

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTUITIVE SURGICAL, INC. AND)
INTUITIVE SURGICAL OPERATIONS,)
INC.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
AURIS HEALTH, INC.,) **DEMAND FOR JURY TRIAL**
)
Defendant.)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. (collectively, “Intuitive”), for their Complaint against Defendant Auris Health, Inc. (“Auris”), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*

SUMMARY

2. Intuitive has for more than 20 years been a global technology leader in minimally invasive robotic-assisted surgery, having invested substantial sums into research and development of its surgical platforms. Intuitive’s da Vinci® Surgical System (“the da Vinci® System”) enables surgeons to operate through a few small incisions or the belly button from a nearby ergonomic console. The da Vinci® System features a magnified 3D HD vision system and tiny, wristed instruments that bend and rotate with much greater dexterity than the human hand. As a result of this technology, the da Vinci® System enables surgeons to operate with enhanced vision, precision, and control.

3. The original prototype for the da Vinci® System was developed in the late 1980s

at the former Stanford Research Institute under contract to the U.S. Army. While initial work was funded in the interest of developing a system for remotely performing battlefield surgery, the founders of Intuitive grasped that this technology could revolutionize surgery more generally.

4. Intuitive Surgical was founded in 1995 and the da Vinci® System was launched in 1999. In 2000, the da Vinci® system became the first robotic surgical system cleared by the FDA for general laparoscopic surgery. In the following years, the FDA cleared the da Vinci® System for thoracoscopic (chest) surgery, and certain cardiac, urologic, gynecologic, pediatric, and transoral otolaryngology procedures.

5. To date, Intuitive has launched four robotic-assisted surgical system models, including the latest model, the da Vinci Xi® System. The da Vinci® Systems are in use in 64 countries, all 50 U.S. States, and all top-ranked U.S. hospitals for cancer, urology, gynecology or gastroenterology, including: Memorial Sloan Kettering Cancer Center, University of Texas-M.D. Anderson Cancer Center, the Mayo Clinic, Johns Hopkins Hospital, the Cleveland Clinic, Christiana Care Health System and Beebe Healthcare. More than 5 million procedures using the da Vinci® System have been performed worldwide. The use of the da Vinci® System has transformed patient care, including through less blood loss, fewer complications, shorter hospital stays, smaller incisions for minimal scarring, and faster recovery and return to daily life.

6. With over 20 years of experience in the field, Intuitive has a deep understanding of robotic-assisted surgical technology and surgeon needs. This begins with Intuitive's robotic platforms and includes a broad instrument product line, imaging solutions, training programs and technology, clinical validation, field clinical support, field technical support, and program optimization. Surgeons, hospitals, and patients benefit from the large community of users within Intuitive's robotic-assisted surgical ecosystem, which likewise can deliver improved surgical outcomes.

7. Intuitive has invested over a billion dollars in research and development leading to, among other things, the inventions at issue in this lawsuit.

8. Intuitive generally relies upon its intellectual property rights to protect its

proprietary technology. Intuitive owns or has exclusive field-of-use licenses for more than 2,750 United States and foreign patents and more than 1,900 United States and foreign patent applications.

9. Intuitive is developing a new flexible surgical robotic platform that can be used in imaging and treatment to access hard-to-reach areas (such as the peripheral lung) through the use of natural openings, such as the mouth. Thus, for example, this platform allows physicians to reach nodules in the peripheral lung that were simply out of reach before. (Report on Clinical Study, Press Release ISRG available at <http://investor.intuitivesurgical.com/mobile.view?c=122359&v=203&d=1&id=2313878>).

10. Intuitive welcomes fair competition. However, as discussed more fully below and in the attachments to this Complaint, Auris has competed unfairly and unlawfully by infringing Intuitive's intellectual property to create competing, unlicensed products.

THE PARTIES

11. Intuitive Surgical, Inc. is a Delaware corporation with its principal place of business in Sunnyvale, California.

12. Intuitive Surgical Operations, Inc. is a Delaware corporation with its principal place of business in Sunnyvale, California.

13. Auris Health, Inc., formerly Auris Surgical Robotics, Inc., is a Delaware corporation with its principal place of business in Redwood City, California.

