

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

P TECH, LLC,)	
)	
Plaintiff,)	
)	Case No. _____
v.)	
)	
INTUITIVE SURGICAL, INC.)	
)	
Defendant.)	JURY TRIAL DEMANDED
)	

COMPLAINT

Plaintiff, P Tech, LLC (“P Tech”), for its Complaint of patent infringement against Defendant Intuitive Surgical, Inc. (“Intuitive”), hereby alleges as follows:

Parties

1. P Tech is a Delaware limited liability company with its principal place of business located in Florida.
2. Intuitive is a Delaware corporation with its principal place of business at 1020 Kifer Road, Sunnyvale, California 94086.

Jurisdiction and Venue

3. This is an action for patent infringement under 35 U.S.C. § 271 *et seq.* The Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).
4. The Court has personal jurisdiction over Intuitive because Intuitive is a Delaware corporation and, on information and belief, is registered with the State of Delaware to transact business in Delaware.
5. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because Intuitive is incorporated in this district.

Background

6. On October 6, 2015, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,149,281 (“the ‘281 patent”), entitled “Robotic System for Engaging a Fastener With Body Tissue” to P Tech. Dr. Peter Bonutti is the sole named inventor of the ‘281 patent. A true and accurate copy of the ‘281 patent is attached as Exhibit A.

7. The application that matured into the ‘281 patent was filed on June 7, 2013, and is a continuation application of U.S. patent application No. 13/888,957, filed on May 17, 2013, and U.S. patent application No. 10/102,413, filed on March 20, 2002.

8. The ‘281 patent contains three independent claims and seventeen dependent claims. Independent claim 1 of the ‘281 patent follows:

1. A robotic system for engaging a fastener with a body tissue, the system comprising:

a robotic mechanism including an adaptive arm, the robotic mechanism configured to position a fastener relative to the body tissue, the robotic mechanism having first and second force transmitting portions configured to apply at least one of an axial force and a transverse force relative to the fastener;

a computer configured to control the robotic mechanism;

and an adaptive arm interface coupled to the adaptive arm and the computer, the adaptive arm interface configured to operate the computer, wherein a magnitude of the at least one axial force and transverse force applied to the fastener is limited by the computer.

9. On November 24, 2015, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 9,192,395 (“the ‘395 patent”), entitled “Robotic Fastening System” to P Tech. Dr. Peter Bonutti is the sole named inventor of the ‘395 patent. A true and accurate copy of the ‘395 patent is attached as Exhibit B.

10. The application that matured into the ‘395 patent was filed on May 7, 2013 and is a continuation application of U.S. patent application No. 10/102,413 filed on March 20, 2002.

11. The '395 patent contains three independent claims and four dependent claims.

Independent claim 1 of the '395 patent follows:

1. A robotic fastening system comprising:

a robotic mechanism including an adaptive arm configured to position a staple relative to a body portion of a patient;

a robotic arm interface configured to operate the adaptive arm of the robotic mechanism;

a staple having first and second legs;

a fastening member coupled to the adaptive arm, the fastening member having first and second force transmitting portions and configured to secure the body portion with the staple by applying a force from the first and second force transmitting portions to move the first and second legs of the staple toward each other,

at least one of a position sensor configured to indicate a distance moved by the staple and a force measurement device configured to indicate a resistance required to move the staple relative to the body portion; and

a tissue retractor assembly coupled to the robotic mechanism, the tissue retractor assembly including a cannula configured to facilitate insertion of the fastening member through the cannula into a working space inside the patient

12. P Tech is the owner by assignment of the '281 patent and the '395 patent ("the Asserted Patents"), including all rights to sue for past, present, and future infringement of the Asserted Patents.

13. The '281 patent and the '395 patent are generally directed to robotic mechanisms used to deliver staples or other fasteners used to secure internal body tissues during a surgical procedure.

14. The United States Food and Drug Administration ("FDA") recently recognized an "increasing number of adverse events associated with surgical staplers for internal use" and provided "additional recommendations for health care providers to help protect patient safety and reduce the risk of adverse events associated with" with manual and some motor driven staplers.

