Mattear testified that this move occurred on August 31, 2018. (Mattear (Proteor Inc.) Tr. 5519).
- 3330. Mr. Mattear is a certified prosthetist assistant. (Mattear (Proteor, Inc.) Tr. 5511). He testified that, as a prosthetist assistant, he can "evaluate," "fit, "adjust," "modify," but he cannot sign forms associated with "insurance purposes." (Mattear (Proteor, Inc.) Tr. 5511-12). In comparison to a prosthetist assistant, a prosthetist "went to a little more school than" Mr. Mattear. (Mattear (Proteor, Inc.) Tr. 5511).
- 3331. Mr. Mattear estimated that, as of September 2018, he had worked in the prosthetics and orthotics industry for roughly 15 to 17 years. (Mattear (Proteor, Inc.) Tr. 5510).

- 3332. Proteor Inc. is owned by Proteor Holdings. (Mattear (Proteor Inc.) Tr. 5712). Proteor Holdings is entirely owned by family members. (Mattear (Proteor Inc.) Tr. 5712). Nabtesco Corporation does not own Proteor Inc. (Mattear (Proteor Inc.) Tr. 5714).
- 3333. Mr. Mattear reports directly to a supervisor at Proteor Holdings. (Mattear (Proteor Inc.) Tr. 5712). At the time of his deposition in April 2018, Mr. Mattear reported to Frederic Desprez from Proteor Holdings who is located in Dijon, France. (Mattear (Proteor Inc.) 5716-17). He currently reports to Edouard Archambeaued, the COO of Proteor Holdings. (Mattear (Proteor Inc.) Tr. 5717).

Michael Oros

- 3334. Michael Oros is the President and CEP of Scheck & Siress Prosthetics, Incorporated. (Oros (Scheck & Siress) Tr. 4771).
- 3335. Mr. Oros testified that the last time he fit prosthetic devices on patients on a regular basis was in 2016. (Oros (Scheck & Siress) Tr. 4849). Mr. Oros testified that he visits a pediatric clinic half a day a week but is "not involved in the ongoing care of those patients after [he] see[s] them." (Oros (Scheck & Siress) Tr. 4850).
- 3336. Mr. Oros testified that he has not personally tested or fit a Nabtesco knee on a patient. (Oros (Scheck & Siress) Tr. 4868). At the time of his deposition on March 29, 2018, Mr. Oros was not aware of any Nabtesco Allux knees being fit at Scheck & Siress. (Oros (Scheck & Siress) Tr. 4867), (Oros (Scheck & Siress) Dep. at 135).
- 3337. At the time of his deposition on March 29, 2018, Mr. Oros was not aware of any microprocessor knee product offered by DAW. (Oros (Scheck & Siress) Tr. 4868.
- 3338. Mr. Oros was the President of AOPA when the organization sponsored and released the RAND Study on the health economic benefits of MPKs compared to non-MPKs. (Oros (Scheck & Siress) Tr. 4891-92). Mr. Oros testified that he was involved with the RAND study from "start to completion" serving as the clinical expert in that – in the work group." (Oros (Scheck & Siress) Tr. 4893-94).
- 3339. Mr. Oros testified that he has met with Otto Bock's primary owner, Hans Georg Näder, in the past to discuss an acquisition of Scheck & Siress by Otto Bock. (Oros (Scheck & Siress) Tr. 4904; (Oros (Scheck & Siress) Dep. at 231-232).
- 3340. Mr. Oros testified that within the past year Scheck & Siress entered into a partnership agreement with Otto Bock. (Oros (Scheck & Siress) Tr. 4890-91); (Oros (Scheck & Siress) Dep. at 232-33). Mr. Oros testified that one of the goals of the partnership was to develop the health economic argument for the service that Scheck & Siress delivers. (Oros (Scheck & Siress) Tr. 4890-91), (PX05134 (Oros (Scheck & Siress) Dep. at 232-33).
- 3341. Mr. Oros testified that Scheck & Siress will work with Otto Bock on "one-off projects on a new foot" or "a new knee." (PX05134 (Oros (Scheck & Siress) Dep. at 235).

3342. Mr. Oros testified that Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, asked if he "[w]ould be willing to testify on behalf of Ottobock" in this proceeding. (PX05134 (Oros (Scheck & Siress) Dep. at 235-36).

Scott Sabolich

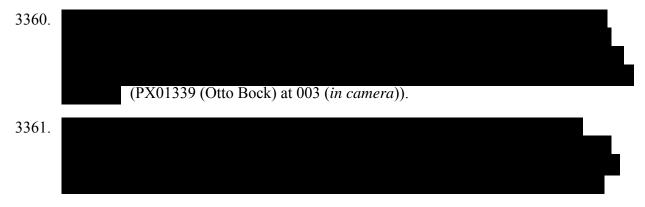
- 3343. Scott Sabolich is the owner and Clinical Director of Scott Sabolich Prosthetics and Research ("SSPR"). (Sabolich (SSPR) Tr. 5788).
- 3344.

(Sabolich (Sabolich Prosthetics & Research) Tr. 5875 (in
<i>camera</i>)); (Sabolich (SSPR) Tr. 5936).
(Sabolich (SSPR) Tr. 5924); (Sabolich
(SSPR) Dep. at 97-98 (in camera))
; (Sabolich (SSPR) Dep. at 242-
243) (testifying that "I'm doing everything I can every day to keep our companies

moving forward. We've got to work together in this craziness. I'm not a manufacturer and they're not a prosthetist, but together we're stronger and we keep moving forward.").

- 3345. Mr. Sabolich testified that Otto Bock asked him to testify in this matter. (Sabolich (SSPR) Tr. 5935); (Sabolich (SSPR) Dep. at 241). Scott Schneider, Otto Bock's Vice President of Government, Medical Affairs, and Future Development, asked him. (Sabolich (SSPR) Tr. 5935); (Sabolich (SSPR) Dep. at 241) (testifying that "Head of medical care, Scott Schneider, put me in contact with Erica Fruiterman.").
- 3346. Mr. Sabolich testified that he met with Respondent's counsel, Sean and Simeon, for "maybe three hours" the Wednesday before his trial testimony (Sabolich (SSPR) Tr. 5935-36).
- 3347. Mr. Sabolich testified that he agreed to testify at this trial because Otto Bock does a lot for him so he tries to do a lot for Otto Bock. (Sabolich (SSPR) Tr. 5936); (Sabolich (SSPR) Dep. at 242-243) (testifying that he agreed to testify because "Ottobock [sic] does a lot for me, I try to do a lot for Ottobock [sic].").
- 3348. Mr. Sabolich testified that "Sabolich Prosthetics is a clinical partner of Otto Bock." (Sabolich (SSPR) Tr. 5925); (Sabolich (SSPR) Dep. at 102-104) (testifying that he formed a "clinical partnership with Otto Bock").
- 3349. Mr. Sabolich testified that his clinical partnership with Otto Bock has been going on about five years though he is "not sure of the exact date." (Sabolich (SSPR) Tr. 5928); (Sabolich (SSPR) Dep. at 102-104) (testifying that the clinical partnership has been going on about five years).
- 3350. Mr. Sabolich testified that Otto Bock does product releases out of his clinic. (Sabolich (SSPR) Tr. 5925); (Sabolich (SSPR) Dep. at 97-98).

- 3351. Mr. Sabolich testified that he has done Face Book Live events from his clinic with Otto Bock. (Sabolich (SSPR) Tr. 5925); (Sabolich (SSPR) Dep. at 97-98).
- 3352. Mr. Sabolich testified that Otto Bock has done photo shoots at his clinic using his patients. (Sabolich (SSPR) Tr. 5925); (Sabolich (SSPR) Dep. at 97-98).
- 3353. Mr. Sabolich testified that Otto Bock has included photos from photos taken at Sabolich Prosthetics in Otto Bock ads. (Sabolich (SSPR) Tr. 5925); (Sabolich (SSPR) Dep. at 97-98).
- 3354. Mr. Sabolich testified that he beta-tests products for Otto Bock as part of his clinical partnership. (Sabolich (SSPR) Tr. 5928); (Sabolich (SSPR) Dep. at 105). He testified that he tests Otto Bock products before they are released to the general public. (Sabolich (SSPR) Tr. 5928); (Sabolich (SSPR) Dep. at 105).
- 3355. Mr. Sabolich tests Otto Bock products on his patients. (Sabolich (SSPR) Tr. 5928-29); (Sabolich (SSPR) Dep. at 105). Mr. Sabolich testified that he provides feedback to Otto Bock about the tested products. (Sabolich (SSPR) Tr. 5929); (Sabolich (SSPR) Dep. at 105). Otto Bock accepts that feedback from him. (Sabolich (SSPR) Tr. 5929); (Sabolich (SSPR) Dep. at 105).
- 3356. Mr. Sabolich testified that as of March 2018, he was product testing feet for Otto Bock. (Sabolich (SSPR) Tr. 5929); (PX05132 (Sabolich (SSPR) Dep. at 239-240).
- 3357. Mr. Sabolich testified that he "sure did" help Otto Bock obtain a prosthetic foot from another manufacturer to assist Otto Bock in development of its feet. (Sabolich (SSPR) Tr. 5929); (Sabolich (SSPR) Dep. at 240) (testifying that Otto Bock requested that Mr. Sabolich provide them with prosthetic feet from another manufacturer)).
- 3358. Mr. Sabolich testified that Michael Leach of Otto Bock asked him to obtain an Össur Pro-Flex XC foot for him and so he "gladly did so." (Sabolich (SSPR) Tr. 5929); (Sabolich (SSPR) Dep. at 240) (testifying that "He asked me would I buy one and sell it to him, so I did."). At the time of the request in October 2017, Mr. Leach worked for Otto Bock's R&D division. (Sabolich (SSPR) Tr. 5929); Sabolich (SSPR) Dep. at 240).
- 3359. Mr. Sabolich testified that his company bought the Össur foot on behalf of Otto Bock. (Sabolich (SSPR) Tr. 5930).



(PX01339 (Otto Bock) at 003 (in camera)).

- 3362. Mr. Sabolich testified that he uses Otto Bock's All Claims division at part of his partnership with Otto Bock. (Sabolich (SSPR) Tr. 5930); (Sabolich (SSPR) Dep. at 108-110). This allows Mr. Sabolich to use Otto Bock contracts with private insurance companies when his clinic does not have a contract with a particular insurer like Aetna or UnitedHealthcare. (Sabolich (SSPR) Tr. 5934); (Sabolich (SSPR) Dep. at 110).
- 3363. Mr. Sabolich testified that he speaks to other clinics who are exploring partnerships with Otto Bock about his experience as an Otto Bock clinical partner. (Sabolich (SSPR) Tr. 5934-35); (Sabolich (SSPR) Dep. at 103).
- 3364. Mr. Sabolich tells Otto Bock that he "will do my best to try to get them on board with our partnership program[.]" (PX01911 (Otto Bock) at 002). Mr. Sabolich testified that he tries to get them on board with Otto Bock's partnership program. (Sabolich (SSPR) Tr. 5935); (Sabolich (SSPR) Dep. at 103) (testifying that he tries to "do his best to try to get them on board with [Otto Bock's] partnership program.").
- 3365. Mr. Sabolich testified that he spoke to Scheck & Siress about the Otto Bock partnership program. (Sabolich (SSPR) Tr. 5935). Mr. Sabolich testified that Scheck & Siress eventually joined the partnership. (Sabolich (SSPR) Tr. 5935); (Sabolich (SSPR) Dep. at 103).

3366.	(RX0393 (Otto Bock) (<i>in camera</i>)).
3367.	(RX0393 (Otto Bock) (in
	camera)). (Sabolich (SSPR) Tr. 5877 (in camera)).
3368.	In his deposition, Mr. Sabolich testified that, "We have a commitment agreement with Ottobock [sic] that we will try to use their parts to give them more market shares." (Sabolich (SSPR) Dep. at 95).
3369.	(Sabolich (SSPR) Tr. 5878 (in camera)).
3370.	(RX0393 (Otto Bock) (in camera)).
3371.	(Sabolich (SSPR) Tr. 5878 (<i>in camera</i>)); (Sabolich (SSPR) Dep. at 94-95)

3372.		(Sabolich
	(SSPR) Tr. 5880 (<i>in camera</i>)).	
		(Sabolich (SSPR) Tr. 5880 (in
	<i>camera</i>)); (Sabolich (SSPR) Tr. 5924)	
	; (Sabolich (SSPR) Dep. at 97-98 (in camera)).	

- 3373. Mr. Sabolich testified that he is involved in research projects with Otto Bock. (Sabolich (SSPR) Tr. 5882). Mr. Sabolich testified about an "outcomes study" that he is "working on with Otto Bock" and that "Dr. Kannenberg and Russ Lundstrom collect our data, collaborate on our data to purpose it" for a talk being given in Vancouver. (Sabolich (SSPR) Tr. 5882).
- 3374. Mr. Sabolich testified that, for the outcomes study, Mr. Lundstrom "takes all of our data and deciphers it into appreciable difference, and then Dr. Kannenberg with his Ph.D. can publish it as actual research findings." (Sabolich (SSPR) Tr. 5882).
- 3375. Mr. Sabolich has been purchasing Otto Bock products for a long time. (Sabolich (SSPR) Tr. 5924).
- 3376. Mr. Sabolich testified that he's known Brad Ruhl of Otto Bock "for quite a while, certainly I think more than ten years." (Sabolich (SSPR) Tr. 5924); (Sabolich (SSPR) Dep. at 96) (testifying that he has known Brad Ruhl "10 years or more.").
- 3377. Mr. Sabolich testified that Walter Governor, formerly of Otto Bock, was his "first rep" and he has known Mr. Governor a "very long time." (Sabolich (SSPR) Tr. 5924); (Sabolich (SSPR) Dep. at 96).
- 3378. Mr. Sabolich further testified that he works directly with Cali Solorio of Otto Bock. (Sabolich (SSPR) Tr. 5924); (Sabolich (SSPR) Dep. at 97-98).
- 3379. Mr. Sabolich testified that he works with the Otto Bock medical care team, including Scott Schneider, former Otto Bock employee Adam McPherson, Russ Lundstrom, and Dr. Andreas Kannenberg. (Sabolich (SSPR) Tr. 5926); (Sabolich (SSPR) Dep. at 97-98).
- 3380. Mr. Sabolich testified that Dr. Kannenberg of Otto Bock trained Mr. Sabolich's outcomes testing team. (Sabolich (SSPR) Tr. 5926).
- 3381. Mr. Sabolich testified that he talks about strategic positions of his clinics with Brad Ruhl of Otto Bock. (Sabolich (SSPR) Tr. 5926); (Sabolich (SSPR) Dep. at 97-98).
- 3382. Mr. Sabolich testified that Brad Ruhl influenced him in deciding to open a Sabolich clinic in Dallas. (Sabolich (SSPR) Tr. 5926-27); (Sabolich (SSPR) Dep. at 97-98) (testifying that "He's the one that helped me decide[] I should go to Dallas").

- 3383. Mr. Sabolich testified that he has met with Hans Georg Näder, the owner of Otto Bock. (Sabolich (SSPR) Tr. 5928); (Sabolich (SSPR) Dep. at 97-98).
- 3384. Mr. Sabolich testified that Otto Bock invited him to tour its facilities in Duderstadt, Germany. (Sabolich (SSPR) Tr. 5928); (Sabolich (SSPR) Dep. at 106). He also visited Otto Bock's R&D facilities in Vienna. (Sabolich (SSPR) Tr. 5928).

Jack Sanders

- 3385. Jack Sanders is a senior clinical program consultant at United Healthcare, a subsidiary of United Health Group. (Sanders (United) Tr. 5371).
- 3386. Mr. Sanders has held this position at United Healthcare for just over five years. (Sanders (United) Tr. 5371).
- 3387. As part of Mr. Sanders's responsibilities, he provides training to the members of United's staff that are charged with reviewing prior-authorization requests and reimbursement claims. (Sanders (United) Tr. 5463-64).
- 3388. The clinical staff that Mr. Sanders trains consists of thousands of nurses, as well as hundreds of physicians (who are referred to internally as medical directors). (Sanders (United) Tr. 5463-64).
- 3389. United Healthcare provides coverage for prosthetic devices and related services, including microprocessor knees. (Sanders (United) Tr. 5465). As a result, Mr. Sanders provides training to his clinical staff on microprocessor knees. (Sanders (United) Tr. 5464). This training includes, among other things, the current state of the equipment and offerings for microprocessor knees available in the marketplace. (Sanders (United) Tr. 5464).

Douglas Smith

- 3390. Douglas Smith is a professor emeritus in the Department of Orthopedic Surgery at the University of Washington in Seattle. (Smith (retired) Tr. 5961). Dr. Smith stopped working as a full time physician in December of 2016. (Smith (retired) Tr. 5965).
- 3391. Dr. Smith's laboratory received \$240,000 in funding directly from Otto Bock each year for three and a half years to study the C-Leg. (Smith (retired) Tr. 6034-35). Otto Bock also spent \$84,000 a year for three years so Dr. Smith could record videos showing how to conduct amputations. (Smith (retired) Tr. 6035).
- 3392. Dr. Smith is not a certified orthotist or prosthetist and does not fabricate limbs for patients. (Smith (retired) Tr. 6036-37).
- 3393. Dr. Smith has not performed an amputation and has not written a prescription for a prosthetic knee since December of 2016. (Smith (retired) Tr. 6038-39).