JURISDICTION AND VENUE

14. This civil action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over Auris, and venue is proper in this district pursuant to 28 U.S.C. § 1400(b), because Auris is a Delaware corporation and thus resides in this district.

FACTS COMMON TO ALL CLAIMS

A. Auris's Use of Intuitive's Patented Technologies

16. Frederic H. Moll ("Moll") co-founded Intuitive in 1995. Moll was Intuitive's first CEO and a member of its Board of Directors from 1995–2003.

17. Moll co-founded Auris in 2007 and is its CEO.

18. Auris has developed a robotic surgical system that competes directly with the da Vinci® System and that will compete with Intuitive's forthcoming flexible surgical robotic platform.

19. On May 26, 2016, the Auris Robotic Endoscopy System ("ARES") was issued a substantial equivalence determination by the FDA.

20. On March 22, 2018, Auris' Monarch Endoscopy Platform ("Monarch") was issued a substantial equivalence determination by the FDA.

21. Following FDA approval for Monarch in March 2018, Auris announced an aggressive timeline for its development and deployment. While bronchoscopy is Monarch's first application, Auris claims that it is a "platform technology" and that the "platform will do other robotic endoscopies." <https://techcrunch.com/2018/03/24/monarch-is-a-new-platform-from-surgical-robot-pioneer-frederic-moll>. Auris claims that it "seeks to leverage the power of flexible robotics to enable new possibilities in endoscopy." <https://www.aurishealth.com/>. Auris CEO Fred Moll has said "We envision additional uses for the technology across future endoscopic clinical indications."

<https://www.businesswire.com/news/home/20180323005162/en/Auris-Health-Unveils-FDA-Cleared-Monarch-Platform-Ushering>.

B. Intuitive Put Auris on Notice of Infringement of the Patents-in-Suit

22. On August 3, 2018, Intuitive sent a letter to Auris providing it with notice of the Patents-in-Suit.

THE PATENTS-IN-SUIT

23. Through the development and subsequent making, using, selling, offering for sale, and/or importing of Monarch, Auris has and continues directly to infringe, contributorily infringe, and/or induce the infringement of:

a. U.S. Patent No. 6,491,701, entitled “Mechanical actuator interface system for robotic surgical tools” (“the ’701 Patent”);

b. U.S. Patent No. 8,142,447, entitled “Mechanical actuator interface system for robotic surgical tools” (“the ’447 Patent”);

c. U.S. Patent No. 8,620,473, entitled “Medical robotic system with coupled control modes” (“the ’473 Patent”);

d. U.S. Patent No. 9,452,276, entitled “Catheter with removable vision probe” (“the ’276 Patent”);

e. U.S. Patent No. 6,246,200, entitled “Manipulator positioning linkage for robotic surgery” (“the ’200 Patent”);

f. U.S. Patent No. 6,800,056, entitled “Endoscope with guiding apparatus” (“the ’056 Patent”);

g. U.S. Patent No. 8,801,601, entitled “Method and system for providing visual guidance to an operator for steering a tip of an endoscopic device toward one or more landmarks in a patient” (“the ’601 Patent”); and

h. U.S. Patent No. 6,522,906, entitled “Devices and methods for presenting and regulating auxiliary information on an image display of a telesurgical system to assist an operator in performing a surgical procedure” (“the ’906 Patent”).

24. The ’701 Patent, the ’447 Patent, the ’473 Patent, the ’276 Patent, the ’200 Patent, the ’056 Patent, the ’601 Patent, and the ’906 Patent (collectively, the “Patents-in-Suit”) are attached hereto as Exhibits 1 through 8.

**FIRST CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 6,491,701)**

25. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

26. By assignment, Intuitive owns all rights, title, and interest in and to the '701 Patent.

27. As detailed more fully in Attachment A, Auris has infringed and continues to infringe at least claim 1 of the '701 Patent by making, using, selling, offering for sale and/or importing Monarch.

28. Auris has committed and continues to commit these acts of infringement without license or authorization.

29. The infringement by Auris has directly and proximately caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interest and costs fixed by this Court pursuant to 35 U.S.C. § 284.