A true and correct copy of the FDA's March 8, 2019 letter to health care providers titled "Safe Use of Surgical Staplers and Staples" is attached hereto as Exhibit C.

15. According to the FDA's March 8, 2019 letter, "[s]ome of the most commonly reported problems in these adverse event reports" concerning surgical staplers and staples include misfiring, difficulty in firing, and failure of the stapler to fire the staple. *Id.*

16. The robotic mechanisms disclosed and claimed in the '281 patent and the '395 patent include sensors and designs that ensure safe and precise stapling and thus prevent the occurrence of the types of adverse events associated with surgical staplers identified in the FDA's March 8, 2019 letter.

Facts Relating to Intuitive's Infringement

17. Intuitive manufactures and sells, among other products, the da Vinci® Surgical System ("da Vinci System"). The da Vinci System is a minimally invasive robotic assisted-surgery system that enables surgeons to operate through small incisions in the patient's abdomen or belly button from a nearby surgeon console.

18. The da Vinci System is used by surgeons in all 50 states in the United States and has been approved by the Food and Drug Administration for general laproscopic surgery, as well as thoracoscopic surgery and certain cardia, urologic, gynecologic, pediatric, and transoral otolaryngology procedures.

19. Each da Vinci system includes a patient cart, a vision cart, and a surgeon console.

20. The patient cart is where the patient is positioned during surgery. Each of the da Vinci patient carts includes one or more adaptive arms on which individual surgical instruments can be connected and used during a surgical procedure. A computer controls movement of these adaptive arms and replicates the movements of the operating surgeon at the surgeon console.

21. Intuitive currently manufactures and sells three different patient carts: the da Vinci X, the da Vinci Xi, and the da Vinci SP.

22. A representative image of the da Vinci Xi, which has four adaptive arms, follows:



23. The vision cart provides, among other things, image processing and information systems for use during the surgical procedure. The vision cart also provides a display of the surgical procedure being performed for viewing by those in the operating room. An image of the vision cart, which is a universal component and is standard for each of the X, Xi, and SP patient carts, follows:



24. The surgeon console is where the surgeon sits and operates the surgical instruments connected to the patient cart. More specifically, the surgeon console includes an adaptive arm interface coupled to the adaptive arm and a computer to allow the surgeon to operate the adaptive arm(s) of the patient cart.

25. In other words, the da Vinci Surgeon Console is configured to control the robotic mechanisms, including the adaptive arms, of the da Vinci System. An image of the surgeon console, which is a universal component and is standard for each of the X, Xi, and SP patient carts, follows:



26. A representative image of a full da Vinci Xi surgical system in use follows (labels added for identification):



Surgeon Console



Patient Cart



Vision Cart

27. Intuitive offers numerous surgical instruments than can be used with the da Vinci System, such as retractors, forceps, staplers, endoscopes, vessel sealers, and bipolar and monopolar energy instruments.

28. Intuitive offers at least two lines of surgical staplers for use with the da Vinci system: (1) the EndoWrist 30 and EndoWrist 45 staplers (collectively “EndoWrist Staplers”); and (2) the SureForm 60 stapler (“SureForm Staplers”).

29. Each of the EndoWrist Staplers and the SureForm Staplers is configured to attach to one of the adaptive arms of the patient cart of a da Vinci System.

30. Each EndoWrist Stapler and SureForm Stapler includes jaws (anvil and reload channel). Representative images of the EndoWrist Stapler and SureForm Stapler follow:

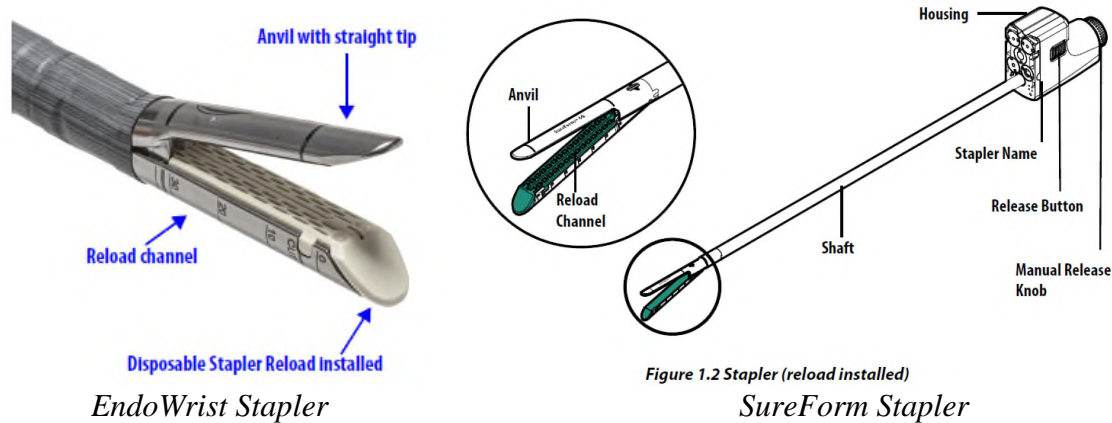


Figure 1.2 Stapler (reload installed)

Exh. D (EndoWrist Manual) at 12; Exh. E (SureForm Manual) at 11.

31. The adaptive arm(s) of the patient cart included in the da Vinci System, which are controlled by the surgeon using the surgeon console, are configured to position the EndoWrist Stapler or SureForm Stapler during a surgical procedure.

32. As stated in Intuitive’s EndoWrist User Manual Addendum, a true and correct copy of which is attached hereto as Exhibit D, the EndoWrist Stapler is “activated from the associated pair of Surgeon Console foot pedals by applying two controls in succession: first, the associated blue pedal applies **clamp**, which compresses the tissue; then the associated yellow pedal **fires** the instrument to staple and cut target tissue.” Exh. D at 24.

33. To clamp the tissue, the jaws of the EndoWrist Stapler close on the tissue and compress it. The amount of force applied by the jaws of the EndoWrist Stapler is controlled by the computer of the da Vinci System.

34. The EndoWrist Staplers use Intuitive’s “SmartClamp” technology, which provides intraoperative feedback to the surgeon and detects whether the jaws of the stapler can adequately close on the tissue to be stapled for the given staple size.

35. The SmartClamp technology of the EndoWrist Stapler “detects whether or not the Stapler jaws can adequately close on the target tissue during clamping. If while clamping the

Stapler detects that the jaws cannot adequately close on the target tissue, clamping stops and a message appears.” *Id.* at 27.

36. The SureForm Stapler is also activated from an associated pair of foot pedals on the surgeon console by applying pressure to the controls in succession.

37. As stated in Intuitive’s SureForm User Manual Addendum, a true and correct copy of which is attached hereto as Exhibit E, the first foot pedal applies “clamp, which compresses the tissue.” The second foot pedal “fires the instrument to staple and cut target tissue, and provide additional compression.” Exh. E at 19.

38. To clamp the tissue, the jaws of the SureForm Stapler close on the tissue and compress it. The amount of force applied by the jaws of the SureForm Stapler is controlled by the computer of the da Vinci System.

39. The SureForm Staplers use Intuitive’s “SmartFire” technology. The “SmartFire” technology measures tissue compression before and during the firing of the stapler.

40. As stated in Intuitive’s SureForm User Manual Addendum, “[t]he stapler uses SmartFire to create the best opportunity for a properly formed staple line while avoiding potential tissue damage, such as serosal tearing, due to an excessive clamp force. SmartFire takes into account multiple variables in order to deliver the appropriate compression for the targeted tissue for the SureForm 60 [staple] reload selected. The SmartFire algorithm can cause the system to pause during firing to allow better tissue compression prior to continuing the fire, this happens automatically without the need for user interaction. . . . Additional pauses can happen during a single firing cycle as SmartFire continuously monitors the appropriate variables that influence staple line formation.” *Id.* at 22.

41. As stated in Intuitive's marketing materials for the SureForm stapler, the "SmartFire" technology "uses more than 1,000 measurements per second to make automatic adjustments to the firing process as staples are being formed." A true and correct copy of a brochure for the SureForm stapler is attached hereto as Exhibit F.





