

**PUBLIC VERSION**

**UNITED STATES INTERNATIONAL TRADE COMMISSION  
WASHINGTON, D.C.**

IN THE MATTER OF

CERTAIN LAPAROSCOPIC SURGICAL  
STAPLERS, RELOAD CARTRIDGES, AND  
COMPONENTS THEREOF

Investigation No. 337-TA-\_\_\_\_

**COMPLAINT UNDER SECTION 337 OF THE  
TARIFF ACT OF 1930, AS AMENDED**

**COMPLAINANT:**

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### I. INTRODUCTION

1. Complainants Ethicon LLC, Ethicon Endo-Surgery, Inc., and Ethicon US, LLC (collectively, “Ethicon”), part of the Johnson & Johnson family of companies, request that the United States International Trade Commission institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, to remedy the unlawful importation into the United States, sale for importation into the United States, and/or sale within the United States after importation by the owner, importer, or consignee (or agents thereof), of certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe Ethicon’s valid and enforceable U.S. Patent No. 9,844,379 (“the ’379 patent”), U.S. Patent No. 9,844,369 (“the ’369 Patent”), U.S. Patent No. 7,490,749 (“the ’749 Patent”), U.S. Patent No. 8,479,969 (“the ’969 Patent”), and U.S. Patent No. 9,113,874 (“the ’874 Patent”) (collectively “Asserted Patents”).

2. Proposed Respondents Intuitive Surgical, Inc., Intuitive Surgical Operations, Inc., Intuitive Surgical Holdings, LLC, and Intuitive Surgical S. De R.L. De C.V. (collectively “Intuitive” or “Respondents”) have engaged in unfair acts in violation of Section 337 through and in connection with the unlicensed importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe, literally or under the doctrine of equivalents, the claims (“Asserted Claims”) of the Asserted Patents identified in the following table:

Patent	Independent Claims	Dependent Claims
’379 Patent	1, 2, 3	n/a
’369 Patent	22	23
’749 Patent	1	n/a
’969 Patent	24	n/a
’874 Patent	19	n/a



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3. Laparoscopic surgery, also referred to as minimally invasive surgery is an alternative to open surgery. Instead of one large incision, laparoscopic surgery involves several smaller incisions. A small camera is inserted through one of the incisions, and the surgical site is displayed on a monitor. Devices called trocars are inserted through the other incisions, and surgical tools are inserted through the trocars. The smaller incisions in laparoscopic surgery offer the potential benefits of reduced recovery time and pain.

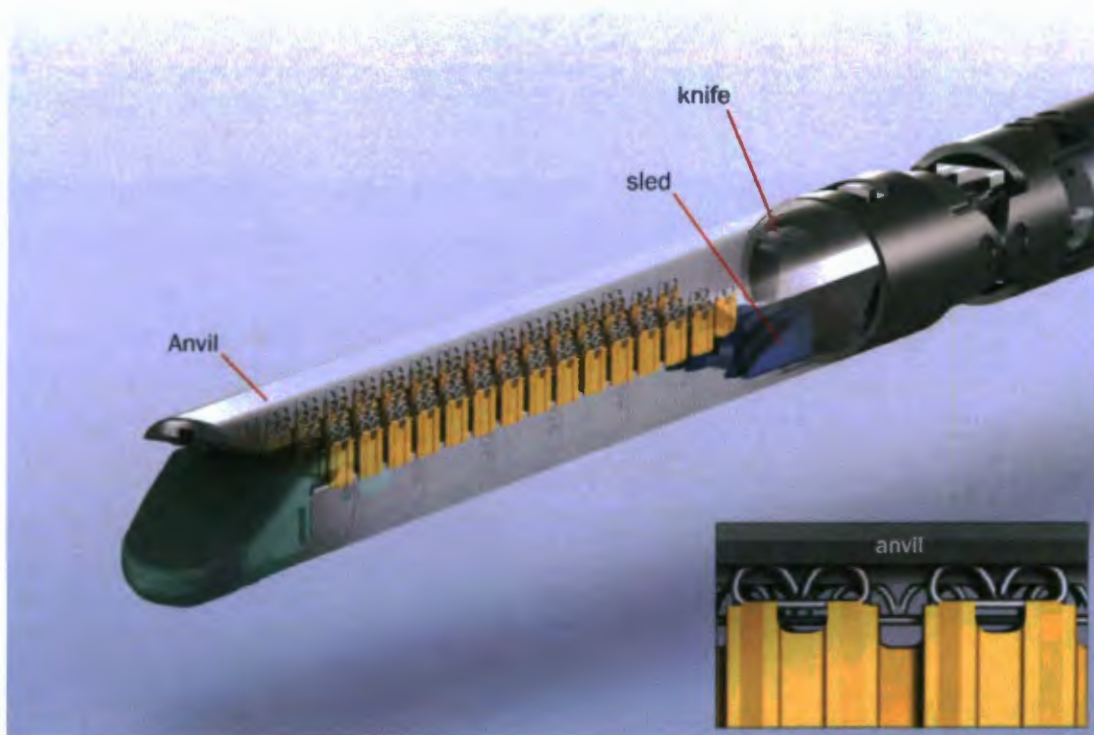
4. Ethicon designs, makes, and sells a variety of laparoscopic surgical stapling instruments, including endocutters (which can also be referred to as surgical staplers). An endocutter is an instrument that both cuts and staples tissue. An endocutter can be used in place of traditional scalpel-and-suture techniques, and is therefore useful in a wide variety of surgical procedures, including thoracic, bariatric, and colorectal surgeries. Ethicon's endocutter products include both powered and non-powered endocutters. In addition, Ethicon offers endocutter products that produce staple lines of different lengths. Ethicon's ECHELON FLEX™ Powered and Powered Plus Staplers include models that produce a 45mm or 60mm stapler line. The figure below illustrates an Ethicon motor-powered endocutter.



Exhibit 1C at p. 12 (annotations in red)

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5. The basic operation of an endocutter is as follows. Prior to use, a stapler reload cartridge is inserted into a channel in one of the stapler jaws. The surgeon then positions the jaws and clamps them around tissue. The endocutter can then be fired, which involves a sled and knife advancing forward in the cartridge toward the end of the jaws. The knife cuts the tissue, and the sled pushes staples upwardly on both sides of the knife into the opposite jaw, referred to as the anvil. When the staples strike the anvil, the staples are bent inwardly to form a staple around the tissue. In this way, tissue on both sides of the cut line is stapled.



6. Ethicon is a market leader in developing endocutter technology. Ethicon introduced its first endocutter in 1996. In 2011, Ethicon introduced to the market its first motor-powered endocutter—the ECHELON FLEX™ Powered Stapler. Ethicon's motor-powered endocutters dramatically reduce the force required to operate an endocutter, thereby minimizing unwanted movement of the device during procedures that could result in increased tissue trauma.