30. The infringement of the '701 Patent by Auris is willful and deliberate. In particular, at least as of August 6, 2018, if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '701 Patent. Such conduct constitutes, at minimum, willful infringement of the '701 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

31. Unless Auris is enjoined from infringing the '701 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**SECOND CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 8,142,447)**

32. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

33. By assignment, Intuitive owns all rights, title, and interest in and to the '447 Patent.

34. As detailed more fully in Attachment B, Auris has infringed and continues to infringe at least claim 1 of the '447 Patent when Auris or its customers use Monarch.

35. Monarch has no substantial non-infringing uses.

36. Doctors who use Monarch directly infringe at least claim 1 of the '447 Patent.

37. Auris has known of the inventions of the '447 Patent since at least November 29, 2016, when Auris was awarded U.S. Patent No. 9,504,604. Auris's U.S. Patent No. 9,504,604 cites to U.S. Patent App. Pub. No. 2009/0248043, which matured into the '447 Patent.

38. Auris has committed and continues to commit these acts of infringement without license or authorization.

39. The infringement by Auris has directly and proximally caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

40. The infringement of the '447 Patent by Auris is willful and deliberate. In particular, at least as of August 6, 2018 if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '447 Patent. Such conduct constitutes, at minimum, willful infringement of the '447 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

41. Unless Auris is enjoined from infringing the '447 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**THIRD CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 8,620,473)**

42. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

43. By assignment, Intuitive owns all rights, title, and interest in and to the '473 Patent.

44. As detailed more fully in Attachment C, Auris has infringed and continues to

infringe at least claim 19 of the '473 Patent by making, using, selling, offering for sale and/or importing Monarch.

45. Auris has committed and continues to commit these acts of infringement without license or authorization.

46. The infringement by Auris has directly and proximally caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

47. The infringement of the '473 Patent by Auris is willful and deliberate. In particular, at least as of August 6, 2018, if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '473 Patent. Such conduct constitutes, at minimum, willful infringement of the '473 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

48. Unless Auris is enjoined from infringing the '473 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**FOURTH CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 9,452,276)**

49. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

50. By assignment, Intuitive owns all rights, title, and interest in and to the '276 Patent.

51. As detailed more fully in Attachment D, Auris has infringed and continues to infringe at least claim 1 of the '276 Patent by making, using, selling, offering for sale and/or importing Monarch.

52. Auris has committed and continues to commit these acts of infringement without license or authorization.

53. The infringement by Auris has directly and proximally caused damage to

Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

54. The infringement of the '276 Patent by Auris is willful and deliberate. In particular, at least as of August 6, 2018, if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '276 Patent. Such conduct constitutes, at minimum, willful infringement of the '276 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

55. Unless Auris is enjoined from infringing the '276 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**FIFTH CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 6,246,200)**

56. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

57. By assignment, Intuitive owns all rights, title, and interest in and to the '200 Patent.

58. As detailed more fully in Attachment E, Auris has infringed and continues to infringe at least claim 1 of the '200 Patent by making, using, selling, offering for sale and/or importing Monarch.

59. Auris has committed and continues to commit these acts of infringement without license or authorization.

60. The infringement by Auris has directly and proximally caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

61. The infringement of the '200 Patent by Auris is willful and deliberate. In particular, at least as of the filing of this Complaint, if not earlier, Auris knew or should have

known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '200 Patent. Such conduct constitutes, at minimum, willful infringement of the '200 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

62. Unless Auris is enjoined from infringing the '200 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**SIXTH CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 6,800,056)**

63. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

64. By assignment, Intuitive owns all rights, title, and interest in and to the '056 Patent.

65. As detailed more fully in Attachment F, Auris has infringed and continues to infringe at least claim 1 of the '056 Patent when Auris or its customers use Monarch.

66. Monarch has no substantial non-infringing uses.

67. Doctors who use Monarch directly infringe at least claim 1 of the '056 Patent.

68. Auris has known of the '056 Patent at least as of August 6, 2018, if not earlier.

69. Auris has committed and continues to commit these acts of infringement without license or authorization.

70. The infringement by Auris has directly and proximally caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

71. The infringement of the '056 Patent by Auris is willful and deliberate. In particular, at least as of August 6, 2018, if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '056 Patent. Such conduct constitutes, at minimum, willful infringement of the '056 Patent, justifying an award of treble damages

pursuant to 35 U.S.C. § 284.