- 3394. At the time of his deposition, Dr. Smith did not know which version of the C-Leg was on the market. (Smith (retired) Tr. 6044). At trial, he did not know the size of Otto Bock's marketing team, how long it took Otto Bock to develop the C-Leg 4 or how much it costs. (Smith (retired) Tr. 6043-44).
- 3395. Dr. Smith does not know how much Össur's Rheo weighs, what happens to the Rheo when the battery dies, how loud the product is, how big Össur's sales force is and how long Össur spent developing the Rheo. (Smith (retired) Tr. 6045-46).
- 3396. Dr. Smith last experience with the Endolite Orion was "at least eight years ago" when he visited two clinics in the United Kingdom. (Smith (retired) Tr. 6046). He has not trialed the Orion 3 on any patients, has never written a prescription for an Orion 3, does not know how the Orion 3 differs from other prosthetic knees and does not know which patients would most benefit from wearing the Orion 3. (Smith (retired) Tr. 6046-47).
- 3397. Dr. Smith has not seen a DAW knee in the last ten years and only knows details about their knees "from looking online." (Smith (retired) Tr. 48). He is not familiar with the battery on the DAW knee, he does not remember speaking with anyone at DAW in the last ten years, does not know how many people DAW has selling MPKs in the United States and does not know how long DAW spent developing its MPK. (Smith (retired) Tr. 6048-49).
- 3398. Dr. Smith is not sure he has ever seen a Nabtesco knee. (Smith (retired) Tr. 6049-50). He has never written a prescription for a Nabtesco Allux and his familiarity with the Allux is limited to what he has seen on the Nabtesco website "and possibly at a booth at a prosthetic meeting." (Smith (retired) Tr. 6050-51). Dr. Smith is not aware of any of his patients ever using an Allux, does not know how big Nabtesco's U.S. sales force is and does not know how long Nabtesco took to develop the Allux. (Smith (retired) Tr. 6051).
- 3399. Dr. Smith is not sure he has ever seen a Freedom Plié 3. (Smith (retired) Tr. 6052). He may not have ever seen a patient using one. (Smith (retired) Tr. 6052). He is not aware of any improvements Freedom made to the Plié knee in 2016 or 2017 because he "did not follow the product." (Smith (retired) Tr. 6053-54). As such, he is not familiar with the product specifications of the Plié 3. (Smith (retired) Tr. 6055).
 - **B.** EXPERT WITNESSES WHO TESTIFIED AT TRIAL

1. Complaint Counsel's Expert Witnesses

Christine Hammer

3400. Christine Hammer is self-employed at Hammer & Associates, a C corporation. (Hammer Tr. 2868). In that position, Ms. Hammer performs a variety of financial and managerial accounting projects. (Hammer Tr. 2870). Some of them are consulting involving accounting systems, management reporting systems, forecasting, strategic planning, and helping companies become more profitable. (Hammer Tr. 2870). She also performs expert witness work. (Hammer Tr. 2870).

- 3401. As a managerial and financial accountant, Ms. Hammer has consulted for companies in several industries including transportation, banking, retailing, computer hardware, computer software, medical diagnostic companies and oil slurry pipelines. (Hammer Tr. 2871).
- 3402. Ms. Hammer has had an active Certified Public Accountant license in California since 1978. (Hammer Tr. 2867). She is also a certified global management accountant. (Hammer Tr. 2867).
- 3403. Ms. Hammer has a Master's in Business Administration from Stanford University and a Bachelor's in Economics and Political Science from Indiana University of Pennsylvania. (Hammer Tr. 2867).
- 3404. Prior to starting Hammer & Associates, Ms. Hammer worked at Crocker Bank where she did forecasting, strategy and estimated synergies related to Crocker Bank's acquisition of Midland Bank. (Hammer Tr. 2869).

Fiona Scott Morton

- 3405. Fiona Scott Morton is the Theodore Nierenberg Professor of Economics at the Yale University School of Management and a senior consultant at Charles River Associates. (Morton Tr. 3847, 3853). At Yale, Dr. Scott Morton teaches Competitive Strategy, an industrial organization class for M.B.A. students and Advanced Competition Economics, an economics class targeted on competition enforcement. (Morton Tr. 3853).
- 3406. Dr. Scott Morton studies industrial economics, a "branch of microeconomics that covers firms, markets and competition. (Morton Tr. 3848). Her empirical work involves working with data sets to study how firms compete with one another. (Morton Tr. 3848). Her research is "primarily focused on competition in the healthcare sector and also on antitrust topics." (Morton Tr. 3853).
- 3407. In 2011 and 2012, Dr. Scott Morton took 19 months of leave from Yale to serve as Deputy Assistant Attorney General for Economic Analysis at the Department of Justice Antitrust Division, which is "known as the chief economist job" at the Antitrust Division. (Morton Tr. 3849). In that position, Dr. Scott Morton oversaw the analysis of "dozens and dozens of mergers" and several proposed divestitures that occurred in that period. (Morton Tr. 3850-51).
- 3408. Dr. Scott Morton received a B.A. in economics from Yale College and a Ph.D. in economics from Massachusetts Institute of Technology. (Morton Tr. 3847). Her academic career began as an assistant professor at the Graduate School of Business at Stanford University. (Morton Tr. 3849). She then became an assistant professor at the Graduate School of Business at the University of Chicago before starting at Yale University in 1999. (Morton Tr. 3849).
- 3409. Dr. Scott Morton has published "twenty-plus" articles in peer-reviewed academic journals relating to the economic analysis of competition among firms. (Morton Tr. 3857). She has also served as referee for AER, QJE and RAND, which are all peer-

reviewed economic journals and frequently presents at professional conferences related to antitrust economic analysis. (Morton Tr. 3857).

2. Respondent Counsel's Expert Witness

David Argue

- 3410. David Argue is a corporate vice president and principal at Economists Incorporated. (Argue, Tr. 6132).
- 3411. Dr. Argue did not testify as an expert in lower limb prosthetics. (Argue, Tr. 6257).
- 3412. Dr. Argue does not have expertise in how to purchase lower limb prosthetics. (Argue, Tr. 6257).
- 3413. Dr. Argue does not have expertise in how to fit lower limb prosthetics. (Argue, Tr. 6257).
- 3414. Dr. Argue did not testify as an expert on microprocessor knees. (Argue, Tr. 6257).
- 3415. Dr. Argue does not have expertise in how to fit microprocessor knees. (Argue, Tr. 6257).
- 3416. Dr. Argue does not have expertise in how to operate a prosthetic clinic. (Argue, Tr. 6257).

James Peterson

- 3417. James Peterson is a principal at Deloitte within the Transactions and Business Analytics LLP division. (Peterson, Tr. 6593-95; RX1048 at 3 (¶ 3) (Peterson Expert Report)).
- 3418. (Peterson, Tr. 6775 (*in camera*); (PX05174 (Peterson (Respondent) Dep. at 20)).
- 3419. Mr. Peterson trial testimony is the first time that he has been an expert witness at trial in an adversarial litigation. (Peterson, Tr. 6602).
- 3420. The current matter was the second time Mr. Peterson had been retained as an expert witness offering an opinion as to whether a particular transaction would yield cognizable efficiencies as defined under the Merger Guidelines, and the first time he issued an expert report on such an opinion. (PX05174 (Peterson (Respondent) Dep. at 11-12)).
- 3421. Mr. Peterson is not familiar with the Commentary on the Merger Guidelines and indicated in his deposition that he does not believe he has reviewed the document or considered it in formulating his opinions on claimed efficiencies in this matter. (PX05174 (Peterson (Respondent) Dep. at 169))

C. WITNESSES WHO TESTIFIED BY DEPOSITION AND/OR INVESTIGATIONAL HEARING ONLY

1. **Respondent's Executives**

Manar Ammouri

- 3422. Manar Ammouri is Freedom's Senior Product Manager. (PX05112 (Ammouri (Freedom) Dep. at 9)). Her responsibilities include working with the R&D team to "prep a product from ideation to requirements to customer feedback to testing of the product before it goes to production." (PX05112 (Ammouri (Freedom) Dep. at 9-10)).
- 3423. She is also responsible for marketing efforts for products, including "the campaigns, the advertising, the logos, any brochures," and any support materials needed to sell the product. (PX05112 (Ammouri (Freedom) Dep. at 9-10)).
- 3424. As Senior Product Manager, Ms. Ammouri is involved in gathering intelligence on competitor products. (PX05112 (Ammouri (Freedom) Dep. at 10-11)). She also directly talks to customers and attends trade shows. (PX05112 (Ammouri (Freedom) Dep. at 10-11)). After she attends trade shows, Ms. Ammouri writes notes regarding what "the customers are doing, clinicians are doing, and then we share [the information] with everybody." (PX05112 (Ammouri (Freedom) Dep. at 12-13)).
- 3425. Ms. Ammouri also works with the Research and Development department at Freedom. (PX05112 (Ammouri (Freedom) Dep. at 14)). She works with R&D to "initially develop an idea from conception. (PX05112 (Ammouri (Freedom) Dep. at 15)). After a product is approved, Ms. Ammouri is "in charge of making sure that [the product] gets through the process and ensures that the product still meets those requirements." (PX05112 (Ammouri (Freedom) Dep. at 15)).
- 3426. Ms. Ammouri is a member of the Quattro development team. (PX05112 (Ammouri (Freedom) Dep. at 69)). The goal of the Quattro development team is to ensure that Freedom has a "viable product that's manufacturable for sale." (PX05112 (Ammouri (Freedom) Dep. at 69)).
- 3427. Ms. Ammouri has been involved with focus groups related to feedback for the Quattro. (PX05112 (Ammouri (Freedom) Dep. at 19)). The goal of the focus groups was to "gauge [clinicians'] initial impressions of the product." (PX05112 (Ammouri (Freedom) Dep. at 22)).

Andreas Eichler

3428. Andreas Eichler is Head of Business Unite Prosthetics Lower Limb Mechatronic Systems at Otto Bock Austria GmbH. (PX05131 (Eichler (Otto Bock) Dep. at 4)). He started working at Otto Bock in 2014. (PX05131 (Eichler (Otto Bock) Dep. at 4-5)).

Walter Joseph Governor

3429. Walter Governor was the Senior Director of Sales and Clinical Services for North America at Otto Bock until February 20, 2018. (PX05130 (Governor (Otto Bock) Dep. at 9)).

Tammie Jacobson

3430. Tammie Jacobson is the IT business solutions manager for infrastructure and technology for Otto Bock. (PX05102 (Jacobson (Otto Bock) Dep. at 4)).

Sven Ehrich

- 3431. Sven Ehrich is the Director of Research and Development, Quality and Regulatory Affairs in Duderstadt at Otto Bock. (PX05155 (Ehrich (Otto Bock) Dep. at 5)).
- 3432. Mr. Ehrich is responsible for all of Otto Bock's development activities at its Duderstadt and Boston sites. (PX05155 (Ehrich (Otto Bock) Dep. at 13)).
- 3433. Mr. Ehrich has held his current position since July 2014. (PX05155 (Ehrich (Otto Bock) Dep. at 17)). Prior to that, he was Director, Global Office, at Giesecke & Devrient in Munich, Germany. (PX05155 (Ehrich (Otto Bock) Dep. at 17)).

Jeremy David Mathews

- 3434. Jeremy Mathews is Freedom's Senior Vice President of Sales and Marketing. (PX05137 (Mathews (Freedom) Dep. at 5)).
- 3435. Mr. Mathews started at Freedom on June 10, 2016 as the Vice President of Domestic Sales. (PX05137 (Mathews (Freedom) Dep. at 13)). He reported to the CEO at the time, David Smith but now reports to David Reissfelder. (PX05137 (Mathews (Freedom) Dep. at 13)).
- 3436. Mr. Mathews is responsible for Freedom's U.S. sales and marketing. (PX05137 (Mathews (Freedom) Dep. at 13)).
- 3437. Mr. Mathews testified that he was hired to increase Freedom product sales. (PX05137 (Mathews (Freedom) Dep. at 17)).
- 3438. Mr. Mathews participates on the Freedom operating committee, executive committee, and the product acceptance committee. (PX05137 (Mathews (Freedom) Dep. at 96-97)).

<u>Helmut Pfuhl</u>

- 3439. Helmut Pfuhl is Executive Vice President, Prosthetics, at Otto Bock. (PX05157 (Pfuhl (Otto Bock) Dep. at 6)).
- 3440. Dr. Pfuhl joined Otto Bock in 1996 as assistant to the owner and "built up the company's strategic planning." (PX05157 (Pfuhl (Otto Bock) Dep. at 15)). His official title at the

time was head of strategic business planning. (PX05157 (Pfuhl (Otto Bock) Dep. at b15)).

- 3441. His second role at Otto Bock was to take "over marketing, which includes international product management, the internal company communication international marketing communication, and the event management, trade shows, et cetera." (PX05157 (Pfuhl (Otto Bock) Dep. at 16)).
- 3442. In 2012, Dr. Pfuhl became head of the prosthetics business unit. (PX05157 (Pfuhl (Otto Bock) Dep. at 17)). The focus of his activity in this role is "portfolio development and portfolio strategy." (PX05157 (Pfuhl (Otto Bock) Dep. at 22)). His group reviews marketing and marketing potential and attempts to figure out "where the growth potentials are the best." (PX05157 (Pfuhl (Otto Bock) Dep. at 22)).

John Robertson

- 3443. John Robertson is Freedom's Senior Vice President of R&D and Irvine Manufacturing. (PX05115 (Robertson (Freedom) Dep. at 5)). Mr. Robertson is responsible for research and development efforts at Freedom. (PX05115 (Robertson (Freedom) Dep. at 7)).
- 3444.

(PX05115 (Robertson (Freedom) Dep. at 7-9) (*in camera*)). His responsibilities include supervising approximately 20 employees in the R&D department at Freedom. (PX05115 (Robertson (Freedom) Dep. at 8)).

} (PX05115 (Robertson

3445.

(Freedom) Dep. at 20-21) (in camera)).

- 3446. Mr. Robertson's responsibilities also included preparing the budget forecasts for the R&D budget and monitoring the spending of the department on a monthly basis. (PX05115 (Robertson (Freedom) Dep. at 11)). He testified at his deposition in March 2018 that he submits the R&D budget to Lee Kim, Freedom's CFO. (PX05115 (Robertson (Freedom) Dep. at 13)).
- 3447. Mr. Robertson served as the chair of Freedom's PAC committee, which he has served on since he first began working at Freedom in approximately 2014. (PX05115 (Robertson (Freedom) Dep. at 20)).
- 3448. { (Robertson (Freedom) Dep. at 11-12) (*in camera*)).

Sönke Rössing

- 3449. Sönke Rössing is Chief Strategy and Human Resource Officer for Otto Bock HealthCare Gmbh. (PX05104 (Rössing (Otto Bock) Dep. at 4)). He has worked at Otto Bock for nine years. (PX05104 (Rössing (Otto Bock) Dep. at 7)). Dr. Rössing has a Ph.D. in business from WHU in Vallendar in Germany. (PX05104 (Rössing (Otto Bock) Dep. at 7)).
- 3450. Dr. Rössing was designated to testify on behalf of Otto Bock to respond to Complaint Counsel's Notice of Deposition to Respondent regarding integration of Freedom into Otto Bock. (PX05104 (Rössing (Otto Bock) Dep. at 8-10)).

Brad Ruhl

- 3451. Brad Ruhl is Managing Director, North America at Otto Bock. (PX05162 (Ruhl (Otto Bock) Dep. at 5)). He assumed this position in 2018. (PX05162 (Ruhl (Otto Bock) Dep. at 8)). Mr. Ruhl took over the position on an interim basis. (PX05162 (Ruhl (Otto Bock) Dep. at 9)).
- 3452. Prior to his current position, Mr. Ruhl was the president of Otto Bock's prosthetics business unit for North America. (PX05162 (Ruhl (Otto Bock) Dep. at 8-9)). He held that position since 2010. (PX05162 (Ruhl (Otto Bock) Dep. at 11)).
- 3453. As the Managing Director, North America, Mr. Ruhl is responsible for prosthetics, orthotics, the division known as "medical care" as well as Otto Bock Orthopedic Services. (PX05162 (Ruhl (Otto Bock) Dep. at 10)).

Ralf Stuch

- 3454. Ralf Stuch is the Chief Sales and Marketing Officer and interim CFO at Otto Bock. (PX05163 (Stuch (Otto Bock) Dep. at 4, 13)).
- 3455. As Chief Sales and Marketing Officer, each of the business units, prosthetics, orthotics and mobility, as well as the marketing functions report in to Mr. Stuch. (PX05163 (Stuch (Otto Bock) Dep. at 13)).
- 3456. Mr. Stuch is on the global management team, which consists of all the executives responsible for each of the business units, each of the regions and each of the management functions. (PX05163 (Stuch (Otto Bock) Dep. at 21)). The global management team discusses strategic projects and global initiatives. (PX05163 (Stuch (Otto Bock) Dep. at 21)).

2. Clinic Customers

Michael Bright

3457. Michael Bright is the owner of North Bay Prosthetics. (PX05141 (Bright (North Bay) Dep. at 10)). Mr. Bright spends about 50% of his time seeing patients. (PX05141 (Bright (North Bay) Dep. at 117)).