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In 2014, Ethicon introduced its ECHELON FLEX™ Powered Plus Stapler with Gripping Surface Technology (GST) stapler reload cartridges, which greatly reduce tissue slippage while firing the stapler. In 2015, Ethicon's parent corporation, Johnson & Johnson, partnered with Verily Life Sciences LLC (formerly Google Life Sciences) to form Verb Surgical Inc. ("Verb"). Verb is developing a surgical platform for release in the United States. Ethicon is in the process of developing laparoscopic instruments for use with Verb's surgical platform. Ethicon has invested considerable resources in developing [REDACTED]

[REDACTED]

[REDACTED]

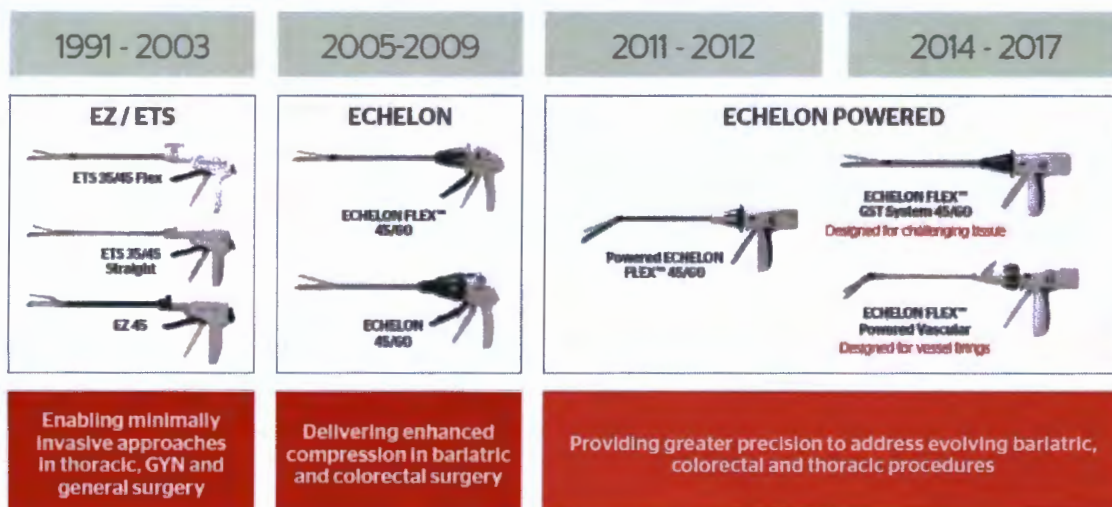


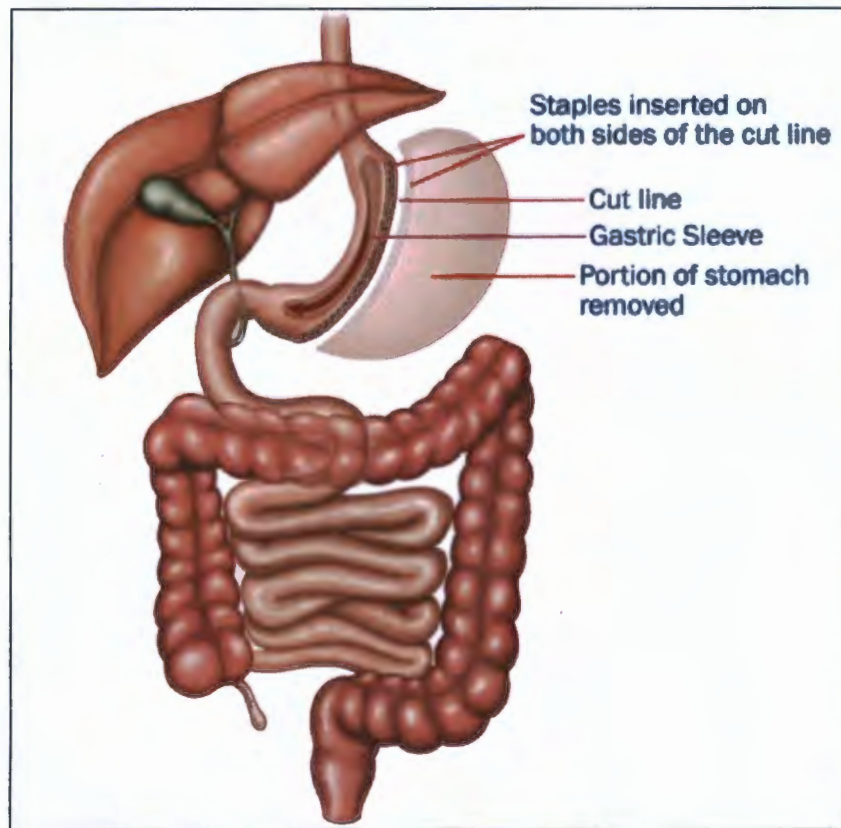
Exhibit 1C at p. 16

7. A 60mm endocutter is a surgeon's preferred length for bariatric surgery. The primary reason that a 60mm endocutter is preferred is because bariatric procedures involve relatively long cut and staple lines compared to other types of surgeries. This is particularly true for the sleeve gastrectomy (illustrated below), which is a popular bariatric procedure in the United States. Using a 60mm endocutter during a bariatric procedure results in fewer firings compared to a shorter endocutter. The length of the 60mm stapler and the thicker tissue involved



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in a bariatric procedure present unique engineering issues. For example, separation of the jaws at their distal end after clamping can be problematic with the longer length stapler, particularly in thicker tissue. Improper spacing of the jaws during firing can lead to malformed staples because the staples may not strike the anvil properly. This can result in tissue that has been cut but not properly sealed, particularly at the distal end of the stapler jaws.



8. Ethicon's 60mm endocutter products are the market leader for use in bariatric surgeries. Due in large part to Ethicon's extensive investments in endocutters and other laparoscopic tools, bariatric procedures have gone from being performed laparoscopically in only 14% of cases as of 2002 to being performed laparoscopically in 98% (or more) of cases today. Ethicon has been a leader in developing the science and tools for ensuring that bariatric

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procedures are safe and have the highest level of clinical value. These investments were made to build the market for Ethicon's 60mm endocutter and its companion tools.

9. Intuitive sells the *da Vinci* robotic surgery systems for use in a variety of surgical procedures. These systems include a surgeon console and a patient cart. The surgeon sits at the console and operates instruments that are mounted onto the patient cart. The primary benefit of Intuitive's robotic surgery systems is converting open procedures to minimally invasive procedures. This particular benefit does not apply to bariatric procedures because, due to Ethicon's investments, the vast majority of bariatric procedures (98% or more) are already performed laparoscopically.

10. Intuitive has been offering their robotic systems since 2000, but did not offer an endocutter that could be attached to its robotic system until 2013. Intuitive introduced its first endocutter, a 45mm endocutter for the *da Vinci Si*<sup>1</sup> robotic system in 2013, and subsequently introduced 45mm and 30mm endocutters for the *da Vinci X/Xi* robotic system in 2014 and 2016, respectively. Intuitive's 45mm and 30mm endocutters for the *da Vinci X/Xi* robotic system infringe at least the '874 Patent and '969 Patent asserted in this case.

11. In the second half of 2018, Intuitive began selling its first 60mm endocutter in order to compete in the bariatric market. Intuitive's 60mm endocutter utilizes a different architecture than its earlier Xi 45/30mm endocutters. In particular, Intuitive pursued a design that employed an I-beam architecture, which is not used in its earlier, shorter endocutters. Given that Ethicon's 60mm endocutter products utilize at least the '379 Patent, '369 Patent, and '749

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<sup>1</sup> Upon information and belief, Intuitive has stated to customers that it is going to discontinue its endocutter instrument for the *da Vinci Si* in 2020.

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Patent asserted in this case, Intuitive knew or should have known that its design would infringe Ethicon patents. Nonetheless, Intuitive pursued this design and launched its 60mm endocutter.

12. Ethicon seeks as relief a permanent limited exclusion order barring from entry into the United States certain laparoscopic surgical staplers, reload cartridges, and components thereof manufactured by or on behalf of Intuitive that infringe one or more of the Asserted Claims of the Asserted Patents. Ethicon also seeks as relief permanent cease and desist orders prohibiting the importation, sale, offer for sale, advertising, marketing, distributing, or the solicitation of any sale by each Respondent of certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more of the Asserted Claims of the Asserted Patents. Ethicon also requests the imposition of a bond upon any importations or sales of infringing laparoscopic surgical staplers, reload cartridges, and components thereof during the 60-day period for Presidential review, pursuant to 19 U.S.C. § 1337(j).

## **II. COMPLAINANTS**

13. Complainant Ethicon LLC (f/d/b as Ethicon Endo-Surgery, LLC) is a limited liability corporation organized under the laws of the State of Delaware, having its headquarters and principal place of business at 475 Street C, Los Frailes, Industrial Park, Guaynabo, PR 00969. Ethicon LLC is the owner by assignment of the entire right, title and interest in the Asserted Patents. Ethicon LLC has exclusively licensed Ethicon Endo-Surgery, Inc. to sell products in the United States that would infringe the Asserted Patents absent a license. Ethicon Endo-Surgery, Inc. has exclusively sublicensed that right to Ethicon US, LLC. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Employees in Ethicon LLC's Puerto Rico facilities engage in demand planning for endocutters.