42. Both the EndoWrist Staplers and SureForm Staplers are adapted to be inserted through a cannula into the working space inside the patient.

43. The EndoWrist Staplers and the SureForm Staplers are used to engage multiple rows of fasteners (surgical staples) with a body tissue inside the patient during a surgical procedure.

44. In addition to delivering multiple rows of staples, the EndoWrist Staplers and SureForm Staplers also transect the body tissue along the middle of the staple line.

45. The staples that are used in the EndoWrist Staplers and the SureForm Staplers are contained in disposable single-use "reload cartridges." The "reload cartridges" are color coded based on staple length and the recommended thickness of the tissue to be stapled as shown in the following exemplary image taken from the SureForm Stapler User Manual Addendum:

Table 1-2 SureForm 60 Reload Specifications

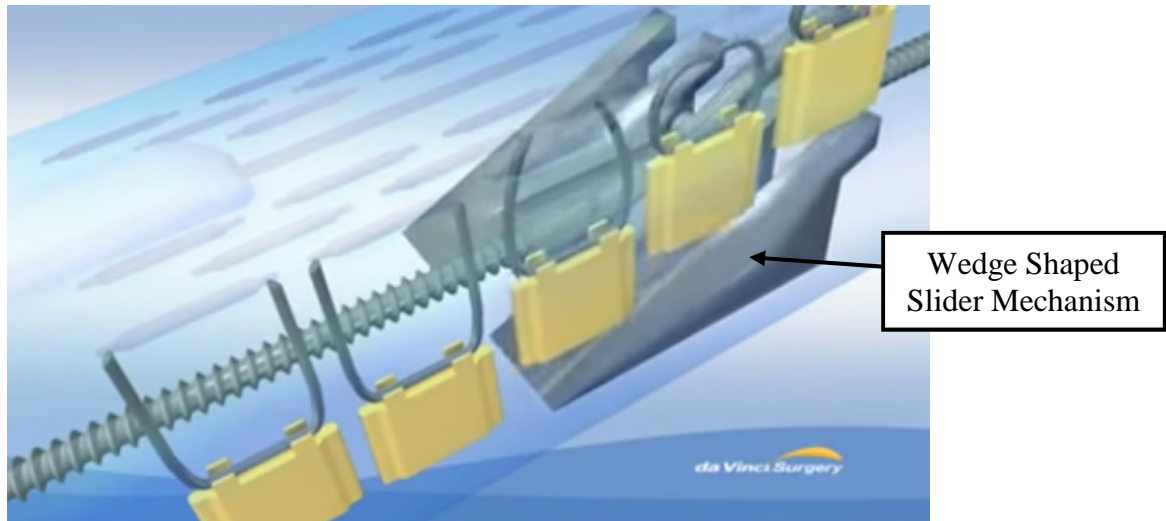
Reload	Component Name	Part Number (PN)	Reload Length (mm)	Staple Leg Length (mm)	Closed Staple Height (mm)	Number of Staples	Total Number of Staggered Staple Rows	Tissue Thickness Range (mm)
	SureForm 60 White Reload	48360W	60	2.5	1.0	90	6	1.0-2.0
	SureForm 60 Blue Reload	48360B	60	3.5	1.5	90	6	1.5-2.4
	SureForm 60 Green Reload	48360G	60	4.3	2.0	90	6	2.0-3.3
	SureForm 60 Black Reload	48360T	60	4.6	2.3	90	6	2.3-4.0

Exh. E at 13. *See also* Exh. D (EndoWrist Stapler User Manual Addendum) at 15-16.

46. Each of the staples used with the EndoWrist Staplers and SureForm Staplers have two legs.

47. The EndoWrist Staplers and SureForm Staplers include a first force transmitting portion and a second force transmitting portion that apply at least one of an axial force or a transverse force to the staple(s).

