

5-31-2022

Making Your Robotic Surgery Systems General Purpose: A Possible Preventive Measure for Induced and Contributory Infringement Liability Arising in Medical Procedures

Mengmeng Du

Follow this and additional works at: <https://scholarship.law.umn.edu/mjlst>

 Part of the [Food and Drug Law Commons](#), [Health Law and Policy Commons](#), [Intellectual Property Law Commons](#), and the [Science and Technology Law Commons](#)

Recommended Citation

Mengmeng Du, *Making Your Robotic Surgery Systems General Purpose: A Possible Preventive Measure for Induced and Contributory Infringement Liability Arising in Medical Procedures*, 23 MINN. J.L. SCI. & TECH. 593 (2022).

Available at: <https://scholarship.law.umn.edu/mjlst/vol23/iss2/5>

Note

Making Your Robotic Surgery Systems General Purpose: A Possible Preventive Measure for Induced and Contributory Infringement Liability Arising in Medical Procedures

*Mengmeng Du**

Not only is robotic surgery among the most important advancements in the medical device industry in the twentieth century, it is also one of the most important implementations of robotics techniques.¹ Robotic surgery systems have enormous advantages over traditional surgical technologies.² Hospitals worldwide have adopted robotic surgery in the treatment of a wide range of conditions.³ Innovation in robotic surgery pushes society forward by providing better health care and extending human lifespan.⁴ Thus, laws in this country should preserve rather than diminish incentives for innovation in this field in order to benefit the public. However, under the current patent system in the United States, secondary liabilities arising from

© 2022 Mengmeng Du

* J.D., 2022, University of Minnesota Law School; M.S. Electrical and Electronics Engineering, 2016, Georgia Institute of Technology; B.E. Automation, 2014, Beijing Institute of Technology. I thank Professor Thomas F. Cotter for guiding me through the note-writing process; Ian Sannes for his comments on previous versions of this Note; the editorial staff at Minnesota Journal of Law, Science & Technology for all of their feedback; and my family and friends who have supported me through law school. Any errors that remain are mine alone.

1. See generally Jeff Glorfeld, *10 Most Exciting Developments with Robots*, COSMOS (Jan. 16, 2019), <https://cosmosmagazine.com/technology/the-10-most-exciting-robotics-developments-of-the-past-12-months/> (detailing interesting and important robotic advancements, including robotic surgery advancements).

2. See *infra* Part I (discussing the advantages that robotic surgery systems have over traditional surgical techniques); *Robotic Surgery*, MAYO CLINIC [hereinafter *Robotic Surgery*], <https://www.mayoclinic.org/tests-procedures/robotic-surgery/about/pac-20394974> (last visited Mar. 14, 2022) (discussing the advantages and risks of robotic surgery).

3. See *Robotic Surgery*, *supra* note 2.

4. See *infra* Part I.A. (discussing the development of robotic surgical technologies).

indirect infringement erode the innovation incentives for robotic surgery system developers in various ways, including increasing R&D costs and incurring expenses for responding to lawsuits.⁵

This Note utilizes the general-purpose characteristic of future robotic surgery systems to develop a new strategy for supplier companies to shield themselves from indirect infringement accusations. This Note unfolds in the following manner. Part I introduces the relevant background information of robotic surgery systems, including the history and the future trend of robotic surgery technology and the government's regulation scheme of robotic surgery systems and devices. Part I also provides an overview of indirect infringement lawsuits brought against robotic surgery system suppliers and the IP strategies suppliers have pursued in response to the situation to demonstrate the need for an alternative legal strategy. Part II analyzes how the general-purpose characteristic of a robotic surgery system provides a valid defense to indirect infringement and how making the robotic surgery system more general-purpose aligns with companies' commercial goals. This Note concludes that making a robotic surgery system more general-purpose provides a defense to secondary liabilities resulting from indirect infringement that is both legally viable and commercially desirable.

I. BACKGROUND

Today, many surgical devices carry some computer-assisted features. Examples familiar to lay people include imaging technologies, such as computerized tomography (CT) scans,⁶ magnetic resonance imaging (MRIs),⁷ X-rays,⁸ and procedures using surgical navigation instruments such as endoscopy⁹ and cardiac catheterization.¹⁰ Robotic surgery systems, robotically-

5. See *infra* Part I.C. (detailing some of the issues with the United States patent system as it relates to robotic surgery technologies).

6. *CT Scan*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675> (last visited Mar. 14, 2022).

7. *MRI*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768> (last visited Mar. 14, 2022).

8. *X-ray*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/x-ray/about/pac-20395303> (last visited Mar. 14, 2022).

9. *Endoscopy*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/endoscopy/multimedia/endoscopy/img-20007299> (last visited Mar. 14, 2022).

10. *Cardiac Catheterization*, MAYO CLINIC, <https://www.mayoclinic.org/>

assisted surgical devices, and surgical robots belong to the category of computer-assisted surgical systems.¹¹ Surgical robots generally refer to mechanical devices and systems that mainly comprise mechanical arms, consoles, and a viewing apparatus, and are computer-centric and human-controlled.¹² Compared to traditional surgery techniques, robotic surgery technology allows physicians to perform a variety of complex procedures with better precision, flexibility, and most importantly, a higher level of control.¹³ These numerous advantages make robotic surgery technology highly desirable in operating rooms, especially where minimally invasive surgical procedures¹⁴ are performed.¹⁵ Experts have also envisioned using robotic surgical systems in telesurgery or remote surgery in the near future.¹⁶

tests-procedures/cardiac-catheterization/about/pac-20384695 (last visited Mar. 14, 2022).

11. See *Computer-Assisted Surgical Systems*, U.S. FOOD & DRUG ADMIN. [hereinafter *Computer-Assisted Surgical Systems*], <https://www.fda.gov/medical-devices/surgery-devices/computer-assisted-surgical-systems> (last visited Mar. 14, 2022) (defining computer-assisted surgical systems, which includes robotic surgery systems and devices).

12. *Robotic Surgery*, *supra* note 2.

13. *Robotic Surgery*, *supra* note 2; G. P. Moustris et al., *Evolution of Autonomous and Semi-Autonomous Robotic Surgical Systems: A Review of the Literature*, 7 INT'L J. MED. ROBOTICS & COMPUTER ASSISTED SURGERY 375, 375 (2011) (suggesting that autonomous control of robotic surgical systems offer advantages such as less tissue-damage to the patient and more intelligent maneuvers to assist the surgeon).

14. Minimally invasive surgery refers to surgical procedures that require a smaller incision on the human body compared to traditional open surgery to complete the procedure. *Minimally Invasive Surgery*, MAYO CLINIC, <https://www.mayoclinic.org/tests-procedures/minimally-invasive-surgery/about/pac-20384771> (last visited Mar. 14, 2022). This technology emerged in the 1980s and is becoming more and more preferred by medical practitioners today. *Id.*

15. Robotic surgery's high precision and better control help further minimize tissue damage and thus is widely implemented in minimally invasive procedures. See Manjunath Siddaiah-Subramanya et al., *A New Era of Minimally Invasive Surgery: Progress and Development of Major Technical Innovations in General Surgery Over the Last Decade*, 3 SURGERY J. 163 (2017) (discussing the application of robotic surgery to minimally invasive surgeries).

16. Telesurgery and remote surgery use wireless networking and robotic technology to allow surgeons to operate on patients who are far away. Paul J. Choi et al., *Telesurgery: Past, Present, and Future*, CUREUS, May 2018, at 1, 1; see also Kenoki Ohuchida & Makoto Hashizume, *Overview of Robotic Surgery*, in ROBOTIC SURGERY 1, 6 (Go Watanabe ed., 2014) (“[I]n the future, robotic system[s] will make it possible to perform surgical procedure[s] in the battlefield or . . . outer space without sending surgeons.”).

A. THE DEVELOPMENT OF ROBOTIC SURGICAL TECHNOLOGY

Although conceived by medical practitioners as far back as 1967, it took nearly thirty years for researchers to complete the first fully functional multipurpose surgical robot.¹⁷ As with other computer-controlled technologies, the development in robotic surgery technology relies heavily on advancements in control engineering, artificial intelligence, and robotics.¹⁸ It started late and developed slowly in the first thirty years.¹⁹ In 1961, the first installed industrial robot was patented.²⁰ Fuzzy logic, which has been widely applied in machine control and the foundation for artificial intelligence, came into existence in 1965.²¹ The first multitasking, parallel programming language for robot control appeared between 1982 and 1986.²² Finally, these and other leaps in mechanical engineering, electrical engineering, material science, and computer science together prepared the industry, and the world saw its first surgical robot—the Arthrobot—created and used for the first time in 1985.²³

In the following thirty years, the industry saw a boom in robotic surgery technology. Computer Motion, Inc. developed one of the earliest commercial surgery robots, Automated Endoscopic System for Optimal Positioning (AESOP) for intra-abdominal surgeries, which FDA approved in 1994.²⁴ Four years later, Computer Motion introduced the ZEUS Robotic Surgical

17. Evalyn I. George et al., *Origins of Robotic Surgery: From Skepticism to Standard of Care*, 22 J. SOC'Y LAPAROENDOSCOPIC SURGEONS, Oct.–Dec. 2018, at 1, 1.

18. See *id.* at 7–12 (discussing the advancements in robotic surgery technology and the influence of better control systems, haptic feedback programming, and improved robotic techniques).

19. *Id.* at 1.

20. See U.S. Patent No. 2,988,237 (issued June 13, 1961) (describing the “programmed article transfer” device and its use).

21. Lotfi A. Zadeh, *Fuzzy Sets*, 8 INFO. & CONTROL 338, 338 (1965).

22. See Stevo Bozinovski, *Parallel Programming for Mobile Robot Control: Agent-Based Approach*, in 14TH INTERNATIONAL CONFERENCE ON DISTRIBUTED COMPUTING SYSTEMS, 202, 202–03 (1994) (“From 1982 to 1986 we carried out the ADRIEL (ADaptive Robot of the Institute of ELectronics) project: to design and construct mobile robots for educational purposes.”).

23. Olga Lechky, *World's First Surgical Robot in B.C.*, 21 MED. POST 92 (1985).

24. Alberto Mendivil et al., *Emergence of Robotic Assisted Surgery in Gynecologic Oncology: American Perspective*, 114 GYNECOLOGIC ONCOLOGY S24, S25 (2009); see *Robotic Surgery*, NASA (2000), <https://spinoff.nasa.gov/spinoff2000/hm1.htm> (providing further details about AESOP).