72. Unless Auris is enjoined from infringing the '056 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**SEVENTH CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 8,801,601)**

73. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

74. By assignment, Intuitive owns all rights, title, and interest in and to the '601 Patent.

75. As detailed more fully in Attachment G, Auris has infringed and continues to infringe at least claim 1 of the '601 Patent when Auris or its customers use Monarch.

76. Monarch has no substantial non-infringing uses.

77. Doctors who use Monarch directly infringe at least claim 1 of the '601 Patent.

78. Auris has known of the '601 Patent at least as of August 6, 2018, if not earlier.

79. Auris has committed and continues to commit these acts of infringement without license or authorization.

80. The infringement by Auris has directly and proximally caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

81. The infringement of the '601 Patent by Auris is willful and deliberate. In particular, at least as of August 6, 2018, if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '601 Patent. Such conduct constitutes, at minimum, willful infringement of the '601 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

82. Unless Auris is enjoined from infringing the '601 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

**EIGHTH CAUSE OF ACTION
(INFRINGEMENT OF U.S. PATENT NO. 6,522,906)**

83. Intuitive incorporates each of the preceding paragraphs as if fully set forth herein.

84. By assignment, Intuitive owns all rights, title, and interest in and to the '906 Patent.

85. As detailed more fully in Attachment H, Auris has infringed and continues to infringe at least claim 51 of the '906 Patent when Auris or its customers use Monarch.

86. Monarch has no substantial non-infringing uses.

87. Doctors who use Monarch directly infringe at least claim 51 of the '906 Patent.

88. Auris has known of the '906 Patent at least as of the filing of this Complaint, if not earlier.

89. Auris has committed and continues to commit these acts of infringement without license or authorization.

90. The infringement by Auris has directly and proximally caused damage to Intuitive. This infringement entitles Intuitive to monetary relief in an amount which, by law, cannot be less than a reasonable royalty, together with interests and costs fixed by this Court pursuant to 35 U.S.C. § 284.

91. The infringement of the '906 Patent by Auris is willful and deliberate. In particular, at least as of the filing of this Complaint, if not earlier, Auris knew or should have known that its making, using, selling, offering to sell, and/or importing Monarch does and will constitute an unjustifiably high risk of infringement of the '906 Patent. Such conduct constitutes, at minimum, willful infringement of the '906 Patent, justifying an award of treble damages pursuant to 35 U.S.C. § 284.

92. Unless Auris is enjoined from infringing the '906 Patent, Intuitive will suffer irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

Plaintiffs Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. respectfully

request that the Court find in their favor and against Defendant Auris Health, Inc., and that the Court grant them the following relief:

- a. For entry of judgment that the '701 Patent, the '447 Patent, the '473 Patent, the '276 Patent, the '200 Patent, the '056 Patent, the '601 Patent, and the '906 Patent have been and continue to be directly and/or indirectly infringed by Auris, either literally or under the doctrine of equivalents;
- b. For a declaration that each of the Patents-in-Suit is valid and enforceable;
- c. For permanent injunctions enjoining the aforesaid acts of infringement by Auris, its officers, agents, servants, employees, attorneys, parent and subsidiary entities, assigns and successors in interest, and those persons acting in concert with them, including related individuals and entities, customers, representatives, distributors, and dealers. In the alternative, if the Court finds that an injunction is not warranted, Intuitive requests an award of post-judgment royalty to compensate for future infringement;
- d. For an accounting of all damages sustained by Intuitive as the result of the acts of infringement by Auris;
- e. For the award to Intuitive of damages so ascertained, together with pre-judgment interest as provided by law;
- f. For entry of judgment that Auris's infringement is willful, and for an award of treble damages pursuant to 35 U.S.C. § 284;
- g. For judgment that this case is exceptional, and for an award of all costs, disbursements, and attorneys' fees pursuant to 35 U.S.C. § 285; and
- h. For such other and further legal and/or equitable relief as the Court shall deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Intuitive demands a jury trial on all issues so triable.

/s/ Karen E. Keller

Karen E. Keller (No. 4489)

David M. Fry (No. 5486)

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Dated: August 31, 2018