- 3458. Mr. Bright is a certified prosthetist and a certified orthotist. (PX05141 (Bright (North Bay) Dep. at 11)).
- 3459. North Bay Prosthetics is "a health provider that provides prosthetic and orthotic care to [its] patients." (PX05141 (Bright (North Bay) Dep. at 13)). North Bay Prosthetics has six locations, all within California. (PX05141 (Bright (North Bay) Dep. at 14-15)). Clinical staff at North Bay Prosthetics are "involved directly in patient care and fabrication and assembly of the prosthetic and orthotic devices." (PX05141 (Bright (North Bay) Dep. at 16)).
- 3460. North Bay practitioners only fit patients with Otto Bock and Freedom MPKs. (PX05141 (Bright (North Bay) Dep. at 35-36)). North Bay practitioners conducted trials on patients of the Endolite Orion and Ossur Rheo but no patients were permanently fit with either MPK because the patients preferred the "feel and function" of either the Freedom Plié or the Otto Bock C-Leg. (PX05141 (Bright (North Bay) Dep. at 37-38)).
- 3461. Mr. Bright attends "conventions and other gatherings of prosthetists at which manufacturers of microprocessor knees exhibit their latest products." (PX05141 (Bright (North Bay) Dep. at 39-40)). He has "observed exhibitions by manufacturers in connection with those types of gatherings of new model – newer models of microprocessor knees" in the last three years. (PX05141 (Bright (North Bay) Dep. at 40)).
- 3462. North Bay fits about 10 MPKs per year and spends close to \$160,000 annually on MPKs. (PX05141 (Bright (North Bay) Dep. at 74)). North Bay spends "anywhere from \$400 to \$3,000 for the mechanical knees." (PX05141 (Bright (North Bay) Dep. at 74)).

Jonathan Endrikat

- 3463. Jonathan Endrikat is CEO of Empire Medical, Inc. ("Empire"). (PX05001 (Endrikat (Empire) IHT at 4)). He took on that title in 2014. (PX05001 (Endrikat (Empire) IHT at 8)). As CEO, Mr. Endrikat is involved in "strategic direction, collections, human resources, operations and dealing with the board of directors." (PX05001 (Endrikat (Empire) IHT at 8)).
- 3464. Mr. Endrikat started Empire in 2009, when he was the operations manager. (PX05001 (Endrikat (Empire) IHT at 7-8)).
- 3465. Empire, located in Medford, Oregon, is a "virtual distributor in the prosthetic and orthotic industry." (PX05001 (Endrikat (IHT at 9-10)). Empire's 2016 revenues were \$16.5 million. (PX05116 (Endrikat (Empire Medical) Dep. at 21)). "The heart of what Empire does is we're a comparative software based on L Codes." (PX05116 (Endrikat (Empire Medical) Dep. at 17)). A customer can use Empire's software to place all of their prosthetic and orthotic orders, which simplifies their purchasing. (PX05001 (Endrikat (Empire) IHT at 9)). When customers place orders through Empire, they use an Empire account number so that the product is shipped to the customer, then the invoice is sent to Empire for payment. (PX05116 (Endrikat (Empire Medical) Dep. at 21-22)). Empire

can also facilitate orders for customers that have an existing account with a specific manufacturer. (PX05116 (Endrikat (Empire Medical) Dep. at 21-22)).

- 3466. In his role, Mr. Endrikat works with prosthetists with ordering issues, with "questions about pricing, L Codes, product options" as well as "data research" and "purchasing data." (PX05116 (Endrikat (Empire Medical) Dep. at 16-17)).
- 3467. Empire contracts directly with prosthetic manufacturers and distributors. (PX05116 (Endrikat (Empire Medical) Dep. at 26-27)). Mr. Endrikat personally negotiates contracts with MPK manufacturers. (PX05116 (Endrikat (Empire Medical) Dep. at 50)).

Anthony Filippis

- 3468. Anthony Filippis has been CEO of Wright & Filippis since 1997. (PX05167 (Filippis (Wrights & Filippis) Dep. at 10)).
- 3469. Mr. Filippis is a certified prosthetist and orthotist. (PX05167 (Filippis (Wrights & Filippis) Dep. at 10)). In the mid -2000s, Mr. Filippis moved to a business administrative role. (PX05167 (Filippis (Wrights & Filippis) Dep. at 14)).

James Curtis Patton, III

3470. James Curtis Patton, III is the President and owner of Prosthetic Solutions. (PX05151 (Patton (Prosthetic Solutions) Dep. at 7)). He started Prosthetic Solutions in October of 2015. (PX05151 (Patton (Prosthetic Solutions) Dep. at 7)).

Jeffrey Sprinkle

- 3471. Jeffrey Sprinkle is the owner of Sprinkle Prosthetics. (PX05168 (Sprinkle (Sprinkle) Dep. at 4)).
- 3472. Mr. Sprinkle is a certified prosthetist orthoptist. (PX05168 (Sprinkle (Sprinkle) Dep. at 4)). He went to prosthetic orthotic school at UT Southwestern in Dallas, Texas and graduated there with a Bachelor of Science degree in prosthetics and orthotics in 1995. (PX05168 (Sprinkle (Sprinkle) Dep. at 11)).
- 3473. As the owner, Mr. Sprinkle does "everything from seeing all the patients either at the office, the hospital, nursing homes, [and] at patients' homes." (PX05168 (Sprinkle (Sprinkle) Dep. at 14)). He supervised the other employees, is involved in marketing, and is involved in the procurement of lower-limb prosthetics. (PX05168 (Sprinkle (Sprinkle) Dep. at 14-15)). He spends approximately 80 percent of his time seeing patients. (PX05168 (Sprinkle (Sprinkle) Dep. at 16)).
- 3474. Sprinkle Prosthetics operates one clinical office in Spartanburg, South Carolina. (PX05168 (Sprinkle (Sprinkle) Dep. at 18)).

Keith Watson

- 3475. Keith Watson is President of Fourroux Prosthetics. (PX05166 (Watson (Fourroux) Dep. at 4)).
- 3476. As President, Mr. Watson's responsibilities are to "provide guidance for [Fourroux's] clinicians and [] staff, to remove barriers to [Fourroux's] growth, and to make sure that [Fourroux] stand[s] by our vision, which is we make people whole." (PX05166 (Watson (Fourroux) Dep. at 21)).

James Weber

- 3477. James Weber is the President and CEO of Prosthetic & Orthotic Care. (PX05135 (Weber (P&O Care) Dep. at 4)).
- 3478. Mr. Weber does not have any degrees or certifications related to clinical prosthetics. (PX05135 (Weber (P&O Care) Dep. at 12)).
- 3479. Mr. Weber does not participate in any of the continuing education programs that manufacturers offer to prosthetic clinics. (PX05135 (Weber (P&O Care) Dep. at 13)).
- 3480. Mr. Weber testified that he does not "get into specifics" when it comes to discussing the features of microprocessor knees, and stated that, "it's the practitioner preference in our business as to all component that they work with relative to their patients." (PX05135 (Weber (P&O Care) Dep. at 14-15)).
- 3481. Mr. Weber does not see prosthetic patients clinically at P&O clinics. (PX05135 (Weber (P&O Care) Dep. at 18)).
- 3482. Mr. Weber testified that Otto Bock has a close relationship with P&O Care. (PX05135 (Weber (P&O Care) Dep. at 72)).
- 3483. Mr. Weber "know[s] a lot of the Otto Bock people" and has known Brad Ruhl, Otto Bock North America's Managing Director, since 2002 and regards him as a personal friend. (PX05135 (Weber (P&O Care) Dep. at 71)).
- 3484. Mr. Weber testified that that Brad Ruhl asked him "if [he] would consider being a witness and had the Duane Morris attorney call [him]" regarding the FTC's investigation of the Freedom acquisition. (PX05135 (Weber (P&O Care) Dep. at 74)).
- 3485. When asked if he had any close business associates at Freedom, Mr. Weber testified that he knows Maynard Carkhuff from the American Orthotics & Prosthetics Association Board and has known him for "probably six years, seven maybe." (PX05135 (Weber (P&O Care) Dep. at 76)).

Paul Weott

3486. Paul Weott is the owner of Orthotic and Prosthetic Centers. (PX05140 (Weott (O&P Centers) Dep. at 4)). Mr. Weott has been the owner for approximately 20 years. (PX05140 (Weott (O&P Centers) Dep. at 11)).

- 3487. Mr. Weott is a certified prosthetist. (PX05140 (Weott (O&P Centers) Dep. at 12)).
- 3488. Orthotic and Prosthetic Centers operates 23 locations in Florida, North Carolina, and South Carolina. (PX05140 (Weott (O&P Centers) Dep. at 9)).
- 3489. Orthotic and Prosthetic Centers has 111 employees. (PX05140 (Weott (O&P Centers) Dep. at 9)). Approximately 30 employees are certified prosthetists. (PX05140 (Weott (O&P Centers) Dep. at 9)).

Rob Anthony Yates

- 3490. Rob Anthony Yates is the president and CEO for David A. Yates and Associates, Incorporated, also known as JP&O Prosthetic & Orthotic Laboratory and Jonesboro Prosthetic & Orthotic Laboratory ("Jonesboro"). (PX05108 (Yates (Jonesboro) Dep. at 5)). He took on that title in 2007. (PX05108 (Yates (Jonesboro) Dep. at 14)).
- 3491. As president and CEO, Mr. Yates is "responsible for the overall management and performance and success of the organization." (PX05108 (Yates (Jonesboro) Dep. at 14)). He also provides patient care and devotes "50 percent of [his] time" to patient care. (PX05108 (Yates (Jonesboro) Dep. at 14)).
- 3492. In his time spent performing patient care, Mr. Yates "will see the patient, take a history, you know, that's related to their care, the reason I'm seeing them, evaluate their needs, formulate a treatment plan of care for them related to their prosthetic or orthotic management, take whatever measurements/impressions are necessary in order to fabricate the device, direct [his] technical team to fabricate whatever they need to fabricate, [and] direct [his] purchasing staff to purchase whatever they need to purchase." Once the prosthetic device is ready for fitting, Mr. Yates will fit the prosthesis on the patient and "regularly interface with physicians, physical therapists, about that patient's care, their needs for changes or training to ensure success" with the prosthetic device, particularly with lower limb prostheses or with limb prostheses, more complex devices." (PX05108 (Yates (Jonesboro) Dep. at 18-19)).
- 3493. In 2017, Mr. Yates provided roughly 30 prosthetic limbs, including microprocessor and non-microprocessor knees. (PX05108 (Yates (Jonesboro) Dep. at 19)).
- 3494. Jonesboro is located in Jonesboro, Arkansas and "five other communities in Arkansas and Missouri." (PX05108 (Yates (Jonesboro) Dep. at 20)). All six locations employ prosthetists that see patients and fit patients with prosthetic limbs. (PX05108 (Yates (Jonesboro) Dep. at 22)).

3. Other Market Participants

Juerg Baggenstoss

3495. Jürg Baggenstoss is a Manager at A.T. Kearney (International) AG in Switzerland. (PX05154 (Baggenstoss (A.T. Kearney) Dep. at 4)). As a manager, Mr. Baggenstoss is "mostly responsible for delivering projects, and [is] involved in business development."



Hugues Belzidsky

- 3498. Hugues Belzidsky is President of DAW Industries. (PX05147 (Belzidsky (DAW) Dep. at 4)).
- 3499. Mr. Belzidsky began working at DAW Industries in 1975. As President, four employees report directly to him. He does not report to anyone within DAW Industries. (PX05147 (Belzidsky (DAW) Dep. at 14)).

Glenn Choi

- 3500. Glenn Choi is President of ST&G USA Corporation ("ST&G"). (PX05117 (Choi (ST&G) Dep. at 4)). He has held this position for eleven years. (PX05117 (Choi (ST&G) Dep. at 11)).
- 3501. From 1998 to 2005, Mr. Choi worked as director of research and development at United States Manufacturing Company, a company that manufactured lower limb prosthetic devices, upper limb prosthetic devices, and orthotic braces. (PX05117 (Choi (ST&G) Dep. at 12)).
- 3502. Mr. Choi's role at ST&G includes overall management of the business, as well as managing business development for the company. (PX05117 (Choi (ST&G) Dep. at 11)). On a day-to-day basis, Mr. Choi spends the majority of his time reviewing sales data, addressing issues with his team, and looking at future business development processes. (PX05117 (Choi (ST&G) Dep. at 11)).
- 3503. ST&G sells "mainly lower limb prosthetics and small amount of orthotics." (PX05117 (Choi (ST&G) Dep. at 15)).
- 3504. Including Mr. Choi, ST&G has a total of thirteen employees. (PX05117 (Choi (ST&G) Dep. at 19)).

Thomas Chung

- 3505. Thomas Chung is Vice President at Health Evolution Partners. (PX05113 (Chung (HEP) Dep. at 9)). Mr. Chung joined HEP in June 2011 as an Associate. (PX05113 (Chung (HEP) Dep. at 14-15)) He was elevated to Vice President in February 2014. (PX05113 (Chung (HEP) Dep. at 15)).
- 3506. Mr. Chung was on the original investment team when Freedom became a portfolio company for HEP in 2012. (PX05113 (Chung (HEP) Dep. at 17)). Mr. Chung testified that as an associate his responsibilities relating to Freedom included preparing "modeling, legal documentation, presentation[s]" and "general administrative duties." (PX05113 (Chung (HEP) Dep. at 17-18)). Mr. Chung would provide his financial modeling to the HEP investment committee, which "oversees any and all major decisions that the fund does, particularly with regard to acquisition and sale of assets and major decisions about the direction that portfolio companies take." (PX05113 (Chung (HEP) Dep. at 18-19, 21)).
- 3507. When he became a Vice President, Mr. Chung maintained the same responsibilities he had as an associate in addition to providing the investment committee with his perspectives on the various portfolio companies, including Freedom. (PX05113 (Chung (HEP) Dep. at 23)).
- 3508. As part of his responsibilities relating to Freedom, Mr. Chung would interact directly with Freedom employees. (PX05113 (Chung (HEP) Dep. at 24)). Lee Kim, CFO of Freedom, was the employee Mr. Chung "interacted with most." (PX05113 (Chung (HEP) Dep. at 24)). Mr. Chung would interact with Mr. Kim on a day-to-day basis. (PX05113 (Chung (HEP) Dep. at 24)). His interactions with Mr. Kim included "Discussion of board materials, discussion of projections, discussion of debt amendments, discussion of any sort of, maybe, you know, strategic recommendations they were making, whether to HEP or external parties." (PX05113 (Chung (HEP) Dep. at 25)).
- 3509. Mr. Chung would regularly attend Freedom board of directors meetings. (PX05113 (Chung (HEP) Dep. at 26). Mr. Chung testified that he attended board of directors meetings "to provide another set of ears" and "to expedite any analysis or any kind of to-do's that might follow from the board of directors meetings to partnership." (PX05113 (Chung (HEP) Dep. at 26). Beginning in 2015, Mr. Chung would regularly send "e-mail summaries" of the board meetings to the HEP partners. (PX05113 (Chung (HEP) Dep. at 27).

Achilleas Dorotheou

- 3510. Achilleas Dorotheou is the VP and Head of Human Motion, Business Unit at Parker-Hannifin Corporation. (PX05125 (Dorotheou (Parker-Hannifin) Dep. at 4)).
- 3511. Parker-Hannifin is a conglomerate of different industrial businesses, "notably hydraulics, aerospace, and other industrial businesses." (PX05125 (Dorotheou (Parker-Hannifin) Dep. at 7)).

- 3512. At the time of the Merger, Parker Hannifin was the minority shareholder of Freed. (Carkhuff (Freedom) Tr. 311).
- 3513. Mr. Dorotheou became a board member of Freedom in approximately December 2015. (PX05125 (Dorotheou (Parker-Hannifin) Dep. at 10)).
- 3514. Mr. Dorotheou was a member of the board of directors of Freedom at the time of the Merger. (PX05125 (Dorotheou (Parker-Hannifin) Dep. at 10); PX05103 (Kim (Freedom) Dep. at 113-114)).

Karl Michael Fillauer

- 3515. Karl Michael Fillauer is CEO of Fillauer Companies, Inc. ("Fillauer"), headquartered in Chattanooga, Tennessee. (PX05105 (Fillauer (Fillauer) Dep. at 5)).
- 3516. As CEO, Mr. Fillauer is responsible for "the overall direction of the company, the strategic plan going forward, and to oversee the divisions within Fillauer" to ensure they are profitable. (PX05105 (Fillauer (Fillauer) Dep. at 10-11)).
- 3517. Fillauer, which is a private company, operates three separate entities in Chattanooga: the corporate headquarters, the manufacturing division and a patient care clinic. (PX05105 (Fillauer (Fillauer) Dep. at 11)). In Salt Lake City, Fillauer owns Motion Control and Fillauer Composites. (PX05105 (Fillauer (Fillauer) Dep. at 11)). Fillauer Europe is based in Stockholm, Sweden. (PX05105 (Fillauer (Fillauer) Dep. at 11)). Fillauer North Carolina is "orthotics-focused." (PX05105 (Fillauer (Fillauer) Dep. at 11)).