System,²⁵ which was exclusively tailored for treatment in minimally invasive microsurgery procedures such as beating heart surgery and endoscopic coronary artery bypass grafting that typically employ an endoscopy and tissue retractor.²⁶

After Intuitive Surgical, Inc.²⁷ acquired Computer Motion in 2003,²⁸ Intuitive Surgical's main product, the da Vinci series,²⁹ replaced ZEUS and has dominated the market of robotic surgery system ever since.³⁰ Since launching the first da Vinci surgical system in 2000, Intuitive Surgical has marketed altogether at least four generations of surgical robot—the da Vinci Standard System, the da Vinci S System, the da Vinci Si Surgical System, and the da Vinci SP Surgical System, respectively, in the past twenty years.³¹ Built based on the technologies developed in ZEUS, different generation da Vinci systems share the main components—a surgical console, surgical cart, and vision cart.³² Earlier versions of da Vinci systems also resemble ZEUS in functionality aspects—they are specialized surgical robots developed mainly for particular uses within certain cavities of the human body.³³ Major improvements on generations of da Vinci systems include expansion of the types and sizes of available wristed instruments attachable to the surgical console for operating on patients, the imaging techniques—including equipment of high-definition video to assist vision of surgeons—

25. Mendivil et al., *supra* note 24, at S25.

26. Jacques Marescaux & Francesco Rubino, *The ZEUS Robotic System: Experimental and Clinical Applications*, 83 SURGICAL CLINICS NORTH AM. 1305, 1306–11 (2003).

27. INTUITIVE SURGICAL, <https://www.intuitive.com/en-us> (last visited Mar. 14, 2022). Founded in 1995, Intuitive Surgical has aimed at developing a “reliable, intuitive, surgical device that would deliver the benefits of minimally invasive surgery to the patient while preserving the benefits of open surgery for the operator.” M.E. Hagen & M.J. Curet, *The da Vinci Surgical Systems*, in ROBOTIC SURGERY 9, 10 (Go Watanabe ed., 2014).

28. *Intuitive Surgical and Computer Motion Close Merger*, INTUITIVE SURGICAL (June 30, 2003), <https://isrg.intuitive.com/node/7401/pdf>.

29. See *Intuitive History*, INTUITIVE SURGICAL [hereinafter *Intuitive History*], <https://www.intuitive.com/en-us/about-us/company/history> (last visited Nov. 28, 2020) (discussing the history of Intuitive and the da Vinci series).

30. In fact, the da Vinci Surgical System is still “the only commercially available master-slave robotic system.” See Ohuchida & Hashizume, *supra* note 16, at 2.

31. *Intuitive History*, *supra* note 29.

32. Hagen & Curet, *supra* note 27, at 11.

33. *Id.*

and improvement to user interfaces—such as the adding of a second console for two surgeons to collaborate in a surgery or training.³⁴

The market for robotic surgery systems continues to grow.³⁵ Though Intuitive Surgical's da Vinci remains currently the only commercially available product as of 2020,³⁶ the bright future of minimally invasive surgery and telesurgery has incentivized more medical device companies to develop their own robotic surgery systems. Examples include the VELYS Robotic-Assisted Solution, created by Johnson & Johnson,³⁷ and the Hugo RAS System from Medtronic.³⁸

The room for improvement remains large for robotic surgery systems besides the endless pursuit of better control and higher precision. Current problems of robotic surgical systems center on the high purchase cost of robotic surgery systems.³⁹ Common

34. *Id.*

35. *Compare Medical Robotics and Computer-Assisted Surgery: The Global Market*, BCC RSCH. (June 2014), <https://www.bccresearch.com/market-research/healthcare/medical-robotics-mrcas-market-hlc036f.html> (“The global market for medical robotics and computer-assisted surgical . . . equipment was worth nearly \$2.7 billion in 2013. The market is projected to approach \$3.3 billion in 2014 and \$4.6 billion by 2019 . . .”), *with Medical Robotics and Computer-Assisted Surgery: The Global Market*, BCC RSCH. (July 2021), <https://www.bccresearch.com/market-research/healthcare/medical-robotics-mrcas-market.html> (“The global market for surgical robotics and computer-assisted surgery should grow from \$6.1 billion in 2020 to \$11.6 billion by 2025 with a compound annual growth rate . . . of 13.5% for the period of 2020-2025.”).

36. Ohuchida & Hashizume, *supra* note 16, at 2.

37. The FDA gave DePuy Synthes 510(k) FDA clearance on January 19, 2021, for VELYS Robotic-Assisted Solution designed for use in a knee replacement surgery system. *DePuy Synthes Receives 510(k) FDA Clearance for VELYS Robotic-Assisted Solution Designed for Use with the ATTUNE Total Knee System*, JOHNSON & JOHNSON: DEPUY SYNTHES (Jan. 19, 2021), <https://www.jnjmedicaldevices.com/en-US/news-events/depuv-synthes-receives-510k-fda-clearance-velys-robotic-assisted-solution-designed>. DePuy Synthes is “the Orthopaedics Company of Johnson & Johnson.” DEPUY SYNTHES, <https://www.jnjmedicaldevices.com/en-US/companies/depuv-synthes> (last visited Mar. 14, 2022).

38. *Hugo RAS System*, MEDTRONIC, <https://www.medtronic.com/covidien/en-us/robotic-assisted-surgery/hugo-ras-system.html> (last visited Mar. 14, 2022).

39. In 2008, Hansen Medical's Sensei robotic system cost \$675,000, and the da Vinci system cost \$1.3 million. Barnaby J. Feder, *Prepping Robots To Perform Surgery*, N.Y. TIMES (May 4, 2008), <https://www.nytimes.com/2008/05/04/business/04moll.html>. Medical institutes often pay additional amounts to

criticisms of the da Vinci series involve its costly price to equip, its system complication, and the advantages it yields over traditional surgery methods are less significant than expected.⁴⁰ Moreover, the da Vinci series has also received criticism for its lack of versatility and relatively limited surgical field applications.⁴¹ These problems are correlated—a single robotic surgery system capable of treating a larger variety of complex procedures reduces the number of surgical systems a healthcare entity needs to install and the amount of time necessary for training physicians, thereby significantly lowering costs for the healthcare entity.⁴²

Robotic surgery innovators now aim to make their devices and systems more general-purpose to address these issues.⁴³ Older robotic surgery devices like ASEOP, ZEUS, and the early da Vinci Standard systems focused on a specific surgical technique or medical treatment for which the technology could most adequately provide surgical control.⁴⁴ For example, the early da Vinci systems specialized in particular laparoscopic surgery procedures that involve visualization and tissue retraction.⁴⁵ Intuitive Surgical's continued research efforts

train physicians to use robotic surgery systems on top of the system's initial price. *See id.*

40. See Tsuyoshi Kaneko et al., *Robotic Surgery for Mitral Valve Disease*, in *ROBOTIC SURGERY* 111, 119 (Go Watanabe ed., 2014) (“Despite [an] optimistic view, many surgeons [may not adopt these systems due to] concern[s] with the complexity and procedure cost . . .”).

41. Gyu-Seog Choi, *Lateral Pelvic Node Dissection for Advanced Rectal Cancer: Current Debates and Use of the Robotic Approach*, in *ROBOTIC SURGERY* 75, 76 (Go Watanabe ed., 2014) (“Unfortunately, the da Vinci robotic system also comes with disadvantages, including limited range of surgical field, an intuitive but not versatile approach, and high costs.”).

42. See U. Hagn, et al., *The DLR MIRO: A Versatile Lightweight Robot for Surgical Applications*, 35 *INDUS. ROBOT: INT'L J.* 324, 324 (2008) (“Specialized [robotic] systems . . . like . . . the da Vinci surgical system . . . can fulfil[] the dedicated task very well, but link the financial amortization in the clinic to single medical procedures.”).

43. According to German Aerospace Center (DLR) researchers, the older “specialized” systems designed for specific techniques or treatments are being phased out by “versatile” systems that can operate in various surgical applications and special settings. *Id.*

44. *See id.*; see also George et al., *supra* note 17, at 1, 7, 9–10 (giving a comprehensive history of robotic surgery device evolution).

45. M.E. Hagen & M.J. Curet, *Development of Robotic Systems*, in *ROBOTIC SURGERY* 21, 22–23 (Go Watanabe ed., 2014); see also Ann Marie McGuiness, *Robotics in Minimally Invasive Surgery*, *SURGICAL TECHNOLOGIST*, Dec. 2000, at 11, 14 (detailing how the da Vinci system works and its surgical applications).

expanded use of robotic devices to other surgery fields, including neurosurgery, orthopedics, and urology.⁴⁶ The latest da Vinci SP, for instance, specializes in urological surgeries in addition to its traditional gastrointestinal uses.⁴⁷ Intuitive Surgical's competitors have also put significant efforts into developing more versatile and general-purpose robotic surgery systems. For example, German Aerospace Center (DLR) developed DLR MIRO, a versatile and lightweight surgical robotic system.⁴⁸ The MIRO robot is designed to "fit seamlessly into existing surgical procedures and clinical environments" and to "comply with rapidly changing development in medical treatment and safety."⁴⁹ Thus, the trend towards future general-purpose robotic surgery technology is apparent.

B. ADMINISTRATIVE REGULATION OF ROBOTIC SURGICAL DEVICES AND SYSTEMS

Surgeons use robotic surgical devices and systems in procedures that preserve human lives. Administrative regulation of robotic surgical devices is necessary to protect public health but must be carefully balanced to not stifle technological innovation.⁵⁰ Many countries have not established

"Tissue retraction" is a surgical term of art, roughly defined as holding back tissue for the surgeon's access and line of sight, or to prevent damage to surrounding structures. *See generally* P.R.C. Steele et al., *Current and Future Practices in Surgical Retraction*, 11 SURGEON 330, 330, 333–34 (2016) (reviewing different forms of retraction methods).

46. Hagen & Curet, *supra* note 45, at 24–25. "So far, more than 2,300 da Vinci systems have been installed worldwide. Many kinds of surgical operations, such as general surgery, gynecologic surgery, urologic surgery, pediatric surgery, cardiothoracic surgery, and other operations were performed using the da Vinci Surgical System." Ohuchida & Hashizume, *supra* note 16, at 2 (internal citations omitted).

47. Thom E. Lobe, *Da Vinci SP Surgical System, EndoWrist SP Instruments, and Accessories*, SAGES (July 29, 2019), <https://www.sages.org/publications/tavac/da-vinci-sp-surgical-system-endowrist-sp-instruments-and-accessories>.

48. Hagn et al., *supra* note 42, at 324. The new generation MIRO DLR included a "compact, slim and lightweight robot (LWR) arm." *Id.* The DLR researchers considered this arm a "versatile core component for various existing and future medical robotic procedures," whereas previous systems used components with a "stiff structure[] and relatively high mass" like those used in industrial robots. *Id.*

49. *Id.* at 325.

50. *See* Ronald Leenes et al., *Regulatory Challenges of Robotics: Some Guidelines for Addressing Legal and Ethical Issues*, 9 L. INNOVATION & TECH. 1, 7 (2017) ("Another, related, dilemma presents itself in the regulation of

a clear regulatory framework for robotic surgical devices and systems, as the technology only appeared in the commercial market less than twenty years ago and has been developing at a rapid speed.⁵¹ Many countries choose to treat robotic surgical devices as a subcategory of medical devices and systems, applying corresponding regulations.⁵² The United States is one such country.