14. Complainant Ethicon Endo-Surgery, Inc. is a corporation organized under the laws of the State of Ohio having its headquarters and principal place of business at 4545 Creek Road, Cincinnati, OH 45242. Ethicon Endo-Surgery, Inc. engages in research and development, manufacturing, sterilization, training, and marketing activities in its United States facilities concerning endocutters, reload cartridges, and components thereof as well as other surgical devices.

15. Complainant Ethicon US, LLC is a limited liability corporation organized under the laws of the State of Texas having its headquarters and principal place of business at 4545 Creek Road, Cincinnati, OH 45242. Ethicon US, LLC is a wholly-owned subsidiary of Ethicon Endo-Surgery, Inc. Ethicon US, LLC engages in marketing and sales of endocutters, reload cartridges, and components thereof as well as other surgical devices in the United States.

### **III. PROPOSED RESPONDENTS**

#### **A. Intuitive Surgical, Inc.**

16. Respondent Intuitive Surgical, Inc. is a corporation organized under the laws of the State of Delaware, having its headquarters and a principal place of business at 1020 Kifer Road, Building 101, Sunnyvale, CA 94086. Upon information and belief, Intuitive Surgical, Inc. designs, manufactures, imports into the United States, sells for importation in the United States, and/or sells after importation in the United States laparoscopic surgical staplers, reload cartridges, and components thereof that infringe the Asserted Patents.

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### **B. Intuitive Surgical Operations, Inc.**

17. Respondent Intuitive Surgical Operations, Inc. is a privately-held corporation that is a wholly-owned subsidiary of Intuitive Surgical, Inc., and is organized under the laws of the State of Delaware, with its principal place of business at 1020 Kifer Road, Sunnyvale, CA 94086. Upon information and belief, Intuitive Surgical Operations, Inc. designs, manufactures, imports into the United States, sells for importation in the United States, and/or sells after importation in the United States laparoscopic surgical staplers, reload cartridges, and components thereof that infringe the Asserted Patents.

### **C. Intuitive Surgical Holdings, LLC**

18. Respondent Intuitive Surgical Holdings, LLC is a privately-held limited liability corporation that is a wholly-owned subsidiary of Intuitive Surgical, Inc., and is organized under the laws of the State of Delaware, with its principal place of business at 1020 Kifer Road, Sunnyvale, CA 94086. Upon information and belief, Intuitive Surgical Holdings, LLC designs, manufactures, imports into the United States, sells for importation in the United States, and/or sells after importation in the United States laparoscopic surgical staplers, reload cartridges, and components thereof that infringe the Asserted Patents.

### **D. Intuitive Surgical S. De R.L. De C.V.**

19. Upon information and belief, Respondent Intuitive Surgical S. De R.L. De C.V. is a privately-held corporation that is a wholly-owned subsidiary of Intuitive Surgical, Inc., and is organized under the laws of Mexico, with its principal place of business at Circuito Internacional Sur #21-A Parque Industrial Nelson, Carretera A San Luis R.c., Km 14 Mexicali Baja California, Mexico 21397. Upon information and belief, Intuitive Surgical S. De R.L. De C.V. designs, manufactures, imports into the United States, sells for importation in the United States, and/or



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sells after importation in the United States laparoscopic surgical staplers, reload cartridges, and components thereof that infringe the Asserted Patents.

### **IV. THE PRODUCTS AT ISSUE**

20. The Accused Products are laparoscopic surgical staplers, associated reload cartridges, and components thereof imported into the United States, sold for importation into the United States, and/or sold within the United States after importation by or on behalf of Respondents that infringe the Asserted Claims of the Asserted Patents. The accused laparoscopic surgical staplers and associated reload cartridges are surgical instruments used in laparoscopic surgical procedures to both cut and staple tissue.

21. Exemplary laparoscopic surgical staplers and associated reload cartridges that infringe the Asserted Claims of the Asserted Patents include (1) the SureForm 60mm and 45mm Stapler and associated White, Blue, Green and Black Reloads; (2) the EndoWrist Xi 45 Stapler and associated White, Blue and Green Reloads; (3) the EndoWrist Xi 30 Staplers and associated Gray, White, Blue, and Green Reloads. Ex. 4; Ex. 41.

22. The SureForm 60 and SureForm 60 Reloads were approved for marketing by the FDA in July 2018. Ex. 5. Upon information and belief, the SureForm 60 and/or SureForm 60 Reloads have been imported into the United States, sold for importation into the United States, and/or sold within the United States after importation, by or on behalf of Intuitive. In addition, the SureForm 45 and SureForm 45 Reloads were approved for marketing by the FDA in January 2019 and the system “is the same as the predicate SureForm 60 from a design perspective with the exception of the staple line length itself.” Ex. 6 at 4.

23. The EndoWrist Xi 30 and 45 Staplers and Stapler Reloads were approved for marketing by the FDA in March 2016 and July 2014, respectively. The EndoWrist Xi 30 and 45

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Staplers and/or Stapler Reloads have been imported into the United States, sold for importation into the United States and/or sold within the United States after importation, by or on behalf of Intuitive. Ex. 41; Ex. 42.

24. The products identified herein are merely illustrative of the type of infringing products that Intuitive manufactures and imports into the United States, sells for importation into the United States, and/or sells within the United States after importation in violation of Section 337. Ethicon's identification of specific models is not intended, either implicitly or explicitly, to limit the scope of the investigation or the scope of relief to which Ethicon is entitled.

### **V. THE PATENTS AT ISSUE**

#### **A. U.S. Patent No. 9,844,379**

##### **i. Identification of the Patent and Ownership by Complainant**

25. Ethicon LLC owns by assignment the entire right, title, and interest in the '379 Patent entitled "Surgical Stapling Instrument Having a Clearanced Opening," which issued on December 19, 2017. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '379 Patent is attached as Exhibit 7.

26. The '379 Patent issued from United States Patent Application No. 15/064,075, which was filed on March 8, 2016, and names Frederick E. Shelton IV, Michael E. Setser, and William B. Weisenburgh II as inventors. The '379 Patent expires on June 1, 2025. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the record assignments of the '379 Patent are attached as Exhibit 8.

27. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '379 Patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices A and B, respectively.

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### **ii. Non-Technical Description of the '379 Patent**

28. The '379 Patent generally concerns a surgical stapling device that is configured such that a firing member cannot be advanced when a staple cartridge is not attached to the device. The stapling device includes a pair of jaws, with one of the jaws rotatable relative to the other jaw. The detachable cartridge contains staples, and the device includes an anvil that is configured to deform the staples when ejected from the cartridge. The device also includes a firing member with first and second cams that engage each of the jaws, respectively, and a lockout configured to block advancement of the firing member when a detachable cartridge is not attached to the stapling assembly. If a clinician were able to fire the device without a staple cartridge present in the device, the firing member could sever clamped tissue without stapling the tissue. This would be catastrophic for the patient due to the leakage of blood or other fluids from the severed (and unstapled) tissue.

### **iii. Foreign Counterparts to the '379 Patent**

29. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 9 identifies each foreign patent, each foreign patent application (not already issued as a patent) and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '379 Patent with an indication of the prosecution status of each such patent application.

## **B. U.S. Patent No. 9,844,369**

### **i. Identification of the Patent and Ownership by Complainant**

30. Ethicon LLC owns by assignment the entire right, title, and interest in the '369 Patent entitled "Surgical End Effectors with Firing Element Monitoring Arrangements," which issued on December 19, 2017. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '369 Patent is attached as Exhibit 10.