48. More specifically, each of the EndoWrist Staplers and SureForm Staplers include a wedge-shaped sliding mechanism (first force transmitting portion). When the stapler is “fired,” the wedge-shaped sliding mechanism is activated and is driven along the length of the stapler by a motor and worm gear. This slider mechanism is shown in the following image depicting the functionality of the EndoWrist stapler in use:



49. The force applied by the wedge-shaped slider mechanism is prescribed and controlled by the computer of the da Vinci system.

50. The EndoWrist and SureForm Staplers also include a top clamp arm or “anvil” (a second force transmitting portion). This “anvil” structure is shown in the following images taken from the SureForm User Manual Addendum and the EndoWrist User Manual Addendum:

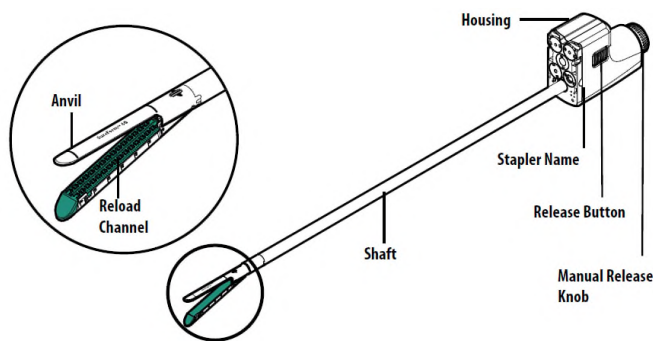
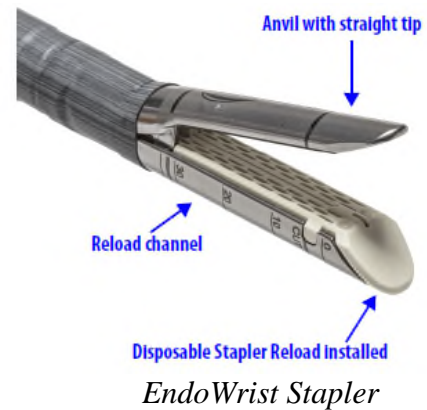


Figure 1.2 Stapler (reload installed)
SureForm Stapler



Exh. E at 11; Exh. D at 12.

51. As the staples are moved by the wedge-shaped sliding mechanism, the two legs of the open end of the staples are forced toward each other by the anvil of the stapler.

52. The force applied to the staple(s) from the first and second force transmitting portions of the EndoWrist Staplers and the SureForm Staplers thus moves the first and second legs of the staple(s) toward each other in order to secure the body tissue.

53. As stated in the EndoWrist User Manual Addendum, “[t]he Reload channel holds the Stapler Reload, and the anvil contains features that form the staples to capture tissue.” Exh. D at 12.

54. Similarly, and as stated in the SureForm User Manual Addendum, “[t]he Reload Channel holds the SureForm 60 reload, and the anvil contains features that form the staples to capture tissue.” Exh. E at 10.

55. On information and belief, the da Vinci System in combination with an EndoWrist Stapler includes a force measurement device that is configured to indicate the resistance required to move the staple(s) in a reload cartridge relative to the body tissue when the EndoWrist Stapler is fired.

56. On information and belief, the da Vinci System in combination with a SureForm Stapler includes a force measurement device that is configured to indicate the resistance required to move the staple(s) in a reload cartridge relative to the body tissue when the SureForm Stapler is fired.

57. On information and belief, Intuitive has made, used, sold, or offered for sale its da Vinci System and EndoWrist Staplers and SureForm Staplers which, based on publicly available information and pre-suit correspondence with Intuitive, implements the specific elements described and claimed in P Tech’s ‘281 patent and ‘395 patent. In accordance with Fed. R. Civ. P. 11(b)(3), based at least on publicly available information, P Tech believes that its allegations will have additional evidentiary support after a reasonable opportunity for discovery.

Count I – Infringement of U.S. Patent No. 9,149,281

58. P Tech incorporates by reference paragraph 1 through 57 of this Complaint as if more fully set forth herein.

59. Intuitive's manufacture, use, offers for sale and/or sale of the EndoWrist Staplers for use with the da Vinci System infringes at least claim 1 of the '281 patent literally and/or under the doctrine of equivalents.