1. Approval and Clearance Regulation

In the United States, robotic surgery devices and systems, like other medical devices, must be reviewed by the United States Food and Drug Administration (FDA) before entering into commercial markets.⁵³ Device regulation started in the United States after enactment of the Medical Device Amendments of 1976, which modified the Federal Food, Drug, and Cosmetic Act (FFDCA).⁵⁴ The 1976 Amendments stipulate a risk-based regulation scheme for medical devices.⁵⁵ Specifically, the FDA established a scheme that classifies medical devices depending on the device's intended use and indicated use according to the device's labeling.⁵⁶ So far, the FDA has established classifications for approximately 1,700 different generic types of

emerging technologies. On the one hand, we have the concern that premature and obtrusive legislation might hamper scientific advancement and prevent potential advantages from materialising, and burden competitiveness or cause economic or other inefficiencies. At the same time, somehow paradoxically, the lack of a reliable and secure legal environment may equally hinder technological innovation.”)

51. *See id.* For example, the European Union has no specific regulation for robotic surgery system like the da Vinci. *Id.* at 8.

52. The European Union, for instance, regulates da Vinci as a Class IIb medical device based on Annex IX of the Medical Devices Directive (MDD). *Id.* (citing Council Directive 93/42/EEC, annex IX, 1993 O.J. (L 169) (EC)). “Surgical robots[] . . . are treated no different than other medical devices used in surgical operations, such as scissors and scalpels. The MDD solely regulates the function, design and construction requirements of medical devices and not the risks involved in robot surgery, which are determined by a complex human-machine interplay.” *Id.* at 9.

53. 21 U.S.C. § 360(c). The FDA's Center for Devices and Radiological Health (CDRH) is responsible for medical device review. JUDITH A. JOHNSON, CONG. RSCH. SERV., R42130, FDA REGULATION OF MEDICAL DEVICES 1 (2016).

54. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360).

55. 21 U.S.C. § 360(h)(2).

56. *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device> (last visited Mar. 14, 2022).

devices and grouped them into sixteen panels.⁵⁷ Medical devices are divided into three regulatory classes based on intrinsic risk—Classes I, II, and III (in order from lowest to greatest risk)—each of which entails different FDA approval requirements.⁵⁸ Most robotic surgery systems fall into Class III, as they are deemed as “those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.”⁵⁹ The FFDCA provides two main paths—namely, premarket approval approach and 510(k) approach—for Class III medical device manufacturers to bring such devices to market.⁶⁰ The premarket approval approach consists of two steps—conducting clinical studies to generate evidence providing a reasonable assurance that a device new to the market is safe and effective, and submitting a premarket approval application containing such evidence to the FDA.⁶¹ The premarket approval results in FDA approval of a novel device.⁶² The 510(k) approach, on the other hand, requires submitting a premarket notification through the “510(k) process” if the manufacturer intends to introduce a device substantially equivalent to another device already on the market, or if the manufacturer seeks a new indication (e.g., a new population, a new disease, or a new condition) for a currently marketed device.⁶³ The 510(k) process thus results in FDA clearance, rather than approval.⁶⁴ Compared to the premarket approval

57. *Id.*

58. *Id.*

59. 21 C.F.R. 814; *Premarket Approval*, U.S. FOOD & DRUG ADMIN. [hereinafter *PMA*], <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma#when> (last visited Nov. 28, 2020).

60. Johnson, *supra* note 53, at Summary.

61. *Id.*

62. *Id.*

63. *Id.* at 19–20. Some Class III pre-amendment devices may require a Class III 510(k). For details regarding 510(k) process, see *510(k) Clearances*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances> (last visited Nov. 28, 2020).

64. Johnson, *supra* note 53, at 19–20.; see also *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k> (last visited Mar. 24, 2022) (discussing circumstances when a 510(k) is required).

64. Johnson, *supra* note 53, at 19–20.

approach, the 510(k) process is much less rigorous,⁶⁵ much less expensive, and much less time-consuming, and therefore is favored by robotic surgery device and system manufacturers.⁶⁶ As an alternative to premarket approval application and normal 510(k) process, a third track called the De Novo classification applies to innovative devices which pose health risks that stand between the levels required by premarket approval application and normal 510(k) process.⁶⁷ Theoretically, the De Novo classification provides a “failsafe position” for novel medical devices which were automatically placed in Class III after receiving a “not substantially equivalent” determination in response to a 510(k) submission.⁶⁸ Nonetheless, empirical studies show that in practice, surgery devices and systems suppliers rarely seek De Novo review compared to the other two pathways.⁶⁹

As indicated above, obtaining FDA clearance and approval for medical devices takes time. The FDA approval process can take about seven years, causing significant delays in the commercialization of a medical device.⁷⁰ The FDA clearance process for a Class III medical device itself can be shorter, taking

65. In his report, Johnson stated three characteristics of the 510(k) process contribute to this difference: (1) the FDA generally does not require premarket inspections of how devices were manufactured; (2) the FDA does not require post-market studies as a condition of clearance; and (3) the FDA has limited authority to rescind or withdraw clearance if a 510(k) device is not safe or effective. Johnson, *supra* note 53, at 20.

66. *Id.* at Summary.

67. The De Novo classification was added by the Food and Drug Administration Modernization Act of 1997. *Evaluation of Automatic Class III Designation (De Novo) Summaries*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries> (last visited Jan. 16, 2021).

68. *Id.*

69. David Britton, *Automating Surgery: The Law of Autonomous Surgical Robots*, J.L. TECH. TEX. (May 1, 2016), http://jolttx.com/2016/05/01/automating-surgery-law-autonomous-surgical-robots/#_ftnref35.

70. See Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Process for Drugs*, JACC: BASIC TO TRANSLATIONAL SCIENCE 170, 170 (Apr. 2016) (“New drug and device approval in the United States take an average of 12 and 7 years, respectively, from pre-clinical testing to approval. Costs for development of medical devices run into millions of dollars”); Hagen & Curet, *supra* note 45, at 25 (mentioning that the lengthy FDA approval process caused significant delays in the commercialization of the first surgical robot ROBODOC).

between one week and eight months.⁷¹ Yet it could take years for medical device designers and manufactures to gather the necessary data to meet the FDA requirements for submission. Intuitive Surgical's struggle to obtain FDA approval and clearance for its da Vinci surgical systems tells the story. Intuitive Surgical first obtained FDA approval and clearance in 1997, but only for visualization and tissue retraction.⁷² It was not until 2000 that the device's full instrumentation could be used for general laparoscopic surgery indications including cholecystectomy and Nissen fundoplication.⁷³ In 2002, the FDA approved the da Vinci surgical system for mitral valve surgery and atrial septal defect (ASD) repair.⁷⁴ Intuitive Surgical has kept spending efforts on having its da Vinci cleared for a larger variety of surgeries ever since.⁷⁵

2. Label and Labeling Regulation

Another important administrative regulation on robotic surgery systems is related to labels and labeling.⁷⁶ All FDA-approved or -cleared medical devices, including robotic surgery systems, must contain a label that adequately informs a user of proper uses of the device and complies with labeling requirements developed by the FDA.⁷⁷ The FFDCA defines a "label" as "a display of written, printed, or graphic matter upon the immediate container of any article . . ."⁷⁸ Title 21 of the Code of Federal Regulations (C.F.R.) prescribes labeling regulations for medical devices.⁷⁹ Note that labeling is a concept

71. See EMERGO, HOW LONG IT TAKES THE US FDA TO CLEAR MEDICAL DEVICES VIA THE 510(K) PROCESS (Mar. 2017) (showing that it takes an average of five months for 510(k) submission to clear, and that different types of devices have different clearance times).

72. George et al., *supra* note 17, at 10.

73. George et al., *supra* note 17, at 10; Hagen & Curet, *supra* note 27, at 11.

74. Go Watanabe, *Cardiac Surgery: Overview*, in ROBOTIC SURGERY 87, 92 (Go Watanabe ed., 2014).

75. See George et al., *supra* note 17, at 10.

76. Johnson, *supra* note 53, at 40.

77. *Id.*; see also DIV. OF SMALL MFRS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, LABELING: REGULATORY REQUIREMENTS FOR MEDICAL DEVICES 43 (1989), <https://www.fda.gov/media/74034/download>.

78. 21 U.S.C. § 321(k) (1938).

79. See *Device Labeling*, U.S. FOOD & DRUG ADMIN. (Oct. 23, 2020), <https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling>.

different from a label. The FDCA defines “labeling” as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce.”⁸⁰ The FDA and courts have held the view that “most, if not all advertising, is labeling.”⁸¹ Accordingly, advertising on medical devices must comply with relevant FDA regulations on labeling.

Medical devices must conform to the general device labeling requirements under 21 C.F.R. § 801.⁸² Several relevant requirements are discussed in the following. Specifically, § 801.1 stipulates that the label of a device shall contain necessary information of its manufacturers, packers, or distributors such as their names and addresses.⁸³ Section 801.4 requires disclosure of intended uses for the device, which are determined by the “objective intent of the persons legally responsible for the labeling of [devices].”⁸⁴ Such persons should provide adequate labeling to their best knowledge in accordance with all uses for conditions or purposes other than those intended.⁸⁵ Section 801.5 asks for adequate directions under which a layman can safely use a device for its intended purposes.⁸⁶ Of note, theoretically, robotic surgery systems and devices are exempted from this particular requirement as they require assistance from practitioners.⁸⁷ Section 801.6 requires labeling of a device not to contain any false or misleading statement “with respect to another device or a drug or a food or cosmetic.”⁸⁸ Furthermore,

80. *Id.*; 21 U.S.C. § 321(m) (1938).

81. DIV. OF SMALL MFERS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, *supra* note 77, at 3 (“The distinction between labeling and advertising . . . is often superficial or nebulous . . . Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising.”).

82. 21 C.F.R. § 801 (2022). “All devices must conform to the general labeling requirements,” while “[c]ertain devices require specific labeling.” Johnson, *supra* note 53, at 36 (citation omitted). These devices do not include robotic surgery devices and systems. *See id.* at 36 n. 232.

83. 21 C.F.R. § 801.1 (2022).

84. 21 C.F.R. § 801.4 (2022).

85. *See* DIV. OF SMALL MFERS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, *supra* note 77, at 5 (using a manufacturer of dental X-ray equipment who is routinely selling his product to podiatrists as an example).

86. 21 C.F.R. § 801.5 (2022).

87. *See* 21 C.F.R. § 801.109 (2022); *see also* DIV. OF SMALL MFERS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, *supra* note 77, at 8.