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31. The '369 Patent issued from United States Patent Application No. 14/319,004, which was filed on June 30, 2014, and names Thomas W. Huitema, Charles J. Scheib, Cortney E. Henderson, Frederick E. Shelton IV, and Jason L. Harris as inventors. The '369 Patent expires on October 20, 2035. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the record assignments of the '369 Patent are attached as Exhibit 11.

32. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '369 Patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices C and D, respectively.

### **ii. Non-Technical Description of the '369 Patent**

33. The '369 Patent generally concerns a surgical stapling device comprising a firing element having a vertical portion and a laterally extending foot (*e.g.*, an E-beam) and a closed channel configuration. The stapling device includes an end effector having a channel that supports a staple cartridge. The channel includes an internal passageway that is sized to accommodate a laterally extending foot of the firing element, and a proximal channel opening that affords the clinician a view of the foot of the firing element during use. This closed channel configuration provides for a stiffer elongate channel, which can reduce twisting and spreading, while also providing the clinician the benefit of viewing the firing element during use.

### **iii. Foreign Counterparts to the '369 Patent**

34. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 12 identifies each foreign patent, each foreign patent application (not already issued as a patent) and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '369 Patent with an indication of the prosecution status of each such patent application.

**C. U.S. Patent No. 7,490,749**

**i. Identification of the Patent and Ownership by Complainant**

35. Ethicon LLC owns by assignment the entire right, title, and interest in the '749 Patent entitled "Surgical Stapling and Cutting Instrument with Manually Retractable Firing Member," which issued on February 17, 2009. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '749 Patent is attached as Exhibit 13.

36. The '749 Patent issued from United States Patent Application No. 11/729,355, which was filed on March 28, 2007, and names Christopher J. Schall and Chad P. Boudreaux as inventors. The '749 Patent expires on August 17, 2026. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the record assignments of the '749 Patent are attached as Exhibit 14.

37. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '749 Patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices E and F, respectively.

**ii. Non-Technical Description of the '749 Patent**

38. The '749 Patent generally concerns a surgical stapling device comprising a firing element that moves from a retracted position to a fired position in response to a longitudinal firing motion that is generated by a firing drive. The stapling device also includes a retraction assembly that interfaces with the firing drive and allows the clinician to manually retract the firing member. In contrast to retraction mechanisms that incorporate a spring that exerts a relatively high force to retract a firing member, the retraction assembly described in the '749 Patent enables a surgeon to manually retract the firing member without assistance from springs or other force generating members.

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### iii. Foreign Counterparts to the '749 Patent

39. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 15 identifies each foreign patent, each foreign patent application (not already issued as a patent) and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '749 Patent with an indication of the prosecution status of each such patent application.

### D. U.S. Patent No. 8,479,969

#### i. Identification of the Patent and Ownership by Complainant

40. Ethicon LLC owns by assignment the entire right, title, and interest in the '969 Patent entitled "Drive Interface for Operably Coupling a Manipulatable Surgical Tool to a Robot," which issued on July 9, 2013. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '969 Patent is attached as Exhibit 16.

41. The '969 Patent issued from United States Patent Application No. 13/369,609, which was filed on February 9, 2012, and names Frederick E. Shelton IV as an inventor. The '969 Patent expires on January 10, 2027. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the record assignments of the '969 Patent are attached as Exhibit 17.

42. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '969 Patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices G and H, respectively.

#### ii. Non-Technical Description of the '969 Patent

43. The '969 Patent generally concerns a drive interface for coupling an articulating surgical tool to a robotic system. The tool includes an end effector with a component such as a jaw or a cutting instrument that is selectively movable in relation to another component of the end effector. The end effector is operably coupled to a tool mounting portion via an elongate shaft assembly, the elongate shaft assembly including an articulation joint to facilitate

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articulation about an axis of the shaft. The tool mounting portion can be coupled to a tool drive assembly of a robotic system in order to receive rotary output motions from the tool drive assembly. The tool mounting portion further includes a transmission assembly that is operably engaged with the tool drive assembly and is in meshing engagement with a gear drive to apply motions to the end effector such as clamping or firing. The articulating robotic endocutter of the '969 Patent improves upon prior robotic tools that were not capable of providing sufficient force to clamp or fire an endocutter.

### **iii. Foreign Counterparts to the '969 Patent**

44. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 18 identifies each foreign patent, each foreign patent application (not already issued as a patent) and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '969 Patent with an indication of the prosecution status of each such patent application.

### **E. U.S. Patent No. 9,113,874**

#### **i. Identification of the Patent and Ownership by Complainant**

45. Ethicon LLC owns by assignment the entire right, title, and interest in the '874 Patent entitled "Surgical Instrument System," which issued on August 25, 2015. Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '874 Patent is attached as Exhibit 34.

46. The '874 Patent issued from United States Patent Application No. 14/312,808, which was filed on June 24, 2014, and names Frederick E. Shelton IV, James R. Giordano and Jeffrey S. Swayze as inventors. The '874 Patent expires on January 31, 2026. Pursuant to Commission Rule 210.12(a)(9)(ii), certified copies of the record assignments of the '874 Patent are attached as Exhibit 35.

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47. Pursuant to Commission Rule 210.12(c), a certified copy of the prosecution history of the '874 Patent, as well as each patent and applicable pages of each technical reference mentioned in the prosecution history, are attached as Appendices I and J, respectively.

### ii. Non-Technical Description of the '874 Patent

48. The '874 Patent generally concerns a motor-powered surgical stapling system. The end effector of the stapling system includes an anvil and a cartridge holding staples that are ejected out of the cartridge by distal movement of the firing element. Additional features of the stapling instrument can include an articulation joint for positioning the end effector at an angle in relation to the shaft, and a sensor in the end effector to detect, for example, the presence of a cartridge in the end effector or whether the cartridge has already been fired or spent. The system can also include a remote-user controllable actuation console that is coupled to the motor.

### iii. Foreign Counterparts to the '874 Patent

49. Pursuant to Commission Rule 210.12(a)(9)(v), Exhibit 36 identifies each foreign patent, each foreign patent application (not already issued as a patent) and each foreign patent application that has been denied, abandoned or withdrawn corresponding to the '874 Patent with an indication of the prosecution status of each such patent application.

### F. Licensees Under the Asserted Patents

50. Ethicon LLC has exclusively licensed the Asserted Patents to Ethicon Endo-Surgery Inc., which in turn has exclusively sub-licensed the Asserted Patents to Ethicon US, LLC. Conf. Ex. 19; Conf. Ex. 20.

51. There are no other licensees under the Asserted Patents.

## VI. SPECIFIC INSTANCES OF UNLAWFUL IMPORTATION AND SALE

52. The specific instances of importation of infringing Accused Products or components thereof set forth below are representative examples of Respondents' unlawful



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importation into the United States, sale for importation into the United States, and/or sale within the United States after importation of infringing products.

### A. SureForm Staplers and Reloads

53. Upon information and belief, Respondents collectively manufacture outside of the United States, import, and sell after importation into the United States laparoscopic surgical staplers, reload cartridges, and/or components thereof under certain trade names including SureForm 60 and SureForm 60 Reload, and SureForm 45 and SureForm 45 Reload. The SureForm 60 and SureForm 60 Reloads, and SureForm 45 and SureForm 45 Reloads required FDA approval before they could be marketed in the United States. Ex. 5; Ex. 6. In the applications for FDA approval of the SureForm 60 and SureForm 60 Reloads, and SureForm 45 and SureForm 45 Reloads, Respondents represented that Intuitive Surgical S. de R.L. de C.V., located in Mexico, is a manufacturer of the SureForm 60 and SureForm 60 Reloads, and SureForm 45 and SureForm 45 Reloads. Ex. 21. Intuitive's 2018 SEC 10-K filing also notes that "[w]e manufacture our instruments at our Sunnyvale and Mexicali, Mexico facilities." Ex. 3 at 10; *see also id.* at 32 ("We have a wholly owned manufacturing facility located in Mexicali, Mexico which manufactures reusable and disposable surgical instruments. This facility is registered with the FDA as well as Mexican authorities. The facility is operated under U.S. and international quality system regulations...").