60. Intuitive has made, used, offered for sale, and/or sold (and continues to make, use, offer for sale, and/or sell) its infringing da Vinci System and EndoWrist Staplers within this judicial district and throughout the United States.

61. Intuitive's manufacture, use, offers for sale and/or sale of the SureForm Staplers for use with the da Vinci System infringes at least claim 1 of the '281 patent literally and/or under the doctrine of equivalents.

62. Intuitive has made, used, offered for sale, and/or sold (and continues to make, use, offer for sale, and sell) its infringing da Vinci System and SureForm Staplers within this judicial district and throughout the United States.

63. Intuitive has also indirectly infringed at least claim 1 of the '281 patent under 35 U.S.C. § 271(b) by inducing others to directly infringe. Intuitive's indirect infringement is ongoing.

64. Intuitive has actively induced infringement of the '281 patent, including by selling its EndoWrist Staplers and SureForm Staplers to customers in the United States and facilitating, training, supporting, teaching, directing, and instructing the customers' and/or end-users' infringing use of the stapler, knowing that the manufacture and use of the da Vinci System with the EndoWrist Stapler or SureForm Stapler infringes at least claim 1 of the '281 patent.

65. Intuitive has induced its customers and end-users to directly infringe the '281 patent by using the EndoWrist Staplers and/or SureForm Staplers with the da Vinci system, and taking active steps, directly and/or through contractual relationships with others, with specific intent to cause its customers and/or end users to use the EndoWrist Staplers and/or SureForm Staplers in a manner that infringes at least claim 1 of the '281 patent.

66. Upon information and belief, Intuitive possessed specific intent to induce direct infringement of at least claim 1 of the '281 patent by its customers and/or end-users that used the EndoWrist Staplers and/or SureForm Staplers.

67. Such steps by Intuitive include, among other things, advising, supporting, and directing customers and end-users to use the EndoWrist Staplers and/or SureForm Staplers in an infringing manner, and/or distributing and providing instructions, terms of use, or training that guide users to use the staplers in an infringing manner.

68. Intuitive was objectively aware of, and had knowledge of, the '281 patent as P Tech previously sent a copy of the '281 patent to Intuitive.

69. Intuitive has also contributed to the infringement of the '281 patent under 35 U.S.C. § 271(c) by importing, offering to sell, selling, and/or inducing the use of the EndoWrist Staplers and/or SureForm Staplers within the United States knowing that these products were especially made or adapted for use in a manner that infringes at least claim 1 of the '281 patent.

70. Intuitive's EndoWrist Staplers and SureForm Staplers are each material to the system of claim 1 of the '281 patent and neither is a staple article or commodity of commerce suitable for substantial non-infringing use.

71. Intuitive acted with knowledge of the '281 patent and despite an objectively high likelihood that its actions constituted infringement of at least one valid and enforceable claim of

the '281 patent, and Intuitive knew or should have known that its actions constituted an unjustifiably high risk of infringement of at least one valid and enforceable claim of the '281 patent.

72. Intuitive's infringement of the '281 patent has been knowing and willful.

73. P Tech is being damaged and irreparably harmed by Intuitive's infringement of the '281 patent and is thus entitled to recover damages adequate to compensate P Tech for the infringement complained of herein, but in no event less than a reasonable royalty.

74. Intuitive's infringement has injured and will continue to injure P Tech, unless and until such infringement is enjoined by this Court.

Count II – Infringement of U.S. Patent No. 9,192,395

75. P Tech incorporates by reference paragraph 1 through 74 of this Complaint as if more fully set forth herein.

76. Intuitive's manufacture, use, offers for sale and/or sale of the EndoWrist Staplers for use with the da Vinci System infringes at least claim 1 of the '395 patent literally and/or under the doctrine of equivalents.

77. Intuitive has made, used, offered for sale, and/or sold (and continues to make, use, offer for sale, and sell) its infringing da Vinci System and EndoWrist Staplers within this judicial district and throughout the United States.

78. Intuitive's manufacture, use, offers for sale and/or sale of the SureForm Staplers for use with the da Vinci System infringes at least claim 1 of the '395 patent literally and/or under the doctrine of equivalents.