88. 21 C.F.R. § 801.6 (2022).

many robotic surgery systems and devices also need to meet labeling requirements for investigational devices and 510(k) devices, if such a system or device is “the object of a clinical research or investigation,”⁸⁹ or is undergoing a 510(k) clearance process.⁹⁰ The format for the 510(k) submission is outlined in §§ 807.81 to 807.91.⁹¹

The FFDCa urges developers, manufacturers, and sellers to label their medical device products properly and adequately. The FDA warns that “there is often a direct relationship between device misuse and the labeling, especially in the directions for use.”⁹² Medical device firms must take into consideration both who will be using the device and how it will be used in order to draft suitable labeling and avoid certain problems the law is designed to prevent.⁹³ Finally, it is noted that although misbranding and poor label control violate the letter of the law,⁹⁴ inadequate labeling, though potentially problematic, does not always result in violation of the FFDCa.⁹⁵

C. PATENT INFRINGEMENT LAWSUITS AGAINST ROBOTIC SURGERY COMPANIES AND THE HIGH RISK OF SECONDARY LIABILITY ARISING OUT OF INDIRECT INFRINGEMENT

The costs to comply with multiple countries and areas’ administrative regulations have already placed substantive burdens, necessary or not, on robotic surgery companies.⁹⁶ The frequent need to deal with patent infringement accusations, if existing, will certainly drag robotic surgery system developers’ innovation incentives further down.

89. DIV. OF SMALL MFRS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, *supra* note 77, at 15.

90. *See id.* at 16.

91. *Id.*

92. DIV. OF SMALL MFRS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, *supra* note 77, at 37.

93. *Id.* at 37.

94. Misbranding and false or misleading labeling are proscribed by § 502 of the FFDCa. *Id.* at 3–4. 21 C.F.R. § 820 demands good manufacturing practices from medical device suppliers and proscribes poor label control. *Id.* at 18.

95. *Id.* at 37.

96. *See, e.g.,* Johnson, *supra* note 53, at Summary; Adam Lewin, *Medical Device Innovation in America: Tensions Between Food and Drug Law and Patent Law*, 26 HARV. J.L. & TECH. 403 (2012).

1. Patent Infringement Lawsuits, Frivolous or Not, Cost Significant Amounts of Time and Money to Resolve.

The complexity and sophistication of both the legal and technical aspects of patent infringement disputes determine whether a dispute could persist for years or even decades. Professor Mark A. Lemley has demonstrated in his article *Where to File Your Patent Case* that the trial time in district court alone could vary from 0.67 years to 3.51 years.⁹⁷ If any party appeals, the span of the suit could easily stretch to more than five years.⁹⁸ In an exceptional case, *Grain Processing Corp. v. American Maize-Products Co.*,⁹⁹ the dispute spanned more than eighteen years and nine judicial opinions.¹⁰⁰

While costs for litigating patent infringement matters surge along with length of the suit, it is still not comparable to the potential loss to the accused resulting from remedies that a court would award the patent owner. Sections 283 and 284 of Title 35 of the United States Code respectively stipulate that a court upon finding infringement can grant a patent owner either injunctive or monetary relief or both.¹⁰¹ Section 284 further empowers a court to use its discretion to “increase the damages up to three times the amount found or assessed” should the court find the infringement willful or egregious.¹⁰² Section 285 further stipulates that courts can award reasonable attorney fees to the prevailing party in exceptional cases.¹⁰³ An injunction

97. Mark A. Lemley, *Where to File Your Patent Case*, 38 AIPLA Q.J. 401, 416–18 (2010). In a more recent report produced by the Fish & Richardson law firm in 2019, it was noted that in a patent case, the fact discovery period alone may last from six months to several years and that it typically takes from one to three years for a case to get to trial. FISH & RICHARDSON, A GUIDE TO PATENT LITIGATION IN FEDERAL COURT 6 & 8 (Lawrence K. Kolodney ed., 2019).

98. Compare Lemley, *supra* note 97, at 416–19 (stating trial time in district court can be as long as 3.51 years), with FISH & RICHARDSON, *supra* note 97, at 18 (showing the timeline of the appeal process).

99. 185 F.3d 1341 (Fed. Cir. 1999).

100. *Id.* at 1343 (“This appeal culminates the lengthy and complex history of this case, spanning more than eighteen years and eight prior judicial opinions, three by this court.”).

101. 35 U.S.C. §§ 283–84.

102. 35 U.S.C. § 284 (2011); *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 579 U.S. 93, 110 (2016) (ruling that awards of enhanced damages are to punish and deter “willful” and “egregious” conducts and are discretionary).

103. 35 U.S.C. § 285 (1952). Similar to enhanced damages, award of attorney fees is also a matter within a court’s discretion, and it requires the court to

temporarily or permanently halts all activities deemed infringing by the court, resulting in economic loss for the accused.¹⁰⁴ An injunction could also interrupt the accused's business activities leading to a loss of a market position.¹⁰⁵ The effect of injunctions are so powerful that Justice Kennedy warned in his concurrence in *eBay Inc. v. MercExchange, L.L.C.*¹⁰⁶ that sometimes "the threat of an injunction is employed simply for undue leverage in negotiations . . ." ¹⁰⁷ Monetary damages, which are normally calculated based on either lost profits that the patent owner would have gained but for the infringement or a reasonable royalty that the parties would have successfully negotiated, could be equally, if not more, damaging to the accused than injunctions.¹⁰⁸ To illustrate, even the 3% reasonable royalty rate awarded by the District Court in *Grain Processing Co. v. American Maize-Products Co.* "yielded damages of approximately \$2.4 million, and the lost profits the patent owner sought amounted up to \$35 million, which with applicable interest presently implicate[d] an award approaching \$100 million."¹⁰⁹

Furthermore, accusations of patent infringement could jeopardize a company's reputation.¹¹⁰ Involvement in an infringement lawsuit itself can devastate years of effort by a company. It is not rare to see infringement lawsuits tactically

consider all circumstances and make case-by-case determinations. *Octane Fitness, LLC v. Icon Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014).

104. *Injunctions and Restraining Orders in Patent Infringement Cases*, JUSTIA, <https://www.justia.com/intellectual-property/patents/infringement/injunctions-and-restraining-orders-in-patent-infringement-cases/> (last visited Jan. 17, 2021).

105. Jeffri A. Kaminski, *Using Injunctions to Gain Market Share: What's the Harm?*, VENABLE LLP (June 2012), <https://www.venable.com/insights/publications/2012/06/using-injunctions-to-gain-market-share-whats-the-h>.

106. 547 U.S. 388 (2006).

107. *Id.* at 397 (Kennedy, J., concurring). It is particularly problematic when the patented invention is a small component of the product the companies seek to produce, creating a scenario which patent law professionals refer to as "patent holdup." See THOMAS F. COTTER, REMEDIES IN U.S. PATENT LAW 9 (2d ed.) for further discussion.

108. See COTTER, *supra* note 107, at 22.

109. 185 F.3d 1341, 1353 n.4 (Fed. Cir. 1999).

110. See generally Robin Feldman & Evan Frondorf, *Patent Trolls and IPOs: A Perfect Moment to Strike*, COLUMBIA L. SCH. BLUE SKY BLOG (May 26, 2015), <https://clsbluesky.law.columbia.edu/2015/05/26/patent-trolls-and-ipos-a-perfect-moment-to-strike/> (discussing the damaging effect of infringement litigation on company valuation).

filed or threatened against a technology company just to sabotage its efforts in its Initial Public Offering (IPO).¹¹¹

2. Robotic Surgery System Companies are Susceptible to Indirect Infringement of Device and/or System Patents.

35 U.S.C. § 271(a) stipulates that “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent thereof, infringes the patent.”¹¹² In addition, § 271(b) further stipulates that a party can be held liable for actively inducing a third-party’s infringement, and § 271(c) yields that a party who contributes to a third-party’s infringement is likewise liable.¹¹³ The infringement theory under § 271(a) is commonly referred to as “direct infringement,” as the party directly infringes.¹¹⁴ In contrast, the infringement theory under §§ 271(b) and (c) are commonly referred to as “indirect infringement.”¹¹⁵ Together, the three statutes constitute the most commonly-used patent infringement theories.

In practice, when the claimed subject matter in a patent is a device and a supplier makes, manufactures, sells, or imports into the United States a robotic surgery system that is entirely or partially the same or is an equivalent to the claimed device,¹¹⁶ the device patent owner can sue the supplier for directly infringing the patent. Alternatively, the device patent owner can sue the supplier for contributing to or inducing the infringing use of the claimed device by medical practitioners in corresponding medical procedures.

111. *See id.* (discussing the intriguing relationship between IPOs and patents (citing *Certco Inc. v. PayPal Inc.*, Civil Action No. 02-094 (D. Del. Feb. 4, 2002), available at http://www.sec.gov/Archives/edgar/data/1103415/000091205702004798/a2070244zex-99_2.htm)).

112. 35 U.S.C. § 271(a).

113. 35 U.S.C. §§ 287(b) and (c).

114. *See, e.g., Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 483 (1964) (referring to infringement under § 271(a) as “direct infringement”).

115. *See id.*

116. In order to ensure the enforcement of patents, one also infringes under the “doctrine of equivalents,” which requires a comparison between each feature of the accused product and the claimed invention. *See Warner-Jenkinson v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

Usually, the device patent owner will simply list direct infringement and indirect infringement together in a complaint as alternative theories. The following case reflects such a common scenario. On March 15, 2019, P Tech, LLC¹¹⁷ filed a complaint against Intuitive Surgical in the United States District Court for the District of Delaware, contending that Intuitive Surgical's selling of the da Vinci surgical system with Endo Wrist Staplers and SureForm Staplers directly and indirectly infringed two of its patents—U.S. Patent Nos. 9,149,281 and 9,192,395, respectively.¹¹⁸ Specifically, P Tech alleged that the Endo Wrist Stapler and SureForm Staplers Intuitive Surgical used in its da Vinci surgical systems correspond to the claimed inventions in its two device patents, thereby rendering the making and selling of da Vinci surgical systems direct infringement of the two device patents.¹¹⁹ In addition, P Tech alleged that Intuitive Surgical “facilitat[es], train[s], support[s], teach[es], direct[s], and instruct[s]” its customers and/or end-users, who are the healthcare providers at healthcare entities, to use the da Vinci surgical systems equipped with the allegedly infringing Endo Wrist Staplers and/or SureForm Staplers, thereby indirectly infringing its two patents under §§ 271(b) and (c).¹²⁰

In such cases, the accuser ties its indirect infringement charges to its direct infringement charges and strategically lists them as alternative infringement theories in complaint. Because the indirect infringement claims rise and fall with the direct infringement claims, the risk of indirect patent infringement arising out of medical procedures performed by third parties for a robotic surgery system supplier is therefore at least the same as the risk of direct infringement when the patent at issue covers devices or systems.

3. Robotic Surgery System Companies are Also Susceptible to Indirect Infringement of Medical Treatment Method Patents.

Somewhat counterintuitively, under current United States patent law, a robotic surgery system supplier, like all medical

117. *P Tech*, BONUTTI TECHNOLOGIES, <https://bonuttitechnologies.com/designs/p-tech/> (last visited Dec. 5, 2020).

118. Complaint at 19, *P Tech, LLC v. Intuitive Surgical, Inc.*, DED-1-99-cv-de460 (D. Del. Mar. 18, 2019).

119. *Id.* at 7–18.