54. Consistent with the FDA records and Intuitive's 10-K filing, export records from Mexico indicate that SureForm 60 Reloads and components thereof have been exported from Mexico to the United States. Exhibit 24 includes extracted text from a report obtained from Panjiva Inc., a global trade database with import and export data on worldwide commercial shipments. The report was generated by searching Panjiva's database for exports from Mexico

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by Respondents. Pages 3-8 of Exhibit 24 include text from an entry in the report dated February 6, 2019. This entry includes the following in the list of goods shipped: “CARTUCHO POPULADO, VERDE, 60, SUREFORM RELOAD, IS4000” and “CARTUCHO POPULADO, BLANCO, 60, SUREFORM RELOAD, IS4000,” which translate to “POPULATED CARTRIDGE, GREEN, 60, SUREFORM RELOAD, IS4000”; and “POPULATED CARTRIDGE, WHITE, 60, SUREFORM RELOAD, IS4000.” The entry also indicates that the goods were shipped by truck with a destination of “Netherlands, South Korea, United States.” The shipment origin is identified as Mexico, and the shipper is identified as Respondent Intuitive Surgical S. De R.L. De C.V. This record therefore shows that on February 6, 2019, Respondents imported SureForm 60 Reloads to the United States from Mexico.

55. Pages 9-14 of Exhibit 24 include text from an entry in the report dated January 29, 2019. This entry includes the following in the list of goods shipped: “CARTUCHO POPULADO, BLANCO, 60, SUREFORM RELOAD, IS4000, Partes para Sistema quirurgico robotizado” which translates to “POPULATED CARTRIDGE, WHITE, 60, SUREFORM RELOAD, IS4000, Parts for robotic surgical system.” The entry also indicates that the goods were shipped by truck with a destination of “Japan, Netherlands, United States.” The shipment origin is identified as Mexico, and the shipper is identified as Respondent Intuitive Surgical S. De R.L. De C.V. This record therefore shows that on January 29, 2019, Respondents imported SureForm 60 Reloads to the United States from Mexico.

56. Pages 1-2 of Exhibit 24 include text from an entry in the report dated March 20, 2019. This entry includes the following in the list of goods shipped: “CUERPO DE ENSAMBLE PARA CARTUCHO DE GRAPAS PARA INSTRUMENTO DE ROBOT QUIRURGICO,” which translates to “ASSEMBLY BODY FOR STAPLE CARTRIDGE FOR

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SURGICAL ROBOT INSTRUMENT,” and “EMPUJADOR DE GRAPAS PARA CARTUCHO DE GRAPAS PARA INSTRUMENTO DE ROBOT QUIRURGICO,” which translates to “STAPLE PUSHER FOR STAPLE CARTRIDGE FOR SURGICAL ROBOT INSTRUMENT.” The entry also indicates that the goods were shipped by truck with a destination of “Netherlands, United States.” The shipment origin is identified as Mexico, and the shipper is identified as Respondent Intuitive Surgical S. De R.L. De C.V. This record therefore shows that on March, 20, 2019, Respondents imported components of surgical staplers to the United States from Mexico.

57. Pages 15-18 of Exhibit 24 include text from an entry in the report dated January 17, 2019. This entry includes the following in the list of goods shipped: “SUBENSAMBLE CARTUCHO DE GRAPAS QUIRURGICAS PARA INSTRUMENTO DE ROBOT QUIRURGICO,” which translates to “SUB ASSEMBLY CARTRIDGE OF SURGICAL STAPLES FOR SURGICAL ROBOT INSTRUMENT,” and “CARTUCHO DE GRAPAS QUIRURGICAS PARA INSTRUMENTO DE ROBOT QUIRURGICO,” which translates to “CARTRIDGE OF SURGICAL STAPLES FOR SURGICAL ROBOT INSTRUMENT.” The entry also indicates that the goods were shipped by truck with a destination of “Japan, Netherlands, United States,” the shipment origin is identified as Mexico, and the shipper is identified as Respondent Intuitive Surgical S. De R.L. De C.V. This record therefore shows that on January 17, 2019, Respondents imported components of surgical staplers to the United States from Mexico.

58. Respondents are currently marketing and selling in the United States the SureForm 60 and SureForm 60 Reloads that, upon information and belief, are manufactured in Mexico and imported to the United States. Ex. 3 at 45 (“We introduced the SureForm 60mm

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stapler at a measured pace during the second half of 2018 and we intend to broaden availability in 2019.”), *id.* at 47 (“In July 2018, we received U.S. FDA clearance in the U.S. for SureForm 60 instrument with White, Blue, Green, and Black 60mm reloads. In January 2019, we received U.S. FDA clearance in the U.S. for SureForm 45 instrument with White, Blue, Green, and Black 45mm reloads.”); Ex. 22 at 6 (“[W]e plan to broaden the launch of our SureForm 60-millimeter stapler for da Vinci in the first half of 2019.”); Ex. 51 at 5 (“Our 60-millimeter stapler is now in full launch and is used primarily in abdominal surgeries”).

59. Customers and end users in the United States have purchased and used the SureForm 60 and SureForm 60 Reloads that, upon information and belief, were manufactured, at least in part, in Mexico and imported into the United States. Ex. 22 at 6 (“The 60-millimeter stapler is used primarily in abdominal surgeries, including bariatric surgery. Surgeon response has been encouraging and our team has performed well in establishing its supply chain.”); Ex. 23 (“Bariatric surgeon Bobby Bhasker-Rao, MD, of Los Angeles-based miVIP Surgery Centers, used Intuitive Surgical’s SureForm 60 Stapler in an outpatient setting.”); *see also* <https://www.youtube.com/watch?v=wSxiTZwdUFA> (video showing use of SureForm 60 with a SureForm 60 Blue Reload by Dr. Richard L. DiCicco in Florida).

### **B. EndoWrist Xi Staplers and Reloads**

60. Upon information and belief, Respondents collectively manufacture outside of the United States, import, and sell after importation into the United States laparoscopic surgical staplers, reload cartridges, and/or components thereof under certain trade names including EndoWrist Stapler Xi 45/30 and EndoWrist Xi 45/30 Reload. The EndoWrist Stapler Xi 45/30 and EndoWrist Xi 45/30 Reloads required FDA approval before they could be marketed in the United States. Ex. 43; Ex. 44. In the applications for FDA approval of the EndoWrist Stapler Xi

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45/30 and EndoWrist Xi 45/30, Respondents represented that Intuitive Surgical S. de R.L. de C.V., located in Mexico, is a manufacturer of the EndoWrist Stapler Xi 45/30 and EndoWrist Xi 45/30. Ex. 40. Intuitive's 2018 SEC 10-K filing also notes that "[w]e manufacture our instruments at our Sunnyvale and Mexicali, Mexico facilities." Ex. 3 at 10; *see also id.* at 32 ("We have a wholly owned manufacturing facility located in Mexicali, Mexico which manufactures reusable and disposable surgical instruments. This facility is registered with the FDA as well as Mexican authorities. The facility is operated under U.S. and international quality system regulations...").

61. Consistent with the FDA records and Intuitive's 10-K filing, the packaging for the EndoWrist Xi 45 Stapler Reloads indicates that the reloads are "Made in Mexico." Ex. 42. Customers and end-users in the United States have purchased and used the EndoWrist Xi 30/45 and Xi 30/45 Reloads that, upon information and belief, were manufactured, at least in part, in Mexico and imported into the United States. *See* <https://www.youtube.com/watch?v=1hPy-Gr96o0> (video showing use of EndoWrist Xi 45 with a Blue Reload by Dr. Nancy G. Marquez in Texas).