Robert Stuart Gailey, Junior

- 3518. Robert Dr. Robert Stuart Gailey, Jr is the director of the Functional Outcomes and Research Evaluation Center at the University of Miami. (PX05142 (Gailey (University of Miami) Dep. at 4-5)). Dr. Gailey also serves as a professor at the university. (PX05142 (Gailey (University of Miami) Dep. at 16)).
- 3519. Dr. Gailey received a bachelor's and master's degree in physical therapy from the University of Miami and a Ph.D. in prosthetics/orthotics engineering from the University of Strathclyde in Glasgow, Scotland. (PX05142 (Gailey (University of Miami) Dep. at 7-8)). Following the completion of his graduate degrees, Dr. Gailey worked at the University of Miami with clinical, research, student advisory, and administrative responsibilities. His clinical responsibilities at that time included evaluating the fit between the prosthetic device and a patient. (PX05142 (Gailey (University of Miami) Dep. at 10-12)).
- 3520. Dr. Gailey's current responsibilities include clinical responsibilities and performing research. (PX05142 (Gailey (University of Miami) Dep. at 16)). He described the Functional Outcomes and Research Evaluation Center, where he serves as a director, as focused on prosthetics and "research on looking at functional research but mostly geared to even with the prosthetics looking at outcomes and development of devices to improve or enhance the ability for people to use prostheses" (PX05142 (Gailey (University

of Miami) Dep. at 16-17)). The center performs clinical studies in this work. (PX05142 (Gailey (University of Miami) Dep. at 17)).

3521. Dr. Gailey is also a "co-investigator" in research funded by grants from the Department of Veteran Affairs and the Department of Defense. (PX05142 (Gailey (University of Miami) Dep. at 74-75)).

Michael Highsmith

- 3522. Michael Highsmith is the Deputy Chief of the Research and Surveillance division of the Extremity Trauma and Amputation Center of Excellence at the Department of Veterans Affairs ("VA"). (PX05164 (Highsmith (VA) Dep. at 6)). He is also an associate professor in the School of Physical Therapy and Rehab Sciences at the University of Southern Florida and a captain and physical therapist in the Army Reserves. (PX05164 (Highsmith (VA) Dep. at 6)).
- 3523. Dr. Highsmith has not seen prosthetic patients in a clinical setting since 2005. (PX05164 (Highsmith (VA) Dep. at 20)).
- 3524. In his role at the VA, Dr. Highsmith provides leadership to the different VA sites and to create a unified set of outcomes at the different clinical locations. (PX05164 (Highsmith (VA) Dep. at 23-24)).

Jason Kahle

- 3525. Jason Kahle is the CEO of OP Solutions. (PX05119 (Kahle (OP Solutions) Dep. at 4)). He started the company in 2012. (PX05119 (Kahle (OP Solutions) Dep. at 13)). OP Solutions "share[s] space" with Prosthetic Design and Research, where Mr. Kahle serves as Director of R&D and sees patients. (PX05119 (Kahle (OP Solutions) Dep. at 13-14)).
- 3526. As CEO of OP Solutions, Mr. Kahle sees patients when there are "some challenging aspects to it." (PX05119 (Kahle (OP Solutions) Dep. at 15)). Most of the patients he sees are transfemoral amputees. (PX05119 (Kahle (OP Solutions) Dep. at 15-16)).
- 3527. Mr. Kahle is also a "co-principal investigator on several grants" performed by the University of South Florida. (PX05119 (Kahle (OP Solutions) Dep. at 14)).
- 3528. Mr. Kahle has published "somewhere between 40 and 50" articles and approximately half of the articles are related to microprocessor knees. (PX05119 (Kahle (OP Solutions) Dep. at 17-18)). He personally presents the results of his research to owners of prosthetic clinics. (PX05119 (Kahle (OP Solutions) Dep. at 22)).
- 3529. Otto Bock has hired Mr. Kahle twice to perform research projects related to microprocessor knees. (PX05119 (Kahle (OP Solutions) Dep. at 23)).

Larry Fredrick Knudsen

- 3530. Larry Fredrick Knudsen is Vice President of Sales and Marketing at Trulife. (PX05136 (Knudsen (Trulife) Dep. at 4)). Mr. Knudsen has held this position since 1997. (PX05136 (Knudsen (Trulife) Dep. at 10)).
- 3531. As Vice President of Sales and Marketing, Mr. Knudsen is responsible for "developing strategies, managing budgets," ensuring Trulife achieves EBITDA objectives, and managing distributors. (PX05136 (Knudsen (Trulife) Dep. at 9)).
- 3532. Trulife is headquartered in Dublin, Ireland and owns two facilities in the UK, one in Canada, and three in the United States. (PX05136 (Knudsen (Trulife) Dep. at 14)). Trulife sells orthotics, prosthetics, mastectomy products and a Pressure Care product line. (PX05136 (Knudsen (Trulife) Dep. at 14)).
- 3533. In the category of prosthetic products, Trulife sells "prosthetic feet, prosthetic components, prosthetic knees, and then also valves which are incorporated in lower limb system, primarily the socket." (PX05136 (Knudsen (Trulife) Dep. at 15)).

Stuart Marquette

- 3534. Stuart Marquette is Vice President of DAW Industries. (PX05146 (Marquette (DAW) Dep. at 4)). DAW is a "manufacturer and distributor of prosthetic componentries." (PX05146 (Marquette (DAW) Dep. at 14)).
- 3535. Mr. Marquette began working at DAW Industries in 1987. He became the Vice President in approximately 1997. (PX05146 (Marquette (DAW) Dep. at 13)).
- 3536. As Vice President, Mr. Marquette is "in charge of operations." He elaborated that he spends "most of [his] time advising clients, practitioners on which one of [DAW's] knees or components is the best for their patient." (PX05146 (Marquette (DAW) Dep. at 14)).

Blount Swain

- 3537. Blount Swain is president of Ability Dynamics. (PX05158 (Swain (Ability Dynamics) Dep. at 8)).
- 3538. As president, Mr. Swain is responsible for general management of the company including operations, sales, finance, accounting and customer service. (PX05158 (Swain (Ability Dynamics) Dep. at 9)).

PROPOSED CONCLUSIONS OF LAW

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PUBLIC

	,	Respondent Failed to Show that a Divestiture to { Would Not Create a in the U.S. MPK Market	
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PROPOSED CONCLUSIONS OF LAW

I. THE FEDERAL TRADE COMMISSION HAS JURISDICTION OVER THIS MATTER

- 1. The Federal Trade Commission has jurisdiction over Respondent Otto Bock HealthCare North America, Inc., and the subject matter of this proceeding pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45, and Sections 7 and 11 of the Clayton Act, 15 U.S.C. § 18, 21(b).
- 2. The FTC is an administrative agency of the U.S. Government established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.* (2006). The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 18.
- 3. Respondent, including its relevant operating subsidiaries, are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44 (2006), and Section 1 of the Clayton Act, 15 U.S.C. § 12 (2006).

II. CLAYTON ACT SECTION 7 AND FTC ACT SECTION 5 STANDARDS

- 4. Complaint Counsel's antitrust claims are based on Section 7 of the Clayton Act and Section 5 of the FTC Act. Section 7 of the Clayton Act prohibits mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce . . . in any section of the country." 15 U.S.C. § 18. Section 5 of the FTC Act proscribes "[u]nfair methods of competition in or affecting commerce" 15 U.S.C. § 45(a)(1). An acquisition that violates the Clayton Act, by definition, is a violation of Section 5 of the FTC Act. *See, e.g., FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).
- For the Government to prevail in a Section 7 case, "certainty, even a high probability, need not be shown," and "[d]oubts are to be resolved against the transaction." *FTC v. Elders Grain*, 868 F.2d 901, 906 (7th Cir. 1989); *Brown Shoe Co. v. United States*, 370 U.S. 294, at 323.
- 6. Section 7 of the Clayton Act bars mergers "the effect of [which] may be substantially to lessen competition, or to tend to create a monopoly" in "any line of commerce or . . . activity affecting commerce in any section of the country." 15 U.S.C. § 18 (2012). "As the statutory language suggests, Congress enacted Section 7 to curtail anticompetitive harm in its incipiency." *In re Polypore Int'l, Inc.*, No. D-9327, 150 F.T.C. 586, at 598 (F.T.C. Nov. 5, 2010) (citing *Chi. Bridge & Iron Co. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008)). "Congress used the words '*may be* substantially to lessen competition' to indicate that its concern was with probabilities, not certainties[.]" *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 337 (3d Cir. 2016)

(quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)); *ProMedica Health Sys.*, 749 F.3d at 564 (quotation omitted).

- 7. "Section 7 prohibits acquisitions that create a reasonable probability of anticompetitive effects." *Polypore*, 150 F.T.C. at 598. A merger violates Section 7 if it "create[s] an appreciable danger of [anticompetitive consequences] in the future. A predictive judgment, necessarily probabilistic and judgmental rather than demonstrable, is called for." *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 719 (D.C. Cir 2001). As a result, "Section 7 does not require that competitive harm be established with certainty." *Polypore*, 150 F.T.C. at 598 (citations omitted).
- 8. "Even in a consummated merger, the ultimate issue under Section 7 is whether anticompetitive effects are reasonably probable in the future, not whether such effects have occurred as of the time of trial." *Polypore*, 150 F.T.C. at 598-99 (citing *United States v. General Dynamics Corp.*, 415 U.S. 486, 505-06 (1974)).
- Courts typically assess whether a merger violates Section 7 by determining the (1) relevant product market, (2) the relevant geographic market, and (3) the merger's probable effect on competition in those relevant markets. *See United States v. Marine Bancorp.*, 418 U.S. 602, 618-23 (1974); *see also U.S. Steel Corp. v. FTC*, 426 F.2d 592, 595-96 (6th Cir. 1970).
- 10. Courts often rely on the Merger Guidelines framework to assess how acquisitions may harm competition. *See, e.g., ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 565 (6th Cir. 2014); *FTC v. Bass Bros. Enter., Inc.*, 1984 WL 355, *24 (N.D. Ohio 1985).
- Courts traditionally analyze Section 7 cases using a burden-shifting framework. *In re ProMedica Health Sys., Inc.*, No. 9346, 2012 WL 1155392, *12; *Polypore*, 150 F.T.C. at 599 (citations omitted). This framework "first requires the Government to establish a *prima facie* case that an acquisition is unlawful." *Chicago Bridge & Iron, Co. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008) (citations omitted); *see also ProMedica*, 2012 WL 1155392, *12; *Polypore*, 150 F.T.C. at 600; *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990); *Heinz*, 246 F.3d at 715.
- "Under this framework, the government can establish a presumption of liability by defining a relevant product and geographic market and showing that the transaction will lead to undue concentration in the relevant market." *ProMedica*, 2012 WL 1155392, *12; *Polypore*, 150 F.T.C. at 600 (citing *Baker Hughes*, 908 F.2d at 982-83).
- 13. As the Commission has previously noted, establishing a presumption of illegality based on undue concentration "'does not exhaust the possible ways to prove a § 7 violation on the merits." *ProMedica*, 2012 WL 1155392 at *13 (quoting *Whole Foods*, 548 F.3d at 1036) (citations omitted); *see also Polypore*, 150 F.T.C. at 600 (noting that "qualitative evidence regarding pre-acquisition competition between the merging parties can in some cases be sufficient to create a *prima facie* case even without quantitative evidence of changes in market concentration") (citing *Chi. Bridge*, 138 F.T.C. 1024, 1053 (2004); *Merger Guidelines* §2.1.4).

- 14. Once the presumption is established, the burden of rebutting the *prima facie* case shifts to Respondent who can then rebut the presumption by producing "evidence showing that the plaintiff's evidence paints an inaccurate picture of the merger's likely competitive effects." *Polypore*, 150 F.T.C at 600 (citing *Marne Bancorp.*, 418 U.S. 602); *see also Chicago Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008); *Baker Hughes*, 908 F.2d at 982. "The stronger the plaintiff's *prima facie* case, the greater the defendant's burden of production on rebuttal." *Polypore*, 150 F.T.C. at 600 (citing *Heinz*, 246 F.3d at 725; *Baker Hughes*, 908 F.2d at 991); *see also ProMedica Health Sys., Inc.*, 2012 WL 1155392, at *12.
- 15. If Respondent successfully rebuts the *prima facie* case, the burden shifts again to the government, which has the ultimate burden of persuasion. *Chi. Bridge*, 534 F.3d at 423; *Baker Hughes*, 908 F.2d at 983; *ProMedica*, 2011 WL 1219281, at *53.

III. RESPONDENT'S CONSUMMATED MERGER IS PRESUMPTIVELY UNLAWFUL

A. THE RELEVANT MARKET IS THE MANUFACTURE AND SALE OF MICROPROCESSOR PROSTHETIC KNEES TO PROSTHETIC CLINICS IN THE UNITED STATES

- 16. In defining a relevant antitrust market, courts are guided by the Supreme Court's decision in *Brown Shoe*, 370 U.S. 294. Courts also rely heavily on the "hypothetical monopolist test" in U.S. Department of Justice & Federal Trade Commission's Horizontal Merger Guidelines (2010) (hereinafter "Merger Guidelines") as an analytical method for defining relevant markets. See United States v. H&R Block, 833 F. Supp. 2d at 51-52; FTC v. Penn State Hershey Med. Ctr., 838 F.3d 327, 338 (3d Cir. 2016); FTC v. Staples Inc., 190 F. Supp. 3d 100, 121-22 (D.D.C. 2016) (hereinafter "Staples 2016"); ProMedica, 749 F.3d at 565.
- 17. "As the United States Supreme Court observed in [*Brown Shoe*], 'The 'area of effective competition' must be determined by reference to a product market (the 'line of commerce') and a geographic market (the 'section of the country')." U.S. Steel Corp. v. FTC, 426 F.2d 592, 595-96 (6th Cir. 1970) (quoting Brown Shoe, 370 U.S. at 324). In this case, the area of effective competition is the manufacture and sale of microprocessor prosthetic knees to prosthetic clinics in the United States.

B. MICROPROCESSOR PROSTHETIC KNEES IS A RELEVANT PRODUCT MARKET

18. The relevant product market refers to the "product and services with which the defendants' products compete." United States v. Anthem, Inc., 236 F. Supp. 3d 171, 193 (D.D.C. 2017), aff'd 855 F.3d 345 (D.C. Cir.). In other words, the relevant product market is the "line of commerce" affected by a merger. Brown Shoe, 370 U.S. at 324.

- 19. "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. Stated another way, a product market includes all goods that are "reasonable substitutes". *Sysco*, 113 F. Supp. 3d at 25 (citing *Cardinal Health*, 12 F. Supp. 2d at 46; *Staples*, 970 F. Supp. at 1074); *United States v H & R Block, Inc.*, 833 F. Supp. 2d 36, 51 (D.D.C. 2011) (citation omitted) (holding "courts look at '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.").
- 20. To determine whether products are "reasonable substitutes" requires an evaluation of cross elasticity of demand and "functional interchangeability." *Sysco*, 113 F. Supp. 3d at 25. "Interchangeability of use and cross-elasticity of demand look to the availability of products that are similar in character or use to the product in question *and* the degree to which buyers are willing to substitute those similar products for the product." *Polypore*, 150 F.T.C. at 602-03 (quoting *FTC v. Swedish Match*, 131 F.Supp. 2d 151, 157 (D.D.C. 2000)) (emphasis added); *H & R Block, Inc.*, 833 F. Supp. 2d at 51 (quoting *Staples*, 970 F.Supp. at 1074) ("courts look at '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").
- 21. Functional interchangeability, *i.e.*, the fact that some products may superficially (or even under careful examination) appear to be similar in use, does not alone warrant inclusion in the relevant product market. *Staples*, 970 F. Supp. at 1074; *see also H&R Block*, 833 F. Supp. 2d at 54.
- A relevant product market for antitrust purposes "need only include 'reasonable substitutes.'" *Anthem*, 236 F. Supp. 3d at 194-95 (quoting *Sysco*, 113 F. Supp. 3d at 26). Thus the relevant product market "must be drawn narrowly to exclude any other product to which, within reasonable variations in price, *only a limited number of buyers will turn...*" *See Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 612 n.31 (emphasis added).
- 23. To determine cross-elasticity of demand between products, one should consider "the responsiveness of the sales of one product to price changes of the other." United States v. E.I. du Pont De Nemours, 351 U.S. 377, 400 (1956) (hereinafter "du Pont 1956"); Sysco, 113 F. Supp. 3d at 25. For example, "[i]f an increase in the price for product A causes a substantial number of customers to switch to product B, the products compete in the same market." Sysco, 113 F. Supp. 3d at 25; see also du Pont (1956), 351 U.S. at 400.
- 24. A relevant market "does not need to include all of the firm's competitors; it needs to include the competitors that would 'substantially constrain [the firm's] price-increasing ability." *Advocate*, 841 F.3d at 469 (citations omitted); *see also Rebel Oil Co., Inc. v. Atlantic Richfield*, 51 F.3d 1421, 1434 (9th Cir. 1995) ("[A] 'market' is the group of sellers or producers who have the 'actual or potential ability to deprive each other of significant levels of business."").