120. *Id.*

device or system suppliers, could indirectly infringe a medical treatment method patent.¹²¹ In fact, controversy has long surrounded whether patent protection should extend to medical treatment methods, and if so, to what extent.¹²² The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) permits World Trade Organization (WTO) member countries to exclude medical treatment methods from patentability, but leaves the decision to the countries.¹²³ To not overly burden physicians as they seek to administer the best available treatment for patients, four of the “IP5”¹²⁴ jurisdictions choose to hold that medical procedures are per se unpatentable.¹²⁵ The United States chooses to allow medical

121. As demonstrated below, 35 U.S.C. §§ 271(b) and (c) apply here with limitation in § 287(e).

122. See, e.g., Bradley J. Meier, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. LEGIS. 265, 265 (1997).

123. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197, Art. 27(3)(a) (1994) (permitting but not requiring member countries to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”).

124. “IP5” stands for the five largest intellectual property offices in the world, including the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), and the China National Intellectual Property Administration (CNIPA). See FIVE IP OFFICES, <https://www.fiveipoffices.org/index> (last visited Nov. 28, 2020).

125. Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199, art. 52(4) (excluding “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on human or animal body” from patentable subject matter); JAPAN PATENT OFFICE, EXAMINATION GUIDELINES FOR PATENT AND UTILITY MODEL IN JAPAN, Pt. III, Ch. 1, at 8, https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/document/index/03_0100_e.pdf (last visited Nov. 28, 2020) (providing that methods of surgery, therapy, or diagnosis of humans do not meet the industrial applicability requirement under Japanese patent law main paragraph of art. 29(1)); KOREAN INTELLECTUAL PROPERTY OFFICE, PATENT EXAMINATION GUIDELINES, Pt. III, Ch. 1(5), https://www.kipo.go.kr/upload/en/download/patent_examination_guidelines_2018_01.pdf (last visited Nov. 28, 2020) (“A method for treatment of the human body by surgery or therapy and a diagnostic method practiced on the human body are considered to be industrially inapplicable inventions.”); WORLD INTELLECTUAL PROPERTY OFFICE, PATENT LAW OF THE PEOPLE’S REPUBLIC OF CHINA, art. 25(3), <https://www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf> (last visited Nov. 28, 2020) (“Patent rights shall not be granted for . . . methods for the diagnosis or treatment of diseases.”). Note, however, jurisdictions may provide some “work-arounds” while banning patents on medical methods. For example, the

procedures as patentable subject matter.¹²⁶ However, to counter potential harshness this rule might bring to the country's health care system, under legislation enacted in 1996, 35 U.S.C. § 287(c) provides severe limits on remedies for infringing such patents.¹²⁷ Specifically, § 287(c)(1) stipulates that patent owners cannot get any remedy against a "medical practitioner" as defined in § 287(c)(2)(B) with respect to his or her performance of a medical activity or a "related health care entity" as defined in § 287(c)(2)(C), encompassing the responsible doctors, nurses, and related health care entities.¹²⁸ The law, however, leaves medical method patent owners with the option to obtain remedies from medical supply companies which make and sell devices and systems used in the infringing medical activity,¹²⁹ even though the medical practitioners who directly infringe the patented medical methods are exempted from liabilities. A medical procedure patent owner thus can sue the medical equipment suppliers for actively inducing and/or contributing to the medical practitioners' infringing performance of the patented procedure under §§ 271(b) and (c).¹³⁰

EPO generally allows second medical use claims using a format such as "compound X for use in the treatment of disease Y." Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 199, art. 54(5).

126. 35 U.S.C. § 101 stipulates that patentable subject matter includes "process, machine, manufacture, or composition of matter." Medical procedures are deemed a "process." See Lara L. Douglass, *Medical Process Patents: Can We Live Without Them? Should We?*, 3 J. INTELL. PROP. L. 161, 161–62 (1995). There is no law in the United States providing that medical procedures are unpatentable subject matter.

127. In the mid-1990s, Dr. Samuel Pallin first tried to enforce his patent on the method of making incisions in performing eye surgery, inducing outrage in the health care community and public. In response, Congress passed what is encoded as § 287(c). 35 U.S.C. § 287(c). See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY* 169–71 (7th ed. 2017).

128. To counter the harshness that allowing medical procedures to be patented brings to health care systems, Congress passed the bill in 1996 to add § 287(c) mainly to provide immunity for health care providers. 141 CONG. REC. 15290-07 (Oct. 18, 1995) (statement of Sen. Frist) (acknowledging that issuance of patents on medical procedures conflicts with the broader social interest in providing health care); see also Leisa Talbert Peschel, *Revising the Compromise of 35 U.S.C. § 287(c)*, 16 TEX. INTELL. PROP. L.J. 299, 308–10 (2008) (describing the legislative process of the statute).

129. See MERGES & DUFFY, *supra* note 127, at 171.

130. 35 U.S.C. §§ 271(b)–(c). Note the Supreme Court has held that to find indirect infringement, there must be direct infringement under § 271(a). *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 340–42 (1961).

In *Barry v. Medtronic, Inc.*,¹³¹ the medical procedure patent owner Dr. Mark Barry successfully asserted induced infringement of medical method claims in two patents against the medical device producer and seller Medtronic.¹³² In this case, Dr. Barry asserted that surgeons, who were practicing spinal derotation procedures with Medtronic's Vertebral Column Manipulation (KCM) kit,¹³³ directly infringed his two patents claiming a method of aligning spinal vertebrae to correct common spinal deformities like scoliosis.¹³⁴ Dr. Barry accused Medtronic of induced infringement by supplying the surgeons with its KCM kits and providing extensive training materials and instructions relating to the KCM kit.¹³⁵ The District Court found Medtronic liable for inducing surgeons to use its devices to infringe Barry's patents.¹³⁶ The District Court thus ordered Medtronic to pay Dr. Barry \$21,265,416 in damage, including a 20% enhancement of the final damages for the willfulness in its infringement.¹³⁷ Medtronic unsuccessfully appealed to the United States Court of Appeals for the Federal Circuit, challenging the validity of the claims at issue.¹³⁸ The Federal Circuit eventually affirmed the District Court's ruling.¹³⁹ Medtronic petitioned to the United States Supreme Court, and on January 13, 2020, the Court denied certiorari, making the judgement final.¹⁴⁰

Different from indirect infringement on device and system patents discussed in Part I.C.2. above, indirect infringement on method patents is usually asserted alone without direct infringement assertion.¹⁴¹ The indirect infringement theory advanced by Dr. Barry appeals to medical treatment method

131. 914 F.3d 1310 (Fed. Cir. 2019).

132. *Id.*

133. *Id.* at 1310–20.

134. U.S. Patent No. 7,670,358 (filed Mar. 2, 2010); U.S. Patent No. 8,361,121 (filed Jan. 29, 2013).

135. *Id.*

136. *Barry v. Medtronic, Inc.*, 250 F. Supp. 3d 107 (E.D. Tex. 2017).

137. *Id.*

138. *Barry v. Medtronic, Inc.*, 914 F.3d 1310 (Fed. Cir. 2019).

139. *Id.*

140. *Medtronic, Inc. v. Barry*, 2020 U.S. LEXIS 17 (U.S., Jan. 13, 2020).

141. As previously stated, § 287(c)(1) limits recovery from a directly infringing “medical practitioner” but leaves recovery open for induced infringement. As an aside, it is also likely bad public relations for a company to sue doctors.

patent owners, as they only have limited choices in enforcing their patent rights under the current United States patent law. Although patent applicants have paid less attention to protecting medical treatment method patent rights due to the limitations § 287(c) imposes, Dr. Barry's success likely brings medical treatment method patent enforcement back to patent owners and applicants' attention, which could in turn result in a surge in medical treatment method patent owners enforcing their rights against medical device and system suppliers.¹⁴²

4. The Problem of Various Indirect Infringement Liabilities Concern Robotic Surgery System Suppliers Even More than Other Medical Device Suppliers.

Although the various secondary liabilities discussed in Parts I.C.2. and 3. present a problem universal to medical devices, the risk of facing indirect infringement charges increases for robotic surgery system suppliers due to the increased complexity of such systems compared with other medical devices. A robotic surgery system usually incorporates multiple surgical tools and means for controlling the surgical tools to perform designed medical procedures.¹⁴³ The complex structure of the da Vinci surgical system illustrates this point. Specifically, all da Vinci surgical systems comprise a surgical console, a surgical cart, and a vision cart, wherein the surgical cart comprises multiple mechanical arms holding a camera and surgical instruments that a surgeon remotely controls from the surgical console.¹⁴⁴ Theoretically, patents could exist for each instrument in the robotic surgery system and its corresponding use in medical procedure. As a result, the total number of patents a robotic surgery system could possibly infringe

142. Joey Moussa & Doug Portnow, *Protecting Medical Method Patents via Indirect Infringement*, LAW360 (Aug. 14, 2019, 1:05 PM), <https://www.law360.com/articles/1188364/protecting-medical-method-patents-via-indirect-infringement> (stating that medical method claims have been neglected by many patent applicants, and calling to patent owners and applicants' attention that medical method patents can be enforced under indirect infringement theories in view of *Barry v. Medtronic*).

143. *Computer-Assisted Surgical Systems*, *supra* note 11 (describing that RAS devices generally include a bedside cart including multiple hinged mechanical arms, camera, and surgical instruments, a console as a control center for the surgeon to view the field and control movement of surgical instruments, and a separate cart containing supporting hardware and software).

144. Hagen & Curet, *supra* note 27, at 11–13.

increases. Accordingly, the risk of directly or indirectly infringing one's patent for a robotic surgery system supplier increases.

D. ROBOTIC SURGERY SYSTEM COMPANIES' CURRENT DEFENSIVE STRATEGIES AGAINST INDIRECT INFRINGEMENT

Recognizing the risk of indirect patent infringement, and the damages involvement in such lawsuits can have on an innovator, many robotic surgery companies have adopted one or more of the following approaches to cope with the problem.

1. Robotic Surgery System Companies' Litigation Strategies in Patent Infringement Lawsuits

When the accused robotic surgery system supplier has decided to answer the patent infringement suit, the most common litigation strategies adopted include noninfringement defenses and patent invalidity challenges.¹⁴⁵ A noninfringement defense argues that even if the patent at issue is valid, the accused product or process does not fall within the scope of the patent claims.¹⁴⁶ An invalidity defense, on the other hand, argues that the patent claims are invalid and thus do not confer upon the plaintiff a monopoly on the product or process.¹⁴⁷ The United States adopts a non-bifurcated patent litigation system that allows assessment of infringement and validity issues within a single court proceeding.¹⁴⁸ In most cases, defendants try their best arguing both.¹⁴⁹ In *Barry v. Medtronic*, for example, Medtronic challenged the validity of the patents and pleaded noninfringement in the alternative as defenses in the district court.¹⁵⁰

Other than a civil court, a defendant in suit can bring patent validity challenges in front of the United States Patent and

145. Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 71 (2013) ("Nearly every patent lawsuit rises or falls on one of two defenses: invalidity or noninfringement.").

146. *Id.* at 71–76.