## **VII. UNFAIR ACTS OF RESPONDENTS**

62. Respondents unlawfully import into the United States, sell for importation into the United States, and/or sell within the United States after importation, the accused laparoscopic surgical staplers, reload cartridges, and components thereof. The aforesaid acts of Respondents constitute acts of direct infringement and/or indirect infringement.

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**A. Direct Infringement**

63. The Accused Products infringe, either literally or through the doctrine of equivalents, all the limitations of at least one claim of each of the Asserted Patents. Specifically, the Accused Products infringe claims identified in the table below.

<b>SureForm Staplers and SureForm Reloads</b>		
<b>Patent</b>	<b>Independent Claims</b>	<b>Dependent Claims</b>
'379 Patent	1, 2, 3	n/a
'369 Patent	22	23
'749 Patent	1	n/a
'969 Patent	24	n/a

<b>EndoWrist Xi Staplers and EndoWrist Xi Reloads</b>		
<b>Patent</b>	<b>Independent Claims</b>	<b>Dependent Claims</b>
'874 Patent	19	n/a
'969 Patent	24	n/a

64. Claim charts that apply each independent Asserted Claim of each Asserted Patent are attached hereto.

65. Exhibit 25 is a claim chart applying independent claims 1, 2, and 3 of the '379 Patent to the SureForm 60/45 Stapler and SureForm 60/45 Reloads.

66. Exhibit 26 is claim chart applying claim 22 of the '369 Patent to the SureForm 60/45 Stapler and SureForm 60/45 Reloads.

67. Exhibit 27 is a claim chart applying claim 1 of the '749 Patent to the SureForm 60/45 Stapler and SureForm 60/45 Reloads.

68. Exhibit 28 is a claim chart applying claim 24 of the '969 Patent to the EndoWrist Xi Staplers and Xi Reloads and SureForm 60/45 Reloads.

69. Exhibit 38 is a claim chart applying claim 19 of the '874 Patent to the EndoWrist Xi Staplers and Xi Reloads and the *da Vinci X/Xi System*.

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### **B. Indirect Infringement**

70. Respondents are currently actively inducing and have induced infringement of the Asserted Patents pursuant to 35 U.S.C. 271(b) through, among other things, the sale, offer for sale and importation in the United States of Accused Products to direct infringers that include, without limitation, the customers and end users who use Respondents' Accused Products, with the specific intent that the Accused Products be used in an infringing manner. For example, Respondents' importation of SureForm Reloads and EndoWrist Xi Reloads constitutes a violation of 19 U.S.C. § 1337 because such importation induces direct infringement by customers and end users in the United States.

71. Respondents have had knowledge of the Asserted Patents and knowledge that use of the Accused Products infringes the Asserted Patents. On July 12, 2017, Ethicon served Respondents with a complaint filed in the United States District Court for the District of Delaware alleging infringement of, *inter alia*, the '874 Patent and the '969 Patent. On January 31, 2019, Ethicon provided Respondents with a detailed infringement chart identifying how the EndoWrist Xi 45/30 Stapler and Reloads infringe each limitation of claim 19 of the '874 Patent. On August 28, 2018, Ethicon served Respondents with a complaint filed in the United States District Court for the District of Delaware alleging infringement of the '369 Patent and the '749 Patent. The complaint includes detailed allegations identifying how the Accused Products practice each limitation of the Asserted Claims of the '369 Patent and the '749 Patent. On February 1, 2019, Ethicon served Respondents with infringement charts identifying how the Accused Products infringe each limitation of the Asserted Claims of the '369 Patent and the '749 Patent. In addition, on February 11, 2019, Ethicon provided Respondents with a copy of a proposed first amended complaint identifying how the Accused Products infringe the '379 Patent

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and the '969 Patent. The proposed first amended complaint includes detailed allegations identifying how the Accused Products practice each limitation of the '379 Patent and the '969 Patent.

72. Respondents have encouraged customers and end users to use the Accused Products in an infringing manner by providing operating manuals instructing customers and end users to use the Accused Products in an infringing manner. *See* Ex. 29; Ex. 37. Respondents have also supplied reload cartridges to customers and end users that are necessary in order use the Accused Products in an infringing manner. *See* Ex. 29 at 13-15; Ex. 4; Ex. 37 at 14-19; Ex. 41. The use of the accused staplers with an accused reload constitutes direct infringement of the Asserted Claims of the Asserted Patents. The supply of reload cartridges thus induces customers to use the Accused Products in an infringing manner. Respondents have also advertised, marketed, and promoted the use of the Accused Products in an infringing manner. *See e.g.*, Ex. 54; <https://www.intuitive.com/en-us/products-and-services/da-vinci/stapling>. Upon information and belief, Respondents have also providing training and technical support to customers and end users instructing how to use the Accused Products in an infringing manner. Ex. 3 at 9-10.

73. Respondents have also indirectly infringed the Asserted Patents pursuant to 35 U.S.C. § 271(c) by contributing to the infringement of the Asserted Patents by providing and/or selling the Accused Products in the United States to customers and/or end users, structures and features of which constitute a material part of one or more claims of the Asserted Patents, and are not staple articles of commerce suitable for non-infringing uses, and are especially made and or adapted for use in infringing the Asserted Patents. For example, Respondents' importation of SureForm Reloads and EndoWrist Xi Reloads constitutes a violation of 19 U.S.C. § 1337



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because such importation contributes to direct infringement by customers and end users in the United States.

74. The accused laparoscopic staplers and reload cartridges are not staple articles of commerce suitable for non-infringing uses. For example, the SureForm 60 is designed solely for and specifically adapted for use with the *da Vinci* X and Xi surgical systems, and the SureForm 60 White, Blue, Green and Black Reloads are designed solely for and specifically adapted for use with the SureForm 60. Ex. 29 at 6 (“The SureForm 60 is only compatible with the SureForm 60 reloads referenced in this manual”); Ex. 5 at 2 (“The SureForm 60 reloads are not compatible with any other Intuitive Surgical stapler instruments”). The structures and features of the SureForm 60 and the SureForm 60 Reloads constitute a material part of one or more Asserted Claims of the ’379 Patent, the ’369 Patent, the ’749 Patent, and the ’969 Patent. The use of the SureForm 60 with a SureForm Reload constitutes direct infringement of the Asserted Claims of the ’379 Patent, the ’369 Patent, the ’749 Patent, and the ’969 Patent.

75. The EndoWrist Stapler Xi 45 and 30 are designed solely for and specifically adapted for use with the *da Vinci* X and Xi surgical systems, the EndoWrist Stapler Xi 45 White, Blue, and Green Reloads are designed solely for and specifically adapted for use with the EndoWrist Stapler Xi 45, and the EndoWrist Stapler Xi 30 Gray, White, Blue, and Green Reloads are designed solely for and specifically adapted for use with the EndoWrist Stapler Xi 30. Ex. 37 at 6 (“The Stapler 45 is only compatible with the Stapler 45 Reloads referenced in this manual. The Stapler 30 is only compatible with the Stapler 30 Reloads referenced in this manual.”). The structures and features of the EndoWrist Stapler Xi 45/30 and the EndoWrist Xi 45/30 Reloads constitute a material part of the asserted claims of the ’874 Patent and the ’969

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Patent. The use of the EndoWrist Stapler Xi 45/30 with an EndoWrist Xi 45/30 Reload constitutes direct infringement of the asserted claims of the '874 Patent and the '969 Patent.

76. Respondents possessed intent to contributorily infringe the Asserted Patents because they knew that the structures and features of the Accused Products are especially made or adapted for use in an infringement of one or more claims of the Asserted Patents and such features are not staple articles of commerce suitable for non-infringing uses.

### **VIII. HARMONIZED TARIFF SCHEDULE INFORMATION**

77. The articles subject to this complaint are believed to be classified under at least the following headings and subheadings of the Harmonized Tariff Schedule ("HTS") of the United States: 9018.90.80 (Instruments and appliances used in medical, surgical, dental or veterinary sciences, including scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments; parts and accessories thereof; other); 9018.90.99. These HTS numbers are illustrative only and may not exhaustively reflect the HTS classification of all Accused Products. These HTS numbers are not intended to restrict the scope of this investigation or the scope of relief to which Ethicon is entitled.