- 25. Determination of the relevant market "is a matter of business reality—a matter of how the market is perceived by those who strive for profit in it." *FTC v. Staples*, 970 F. Supp. 1066, 1079 (D.D.C. 1997) (internal quotation marks and citation omitted); *see also FTC v. Coca Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986); *see also Aetna*, 240 F. Supp. 3d at 21 ("Ordinary course of business documents reveal the contours of competition of the parties. . .and may be presumed to 'have accurate perceptions of economic realites.") (quoting *Whole Foods*, 548, F.3d at 1045 (Tatel, J.)). As such, "When determining the relevant product market, courts often pay close attention to the defendants' ordinary course of business documents." *Sysco*, 113 F. Supp. 3d at 41 (quoting *H&R Block*, 833 F. Supp. 2d at 52); *Aetna*, 240 F. Supp. 3d at 21 (same).
- 26. Courts frequently define relevant product markets using two analyses—the *Brown Shoe* practical indicia and the hypothetical monopolist test. *See e.g., Sysco*, 113 F. Supp. 3d at 27-34; *Staples 2016*, 190 F. Supp. at 118-22.
- 27. In *Brown Shoe*, the Supreme Court identified a series of "practical indicia" for courts to consider in determining the relevant product market. 370 U.S. at 325. Courts consistently apply these practical indicia in defining relevant antitrust markets. *See e.g.*, *Anthem*, 236 F. Supp. 3d at 194; *Sysco*, 113 F. Supp. at 27; *H&R Block* 833 F. Supp. 2d at 51.
- 28. The indicia outlined in *Brown Shoe* include, "industry or public recognition of the [market] 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." *Brown Shoe*, 370 U.S. at 325; *see also U.S. v. Aetna*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017); *Sysco* 113 F. Supp. 3d at 27; *H&R Block*, 833 F. Supp. 2d at 51; *Rothery Storage & Van Co.*, 792 F.2d at 218 n.4 (D.C. Cir. 1986); *Polypore*, 150 F.T.C. at 603.
- 29. "Practical indicia" serve as "evidentiary proxies for proof of substitutability and crosselasticities of supply and demand." *H&R Block*, 833 F. Supp. 2d at 51 (citing *Rothery Storage & Van*, 792 F.2d at 218); *Polypore*, 150 F.T.C. at 603 (quoting *Brown Shoe*, 370 U.S. at 325) (citations omitted). As the Commission noted in *Polypore*, "[t]hese observable market facts provide evidence of interchangeability and the cross-elasticity of demand." 150 F.T.C. at 603.
- 30. "'[T]he mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes." *Cardinal Health*, 12 F. Supp. 2d at 47 (quoting *Staples*, 970 F. Supp. at 1075-76); *Sysco*, 113 F. Supp. 3d at 26; *see also Swedish Match*, 131 F. Supp. 2d at 164-65 (finding that while moist snuff competed with the product at issue loose leaf snuff it was not in the relevant product market because it was "incapable of inducing substitution sufficient enough to render loose leaf price increases unprofitable[.]").
- 31. Microprocessor prosthetic knees constitutes a distinct relevant market in which to assess the competitive effects of the proposed merger. MPKs can sense variations in

walking cadence and terrain and make thousands of adjustments per second to stiffness and positioning of the knee joint providing increased stability and safety to certain amputees. (CCFF ¶¶ 363-68). The fact that for some amputees MPKs are not medically necessary does not justify defining the relevant product market to include mechanical knees. *See Polypore*, 150 F.T.C. at 604 (defining relevant market based on end use of product).

- 32. MPKs have peculiar characteristics and uses that distinguish them from other types of prosthetic knees. (CCFF ¶¶ 607-700) The unique characteristics and functionality provided by MPKs, which Respondent recognizes in its own documents, supports an MPK product market. (CCFF ¶¶ 657-687). *See Brown Shoe*, 370 U.S. at 325 ("the product's peculiar characteristics and uses" support distinct relevant markets).
- 33. MPKs are used by a distinct subset of amputees who prosthetists determine are healthy enough and regularly engage in activities that make wearing an MPK a medical necessity. (CCFF ¶¶ 400-429, 447-87). See Brown Shoe, 370 U.S. at 325 (the existence of "distinct customers" for a product support distinct relevant markets). Indeed, insurance providers will only provide reimbursement when medical necessity is established. (CCFF § IV.C).
- 34. MPK prices and reimbursement amounts are significantly higher than mechanical knees, (CCFF § VI.B) indicating MPKs constitute a separate market. See FTC v. Staples, Inc., 190 F. Supp. 3d 100, 119-120 (D.D.C. 2016) (discussing distinct pricing as evidence of relevant product market); Aetna, 240 F. Supp. 3d 1, 21 (D.D.C. 2017), ("distinct prices" may be considered in assessing the boundaries of a market) (citing Brown Shoe, 370 U.S. at 325).
- 35. MPKs and mechanical knees are in separate product markets because there is no "responsiveness of the sales of one product to price changes of the other." (CCFF § VI.C.); *du Pont 1956*, 351 U.S. at 400. MPK manufacturers, including Otto Bock and Freedom, "make pricing and marketing decisions based primarily on comparisons with rival [MPKs], with little if any concern about possible competition" from mechanical knees. (CCFF ¶¶ 755-56, 758); *Coca Cola Co.*, 641 F. Supp. at 1133; *H&R Block*, 833 F. Supp. 2d at 53 (development of "pricing and business strategy with [a particular] market and those competitors in mind" is "strong evidence" of the relevant product market); *see also Swedish Match*, 131 F. Supp. 2d at 165 ("The Commission amassed evidence showing that loose leaf pricing is determined upon the basis of competition with other loose leaf products").
- 36. Market definition is a matter of "business reality" of "how the market is perceived by those who strive to profit in it," *Coca-Cola Co.*, 641 F. Supp. at 1132 (D.D.C. 1986), vacated as moot, 829 F.2d 191 (D.C. Cir. 1987). Industry participants, including Respondent, widely recognize MPKs as a distinct market from mechanical knees. (CCFF §§ VI.E). *See Brown Shoe*, 370 U.S. at 325; *Sysco*, 113 F. Supp. 3d at 30 (considering industry recognition as evidence of relevant product market). Otto Bock, Freedom and other MPK manufacturers assess and evaluate a separate MPK market. (CCFF ¶¶ 717-28, 752-58); *see H&R Block, Inc.*, 833 F. Supp. 2d at 52-53 (describing)

merging parties' documents as "strong evidence" of product market definition) (citing *Whole Foods*, 548 F.3d at 1045 (Tatel, J.)). Customers similarly view MPKs and mechanical knees as being in separate markets. (CCFF ¶¶ 649-56); *see Sysco*, 113 F. Supp. 3d at 30 (considering customer perception of the industry as evidence of a relevant product market definition).

- 37. To sell MPKs effectively requires highly specialized sales and clinical personnel (CCFF ¶¶ 1676, 1678, 1686-87, 1692, 1695, 1697-98), which supports an MPK market. See Brown Shoe, 370 U.S. at 325 (presence of "specialized vendors" support distinct relevant markets).
- 38. Non-microprocessor knees (i.e., mechanical knees) are not reasonably interchangeable with microprocessor knees. Unlike MPKs, mechanical knees do not contain a microprocessor and thus do not make adjustments. Mechanical knees are, therefore, less responsive than MPKs to sudden movements and, for certain amputees, lead to a greater risk of falling. (CCFF ¶¶ 607-16); *see Polypore*, 150 F.T.C. at 604 ("The fact that two [products] may have one characteristic in common. . .does not mean that the [products] can be substituted for one another in a particular application if other features are different...").
- 39. In addition to the *Brown Shoe* indicia, courts often rely on the approach prescribed by the *Merger Guidelines*—the hypothetical monopolist test. *See FTC v. Advocate Health Care Network*, 841 F.3d 460, 468-69 (7th Cir. 2016) (applying the hypothetical monopolist test to define a relevant geographic market); *see also ProMedica*, 2012 WL 1155392, *14; *Sysco*, 113 F. Supp. 3d at 33; *Staples 2016*, 190 F. Supp. 3d at 121-22; *Merger Guidelines* § 4.
- 40. Application of the *Merger Guidelines* further supports that MPKs is a relevant antitrust product market. The Merger Guidelines explain that relevant product market definition focuses on "demand substitution factors, i.e., on customers' ability and *willingness* to substitute away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service." *Merger Guidelines* §4 (emphasis added).
- 41. Under the hypothetical monopolist test, a candidate market constitutes a relevant antitrust market if a hypothetical monopolist could profitably impose a "small but significant and non-transitory increase in price" (SSNIP), typically five percent, on at least *one* product of the merging parties in the candidate market. *Merger Guidelines* §§ 4.1.1-4.1.3; *see also CCC Holdings*, 605 F. Supp. 2d at 38 n.12. Here, the relevant inquiry is whether a hypothetical monopolist of all MPKs could profitably impose a SSNIP on either Freedom's Plié or one of Otto Bock's MPKs (if so, MPKs is a relevant market). *See Merger Guidelines* §§ 4.1.1-4.1.3.
- 42. In determining the bounds of the relevant product market, the first step is to apply the hypothetical monopolist test on a candidate market comprised of at least one product of each merging firm. *Merger Guidelines* §§ 4.1.1-4.1.3. The candidate market is too narrow only if enough customers would switch to products outside the candidate

market in the face of a price to render the price increase unprofitable. *Merger Guidelines* §§ 4.1.1-4.1.3. The hypothetical monopolist test "is iterative, meaning it should be repeated with ever-larger candidates until it defines a [relevant market]" *Advocate*, 841 F.3d at 468 (citation omitted). A relevant antitrust product market is defined when a hypothetical monopolist of a candidate market could profitably impose a SSNIP. *Merger Guidelines* §§ 4.1.1-4.1.3.

- 43. As Dr. Scott Morton, Complaint Counsel's expert, concluded MPKs is a relevant product market because it is a set of products over which a hypothetical monopolist of all MPKs could profitably impose a SSNIP on at least one of the merging parties' products. (CCFF § VI.F.1). Because mechanical knees are not substitutes for the K3/K4 patients for whom MPKs are medically necessary, clinics would be unlikely to substitute mechanical knees to such an extent that SSNIP would be profitable. (CCFF §VI.F.2).
- 44. The *Merger Guidelines*, therefore, bolster the conclusion under the *Brown Shoe* factors that it is appropriate to analyze the competitive effects of the Merger separately for MPKs. *See Merger Guidelines* §§ 4.1.1-4.1.3.
- 45. Respondent's attempt to include mechanical knees in the relevant product market violates the principle that the relevant product market should be defined as the smallest product market that will satisfy the hypothetical monopolist test. *See H&R Block*, 833 F. Supp. 2d. at 59 (citing *Merger Guidelines* §4.1.1); *see also Sysco*, 113 F. Supp. 3d at 26-27 (noting that "market definition is guided by the 'narrowest market' principle") (quoting *Arch Coal*, 329 F. Supp. 2d at 120). There is substantial evidence showing that market participants would not respond to a price change for MPKs by switching to mechanical knees, (CCFF ¶¶ 795-806), which proves that a relevant market, excluding mechanical knees, exists. *See e.g., du Pont (1956)*, 351 U.S. at 400 ("An element for consideration as to cross-elasticity of demand between products is the responsiveness of the sales of one product to price changes of the other."); *Merger Guidelines* § 4.
- 46. There is no basis in law or economics for defining the relevant market based on a single attribute of the patient class—e.g. that MPK patients are designated as K3/K4 under the Medicare classification—and then expanding the relevant market non-substitute products used by patients sharing that single attribute. *Cf. Merger Guidelines* §§ 4 (focus in market definition is substitutability); *see also Sysco*, 113 F. Supp. 3d at 25; *du Pont 1956*, 351 U.S. at 400.

C. THE RELEVANT GEOGRAPHIC MARKET IS THE UNITED STATES

47. The relevant geographic market is the area "where the effect of the merger on competition will be direct and immediate." *Advocate*, 841 F.3d at 476 (citing *U.S. v. Philadelphia Nat'l Bank*, 374 U.S. 321, 357) (internal quotations omitted). Here, the relevant geographic market is the United States. (CCFF § VII) (Counsel for Respondent agreed there is no dispute that the relevant geographic market is the United States).

- 48. The United States is where "the defendants compete in marketing their products or services," *H&R Block*, 833 F. Supp. 2d at 50 n.7 (quoting *CCC Holdings*, 605 F. Supp. 2d at 37).
- 49. Relevant geographic market definition is determined by assessing the alternative sources of the relevant product to which customer could turn. *See, e.g., Phila. Nat'l Bank*, 374 U.S. at 359; *Polypore*, 150 F.T.C. at 612; *see also Merger Guidelines* § 4.2.
- 50. The Supreme Court explained that the relevant geographic market must "correspond to the commercial realities of the industry," as determined through a "pragmatic, factual approach." *Brown Shoe*, 370 U.S. at 336 (internal quotations omitted).
- 51. There is substantial evidence that "commercial realities" of the industry, show that the sale of MPKs to clinics located in the United States is a distinct geographic market. (CCFF § VII.B) MPK firms that only operate outside of the United States are not viable options for U.S. prosthetic clinics. (CCFF § VII.B.2).
- 52. Courts commonly use the hypothetical monopolist test prescribed by the *Merger Guidelines* to assess the commercial reality of a relevant geographic market. See FTC v. Penn State Hershey Med. Ctr., 838 F.3d 327, 338 (3d Cir. 2016); St. Alphonsus Med. Ctr. V. St. Luke's Health Sys., Ltd., 778 F.3d 775, 784 (9th Cir. 2015) (quotation omitted).
- 53. "Under the Horizontal Merger Guidelines, a relevant geographic market is the smallest region in which a hypothetical monopolist that was the only seller of the relevant product located within that region could profitably implement a 'small but significant non transitory' increase in price." *Polypore*, 150 F.T.C. at 612 (quoting *Merger Guidelines* § 4.2). If, in response to a SSNIP, enough customers were to purchase from suppliers outside of the proposed geographic market, then the market is too narrow. *See St. Alphonsus Med. Ctr.*, 778 F.3d at 784) (citing *Theme Promotions v. News Am. Mktg. FSI*, 546 F.3d 991, 1002 (9th Cir. 2008).
- 54. Here, the relevant question is whether a hypothetical monopolist of MPKs currently sold in the United States could profitably impose a SSNIP to clinics in the U.S. *See Merger Guidelines* § 4.2. There is extensive evidence showing that customers could not, and would not, turn to an MPK supplier that lacked a substantial U.S. presence. (CCFF § VII.B.2). Because a hypothetical monopolist of MPKs currently sold in the United States could profitably raise prices to U.S. customers, the United States is a relevant geographic market. *See Merger Guidelines* §4.2.

D. HIGH MARKET CONCENTRATION AND MARKET SHARES ESTABLISH A STRONG PRESUMPTION THAT THE MERGER IS ILLEGAL

55. A merger that significantly increases market shares and concentration to high levels creates a presumption that the merger is illegal under Section 7 of the Clayton Act. *Phila. Nat'l Bank*, 374 U.S. at 363; *Heinz*, 246 F.3d at 715; *see also Baker Hughes*,

908 F.2d 982-83. A merger is presumed to violate the Clayton Act and FTC Act if it produces a firm controlling an "undue concentration in the relevant market." *ProMedica*, 2012 WL 1155392 at *12 (citing *Phila. Nat'l Bank*, 374 U.S. at 363; *Baker Hughes*, 908 F.2d at 982-83).

- 56. The Commission may rely on the "closest available approximation" of market shares when calculating concentration levels. *See FTC v. PPG Indus.*, 798 F. 2d 1500, 1505 (D.C. Cir. 1986). The "FTC need not present market shares and HHI estimates with the precision of a NASA scientist." *Sysco*, 113 F. Supp. 3d at 54 (market share estimates were reliable because they were a close approximation); *see also H&R Block*, 833 F.Supp. 2d at 72 (a "reliable, reasonable, close approximation of relevant market share data is sufficient").
- 57. The Herfindahl-Hirschman Index (the "HHI") is the typical measure for determining market concentration. *ProMedica*, 2012 WL 1155392, at *12 (citing *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 37 (D.D.C. 2009)); *see also Polypore,* 150 F.T.C. at 623 (citing *Heinz*, 246 F.3d at 716); *Sysco*, 113 F. Supp. 3d at 52-53. "The HHI is calculated by summing the squares of the individual firms' market shares." *Merger Guidelines* § 5.3; *see also Sysco*, 113 F. Supp. 3d at 52.
- 58. "Sufficiently large HHI figures" establish "[a] prima facie case that a merger is anticompetitive." *Heinz*, 246 F.3d at 716; *Polypore*, 150 F.T.C. at 623 (concentration data was sufficient to create a presumption of illegality).
- 59. Under the *Merger Guidelines*, mergers "that involve an increase in the HHI of more than 200 points" in a highly concentrated market (i.e., with HHI over 2500), are presumptively anticompetitive. *Merger Guidelines* § 5.3; *Sysco*, 113 F. Supp. 3d at 52-53; *H&R Block*, 833 F. Supp. 2d at 71-72; *see Heinz*, 246 F.3d at 716-17.
- 60. Here, the Merger results in an HHI of 5,245 and an increase in HHI of 1,522, (CCFF ¶¶ 964-66), far exceeding the established thresholds to establish a strong presumption that the Merger is likely to enhance market power. *See Merger Guidelines* § 5.3.
- 61. Respondent's own market share estimates prepared in the ordinary course of business are remarkably consistent with market shares calculated by Professor Scott Morton, underscoring the reliability of the shares and concentration levels. (CCFF ¶¶ 967-80); *Sysco*, 113 F. Supp. 3d at 59 (merging parties' ordinary course documents corroborated economic expert's market share calculations).
- 62. Even if one were to accept Respondent's overbroad proposed product market definition and include mechanical knees in the relevant market, the market share and concentration levels would yield market shares and concentration levels that establish, by a wide margin, a presumption of anticompetitive effects. (CCFF ¶¶ 985-990). Therefore, even in the broadest conceivable market, merger is presumptively unlawful. *See Merger Guidelines* § 5.3.