147. *Id.* at 77–85.

148. Different from the United States bifurcated system, in non-bifurcated countries like Germany and China, patent validity is adjudicated by specialized patent courts and infringement courts operate on the presumption that the patent in suit is valid. PAUL GOLDSTEIN & MARKETA TRIMBLE, INT'L INTELL. PROP. L. 566 (5th ed. 2019).

149. *Id.* at 71.

150. *Barry v. Medtronic, Inc.*, 250 F. Supp. 3d 107 (E.D. Tex. 2017).

Trademark Office (USPTO). Specifically, the Leahy-Smith America Invents Act (AIA), passed in 2011, has set up several post-grant proceedings for parties to challenge a patent's validity, including inter partes review (IPR),¹⁵¹ post-grant review (PGR),¹⁵² ex parte reexamination, and covered business method proceedings.¹⁵³ After enactment of the AIA, IPR and PGR soon gained popularity for their relatively low costs and short completion time compared to civil court invalidity challenges.¹⁵⁴ For example, in the patent infringement dispute between P Tech and Intuitive Surgical mentioned in Part C.2. above, after receiving the complaint, instead of defending in court, Intuitive Surgical chose to rapidly file an IPR on P Tech's patents, which the USPTO instituted on September 11, 2020.¹⁵⁵ On March 24, 2020, the District Court granted a stay of the lawsuit in view of the IPR and ordered administrative closure of the case.¹⁵⁶

While problems including lack of certainty, lengthy proceeding times, and passive involvement in the suit surround all of the above-discussed litigation strategies, high cost remains the dominant one. Raising noninfringement and invalidity defenses in court can easily rise into millions of dollars.¹⁵⁷ USPTO post-grant proceedings such as IPR and PGR provide

151. 35 U.S.C. § 311.

152. 35 U.S.C. § 321.

153. Leahy-Smith America Invents Act, 125 Stat. 284, § 6 (2011) (stipulating for post-AIA post-grant proceedings including ex parte reexamination, inter partes review, post-grant review, and covered business method proceedings). Note, however, the covered business method is no longer available after September 16, 2020. *Id.* at § 18(a)(3)(A).

154. See Brian C. Kwok & Nicolas V. Martini, *Post-Grant Review is Becoming Increasingly Popular*, LAW360 (June 1, 2016, 10:32 AM), <https://www.law360.com/articles/802039/post-grant-review-is-becoming-increasingly-popular> (explaining that Post-grant review proceedings are designed to be quick, lasting no more than twelve to eighteen months, and the PTAB's decision regarding patentability is immediately appealable to the Federal Circuit); Ryan Kenny, *Which Invalidity Avenue to Take: Inter Partes Review Verses Post-Grant Review*, IPWATCHDOG (last updated July 31, 2018), <https://www.ipwatchdog.com/2018/07/31/which-invalidity-avenue-ipr-verses-post-grant-review/id=99460/> (providing a high-level overview and comparison of inter partes review and post-grant review).

155. Intuitive Surgical, Inc. v. P Tech, LLC, IPR2020-01687.

156. P Tech, LLC v. Intuitive Surgical, Inc., PACERMONITOR, https://www.pacermonitor.com/public/case/27493647/P_Tech,_LLC_v_Intuitive_Surgical,_Inc (last visited Dec. 5, 2020).

157. Kenny, *supra* note 154 (citing PWC's 2012 Patent Litigation Study).

less expensive options for bringing invalidity challenges.¹⁵⁸ In particular, IPR proceedings cost about ten times less than patent invalidation in civil courts, and PGR proceedings are estimated to be slightly more costly than IPR proceedings.¹⁵⁹ However, both IPR and PGR proceedings still average around \$300,000 to \$350,000.¹⁶⁰

2. Robotic Surgery System Companies' Pre-Suit Preventive Measures

Recognizing the devastating damage patent infringement lawsuits can inflict upon their businesses, robotic surgery system developers have adopted measures to reduce the number of patent infringement accusations against them. One common measure is holding a strong patent portfolio.¹⁶¹ A robotic surgery system company often keeps a strong patent portfolio through obtaining and maintaining patents in the United States as well as in foreign countries. Intuitive Surgical, for instance, held more than a thousand United States and foreign patents covering important aspects of the da Vinci by 2012,¹⁶² and that number continues to grow each year. One's own patents not only confer rights to exclude competitors and protect its most valuable assets, but also the ability to stop others from patenting the technology and thus block potential attacks.¹⁶³ Legal practitioners have commonly referred to such practice as "freedom of action," which means a company, after building its patent portfolio, has sufficient patent or cross-license coverage to launch a new product and is comfortable with the estimated risk of patent infringement.¹⁶⁴ Even in the case where an

158. See Kwok & Martini, *supra* note 154 (explaining the relative cost effectiveness of PGR and IPR proceedings).

159. *Id.*

160. *Id.*

161. See Sean D. Harding, *Meet the Patents: Fostering Innovation and Reducing Costs by Opening Patent Portfolios*, 11 J. BUS. & TECH. L. 199 (2016) (explaining that many companies maintain a strong patent portfolio due to the threat of incurring substantial costs defending and settling patent litigation targeted against them).

162. Hagen & Curet, *supra* note 27, at 10.

163. See, e.g., Simon Phipps, *A New Way to End the Patent Madness*, INFOWORLD (June 15, 2012, 5:00 AM), <https://www.infoworld.com/article/2617429/a-new-way-to-end-the-patent-madness.html> (explaining that keeping patents as a defense allows one to disarm patent trolls).

164. Kent Richardson & Erik Oliver, *When Strategies Collide: Freedom to Operate Clashes with Freedom of Action in Converging Industries*,

application does not eventually mature into a patent or where the technology is disclosed without filing any patent application, publication of the application or of the technology still constitutes a defensive publishing or technical disclosure which effectively blocks others from claiming rights in the technology.¹⁶⁵ Other common preventive measures adopted by robotic surgery system companies focus on obtaining clearance ahead of launching, or even developing, a new product. Legal practitioners have commonly referred to such practices as “freedom of operation.”¹⁶⁶ The process of obtaining clearance could involve conducting freedom to operate searches, obtaining a competent legal opinion on noninfringement, negotiating licenses from patent owners, and designing around patented features if necessary.¹⁶⁷

Unfortunately, like the litigation strategies discussed in Part I.D.1. above, preventive measures are also not problem-free. First, freedom of action depends on the strength of one’s patent portfolio.¹⁶⁸ However, no matter how strong a patent portfolio one keeps, it is impossible to safeguard every feature of a highly complex system like a surgical robot. Moreover, even if every feature of the surgical robot can be safeguarded by the developer’s own patent portfolio, it still cannot shield the developer from indirect infringement of medical treatment method claims. Freedom of operation, on the other hand, relies heavily on one’s timely and accurate identification of all problematic patents.¹⁶⁹ A less competent and less complete

IPWATCHDOG, <https://www.ipwatchdog.com/2019/03/07/when-strategies-collide-freedom-to-operate-vs-freedom-of-action/id=107084/> (last modified Mar. 7, 2019) (“*Freedom of Action* means having enough patents or enough cross-licenses such that you have the ability to launch products and are comfortable with the risk of patent infringement.”).

165. Note that this practice, though useful in some cases, stands in sharp contrast to keeping the technology a trade secret. *IP and Business: Launching a New Product: Freedom to Operate*, WORLD INTELL. PROP. ORG. MAG. (Sept. 2005), https://www.wipo.int/wipo_magazine/en/2005/05/article_0006.html.

166. *Id.* (“*Freedom to Operate* means testing, prior to launching a product, whether any feature will infringe anyone else’s patents.”).

167. *Id.*

168. Richardson & Oliver, *supra* note 164.

169. See WORLD INTELL. PROP. ORG. MAG, *supra* note 165 (“A Freedom to Operate (FTO) analysis invariably begins by searching patent literature for issued or pending patents, and obtaining a legal opinion as to whether a product, process or service may be considered to infringe any patent(s) owned by others.”).

patent search renders any analysis based thereon useless. Designing-around, in particular, requires accurately identifying the possible infringement ahead of time to allow for the lengthy R&D process. Finally, both freedom of action and freedom of operation investigations cost significant amounts of money.¹⁷⁰ Alternative measures that are less costly, easier to maneuver, and yield more certainty in protection for robotic surgery system companies against secondary infringement liability are desirable and necessary for preserving the innovation incentives.

II. ANALYSIS

As noted in Part I.A. above, robotic surgery innovators have aimed at making their robotic surgery devices and systems more general purpose.¹⁷¹ Researchers in medical treatment procedures and devices have also anticipated that specialized robotic surgery systems will likely lose their niche in the commercial market to general purpose systems in the near future.¹⁷² More versatile robotic surgery systems yield easier maneuverability and significantly reduce the cost for the implementation in hospitals.¹⁷³ This Note argues that the general purpose characteristic of a robotic surgery system provides yet another benefit—it helps shield robotic surgery system suppliers from indirect infringement liabilities arising in medical procedures performed at health care entities.

A. GENERAL PURPOSE ROBOTIC SURGERY SYSTEMS PROVIDE A POSSIBLE “LACK OF KNOWLEDGE/INTENT” DEFENSE TO INDUCED INFRINGEMENT UNDER § 271(B) AND CONTRIBUTORY INFRINGEMENT UNDER § 271(C) FOR THE SUPPLIERS

As a preliminary note, §§ 271(b) and (c) share the same origin of the “overarching concept of ‘contributory infringement.’”¹⁷⁴ In the Patent Act of 1952, Congress designed

170. Here, fees include, but are not limited to, filing and maintaining patents all over the world, conducting patent searches, obtaining legal opinions, licensing fees, and designing-around R&D costs. *See id.* (mentioning these costs in the context of freedom to operate).

171. *See* Hagn et al., *supra* note 42 (noting that versatile systems are gaining favor).

172. *Id.*

173. *Id.*

174. *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 761 (2011).

the sections to “codify in statutory form principles of contributory infringement’ which had been ‘part of our law for about 80 years.’”¹⁷⁵ Though put in separate paragraphs, §§ 271(b) and (c) both relate to the sale of products for others’ infringing uses.¹⁷⁶ While paragraph (b) punishes specifically inducement by the seller, paragraph (c) deals with the other “usual situation in which contributory infringement arises.”¹⁷⁷ As such, courts have long treated §§ 271(b) and (c) as containing the same scienter requirement derived from their predecessor contributory infringement.¹⁷⁸ Therefore, a defense that works through negating the scienter requirement of indirect infringement arguably should apply equally to §§ 271(b) and (c).