### **IX. DOMESTIC INDUSTRY**

78. A domestic industry exists as defined under 19 U.S.C. § 1337(a)(3)(A), (B) and/or (C), comprising continuing significant investments in plant and equipment and employment of labor and capital, and continuing substantial investment in exploitation of the Asserted Patents. Specific non-limiting examples of such investments are provided below.

79. As explained in the accompanying Declaration of Tom O'Brien, Ethicon is a longstanding innovator of tools for use in a variety of surgical procedures, including bariatric, colorectal, gynecologic, thoracic, and hernia surgical procedures. Ethicon's endocutter product

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lines are core to the Ethicon business and reputation as providing best-in-class surgical tools. Ethicon has designed, manufactured, and sold endocutters and associated reload cartridges since the early 1990s. By the mid-2000s, Ethicon had developed and released a 60mm endocutter with particular utility in bariatric surgery. Since that time, Ethicon has continued to innovate its endocutter line. In 2011, Ethicon introduced its first motor-powered endocutter—the ECHELON FLEX™ Powered ENDOPATH® Stapler. The addition of motor power reduces the amount of force and the number of strokes needed when firing (i.e., cutting and stapling tissue), which in turn reduces movement of the device during firing. This results in reduced tension on tissue and, as a consequence, reduced risk of tissue injury. Conf. Ex. 46, ¶¶ 3-4.

80. Ethicon has also supported its products with evidence launches to demonstrate their clinical effectiveness. For example, a 2017 Ethicon-funded study compared the outcomes of manual and powered endocutters (the vast majority of the powered endocutters were Ethicon endocutters) and concluded that “the use of powered staplers was associated with better economic outcomes and a lower rate of bleeding complication/transfusion compared to manual staplers in the real-world setting.” Conf. Ex. 46, ¶ 5 (citing Ex. 48).

81. Ethicon has long been a leading partner with academia, the surgeon community, and payors to elucidate the many life-altering health benefits of bariatric procedures, including the reversal of diabetes. Ethicon has extensively invested its resources in developing the science and the market for bariatric surgery as a way of investment in its endocutter technology and in particular in its 60mm endocutter. In order to maximize return from Ethicon’s development of a 60mm endocutter and its companion tools, Ethicon expended considerable resources to build the science, market, and access to care for bariatric surgery. Ethicon also played a critical role in moving bariatric surgeries from open to laparoscopic procedures in order to reduce

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complications. Conf. Ex. 46, ¶ 6.

82. Ethicon has invested in numerous studies concerning bariatric procedures as part of its “Project Game Changer” initiative. As one example, in 2006, Ethicon commenced funding for the STAMPEDE trial, which showed that intensive medical therapy plus bariatric surgery is superior to intensive medical therapy alone in achieving adequate glycemic control of type 2 diabetes in obese or overweight patients. The American College of Cardiology included the STAMPEDE trial in its list of 2016’s Top 10 trials. Ethicon has invested [REDACTED] in studies associated with Project Game Changer to date, and it has committed [REDACTED] in total. Conf. Ex. 46, ¶¶ 7-9.

83. Ethicon makes extensive use of the inventions claimed in the Asserted Patents. As set forth in greater detail below, Ethicon’s ECHELON FLEX™ Powered Plus system, ECHELON FLEX Powered ENDOPATH® system, ECHELON FLEX™ ENDOPATH® (non-powered) system, [REDACTED], and [REDACTED] [REDACTED] have utilized or currently utilize the Asserted Patents. Ethicon considers the Asserted Patents to be critical to these endocutter devices, as the patented technology comprises a significant aspect of their overall functionality. Moreover, Ethicon had active research and development investments on the technologies claimed in the Asserted Patents at the time the inventions were made, and continues to incur significant and substantial investments in research and development, plant, equipment, labor, and capital. For example, the Asserted Patents name eleven Ethicon inventors, who were employed as scientists and engineers in the United States by Ethicon during the time period when the claimed inventions were made. Nine of these inventors are still employed at Ethicon. The investments in these and other scientists and engineers in the U.S. before, during, and after the filing of the Asserted Patents

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have resulted in ongoing value generated by the Asserted Patents.

84. Ethicon and Medtronic have been the two primary laparoscopic endocutter manufacturers in the United States. Intuitive entered the endocutter market in 2013 with the launch of its EndoWrist *Si* 45mm Stapler.<sup>2</sup> In the United States in 2018, Ethicon held a roughly █% unit share of the 60mm endocutter reload cartridge market, and a roughly █% unit share of the overall endocutter/reload cartridge market; Medtronic held a roughly █% unit share of the 60mm reload cartridge market, and a roughly █% unit share of the overall endocutter/reload cartridge market; and Intuitive held a roughly █% share of the 60mm market, and a roughly █% unit share of the overall endocutter/reload cartridge market. Conf. Ex. 46, ¶¶ 10-11.

85. From January 2013 to June 2018, Ethicon's U.S. net trade sales of its ECHELON FLEX™ Powered Plus endocutters, ECHELON FLEX™ Powered ENDOPATH® endocutters, ECHELON FLEX™ ENDOPATH® endocutters, GST reloads, and ECR reloads totaled █. Conf. Ex. 46, ¶ 12.

### A. Significant Investments in Plant & Equipment

86. Ethicon has made significant investments in plant and equipment for the research, design, manufacture, sterilization, and training for its endocutter products that practice the Asserted Patents. In Blue Ash, Ohio, Ethicon operates a facility for the research and development of Ethicon's endomechanical products. The facility encompasses the research facilities that Ethicon utilizes to improve upon its existing endocutter products and develop additional endocutter products that exploit the Asserted Patents. Substantially all of the research, development, design, engineering, and testing of the Ethicon products that practice the Asserted Patents was done by Ethicon employees using or working within this Ethicon facility in the

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<sup>2</sup> The EndoWrist *Si* 45mm Stapler is not accused in this complaint.

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United States. In Albuquerque, New Mexico, Ethicon owns a [REDACTED] sq. ft. facility (with a [REDACTED] sq. ft. sterilizer) for the sterilization of its endocutter and reload cartridge products that practice the Asserted Patents and are sold in the United States and abroad. Effective February 26, 2019, Ethicon has contracted Jabil Inc. to operate its sterilization facility. The expenditures on plant and equipment are set forth in the accompanying confidential O'Brien declaration. Conf. Ex. 46, ¶¶ 16-24.

87. Ethicon has also made significant investments in manufacturing the domestic industry products in the United States through its manufacturing supplier, Tessy Plastics, who manufactures components of the reload cartridges of the domestic industry products in New York on Ethicon's behalf. Conf. Ex. 46, ¶ 25.

### **B. Significant Employment of Labor & Capital**

88. Ethicon has been and is engaged in the significant employment of labor and capital with respect to the Ethicon products that practice the Asserted Patents. Ethicon employs full-time scientists, researchers, and engineers who design, develop, and test the domestic industry devices that use the Asserted Patents. Substantially all of Ethicon's employees engaged in engineering and research and development of the Ethicon products that practice the Asserted Patents are located in Blue Ash, Ohio. In 2016, 2017, and 2018, Ethicon also employed sterilization personnel at its Albuquerque sterilization facility. Effective February 26, 2019, Ethicon has contracted Jabil Inc. to operate its sterilization facility. Detailed information regarding Ethicon's significant employment of labor and capital may be found in the accompanying confidential O'Brien declaration. Conf. Ex. 46, ¶¶ 26-34.

89. Ethicon has also made significant investments in manufacturing the domestic industry products in the United States through its manufacturing supplier, Tessy Plastics, who

manufactures components of the reload cartridges of the domestic industry products in New York on Ethicon's behalf. Conf. Ex. 46, ¶ 35.