IV. THE MERGER SUBSTANTIALLY REDUCED COMPETITION IN THE U.S. MPK MARKET

- 63. "A plaintiff can bolster a *prima facie* case based on market structure with evidence showing that anticompetitive unilateral . . . effects are likely." *Polypore*, 150 F.T.C. at 600 (citing *Heinz*, 246 F.3d at 717).
- 64. "The elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition." *Merger Guidelines* § 6. This type of anticompetitive effect is referred to as a "unilateral effect," as it does not depend on a coordinated response by other firms in the market. *See Sysco*, 113 F. Supp. 3d at 61 (quoting *H&R Block*, 833 F. Supp. 2d at 81) ("a merger 'is likely to have unilateral anticompetitive effect if the acquiring firm will have the incentive to raise prices or reduce quality after the acquisition, independent of competitive responses from other firms."").
- 65. The Commission and courts have repeatedly found that mergers that eliminate significant head-to-head competition are likely to result in anticompetitive unilateral effects. *See, e.g., ProMedica,* 749 F.3d at 569 ("The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects.") (quoting *Merger Guidelines* §6.1) (internal quotation marks omitted); *Swedish Match,* 131 F. Supp. 2d at169 ("[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).
- 66. "A merger between firms selling differentiated products may diminish competition by enabling the merged firm to profit by unilaterally raising price of *one* or both products above the pre-merger level." *Merger Guidelines* § 6.1 (emphasis added). Where "sales lost due to the price" increase are "merely [] diverted to the product of the merger partner," the recapture of those sales "may make the price increase profitable even though it would not have been profitable prior to the merger." *Merger Guidelines* § 6.1.
- 67. The risk of anticompetitive effects is greater, when the merging firms, as is the case with Otto Bock and Freedom, are particularly close competitors. *Merger Guidelines* § 6.1. ("Unilateral price effects are greater, the more buyers of products sold by one merging firm consider products sold by the other merging firm to be their next best choice.").
- 68. For a merger to yield anticompetitive unilateral price effects, the fraction of buyers that consider the merging firms products to be closest competitors "need not approach a majority" particularly where premerger margins are high, as they are here. (CCFF ¶¶ 778-88, 781); *Merger Guidelines* §6.1. Indeed, "[a] merger may produce significant unilateral effects . . . even though many more sales are diverted to . . . non-merging

firms than to . . . the merger partner." *Merger Guidelines* § 6.1; *see also ProMedica*, 749 F.3d at 569.

- 69. Diversion ratios—"the fraction of unit sales lost by" one of the merging firm's products due to a price increase "that would be diverted to" a product of the other merger partner—are often used to quantify the "extent of direct competition between" products sold by the merging firms. *Merger Guidelines* § 6.1; *see also H&R Block, Inc.*, 833 F. Supp. 2d at 86 (finding harm likely where estimated diversion was only 12 percent). Diversion ratios "can be very informative for assessing unilateral price effects." *Merger Guidelines* § 6.1.
- 70. "Adverse unilateral price effects can arise when the merger gives the merged entity an incentive to raise the price of a product previously sold by *one* merging firm and thereby divert sales to products previously sold by the other merging firm, boosting the profits on the latter products." *Merger Guidelines* § 6.1 (emphasis added).
- 71. Even though they are here, merging parties need not be each other's *closest* competitors for a merger to result in significant unilateral anticompetitive effects. *H&R Block*, 833 F. Supp. 2d at 83-84 (finding unilateral effects where the merging firms were "each other's *second* closest rivals" and the closest competitor to both firms remained independent) (emphasis added); *see also ProMedica*, 749 F.3d at 569 ("For a merger to raise concerns about unilateral effects, however, not every consumer in the relevant market must regard the products of the merging firms as her top two choices."). There only needs to be sufficient diversion between the products of the merging firms to make a price increase on one of the merger partner's products profitable. *See Merger Guidelines* § 6.1.
- 72. Anticompetitive effects can also include "non-price terms and conditions that adversely affect customers, including reduced product quality, reduced product variety, reduced service, or diminished innovation." *Merger Guidelines* § 1. Indeed, withdrawal of a product from the market "that a significant number of customers strongly prefer to those that would remain available . . . can constitute a harm to customers over and above any effects on the price or quality of any given product." *Merger Guidelines* § 6.4.
- 73. "Documents created by the merging parties in the ordinary course of business are often highly probative of both industry conditions and the likely competitive effects of a merger." *Polypore*, 150 F.T.C. at 600 (citing *Merger Guidelines* § 2.2.1); *see also H&R Block*, 833 F. Supp. 2d at 81-82 (relying on defendants' ordinary course documents to conclude merging parties are head-to-head competitors). Indeed, "qualitative evidence on pre-acquisition competition can in some cases be sufficient to create a *prima facie* case even without quantitative evidence of changes in market concentration. *Polypore*, 150 F.T.C. at 600 (citing *Chi. Bridge*, 138 F.T.C. at 1053; *Merger Guidelines* §2.1.4).

- 74. "In a consummated merger, post-acquisition evidence of actual anticompetitive harm may in some cases be sufficient to establish Section 7 liability..." *Polypore*, 150 F.T.C. at 601 (citation omitted). However, the absence of "concrete anticompetitive symptoms . . . does not itself imply that competition has not already been affected." *Gen. Dynamics*, 415 U.S. at 505.
- 75. The Merger eliminated significant and intense head-to-head competition between Otto Bock and Freedom. (CCFF § IX.A). Evidence from a variety of sources, including Respondent's own ordinary course documents, demonstrates that prior to the Merger Otto Bock and Freedom had a history of engaging in intense competition and that competition was set to intensify. (CCFF §§ IX.B). This pre-acquisition competition led to lower prices and improved products and services for customers. (CCFF § IX.A.5). The loss of this competition provides direct evidence of the likely anticompetitive effects of the Merger. *See, e.g., Polypore*, 150 F.T.C. at 625-26 (pre-acquisition competition between merging parties supported likely anticompetitive unilateral effects); *Staples*, 970 F. Supp. at 1083; *Merger Guidelines* § 6.1.
- 76. Diversion estimates created by Respondent in the ordinary course, which is the same analysis applied by Complaint Counsel and its expert, shows that Otto Bock has both the incentive and ability to raise prices for MPKs sold in the United States, if this Court does not stop the Merger and order an effective remedy. See (CCFF ¶¶ 1362-64, 1394-95, 1397-98, 1404); see also H&R Block, Inc., 833 F. Supp. 2d at 86 (finding harm likely where estimated diversions ranged from 12 to 14 percent).
- Here, ordinary course strategic documents shed light on Otto Bock's post-Merger plans and the likely competitive effects of the Merger. (CCFF ¶¶ 1392-1411); *see Polypore*, 150 F.T.C. at 600 ("Evidence that sheds light on the strategic objectives of the merging parties is also probative of likely competitive effects.") (citing *Whole Foods*, 548 F.3d at 1047 (Tatel, J., concurring); Areeda & Hovenkamp, *Antitrust Law* ¶ 964 (3d ed. 2009); *Merger Guidelines* § 2.2.1). These documents unambiguously show that Respondent {

} (CCFF ¶¶ 1394-

1404, 1407-11) (in camera).

- 78. Otto Bock's internal business documents, reveal that Otto Bock viewed the acquisition of Freedom as a way to eliminate a close competitor and increase its already dominant position in the MPK market (CCFF ¶¶ 1353-70, 1381-82), providing further confirmation of the likely unilateral effects that will result from the Merger. *See Polypore*, 150 F.T.C. at 626 (holding that anticompetitive intent is evidence of likely anticompetitive effects). The fact that Otto Bock may have had other non-anticompetitive motivations for the Merger "does not contradict the strong evidence of anticompetitive intent." *Polypore*, 150 F.T.C. at 626.
- 79. The anticompetitive effects of the Merger are evident from the harm that has already occurred since that transaction was consummated. *Polypore*, 150 F.T.C. at 626 (evidence of post-acquisition anticompetitive effects probative of likely

anticompetitive effects). Evidence shows that the Merger provided Otto Bock with the incentive and ability to raise MPK prices and to compete less aggressively with Freedom, and vice versa. (CCFF ¶¶ 1394-95, 1397-98, 1404, 1469-79). Evidence of post-Merger product development delays, (CCFF ¶¶ 1446-68), are also indicative of the likely anticompetitive effects of the Merger. *See Merger Guidelines* § 1.

V. RESPONDENT DID NOT REBUT THE STRONG PRESUMPTION THAT THE MERGER IS ILLEGAL

- 80. Respondent has not produced evidence sufficient to rebut the presumption of harm likely to result from the Merger.
- 81. Respondent bears a heavy burden to rebut the presumption in the instant case given the strength of Complaint Counsel's *prima facie* case. *See, e.g., ProMedica,* 2012 WL 1155392, at *12. "The more compelling the prima facie case'—including other evidence presented by Complaint Counsel that reinforces the structural presumption— 'the more evidence defendant must present to rebut it successfully." *ProMedica,* 2012 WL 1155392 at *25 (quoting *Baker Hughes,* 908 F.2d at 991; *accord Chi. Bridge,* 534 F.3d at 426); *Staples,* 190 F. Supp. 3d at 115.
- 82. While evidence of anticompetitive intent, which is present here, may be probative of the likely effects of the merger, the absence of anticompetitive intent is not a defense to an otherwise anticompetitive merger and cannot rebut a *prima facie* case. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 964a ("evidence of neutral or procompetitive intent cannot be taken to rebut a prima facie case based on market shares"). Indeed, even where there are non-anticompetitive motivations for a merger, that cannot "contradict [] strong evidence of anticompetitive intent." *Polypore*, 150 F.T.C. at 626

A. REMAINING MPK SELLERS WILL NOT PREVENT THE MERGER'S ANTICOMPETITIVE EFFECTS

- 83. Respondent bears the burden to show that "ease of expansion is sufficient 'to fill the competitive void that will result if [it is] permitted to purchase' [its] acquisition target." *H&R Block*, 833 F. Supp. 2d at 73 (quoting *Swedish Match*, 131 F. Supp. 2d at 169); *see also Sysco*, 113 F. Supp. 3d at 80.
- 84. Expansion of existing competitors must be "timely, likely, and sufficient in its magnitude, character, and scope to deter or counteract the competitive effects of concern." *H&R Block*, 833 F. Supp. 2d at 73 (internal quotations omitted); *see also CCC Holdings*, 605 F. Supp. 2d at 47.
- 85. To determine whether the remaining firms would effectively constrain the merged Otto Bock/Freedom, the relevant question is not whether remaining competitors would be able to replace "*some* of the competition provided by [an acquisition target], which [was] vitiated" post-acquisition, but rather whether "such competition will defeat a likely anticompetitive price increase in a post-acquisition . . . market." *See Swedish Match*, 131 F. Supp. 2d at 170 (emphasis added). As the court in *H&R Block* made

clear, harm occurs even if other competitors in the market are present in the marketplace. 833 F. Supp. 2d at 81-89 (blocking the merger even though a competitor with more than 60% share still existed).

- The remaining competitors are unable to "fill the competitive void" left after the 86. Merger in the market for MPKs sold to U.S. clinics. See Swedish Match, 131 F. Supp. 2d at 169. Neither the two next largest MPK suppliers, Össur and Endolite, nor the remaining fringe players, Nabtesco and DAW, could effectively discipline the merged firm's anticompetitive behavior. (CCFF § X). While the remaining firms might conceivably replace "some of the competition" Freedom provided before the merger, because for many clinics those firms' MPKs are unattractive alternatives to the merged firms' MPKs, such competition would be insufficient to defeat post-Merger anticompetitive effects. (CCFF ¶¶ 1493-1527, 1533-47, 1574-1604, 1614-26); see *H&R Block*, 833 F. Supp. 2d at 73-74 (competition from an existing competitor was insufficient because expansion was unlikely to allow it to "compete 'on the same playing field' as the merged company); Chi. Bridge, 138 F.T.C. 1024, *1071 (2004) ("the mere fact that ... fringe firms have an intent to compete does not necessarily mean that those firms are significant competitors capable of replacing lost competition").
- 87. Existing MPK manufacturers are unlikely to expand in a manner that is timely or sufficient to counteract the anticompetitive effects resulting from the transaction. (CCFF § X).

B. NEW ENTRY WILL NOT BE TIMELY, LIKELY, OR SUFFICIENT TO PREVENT THE MERGER'S ANTICOMPETITIVE EFFECTS

- 88. Respondent has "the burden of showing that the entry [] of competitors will be 'timely, likely and sufficient in its magnitude, character, and scope to deter or counteract the competitive effects of concern." *Staples 2016*, 190 F. Supp. 3d at 133 (citation omitted); *see also Sysco*, 113 F. Supp. 3d at 80; *Merger Guidelines* § 9. The higher the barriers to entry, the less likely it is that the "timely, likely, and sufficient" test can be met. *United States v. Visa U.S.A., Inc.*, 163 F. Supp. 2d 322, 342 (S.D.N.Y. 2001).
- 89. "In order to deter the competitive effects of concern, entry must be rapid enough to make unprofitable the overall the actions causing those effects and thus leading to entry, even though those actions would be profitable until entry takes effect." *Merger Guidelines* §9.1. For entry to be considered timely, the "impact of entrants" must be "rapid enough that customers are not significantly harmed by the merger, despite any anticompetitive harm that occurs prior to the entry." *Merger Guidelines* §9.1.
- 90. In addition to being timely, Respondent must show that entry is likely—meaning both technically possible and economically sensible—and that it will replace the competition that existed prior to the merger. *See Cardinal Health*, 12 F. Supp. 2d at 56-57; *Chi. Bridge*, 138 F.T.C. at 1071 (noting new entrants might not replace lost competition).

- 91. To meet their burden that entry is likely, Respondent must "produce evidence sufficient to show that the likelihood of entry 'reaches a threshold ranging from reasonable probability to certainty." *Polypore*, 150 F.T.C. at 632 (quoting *Chi. Bridge*, 534 F.3d at 430 n.10). It is not sufficient merely to identify other firms that might possibly expand. *See H&R Block*, 833 F. Supp. 2d at 73-76.
- 92. "The history of entry in the relevant markets 'is a central factor in assessing the likelihood of entry in the future." *Polypore*, 150 F.T.C. at 633 (quoting *Cardinal Health*, 12 F. Supp. 3d at 56; citing *Merger Guidelines* § 9).
- 93. Even where entry is both timely and likely, it "may not be sufficient to deter or counteract the competitive effects of concern." *Merger Guidelines* §9.3. To prevent harm from the Merger, "the scale [of entry] must be large enough to constrain prices post-acquisition." *Polypore*, 150 F.T.C. at *29 (citing *Chi. Bridge*, 534 F.3d at 429); *see also Cardinal Health*, 12 F. Supp. 2d at 58. Here, a new entrant would need to achieve the size and competitive vigor that Freedom would have achieved absent the Merger. *See Chi. Bridge*, 138 F.T.C. at 1071; *Merger Guidelines* § 9 (entry must be sufficient to "replicate at least the size and strength of one of the merging firms").
- 94. In evaluating sufficiency of entry it is relevant to consider whether "products offered by entrants are [] close enough substitutes to the products offered by the merged firm to render a price increase by the merged firm unprofitable." *Merger Guidelines* § 9.3.
- 95. Respondent failed to demonstrate that entry by any firm would be timely, likely, and sufficient, to counteract the anticompetitive effects resulting from the Merger. (CCFF § XI).

C. RESPONDENT'S ASSERTED EFFICIENCIES DO NOT REBUT THE STRONG PRESUMPTION OF COMPETITIVE HARM

- 96. "High market concentration levels require 'proof of extraordinary efficiencies'" to rebut the presumption of likely anticompetitive effects, and "courts 'generally have found inadequate proof of efficiencies to sustain rebuttal of the government's case." *H&R Block*, 833 F. Supp. 2d at 89 (quoting *Heinz*, 246 F.3d at 720); *Sysco*, 113 F. Supp. at 81-82; *CCC Holdings*, 605 F. Supp. 2d at 72. Indeed, no court has permitted an otherwise unlawful transaction to proceed based on claimed efficiencies. *See Wilhelmsen*, 2018 WL 4705816, at *23 (citing *CCC Holdings*, 605 F. Supp. 2d at 72); *Sysco*, 113 F. Supp. 3d at 82 ("The court is not aware of any case . . . where the merging parties have successfully rebutted the government's *prima facie* case on the strength of the efficiencies.").
- 97. In assessing efficiencies claims, "the court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721; *see also Wilhelmsen*, 2018 WL 4705816, at *23; *H&R Block*, 833 F. Supp. 2d at 89; *CCC Holdings*, 605 F. Supp. 2d at 72–73.