1. The Finding of the Scienter Requirement of §§ 271(b) and (c)

This Part’s analysis starts with the explicit scienter requirement in § 271(c), through analogy to which courts found the implicit scienter requirement in § 271(b). Specifically, § 271(c) recites:

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, *knowing* the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.¹⁷⁹

The plain language of § 271(c) explicitly requires that the contributory infringer know that his products are for infringing use yet he still intends infringement as the result.¹⁸⁰ In *Aro Mfg.*

175. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 485–86 (1964); *see* H.R. REP. NO. 1923, at 9 (1952) (“Paragraphs (b), (c), and (d) relate to the subject referred to as contributory infringement. The doctrine of contributory infringement has been part of our law for about 80 years.”); *see also* P.J. FEDERICO, COMMENTARY ON THE NEW PATENT ACT 28 (1954) (“Paragraph (b) is a broad statement and enactment of the principle that one who actively induces infringement of a patent is likewise liable for infringement. The Committee Report in several places refers to this paragraph as relating to contributory infringement.”).

176. FEDERICO, *supra* note 175, at 27–28.

177. *Id.* (emphasis added) (citing H. R. REP. NO. 1923, at 9).

178. *See* discussion *infra* Part II.A.1. (providing the cases that establish the sections have been treated as having the same scienter requirement).

179. 35 U.S.C. § 271.

180. *Id.*

Co. v. Convertible Top Replacement Co. (Aro II),¹⁸¹ the Supreme Court noted that Congress passed § 271(c) to codify the existing common law contributory infringement which required knowledge and intent of the accused.¹⁸² The *Aro II* Court thus held that § 271(c) contains a scienter requirement that a violator of § 271(c) must know that a patent exists for the product at issue and that the product, when used by others, infringes.¹⁸³

Section 271(b) recites “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”¹⁸⁴ Unlike § 271(c), it does not use words such as “know” or “intent.”¹⁸⁵ Nevertheless, even before the Supreme Court spoke on this issue, federal courts have interpreted the statute as requiring the same scienter requirement as § 271(c). For example, in *Hilgraeve v. Symantec*,¹⁸⁶ the Michigan Eastern District Court ruled that § 271(b) requires knowledge/intent of the defendant since it noted that “[a]lthough section 271(b) does not use the word ‘knowing,’ the case law and legislative history uniformly assert such a requirement.”¹⁸⁷ In 2011, the Supreme Court in *Global-Tech Appliances, Inc. v. SEB S.A.*¹⁸⁸ confirmed that the knowledge/intent requirement of § 271(b) exists through the use of the words “induce” and “actively.”¹⁸⁹ The *Global-Tech* Court stated that:

Although the text of § 271(b) makes no mention of intent, we infer that at least some intent is required. The term ‘induced’ means ‘to lead on; to influence; to prevail on; to move by persuasion or influence.’ . . . The addition of the adverb ‘actively’ suggests that the inducement must

181. 377 U.S. 476, 476 (1964).

182. *Id.* at 487–89 (citing old cases, such as Thomson-Houston Elec. Co. v. Ohio Brass Co., 80 F. 712, 721 (C.A. 6th Cir. 1897), to illustrate that traditional contributory infringement required the defendant know and intend the infringement).

183. *Id.* at 488.

184. 35 U.S.C. § 271.

185. *Id.*

186. 272 F. Supp. 2d 613 (E.D. Mich. 2003).

187. *Id.* at 616 (demonstrating that the Court of Appeals for the Federal Circuit has also constantly interpreted § 271(b) as requiring the same scienter requirement (citing *Water Techs. Corp. v. Calco Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988))).

188. 563 U.S. at 754.

189. *Id.* at 760.

involve the taking of affirmative steps to bring about the desired result¹⁹⁰

To arrive at this interpretation, the *Global-Tech* Court relied on the case law before the enactment of § 271 in the Patent Act of 1952.¹⁹¹ Finding that both §§ 271(b) and (c) originated from the “overarching concept of contributory infringement” and together they codified that concept in the statute, the Supreme Court used its previous interpretation of § 271(c) in *Aro II* to hold that it compels the same scienter requirement for finding liability under § 271(b).¹⁹² Later in *Commil USA v. Cisco System*,¹⁹³ the Supreme Court reaffirmed this scienter requirement of finding induced infringement under § 271(b).¹⁹⁴

2. The Criteria for Finding the Required Knowledge/Intent

Currently, no uniform test or clear-cut standard exists for finding the knowledge/intent required by §§ 271(b) and (c). Nevertheless, decisions by the Supreme Court and lower courts in the past decades offer some guidance on what actions of the accused would reveal the critical knowledge/intent and what would not.

First, direct evidence such as cease-and-desist letters, denial of a license, and witness testimony sheds some light on a defendant’s knowledge and intention. For example, in *Aro II*, the Supreme Court relied on the cease-and-desist letter to find that the defendant possessed the intent and knowledge required for contributory infringement for the infringing conduct occurring after receipt of the letter.¹⁹⁵ In *Mentor H/S v. Medical Device*

190. *Id.* (defining “induce” (citing Webster’s New International Dictionary 1269 (2d ed. 1945))).

191. *Id.* at 761 (describing cases pre-1952 as providing little clarity in interpreting the phrase “induces infringement”).

192. *See id.* at 761, 765 (finding that both sections require knowledge of the existence of the patent that is infringed (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964))).

193. 575 U.S. 632, 642 (2015) (finding that induced infringement requires plaintiff to show that defendant knew his acts were infringing).

194. *Id.* at 640 (“[I]t is necessary to reaffirm what the Court held in *Global-Tech*.”).

195. *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 489–90 (1964) (“For by letter dated January 2, 1954, AB informed Aro that it held the Mackie-Duluk patent; . . . that anyone selling ready-made replacement fabrics for these automobiles would be guilty of contributory infringement of said patents. Thus . . . the knowledge requirement affords Aro no defense with respect to replacement-fabric sales made after January 2, 1954.”).

Alliance,¹⁹⁶ the Federal Circuit found induced infringement based on the fact that the patent owner denied the defendant's request for a license at the outset.¹⁹⁷ Therefore, direct evidence is heavily favored in showing the knowledge/intent of a defendant. Unfortunately, direct evidence might not exist in every indirect infringement case. Also, direct evidence like a cease-and-desist letter or denial of a license cannot show knowledge/intent with respect to infringing conduct that occurs before the event and might not help if the majority of infringing sales have already taken place.¹⁹⁸

Alternatively, *Global-Tech* holds that a plaintiff can prove the knowledge/intent element of indirect infringement through circumstantial evidence.¹⁹⁹ Additionally, in *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*,²⁰⁰ a frequently cited copyright law case where the Supreme Court applied the patent law principles of induced infringement to resolve copyright infringement issues, the Court stated that "active steps . . . taken to encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe."²⁰¹ The same rules in *MGM Studio* shall apply equally to §§ 271(b) and (c), as *MGM Studio* borrowed patent law analyses to arrive at its holdings.²⁰²

196. 244 F.3d 1365, 1379 (2001) (holding that defendant committed direct, contributory, and inducement of infringement).

197. *Id.* at 1379 ("Mentor established at trial that Misonix knew of the existence of the patent because it was denied a license and received a cease-and-desist letter concerning it. Yet Misonix chose to continue selling [the infringing product] . . .").

198. In *Aro II*, the majority of infringing sales occurred after the cease-and-desist letter. *Aro Mfg.*, 377 U.S. at 490.

199. *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 774 (2011) ("Circumstantial facts like these tend to be the only available evidence in any event, for the jury lacks direct access to the defendant's mind.").

200. 545 U.S. 913, 937 (2005) (holding that the inducement rule "premises liability on purposeful, culpable expression and conduct").

201. *See id.* at 936 (citing *Oak Industries, Inc. v. Zenith Electronics Corp.*, 697 F. Supp. 988, 992 (N.D. Ill. 1988)).

202. *See, e.g., id.* at 932, 935–36 (borrowing from patent law and the commerce doctrine, "that distribution of a component of a patented device will not violate the patent if it is suitable for use in other ways" and that clear expression or other affirmative steps are needed for a party to be liable for infringement).

Courts have admitted a variety of circumstantial evidence in addition to those specified in *MGM Studio*. Of great significance to this Note's analysis on infringement relating to robotic surgery systems, is the training and instruction medical device companies provide to physicians. For example, in *Barry v. Medtronic*, the Federal Circuit relied on the training provided by Medtronic and the instructions on every accused device in the period after patenting to rule that the jury could permissibly find inducement.²⁰³ However, not all kinds of instructions of infringing use suffice. The particular facts in a case matter, as courts have adopted a case-by-case approach. In *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*,²⁰⁴ the Federal Circuit distinguished instructions merely “describ[ing] an infringing mode” from those “‘recommend[ing], ‘encourag[ing],’ or ‘promot[ing]’ an infringing use, or suggesting that an infringing use ‘should’ be performed.”²⁰⁵ The *Takeda* Court further opined that the mere existence of direct infringement by physicians or the mere knowledge of possible infringement by others does not amount to inducement, since inducement requires specific intent and affirmative actions to induce.²⁰⁶ Moreover, in *Howmedica Osteonics Corp. v. Tranquil Prospect, Ltd.*,²⁰⁷ the District Court ruled and the Federal Circuit later affirmed that the accused medical device supplier did not induce infringement since the plaintiff failed to demonstrate precise

203. 914 F.3d 1310, 1336 (Fed. Cir. 2019) (affirming the judgement of the District Court that Medtronic induced infringement after the issuance of Dr. Barry's patents).

204. 785 F.3d 625 (Fed. Cir. 2015) (holding that Takeda failed to show sufficient evidence to support a finding of inducement).

205. *Id.* at 631 (citations omitted); *see also* *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899 (2013) (ruling that simply selling a product capable of being used in infringing manner is not sufficient to create substantial controversy regarding inducement); *GE v. Sonosite, Inc.*, 568 F. Supp. 2d 983 (W.D. Wis. 2008) (ruling that bare listing of features, among others, on specification sheets that did not instruct customer to perform particular method or explain how to do anything does not count towards inducement).

206. *Takeda*, 785 F.3d at 631 (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003)).

207. 482 F. Supp. 2d 1045 (N.D. Ind. 2007), *aff'd*, 260 Fed. Appx. 291 (Fed. Cir. 2008) (finding that the plaintiff failed to prove literal infringement because he failed to show that the products met every limitation set forth in the asserted claims).

evidence that when a surgeon followed the supplier's protocols that surgeon necessarily practiced the asserted patent claim.²⁰⁸

Other important sources of circumstantial evidence are a medical device or system's FDA labels and related FDA information. Similar to pharmaceutical products, robotic surgery and other medical devices and systems need to obtain FDA approval and clearance before entering the market.²⁰⁹ And because the FDA classifies medicines and medical devices relying on their intended and indicated use, FDA application and approval materials arguably reveal infringing intent and knowledge of manufacturers and sellers.²¹⁰ Specifically, courts have viewed a defendants' failure to exert reasonable effort to avoid using infringing language on product labels and FDA applications as a tell-tale sign of intention to induce infringement.

For example, in *AstraZeneca LP v. Apotex, Inc.*,²¹¹ the District Court of New Jersey faced a lack of the defendant's promotional and marketing activities,²¹² but nevertheless found the defendant's "affirmative intent" by showing specific intent to infringe through infringing language on the product label as well as in the failure to find and use alternative, non-infringing language for its label.²¹³ The Federal Circuit affirmed the district court's reasoning.²¹⁴

208. *Id.* at 1062–63.