79. Intuitive has made, used, offered for sale, and/or sold (and continues to make, use, offer for sale, and/or sell) its infringing da Vinci System and SureForm Staplers within this judicial district and throughout the United States.

80. Intuitive has also indirectly infringed at least claim 1 of the '395 patent under 35 U.S.C. § 271(b) by inducing others to directly infringe. Intuitive's indirect infringement is ongoing.

81. Intuitive has actively induced infringement of the '395 patent, including by selling its EndoWrist Staplers and SureForm Staplers to customers in the United States and facilitating, training, supporting, teaching, directing, and instructing the customers' and/or end-users' infringing use of the stapler, knowing that the manufacture and use of the da Vinci System with the EndoWrist Stapler or SureForm Stapler infringes at least claim 1 of the '395 patent.

82. Intuitive has induced its customers and end-users to directly infringe the '395 patent by using the EndoWrist Staplers and/or SureForm Staplers with the da Vinci system, and taking active steps, directly and/or through contractual relationships with others, with specific intent to cause its customers and/or end users to use the EndoWrist Staplers and/or SureForm Staplers in a manner that infringes at least claim 1 of the '395 patent.

83. Upon information and belief, Intuitive possessed specific intent to induce direct infringement of at least claim 1 of the '395 patent by its customers and/or end-users that used the EndoWrist Staplers and/or SureForm Staplers.

84. Such steps by Intuitive include, among other things, advising, supporting, and directing customers and end-users to use the EndoWrist Staplers and/or SureForm Staplers in an infringing manner, and/or distributing and providing instructions, terms of use, or training that guide users to use the staplers in an infringing manner.

85. Intuitive was objectively aware of, and had knowledge of, the '395 patent as P Tech previously sent a copy of the '395 patent to Intuitive.

86. Intuitive has also contributed to the infringement of the '395 patent under 35 U.S.C. § 271(c) by importing, offering to sell, selling, and/or inducing the use of the EndoWrist Staplers and/or SureForm Staplers within the United States knowing that these products were especially made or adapted for use in a manner that infringes at least claim 1 of the '395 patent.

87. Intuitive's EndoWrist Staplers and SureForm Staplers are each material to the system of claim 1 of the '395 patent and neither is a staple article or commodity of commerce suitable for substantial non-infringing use.

88. Intuitive acted with knowledge of the '395 patent and despite an objectively high likelihood that its actions constituted infringement of at least one valid and enforceable claim of the '395 patent, and Intuitive knew or should have known that its actions constituted an unjustifiably high risk of infringement of at least one valid and enforceable claim of the '395 patent.

89. Intuitive's infringement of the '395 patent has been knowing and willful.

90. P Tech is being damaged and irreparably harmed by Intuitive's infringement of the '395 patent and is thus entitled to recover damages adequate to compensate P Tech for the infringement complained of herein, but in no event less than a reasonable royalty.

91. Intuitive's infringement has injured and will continue to injure P Tech, unless and until such infringement is enjoined by this Court.

Jury Demand

92. P Tech requests a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, on all issues triable to a jury.

Prayer for Relief

WHEREFORE, Plaintiff P Tech, LLC seeks a judgment against Defendant Intuitive Surgical, Inc. including the following:

- A. An injunction ordering that Defendant, and each of its respective officers, agents, servants, employees, and attorneys, and all of those persons in active concert or participation with it, be enjoined permanently from directly or indirectly infringing U.S. Patent Nos. 9,149,281 and 9,192,395 and from selling the da Vinci System with EndoWrist Staplers and SureForm Staplers;
- B. Plaintiff be awarded damages against Defendant accrued from the date of issue of the Asserted Patents;
- C. Prejudgment and post-judgment interest;
- D. An assessment of Plaintiff's costs against Defendant;
- E. An assessment of Plaintiff's reasonable attorneys' fees under 35 U.S.C. § 285 against Defendant; and
- F. Such other and further relief as this Court may deem just and proper.

Date: March 15, 2019

Respectfully submitted,

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