- 98. Respondent bears the heavy burden of establishing that its claimed efficiencies are cognizable, meaning they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Merger Guidelines* § 10; *see also Heinz*, 246 F.3d at 720; *Staples 2016*, 190 F. Supp. 3d at 137-38 n.15; *Sysco*, 113 F. Supp. 3d at 82.
- 99. For claimed efficiencies to be verifiable, it must be "possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency[.]" *H&R Block*, 833
 F. Supp. 2d at 89 (quoting *Merger Guidelines* § 10); *see also Sysco*, 114 F. Supp. 3d at 82. Because "[e]fficiencies are inherently difficult to verify and quantify' . . . 'it is incumbent upon the merging firms to substantiate efficiency claims." *H&R Block*, 833 F. Supp. 2d at 89 (quoting *Merger Guidelines* § 10); *see also Wilhelmsen*, 2018
 WL 4705816, at *23. To meet this high standard, Respondent's "estimate of the predicted saving must be reasonably verifiable by an independent party." *H&R Block*, 833 F. Supp. 2d at 89; *see also Sysco*, 114 F. Supp. 3d at 82.
- 100. To be merger-specific, claimed efficiencies, "must represent a type of cost saving that could not be achieved without the merger." *H&R Block*, 833 F. Supp. 2d at 89; *see also Sysco*, 113 F. Supp. 3d at 82. If a company could achieve its purported cost savings either alone or via a less anticompetitive alternative, such as a licensing agreement or less anticompetitive transaction, then its claimed efficiencies are not merger-specific. *See H&R Block*, 833 F. Supp. 2d at 90; *Cardinal Health*, 12 F. Supp. 2d 34 at 62; *Merger Guidelines* § 10, n.13. "Defendants bear the burden of demonstrating that their claimed efficiencies are merger specific," *Sysco*, 113 F. Supp. 3d at 82 (citing *H&R Block*, 833 F. Supp. 2d at 89).
- 101. Claimed efficiencies, even if verifiable, are not cognizable if they could be achieved without the merger. *See Sysco*, 113 F. Supp. 3d at 84 (holding that, despite the "rigor and scale of the analysis," defendants' efficiencies claims are inadequate because they are not merger specific); *Cardinal Health*, 12 F. Supp. 2d at 62 ("In light of the anti-competitive concerns that mergers raise, efficiencies, no matter how great, should not be considered if they could also be accomplished without a merger."); *Merger Guidelines* § 10.
- 102. To be cognizable, efficiencies claims cannot "arise from anticompetitive reductions in output or service." *Merger Guidelines* §10. see also Penn State Hershey, 838 F.3d at 348-49; *Heinz*, 246 F.3d at 722; *Univ. Health*, 938 F.2d at 1223. Raising price or discontinuing a product, which could result in cost savings for a merged firm, are not cognizable. See Merger Guidelines § 10.
- 103. To launch successful efficiencies defense, in addition to establishing its claims are cognizable, Respondent must show that its claimed efficiencies would benefit customers. See, e.g., FTC v. Penn State Hershey Med. Ctr., 838 F.3d 327, 351 (3d Cir. 2016); FTC v. Univ. Health, Inc., 938 F.2d 1206, 1223 (11th Cir. 1991). Price reductions to customers "are expected when efficiencies reduce the merged firm's marginal costs," but "reductions in fixed costs . . . typically are not expected to lead to

immediate price effects and hence to benefit consumers in the short term." FED. TRADE COMM'N AND U.S. DEP'T OF JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES (2006).

- 104. Respondent failed to establish their efficiencies claims are cognizable because it failed to provide the kind of substantiation needed to allow for independent verification of their claims. See (CCFF § XII.B.1); Merger Guidelines § 10. Even if the requisite verifiability were possible, Respondent's efficiencies claims are not cognizable because much of the alleged savings could be achieved without the merger. See (CCFF § XII.B.2.); Merger Guidelines § 10.
- 105. Respondent's efficiencies defense also fails because there is no evidence its expected cost savings are likely to "benefit competition and, hence, consumers." Univ. Health, 938 F.2d at 1223; see (CCFF § XII.C.); Penn State Hershey, 838 F.3d at 348-49; Heinz, 246 F.3d at 722.

D. RESPONDENT FAILED TO MEET ITS BURDEN TO SHOW THAT FREEDOM IS A FAILING FIRM

- 106. The failing firm defense requires Respondent to meet strict standards. See, e.g., Mich. Citizens for an Indep. Press v. Thornburgh, 868 F.2d 1285, 1288 (D.C. Cir. 1989) (explaining that the Supreme Court has "narrowly confined the scope of the doctrine") (citing Citizen Publ'g Co. v. United States, 394 U.S. 131, 137-38 (1969)); FTC v. Warner Commc'ns, 742 F.2d 1156, 1164 (9th Cir. 1984) (noting that the defense has "strict limits"); United States v. Energy Sols., Inc., 265 F. Supp. 3d 415, 445. Indeed, the "doctrine is 'narrow in scope' and it 'rarely succeeds.'" Energy Sols., Inc., 265 F. Supp. 3d at 444 (internal citations omitted).
- 107. "The burden of proving that the requirements of the [failing company defense] are met is on those who seek refuge under it." *Citizen Publ'g*, 394 U.S. at 133.
- 108. The failing firm defense requires more than a mere showing of financial weakness. *See Warner Commc'ns*, 742 F.2d at 1164 ("a 'weak company' defense would expand the failing company doctrine."). To qualify, "[a] company invoking the defense has the burden of showing that its 'resources [were] so depleted and the prospect of rehabilitation so remote that it faced the grave probability of a business failure' ... and further that it tried and failed to merge with a company other than the acquiring one." *Gen. Dynamics*, 415 U.S. at 507 (quoting *Int'l Shoe Co. v. FTC*, 280 U.S 291, 302 (1930); citing *Citizen Publ'g*, 394 U.S. at 138); *see also Energy Sols.*, 265 F. Supp. 3d at 444.
- 109. Under the *Merger Guidelines*, a successful failing firm defense requires Respondent to prove: (1) the allegedly failing firm would be unable to meet its financial obligations in the near future; (2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act; *and* (3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers that would keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed

merger. *Merger Guidelines* §11. The defense cannot succeed if even one element is not satisfied. *See Merger Guidelines* §11; *Energy Sols.*, 265 F. Supp. 3d at 444-45 (rejecting failing firm defense on basis that defendants failed to show the acquirer was the only available purchaser without considering whether the firm being acquired was at risk of imminent failure).

- 110. To show that a company would be unable "to reorganize successfully under Chapter 11 of the Bankruptcy Act," *Merger Guidelines* § 11, "[t]he prospects of reorganization . . . would have had to be dim or nonexistent." *Citizen Pub. Co.*, 394 U.S. at 138.
- 111. Even where a firm is at risk of imminent failure and could not reorganize through bankruptcy, invocation of the defense requires a showing that the allegedly failing firm made unsuccessful "good-faith efforts to elicit reasonable alternative offers … that would both keep it in the market and pose a less severe danger to competition." *Energy Sols.*, 265 F. Supp. 3d at 445 (quoting *Dr. Pepper/Seven–Up Co. v. FTC*, 991 F.2d 859, 865 (D.C. Cir. 1993)); see also Merger Guidelines § 11.
- 112. "The failing company doctrine plainly cannot be applied in a merger . . . unless it is established that the company that acquires the failing company . . . is the only available purchaser." *Citizen Pub. Co.*, 394 U.S. at 131; *see also U.S. v. Energy Sols.*, *Inc.*, 265 F. Supp. 3d 415, 445 (D. Del. 2017). Having a limited number of firm offers to purchase a company, even in an industry where "there may be few (if any) potential buyers that would not raise some anti-trust concerns," is not in and of itself proof that there were no other possible acquirers for the business. *See Energy Sols.*, 265 F.Supp. 3d at 445 (rejecting failing firm defense where only one firm offer was made when "[t]here was no clear 'for sale' sign until [defendants] announced its transaction").
- 113. When a firm fails to respond to expressions of interest by other firms in its own industry, it cannot be said to have conducted the search for the alternative available purchaser that the failing company defense requires. *FTC v. Harbour Group Investments*, 1990 WL 198819, *5 (D.D.C. 1990).
- 114. In Harbour Group, the court rejected a failing firm defense based on defendants' failure to prove that the acquiring company was the "only available purchaser." 1990 WL 198819, at *2. Defendants asserted that the failing company's creditor "intend[ed] to call in its loan at any moment" while the government argued defendants "produced no evidence directly from the [creditor] that the loan would be called immediately." Harbour Grp., 1990 WL 198819 at *2. Although the court acknowledged the company's "sales [were] down, it [held] considerable debt, and its future [was] uncertain," it could not avail itself of the failing company defense due to an inadequate sales process that did not include outreach to several smaller firms in the industry. Harbour Grp., 1990 WL 198819 at *2. The court rejected defendants' argument that, "it is unreasonable to require it to approach smaller companies in the industry," recognizing that, "at least in some cases, approaching smaller companies in a given industry might be exactly what is required of a company seeking the protection of the failing company defense." Harbour Grp., 1990 WL 198819, at *4.

- 115. A "reasonable alternative offer" is "any offer to purchase the assets of the failing firm for a price above the liquidation value of those assets." *Merger Guidelines* § 11, n. 6; *Energy Sols., Inc.*, 265 F.Supp 3d at 446. The strict limits of the failing firm defense require that a firm show that it searched for such an alternative offer even though an offer at liquidation value is likely to be less than the fair value of the company. *See Energy Sols., Inc.*, 265 F. Supp. 3d at 446.
- 116. Respondent cannot seek protection under the failing firm defense because it failed to demonstrate that, at the time of the Merger, Freedom was unable to meet its financial obligations. *Merger Guidelines* § 11. Improvements to Freedom's financial conditions, (CCFF § XIII.A.3-4), the clean audit of its financial statements by independent auditors, (CCFF § XIII.B.1), and Freedom's own actions in the months leading up to the merger, (CCFF § XIII.B.2), are inconsistent with a company whose "assets would otherwise exit the market." *See Merger Guidelines* § 11.
- 117. Having presented no testimony from either of Freedom's creditors, Respondent failed to establish that Freedom's creditors would have forced it into bankruptcy or liquidation. *See* (CCFF § XIII.B.3.a). To the contrary, the evidence indicates that such actions by the creditors were unlikely. (CCFF § XIII.B.1.a). Thus, Respondent failed to show that Freedom faced "the grave probability of a business failure" because of its outstanding debt. *Gen. Dynamics*, 415 U.S. at 507 (internal quotations omitted); *see also Energy Sols.*, 265 F. Supp. 3d at 444.
- 118. Respondent also failed to produce evidence that Freedom could not successfully reorganize under Chapter 11 of the Bankruptcy Act. (CCFF § XIII.C). As Ms. Hammer concluded, Freedom's seemingly successful reorganization outside of bankruptcy indicated that the company was a good candidate for reorganization in bankruptcy. (CCFF ¶¶ 2064-69, 2071; § XIII.A.2-4).
- 119. Even if Freedom were facing "imminent failure" and could not reorganize through bankruptcy, Respondent cannot immunize its otherwise unlawful transaction because Freedom did not conduct "good-faith efforts to elicit reasonable alternative offers." *See* (CCFF § XIII.D.); *Energy Sols*, 265 F. Supp. 3d at 444-45; *Harbour Group*, 1990 WL 198819 at *2-3. Freedom and its banker made "minimal efforts . . . to contact obvious companies in its own industry that appear to be willing to at least entertain the notion of purchasing" Freedom. *See* (CCFF § XIII.D.2); *Harbour Group*, 1990 WL 198819 at *6. Freedom did not attempt to solicit interest from firms in the lower limb prosthetics industry because they were deemed too small to participate in the process (CCFF § XIII.D.2) and interest from another potential buyer was ignored. (CCFF § XIII.D.2.b.1). Freedom was instead "focused on obtaining what it perceived to be [its] fair value, not an offer above liquidation value." *See* (CCFF § XIII.E.1-2, XIII.D); *Energy Sols.*, F. Supp. 3d at 446.
- 120. Respondent also failed to meet its burden to establish that the alternative offer from Össur, (CCFF § XIII), would have resulted in an acquisition of Freedom that would

pose the same or more a severe danger to competition as the Merger. *See Energy Sols.*, 265 F. Supp. 3d at 445; *Merger Guidelines* § 11.

E. RESPONDENT FAILED TO DEMONSTRATE THAT FREEDOM IS A "FLAILING FIRM"

- 121. "Financial weakness ... is probably the weakest ground of all for justifying a merger" and "certainly cannot be the primary justification." *Kaiser Aluminum & Chem. Corp.* v. FTC, 652 F.2d 1324, 1339, 1341 (7th Cir. 1981); see also Univ. Health, 938 F.2d at 1221; Warner Commc'ns, 742 F.2d at 1164; ProMedica, 2012 WL 1155392, at *25. "[C]ourts have imposed an extremely heavy burden on defendants seeking to rebut the structural presumption on this ground." ProMedica, 2012 WL 1155392, at *25.
- 122. The fact that a company "faced financial obstacles to going forward as an independent" entity is not sufficient to satisfy Respondent's burden. *ProMedica*, 2012 WL 1155392, at *25. To rebut the strong presumption established by Complaint Counsel, Respondent must "'make[] a *substantial showing* that [Freedom's] weakness, which cannot be resolved by any competitive means, would cause [Freedom's] market share to reduce to a level that would undermine the government's prima facie case." *ProMedica*, 2012 WL 1155392, at *25 (quoting *Univ. Health*, 938 F.2d at 1221) (emphasis added).
- 123. In *ProMedica*, the Commission blocked a transaction between two competing hospitals after rejecting Respondents' argument that the acquired hospital's weak financial condition rebutted the presumption of competitive harm. Much like Freedom was here, the acquired firm in *ProMedica*, under the leadership of a new CEO, "was making significant improvements in its performance, and was *growing* prior to the Joinder." 2012 WL 1155392, at *25. Although the acquired company "was struggling financially as a stand-alone entity during the years leading up to the Joinder and faced significant financial obstacles to going forward as an independent" company, the Commission held that it was "not one of those 'rare cases' where . . . financial weakness rebuts the presumption of illegality." 2012 WL 1155392, at *25, *30.
- 124. Rather than rebutting the presumption, there is substantial evidence showing that both Freedom and Otto Bock expected Freedom to *gain* market share with the introduction of the Quattro. *See* (CCFF ¶¶ 1178, 1230-37, 1272, 1275); *ProMedica*, 2012 WL 1155392, at *25, 30 (stating that financial difficulties "are relevant only where they indicate that market shares would decline in the future and by enough to bring the merger below the threshold of presumptive illegality") (internal quotations omitted). Indeed, Freedom's current market share likely understates its future competitive significance. (CCFF ¶¶ 1338-83, 1405-1411); *ProMedica*, 2012 WL 1155392, at *25, 30.
- 125. Even if Freedom's financial weakness were such that its market share was expected to decline, the Court must assess whether Respondent demonstrated "there was no other competitive means by which [Freedom] could have addressed its financial difficulties." *See ProMedica*, WL 1155392, at *30. Given Freedom's inadequate

sales process, (CCFF § XIII.D.2), Respondent cannot meet its burden of showing that such Freedom's weakness "cannot be resolved through ... acquisition by [someone] other than a leading competitor." *ProMedica*, 2012 WL 1155392, at *26 (quoting *Univ. Health*, 938 F.2d at 1221). Although Freedom's outstanding debt certainly raised the specter of uncertainty for the company, this "weakness" could have been resolved through its acquisition by another company. *See* (CCFF ¶¶ 113, 2121-2163, 2166-2193); *ProMedica*, 2012 WL 1155392, at *26.

F. RESPONDENT FAILED TO SHOW THAT HANGER IS A "POWER BUYER" THAT WILL PREVENT POST-MERGER MPK PRICE INCREASES

- 126. "[C]ourts have not yet found that power buyers alone enable a defendant to overcome the government's presumption of anti-competitiveness. . . ." *Chi. Bridge*, 534 F.3d at 440 (quoting *Cardinal Health*, 12 F. Supp. 2d at 58). Indeed, "the economic argument for even *partially* rebutting a presumptive case because a market is dominated by large buyers, is weak." *Chi. Bridge*, 534 F.3d at 440 (citations omitted).
- 127. The mere existence of "powerful buyers" that can "negotiate favorable terms with their suppliers" does not eliminate the possibility of anticompetitive effects. *Merger Guidelines* § 8 ("Even buyers that can negotiate favorable terms may be harmed by an increase in market power."); *see also Polypore*, 150 F.T.C. at 636. The relevant question is "whether the merger will cause such a significant increase in the [merging firms'] bargaining leverage that they will be able to profitably impose" a price increase. *Penn State Hershey*, 838 F.3d at 346. Where a merger "eliminates a supplier whose presence contributed significantly to a buyer's negotiating leverage," the merger is likely to cause competitive harm. *Chi. Bridge*, 534 F.3d at 440; *In re ProMedica Health Sys., Inc.,* Docket No. 9346, Comm'n Op. at 36-37 (finding that "an increase in the hospital provider's bargaining leverage translates to an increase in its reimbursement rates"); *Merger Guidelines* § 8.
- 128. Combining the two largest and closest competitors of MPKs eliminates even the most powerful buyers' ability to "resist [Otto Bock's] pricing demands" post-Merger. *ProMedica*, 2012 WL 1155392 at *45. While large customers like Hanger may have negotiating leverage today, the elimination of Freedom as an independent competitor will enable Otto Bock to extract higher prices than it would have been able to absent the merger. *See ProMedica*, 2012 WL 1155392 at *45 (finding that, even though managed care organizations had leverage of their own in negotiations with hospitals, they would find it harder to resist the merged hospital's price demands post-merger).
- 129. Even if power buyers in a market could "avoid price increases as a result of their size and sophistication, there is no reason to believe that other [] customers would fare as well." *Polypore*, 150 F.T.C. at 637; *Merger Guidelines* § 8 (explaining that "even if some powerful buyers could protect themselves, the Agencies also consider whether market power can be exercised against other buyers"). Where prices are individually negotiated, as is the case here, (CCFF ¶¶ 563-86), "smaller buyers would not be protected by [any] resistance offered by larger, more powerful customers." *Polypore*, 150 F.T.C. at 637-38 (citing *United States v. United Tote, Inc.*, 768 F. Supp. 1064,

1085 (D. Del. 1991) (large customers that could protect themselves would not shelter smaller buyers from increased prices); *Bass Bros.*, 1984 WL 355 at *16 (large buyers could not protect remainder of purchasers)). Thus, whether Hanger has the ability to resist anticompetitive price increases post-Merger is irrelevant to the assessment of whether "smaller buyers," of MPKs, {

}, (CCFF ¶¶ 3109-10) (*in camera*), could resist such price increase. *See Polypore*, 150 F.T.C. at 637-38.