209. *See* discussion *supra* Part I.B.

210. *Id.*

211. 623 F. Supp. 2d 579 (D.N.J. 2009), supplemented, 623 F. Supp. 2d 615 (D.N.J. 2009), *aff'd*, 633 F.3d 1042 (Fed. Cir. 2010).

212. *Id.* at 603 (discussing that Apotex produced expert testimony showing a lack of promotional and marketing activities by Apotex).

213. *Id.* at 605. Defendant Apotex argued that it was forced to include the infringing language on the label to comply with FDA's requirement. *Id.* at 604. However, Plaintiff AstraZeneca argued that Apotex could have attempted to develop a label with alternative language which would not induce infringement. *Id.* at 606. The district court sided with AstraZeneca since no evidence showed that Apotex even made such an attempt to avoid induced infringement. *Id.* at 603–07.

214. *Id.* at 1060–61 ("This court again agrees with AstraZeneca. As explained above, the district court's specific intent finding was not based solely on the proposed label, but also on Apotex's decision to proceed with its plan to distribute the drug despite being aware that the label presented infringement problems.").

Then, the Federal Circuit reiterated in *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*,²¹⁵ that “[d]epending on the clarity of the instructions, the decision to continue seeking FDA approval of those instructions may be sufficient evidence of specific intent to induce infringement.”²¹⁶ The Federal Circuit also stated that “‘vague’ instructions that require one to ‘look outside the label to understand the alleged implicit encourage[ment]’ do not, without more, induce infringement.”²¹⁷ Further, in *Sanofi v. Watson Labs. Inc.*,²¹⁸ the Federal Circuit inferred the defendant’s intent to induce infringement from “interpreting the label’s express statement of indications of use and the internally referred-to elaboration of those indications.”²¹⁹

The Supreme Court held in *Global-Tech* that the scienter requirement is met if a defendant subjectively believes in a “high probability” that a patent exists and his actions might lead to infringement of that patent, yet takes deliberate actions to avoid learning it.²²⁰ The *Global-Tech* Court, however, rejected using deliberate indifference to a known risk that a patent exists as the appropriate standard for finding knowledge or intent, and articulated that meeting the criminal law standard for willful blindness is sufficient to satisfy the scienter requirement.²²¹ Additionally, the *Commil* Court held that while a sincere belief of noninfringement provides a valid defense to induced infringement, a sincere belief of patent invalidity alone does not.²²²

Lastly, while § 271(c) contains a “substantial noninfringing use” restriction,²²³ § 271(b) does not.²²⁴ Therefore, the fact that

215. 845 F.3d 1357 (Fed. Cir. 2017).

216. *Id.* at 1368–69 (citing *AstraZeneca*, 633 F.3d at 1059–60).

217. *Id.* (citing *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 632, 634 (Fed. Cir. 2015)).

218. 875 F.3d 636 (Fed. Cir. 2017).

219. *Id.* at 645–47.

220. *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011).

221. *Id.* at 766–68.

222. If the defendant believes that its actions will induce others to literally infringe the claims, he sincerely believes that its acts will lead to infringement. It does not matter that he also believes the patent is invalid. *Id.*; see also *Commil USA, LLC v. Cisco Sys.*, 135 S. Ct. 1920 (2015).

223. See discussion *infra* Part II.B.1. on the “substantial noninfringing use” restriction of § 271(c).

224. See 35 U.S.C. § 271(b)–(c) (commonly known as the indirect infringement provisions).

the accused product has other substantial noninfringing uses, indicated in the instruction or label or not, does not defeat inducement once the required knowledge/intent is found.²²⁵

3. The General Purpose Characteristic of Robotic Surgery System Companies May Negate the Knowledge/Intent to Induce or Contribute to Infringement of Others During Medical Procedures

The analysis in Part II.A.1. and 2. above demonstrates that a court's finding of induced or contributory patent infringement, especially its finding of the knowledge/intent element, relies heavily on the surrounding facts in a case. Even a slight deviation in factual finding could lead to different results. For example, while a product instruction or label that merely describes the infringing mode alone does not induce infringement under the current law, a product instruction or label that uses infringing language to describe the infringing mode likely induces infringement.²²⁶ A specialized robotic surgery system has specific, evident, and limited uses.²²⁷ A general purpose robotic surgery system, on the other hand, is expected to have more generic and versatile uses.²²⁸ Facts surrounding specialized and general purpose robotic surgery systems are different. This difference opens up the possibility of new defenses against indirect infringement for developers, manufactures, and sellers of robotic surgery systems. The versatility of general purpose robotic surgery systems may defeat the knowledge/intent requirement by §§ 271(b) and (c) through one or more of the following ways.

First, general purpose robotic surgery systems will likely implement structures and technology that are more complex than those implemented by specialized robotic surgery systems.

225. *See* *Sanofi v. Watson Labs. Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) (reasoning that there can be liability for inducing an infringing use of a drug though the label contains other substantial noninfringing uses).

226. *Compare* *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 630–32 (Fed. Cir. 2015) (holding that a drug label indicating that a specific infringing use had not been studied was not enough to induce infringement), *with* *AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579 (D.N.J. 2009) (holding that when language explaining an infringing use is on the label, it may induce some consumers to partake in that infringing use).

227. For example, Intuitive Surgical's newest da Vinci SP currently is mainly cleared for urology surgeries. *See supra* Part I.A.

228. *Id.*

The evolution of Intuitive Surgical's da Vinci surgical systems illustrates this point—the types and sizes of available wristed instruments expanded²²⁹ and the newer da Vinci versions include even more consoles.²³⁰ More complex system structures and technology means more surrounding facts that may be investigated and analyzed in patent infringement litigation. It increases the cost for potential plaintiffs who may wish to pursue litigation against robotic surgery system suppliers. Litigants who do not have strong enough claims are thus more likely deterred by that larger expense.

Secondly, as a robotic surgery system becomes more versatile, it may be possible for its supplier to provide product instruction and training at a more general level. For example, for steps commonly or similarly required by a group of different procedures, it may be possible to provide more generalized instructions instead of associating specific procedures with the steps. Under the current law, relatively general instruction and training materials are unlikely to demonstrate specific intent to induce infringement by others.²³¹ In this way, the general purpose characteristic of a robotic surgery system likely reduces the risks of secondary liabilities arising out of others' use.²³²

Thirdly, the versatility of a robotic surgery system provides companies with more advertising options. Suppliers of such systems will arguably have more space to choose, for example, to selectively demonstrate more general-level features and functions of the product in which it feels most confident and to avoid risky, overly-specific descriptions in promotions and advertisement. Selective advertising does not violate the FFDCA.²³³ It may not be possible to draft a generalized label, since the FFDCA general labeling requirement demands a robotic surgery system supplier disclose all intended uses for the device, including any actual uses of which the supplier reasonably knows.²³⁴ However, the FFDCA does not impose such requirements on advertising, or on all labeling, though it does make misbranding and poor label control violations the letter of

229. Hagen & Curet, *supra* note 27, at 11.

230. *Id.*

231. *See supra* Part II.A.2 (describing the specific intent requirement).

232. *Id.*

233. *See* 21 C.F.R. § 801.5 (outlining the requirements for adequate directions of use in device labeling).

234. *See supra* Part I.B.2 (discussing existing labeling requirements).

the law.²³⁵ This practice thus also likely reduces the possibility of improper advertising, which may be used to prove the knowledge/intent element for indirect infringement.²³⁶

B. GENERAL PURPOSE ROBOTIC SURGERY SYSTEMS PROVIDES A POSSIBLE “SUBSTANTIAL NONINFRINGEMENT USE” DEFENSE TO CONTRIBUTORY INFRINGEMENT ARISING UNDER § 271(C) FOR THE SUPPLIERS

As mentioned in Part II.A.2. above, different from § 271(b), § 271(c) contains a “substantial noninfringing use” restriction.²³⁷ The plain language of § 271(c) exempts any material or apparatus that is “a staple article or commodity of commerce suitable for substantial noninfringing use.”²³⁸ As established in yet another copyright law case that borrowed patent law principles governing contributory infringement, *Sony Corp. of America v. Universal City Studios, Inc.*,²³⁹ “[u]nless a commodity ‘has no use except through practice of the patented method,’ the patentee has no right to claim that its distribution constitutes contributory infringement.”²⁴⁰ In *Koninklijke Philips N.V. v. Zoll Med. Corp.*,²⁴¹ the Federal Circuit articulated an important requirement for finding substantial noninfringing use of an accused product: The infringing component must not be “separate and distinct” from other functions of the composite product, in order to ensure that a contributory infringer does not escape liability “merely by embedding the infringing apparatus in a larger product with some additional, separable feature before importing and selling it.”²⁴²

Accordingly, one possible defense for general purpose robotic surgery systems suppliers against contributory infringement under § 271(c) is arguing that the systems have

235. *See id.*; *see also* DIV. OF SMALL MFRS. ASSISTANCE OFF. OF TRAINING & ASSISTANCE, *supra* note 77, at 37 (“[I]nadequate labeling, or labeling that is less than it can or should be, may not always violate the law . . .”).

236. *Id.*

237. *See supra* Part II.

238. 35 U.S.C. § 271(c).

239. 464 U.S. 417 (1984).

240. *Id.* at 441 (citing *Dawson Chemical Co. v. Rohm & Hass Co.*, 448 U.S. 176, 198–99 (1980)).

241. 656 Fed. Appx. 504 (Fed. Cir. 2016).

242. *Id.* at 524–25 (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009) and *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1330 (Fed. Cir. 2010)).

other substantial noninfringing uses. Ideally, a general purpose robotic surgery system should utilize the same set of physical components to perform a variety of surgical procedures under the surgeon's control. Because the accused component would be the system as a whole, which is not "separate and distinct," when one mode of the system is accused of contributing to infringing use by a medical practitioner, the availability of other system modes thus may offer a valid "substantial noninfringing use" defense to the system supplier.

CONCLUSION

In conclusion, the general purpose characteristic of a robotic surgery system may provide an alternative defense strategy for its manufacturers and sellers against indirect infringement liabilities arising out of medical procedure performances using the system. Specifically, the system's versatility may help negate the knowledge/intent element required by both 35 U.S.C. §§ 271(b) and (c). The increased complexity of the system generates more surrounding facts. It therefore may be possible to use higher-level product descriptions and instructions, as well as selective advertising strategies, to avoid identifying particular modes of operation which run the risk of showing infringing intent and knowledge. Further, the same system versatility demonstrates that substantial noninfringing uses of the system necessarily exist, yielding a "substantial noninfringing use" defense to contributory infringement under § 271(c).

Utilizing the general purpose characteristic of a robotic surgery system as a legal defense is advantageous. It is cost-efficient and aligns with the trend in robotic surgery technology of developing more general purpose systems capable of various uses, and thus best captures the companies' commercial interests. The defense, if valid, is relatively strong and could substantially deter frivolous lawsuits and patent infringement harassment.