**C. Substantial Investments in Exploitation Through Engineering and Research & Development**

90. Ethicon has made substantial investments in its endocutter products and prototypes that practice the Asserted Patents, including by way of example, investments in engineering, research, and development. Substantially all of the research, development, design, and engineering of the Ethicon products and prototypes that practice the Asserted Patents was performed by Ethicon employees working within the United States at Ethicon's facilities in Blue Ash, Ohio. In particular, the Ethicon products that practice the Asserted Patents were conceived, researched, and developed in the United States. Detailed information regarding Ethicon's research and development expenditures may be found in the accompanying confidential O'Brien declaration. Conf. Ex. 46, ¶¶ 16, 26, 36-37.

91. Ethicon has also established in the United States an extensive training support program for its endocutter products and has incurred substantial investments in such activities. Conf. Ex. 46, ¶ 9.

**D. Ethicon's Practice of the Asserted Patents**

92. Ethicon's ECHELON FLEX™ Powered Plus system and associated reloads that have been the subject of Ethicon's significant and substantial investments in the United States, as described herein, practice at least one valid claim of each of the '379 Patent, the '369 Patent, and the '749 Patent.

93. Ethicon's ECHELON FLEX™ Powered ENDOPATH® system and associated reloads that have been the subject of Ethicon's significant and substantial investments in the

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United States, as described herein, practice at least one valid claim of each of the '379 Patent, and the '749 Patent.

94. Ethicon's ECHELON FLEX™ ENDOPATH® (non-powered) system and associated reloads that have been the subject of Ethicon's significant and substantial investments in the United States, as described herein, practice at least one valid claim of each of the '379 Patent and the '749 Patent.

95. Ethicon's [REDACTED], that has been the subject of Ethicon's significant and substantial investments in the United States, as described herein, practices at least one valid claim of each of the '379 Patent, the '369 Patent, and the '749 Patent.

96. Ethicon's [REDACTED], that has been the subject of Ethicon's significant and substantial investments in the United States, as described herein, practices at least one valid claim of each of the '379 Patent, the '369 Patent, the '749 Patent, the '969 Patent, and the '874 Patent.

97. Pursuant to Commission Rule 210.12(a)(9)(ix), claim charts applying an exemplary claim of each of the Asserted Patents to an exemplary product are attached as Confidential Exhibit 30 (claim 3 of the '379 Patent), Confidential Exhibit 31 (claim 22 of the '369 Patent), Confidential Exhibit 32 (claim 1 of the '749 Patent), Confidential Exhibit 33 (claim 24 of the '969 Patent), and Confidential Exhibit 39 (claim 9 of the '874 Patent).

### **X. RELATED LITIGATION**

98. On June 30, 2017, Ethicon filed a complaint in the United States District Court for the District of Delaware (C.A. 17-871) against Intuitive alleging infringement of the '874 Patent and the '969 Patent, as well as U.S. Patent No. 8,991,677, U.S. Patent No. 8,998,058, U.S. Patent



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No. 9,084,601, and U.S. Patent No. 9,585,658. On November 13, 2017, Ethicon filed a supplemental complaint adding infringement allegations for U.S. Patent No. 8,616,431. On March 20, 2019, the District Court ordered a stay of the litigation pending the outcome of *inter partes* review proceedings.

99. On May 16, 2018, Intuitive filed a petition for *inter partes* review (IPR2018-00938) of the '874 Patent. The petition included four grounds: (i) anticipation of claims 1-7, 9-14, 16-17, 19-21; (ii) obviousness of claims 2-4, 9-18, 21; (iii) obviousness of claim 8; and (iv) obviousness of claims 1-8, 19. On December 4, 2018, the PTAB issued a decision denying institution of the petition having determined that Intuitive failed to establish a reasonable likelihood that it would prevail as to any challenged claim. On December 20, 2018, Intuitive filed a request for rehearing of the decision denying institution.

100. On June 14, 2018, Intuitive filed three petitions for *inter partes* review of the '969 Patent—IPR2018-01247, IPR2018-01248, and IPR2018-01254. The -01247 IPR was instituted on January 15, 2019 with respect to the grounds asserting that claims 19-26 of the '969 Patent are unpatentable as obvious. The oral hearing is scheduled for September 18, 2019 and a final written decision is due by January 15, 2020. The -01254 IPR was instituted on January 15, 2019 with respect to the grounds asserting that claims 1-11 and 24 of the '969 Patent are unpatentable as obvious. The oral hearing is scheduled for September 18, 2019 and a final written decision is due by January 15, 2020. The -01248 was instituted on February 7, 2019 with respect to the grounds asserting that claims 24-26 of the '969 Patent are unpatentable as obvious. The oral hearing is scheduled for October 17, 2019 and a final written decision is due by February 7, 2020.

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101. On August 27, 2018, Ethicon filed a complaint in the United States District Court for the District of Delaware (C.A. 18-1325) against Intuitive alleging infringement of the '369 Patent and the '749 Patent. The complaint also alleged infringement of U.S. Patent Nos. 8,602,287, 8,602,288 and 9,326,770. On March 12, 2019, Ethicon filed a motion for leave to amend the complaint to add claims of infringement of the '379 Patent and the '969 Patent, and to drop the claim of infringement of U.S. Patent No. 9,326,770.

102. On March 27, 2019, Intuitive filed a petition for *inter partes* review (IPR2019-00880) of the '749 Patent. The petition included two grounds alleging anticipation and obviousness of claims 1 and 3. Ethicon's Patent Owner Preliminary Response is due by July 5, 2019, and the PTAB's Institution Decision is due by October 5, 2019.

103. On May 9, 2019, Intuitive filed a petition for *inter partes* review (IPR2019-01066) of the '369 Patent. The petition includes three grounds alleging obviousness of claims 1, 15, 22 and 23. Ethicon's Patent Owner Preliminary Response is due by August 16, 2019, and the PTAB's Institution Decision is due by November 16, 2019.

### **XI. RELIEF REQUESTED**

104. WHEREFORE, by reason of the foregoing, Ethicon respectfully requests that the United States International Trade Commission:

- (a) Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, into the violations by Respondents of Section 337 arising from the importation into the United States, sale for importation, and/or sale within the United States after importation of Respondents' products that infringe one or more claims of the Asserted Patents.

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- (b) Schedule and conduct a hearing, pursuant to 19 U.S.C. § 1337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337 of the Tariff Act of 1930, as amended; and, following the hearing, determine that there has been a violation of Section 337 of the Tariff Act of 1930, as amended;
- (c) Issue a permanent limited exclusion order, excluding from entry for consumption into the United States, or withdrawal from a warehouse for consumption, certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents and which are manufactured by or on behalf of, or imported by or on behalf of Respondents, or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, for the remaining terms of the Asserted Patents, except under license of Complainants or as provided by law;
- (d) Issue permanent cease-and-desist orders, pursuant to 19 U.S.C. § 1337(f), directing Respondents and any of their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) or majority-owned business entities, successors, and assigns, from either directly engaging in or for, with or otherwise on behalf of Respondents, (A) importing or selling for importation into the United States certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (B) marketing, distributing, offering for sale,

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selling, or otherwise transferring, in the United States imported laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (C) advertising imported laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (D) soliciting U.S. agents or distributors for laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (E) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (F) testing imported laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (G) updating or upgrading imported laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; (H) operating imported laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents; or (I) supporting, servicing, and/or repairing imported laparoscopic surgical staplers, reload cartridges, and components thereof that infringe one or more claims of the Asserted Patents.

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- (e) Impose a bond upon any importations or sales of infringing laparoscopic surgical staplers, reload cartridges, and components thereof during the 60-day period for Presidential review, pursuant to 19 U.S.C. § 1337(j); and
- (f) Grant all such other and further relief as the Commission has authority to grant and deems appropriate under the law, based upon the facts complained of herein and as determined by the Investigation.

Dated: May 28, 2019

Respectfully Submitted,

  
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