G. RESPONDENT'S { } FAIL TO CURE ITS ANTICOMPETITIVE MERGER

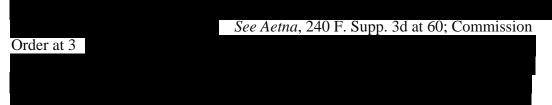
- 1. MATERIALITY OF EVIDENCE RELATED TO RESPONDENT'S PROPOSED
- 130. When presenting evidence of a "planned divestiture" as rebuttal to a *prima facie* case a respondent bears the burden of showing that (1) "the divestiture . . . replace[s] the competitive intensity lost as a result of the merger;" and (2) its proposal is "sufficiently non-speculative for the court to evaluate its effects on future competition." *Aetna*, 240 F. Supp. 3d at 60 (internal quotation marks omitted); *see FTC v. Staples*, 190 F.Supp.3d 100, 137 n.5 (2016).
- 131. Like any aspect of Respondent's rebuttal, the more "compelling the [FTC's] prima facie case, the more evidence the defendant must present [regarding the divestiture] to rebut successfully." *Baker Hughes*, 908 F.2d at 991.

2. PLANNED DIVESTITURE DOES NOT AFFECT LEGALITY OF A CONSUMMATED MERGER

- 132. Courts have been willing to consider the impact of remedial divestitures in assessing whether an unconsummated merger would have an anticompetitive effect. *See, e.g., FTC v. Libbey*, 211 F. Supp. 2d 34, 46 (D.D.C. 2002). In consummated mergers, however, it is not feasible to modify the offending transaction with a planned divestiture of assets because it has already occurred. Instead, the Court must assess the legality of the transaction without regard to any proposed divestiture. A planned divestiture can only "impact . . . the existence or magnitude of likely post-divestiture competitive harms." Opinion and Order of the Commission, *Otto Bock HealthCare North America*, Docket No. 9378 (April 4, 2018) ("Commission Order") at 6.
- 133. A firm's decision to refrain from engaging in anticompetitive behavior does not legalize an otherwise unlawful transaction. *FTC v. Consolidated Foods Corp.*, 380 U.S. 592, 598 (1965) ("the force of § 7 is still in probabilities, not in what later transpired"). Giving such post-acquisition evidence "conclusive weight or allow[ing it] to override all probabilities" would allow "acquisitions [to] go forward willy-nilly, [while] parties bid[e] their time." *Consol. Foods Corp.*, 380 U.S. at 598. As the Supreme Court cautioned, "If a demonstration that no anticompetitive effects had occurred at the time of trial or of judgment constituted a permissible defense to a § 7 divestiture suit, violators could stave off such actions merely by refraining from

aggressive or anticompetitive behavior when such a suit was threatened or pending." *United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 505 (1974). Refraining from price increases in the wake of a transaction, does not preclude a determination that an acquisition violated Section 7. Commission Order at 4 n.3.

- 134. The { The are insufficient to replace the competition between Otto Bock and Freedom lost because of the Merger.
- 135. With a *prima facie* case established, Respondent bears the burden of producing evidence that the proposed divestiture negates the anticompetitive effects of the transaction. U.S. v. Franklin Electric Co. 130 F. Supp. 2d 1025, 1033 (2000); Staples 2016, 190 F. Supp. 3d at 137 n.5 (2016); Aetna, 240 F. Supp. 3d at 60. "[A] defendant may introduce evidence that a proposed divestiture would 'restore [the] competition' lost by the merger counteracting the anticompetitive effects of the merger." Aetna, 240 F. Supp. 3d at 60 (citing Sysco, 113 F. Supp. 3d at 72). The more "compelling the [FTC's] prima facie case, the more evidence the defendant must present [regarding the divestiture] to rebut successfully." Baker Hughes, 908 F.2d at 991.
- 136. Restoring competition is the "key to the whole question of an antitrust remedy." U.S. v. du Pont & Co., 366 U.S. 316, 326 (1961). In all Section 7 cases, "relief . . . must be 'effective to redress the violations." FTC v. Ford Motor Co., 405 U.S. 562, 573 (1972).
 - a) <u>Respondent's { } Are Too Speculative to</u> Evaluate Effects on Future Competition
- 137. Before it is possible to consider whether a proposed divestiture would effectively restore competition, Respondent must "produc[e] evidence that the divestiture will actually occur." *Aetna*, 240 F. Supp. 3d at 60. The divestiture must be "sufficiently non-speculative for the court to evaluate its effects on future competition." *Aetna*, 240 F. Supp. 3d at 60. Indeed, as the court in *Aetna* noted a "defendant cannot produce evidence showing that [a] divestiture would create an effective competitor unless they first produce evidence that the divestiture is likely to occur." *Aetna*, 240 F. Supp. 3d at 60.
- 138. Defendants in both *Aetna* and *Sysco* presented evidence of executed asset purchase *and* transition services agreements.



(CCFF ¶¶ 2271, 2273-76, 2286, 2377-2412, 2440-47, 2729-62, 2821-59) (*in camera*); *see also Aetna* 240 F. Supp. 3d at 60.

- b) <u>Respondent's {</u>} are Insufficient to Restore Competitive Intensity
- 139. To successfully rebut a *prima facie* case, Respondent must demonstrate that "the divestiture [] 'replace[s] the <u>competitive intensity</u> lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72) (emphasis in original); *see also* Antitrust Division Policy Guide to Merger Remedies (October 2004) (hereinafter, "2004 DOJ Merger Remedies Guide"). Replacing "competitive intensity" is not merely an exercise in "returning [the market] to premerger HHI levels. . .[and] attributing to the [divestiture buyer] past sales associated with those assets." *See* 2004 DOJ Merger Remedies Guide.
- 140. In determining whether a proposed divestiture is capable of "replacing the competitive intensity lost as a result of the merger," the Court must consider whether "the divestiture assets [are] substantial enough to enable the purchaser to *maintain the premerger level of competition.*" *Sysco*, 113 F. Supp. 3d at 73 (quoting 2004 DOJ Remedies Guide) (emphasis in original).
- 141. The "natural remedy" for a Section 7 violation is to undo the acquisition by divesting the existing business entity, U.S. v. DuPont, 366 U.S. at 329; see Ford Motor Co., 405 U.S. at 573 (stating that "[c]omplete divestiture is particularly appropriate where . . . acquisitions violate the antitrust laws); RSR Corp. v. FTC, 602 F.2d 1317 (stating that "complete divestiture of all pre-merger assets is the usual remedy for a Section 7 violation"). The Commission has held that "complete divestiture is generally the most appropriate way to restore competition lost through an unlawful acquisition." Polypore, 150 F.T.C. at *33 (citing United States v. E.I. du Pont de Nemours & Co., 366 U.S. 316, 329 (1961); Chi. Bridge, 534 F.3d at 441).
- 142. Divestiture of an ongoing business is more likely to restore competition than a divestiture of selected assets. *See e.g.*, THE FTC's MERGER REMEDIES 2006-2012, A REPORT OF THE BUREAUS OF COMPETITION AND ECONOMICS (January 2017) at 11, 32 (hereinafter FTC Remedy Study) (showing that a divestiture of less than an ongoing business poses enhanced risk and that both acquirer and respondent must be prepared to demonstrate why a more limited asset package is likely to maintain or restore competition). In *Aetna*, the court recognized that "[d]ivestiture of an 'existing business entity' is more likely to 'effectively preserv[e] the competition that would have been lost through the merger,' because it would have the 'personnel, customer lists, information systems, intangible assets, and management infrastructure' necessary to completion." 240 F. Supp. 3d at 60 (citation omitted).
- 143. The court must assess whether a divestiture of discrete assets, as opposed to an "existing business entity," is sufficient to restore the competitive intensity that existed

before the merger. *See, e.g., Aetna*, 240 F. Supp. 3d at 60. It may be necessary to require "divestiture of assets outside the relevant market where divestiture of those assets is necessary to restore competition within the relevant market." *Polypore*, 150 F.T.C. at *33, FTC Remedy Study at 32 ("[A] proposal to divest selected assets as a remedy may need to include, for example, assets relating to complementary products outside of the relevant market[.]"); *Chi. Bridge* 138 F.T.C. at 1163-64 (ordering a divestiture of water tank business to support the cryogenic tanks business of concern to ensure viability).

- 144. A key component of successful divestitures is sufficient "access to employees who understood the relevant products." FTC Remedy Study at 25. Where the asset package is too limited, however, and "employees . . . did not transfer with the selected assets," the divestitures "did not maintain competition." FTC Remedy Study at 23-24. An ongoing business, however, has the personnel necessary for competition. *Aetna*, 240 F. Supp. 3d at 60.
- 145. Representations from divestiture buyers about the sufficiency of divestiture assets to restore competition should not be relied on too heavily because buyers lack sufficient information themselves to make a reliable assessment. *See* Fed'l Trade Comm'n, The Evolving Approach to Merger Remedies, 2000 WL 739461 at *6 (May 1, 2000) ("buyers sometimes—too often, in fact—have a serious informational disadvantage. They may not fully know what assets they need to succeed in the business, or whether the assets offered by respondents are up to the task."); *Chi. Bridge*, 138 F.T.C. at *1162. Much of what the proposed buyers know about the divestiture assets is based upon information and representations from Respondent. (CCFF ¶ 2440-2500) (all four potential buyers have conducted very limited due diligence). However, "common sense tells us that Respondents' self-interests will be best served by creating less rather than more competition from the divested assets." *Chi. Bridge*, 138 F.T.C. at 1162. Here, {

(CCFF ¶¶ 2440-2500) (in

camera).

- 146. As this Court observed, the risk that a proposed divestiture negotiated by Respondent is inadequate is significant because "a seller has the incentive to create a weak competitor with its divestiture package, [and] buyers may lack the necessary information to assess properly the asset package." *Chi. Bridge*, 138 F.T.C. at *1162.
- 147. { (CCFF ¶¶ 1090-91, 2501-23, 2556-57, 2561-62 2639-40, 2645-46) (*in camera*); *see Aetna*, 240 F. Supp. 3d at 60. Respondent failed to demonstrate that { }

c) <u>Entanglements Prevent {</u>} from Being <u>Independent Competitors</u>

- 148. The court must also evaluate whether a divestiture buyer can be "considered a truly independent competitor" when assessing the divestiture's ability to cure competitive harm. *See CCC Holdings*, 605 F. Supp. 2d at 59 ("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"") (citations omitted) (emphasis in original).
- 149. The court in *Aetna* recognized that ongoing entanglements between the seller and buyer of divested assets "leave[] the buyer susceptible to the seller's actions—which are not aligned with ensuring that the buyer is an effective competitor. 240 F. Supp. 3d at 60, 71 (citations omitted); *see also Sysco*, 113 F. Supp. 3d at 77. Here, regardless of the identity of the divestiture buyer, the proposed divestiture would require ongoing contractual entanglements between competitors. (CCFF ¶ 2309-11, 2404-06). For example,

} ((CCFF ¶¶ 2405-12) (in camera)).

- d) <u>Respondent Failed to Show that a Divestiture to {</u>} <u>Would</u> <u>Not Create Harm in the U.S. MPK Market</u>
- **150.** The purpose of a divestiture "is to restore competition lost through the unlawful acquisition," not to create a new competitive problem. *Polypore*, 150 F.T.C. at *33 (citing *Evanston Northwestern*, Comm'n Op. on Remedy at 3 (Apr. 28, 2008); *Ford Motor Co. v. United States*, 405 U.S. 562, 573 (1972)). {
- 151. } United States v. Bazaarvoice, Inc., 2014 U.S. Dist. LEXIS 3284, 238 (N.D. Cal. 2014) (quoting

Bazaarvoice, Inc., 2014 U.S. Dist. LEXIS 3284, 238 (N.D. Cal. 2014) (quoting *Merger Guidelines* at §5.3)); *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 124 (D.D.C. 2004).

VI. REMEDY

- 152. Divestiture of Freedom's ongoing business is the necessary and appropriate remedy to "restore competition to the state in which it existed prior to, and would have continued to exist but for, the illegal merger." *In re B.F. Goodrich Co.*, 110 F.T.C. 207 at 345 (1988) (quoting *In re RSR Corp.*, 88 F.T.C. 800, 893 (1976)).
- 153. "[U]ndoing of the acquisition" is the "natural remedy" to cure the anticompetitive harms of an unlawful acquisition. *U.S. v. DuPont*, 366 U.S. at 329; *see Ford Motor Co.*, 405 U.S. at 573 (stating that "[c]omplete divestiture is particularly appropriate

where . . . acquisitions violate the antitrust laws); *RSR Corp. v. FTC*, 602 F.2d 1317 (stating that "complete divestiture of all pre-merger assets is the usual remedy for a Section 7 violation").

- 154. Where, as here, the government has established a strong case of liability "all doubts as to the remedy are to be resolved in its favor." *E.I. du Pont*, 366 U.S. at 334; *see also Polypore*, 150 F.T.C. at 639. "The manner and scope of divestiture are subject to the Commission's broad discretion. *ProMedica*, 2012 WL 1155392 at *48 (citing *Jacob Siegal Co. v. FTC*, 327 U.S. 608, 611-13 (1946); *Chi. Bridge*, 534 F.3d at 440-42). In exercising its discretion, the Commission may select a remedy that bears a "reasonable relation to the unlawful practice found to exist." *Jacob Siegal Co.*, 327 U.S. at 611-13.
- 155. Both this Court and the Supreme Court have declared complete divestiture as "the usual and proper remedy where a violation of Section 7 has been found." *Polypore*, WL9434806 at *256 (citing *E. I. du Pont*, 366 U.S. at 329; *Ford Motor Co. v. United States*, 405 U.S. 562, 573 (1972)).
- 156. "Complete divestiture is generally the most appropriate way to restore competition lost through an unlawful acquisition." *Polypore*, 150 F.T.C. at 639 (citing *E. I. du Pont*, 366 U.S. at 329; *Chi. Bridge*, 534 F.3d at 441). Indeed, as this Court recognized, "complete divestiture is the appropriate remedy to most effectively 'pry open to competition [the] market[s] that [have been closed by [Respondent's] illegal restraints." *Polypore*, 2010 WL9434806 at *256 (quoting *E. I. du Pont*, 366 U.S. at 323).
- 157. The Commission "may order divestiture of assets outside the relevant market where divestiture of those assets is necessary to restore competition within the relevant market." *Polypore*, 150 F.T.C. at 639 (citing *Chi. Bridge*, 138 F.T.C. at 1163-64); *see also* FTC Remedy Study at 32 ("[A] proposal to divest selected assets as a remedy may need to include, for example, assets relating to complementary products outside of the relevant market.]").
- 158. Divestiture of an entire ongoing business is "simple, relatively easy to administer, and sure. It should always be in the forefront of a court's mind when a violation of § 7 has been found." *E.I. du Pont*, 366 U.S. at 330-31. Divestiture of an ongoing business entity has the highest likelihood of restoring competition to premerger levels. *See* FTC Remedy Study at 5 ("all remedies involving divestitures of assets comprising ongoing businesses succeeded, confirming that such divestitures are most likely to maintain or restore competition.").
- 159. Divestiture of Freedom's ongoing business is the necessary and appropriate remedy to "restore competition to the state in which it existed prior to, and would have continued to exist but for, the illegal merger." *In re B.F. Goodrich Co.*, 110 F.T.C. 207 at 345 (1988) (quoting *In re RSR Corp.*, 88 F.T.C. 800, 893 (1976)). The limited divestiture of assets proposed by Respondent fails to restore competition because it would deprive the buyer of critical assets, rights, and personnel necessary to match the competitive

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vigor of the pre-acquisition Freedom in the MPK market. *See Sysco*, 113 F. Supp. 3d at 73; FTC Remedy Study at 23.

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COMPLAINT COUNSEL'S EXHIBIT INDEX

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2018, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark Secretary Federal Trade Commission 600 Pennsylvania Ave., NW, Rm. H-113 Washington, DC 20580 <u>ElectronicFilings@ftc.gov</u>

The Honorable D. Michael Chappell Administrative Law Judge Federal Trade Commission 600 Pennsylvania Ave., NW, Rm. H-110 Washington, DC 20580

I also certify that I delivered via electronic mail a copy of the foregoing document

to:

Edward G. Biester III Sean P. McConnell Wayne A. Mack Erica Fruiterman Sarah Kulik William Shotzbarger Duane Morris LLP 30 South 17th Street Philadelphia, PA 19103 egbiester@duanemorris.com spmcconnell@duanemorris.com WAMack@duanemorris.com efruiterman@duanemorris.com sckulik@duanemorris.com

Counsel for Respondent Otto Bock Healthcare North America, Inc.

Dated: November 20, 2018

By: <u>/s/ Daniel Zach</u> Daniel Zach

Counsel Supporting the Complaint

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

November 20, 2018

By: <u>/s/ Daniel Zach</u>