

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

BOSTON SCIENTIFIC CORPORATION,
a Delaware corporation; and BOSTON
SCIENTIFIC SCIMED, INC., a Minnesota
corporation,

Plaintiff,

v.

COOK GROUP INCORPORATED, an
Indiana corporation; and COOK
MEDICAL LLC, an Indiana limited
liability company

Defendants.

Civil Action No. 1:17-cv-03448-JRS-MJD

JURY TRIAL DEMANDED

**SECOND AMENDED AND SUPPLEMENTAL
COMPLAINT FOR PATENT INFRINGEMENT**

For its Second Amended and Supplemental Complaint against Cook Group Incorporated and Cook Medical LLC (collectively “Defendants”), Plaintiffs Boston Scientific Corporation (“BSC”) and Boston Scientific Scimed, Inc. (“BSSI”; collectively “Plaintiffs”), by its attorneys, allege as follows:

NATURE OF THE ACTION

1. In this action, Plaintiffs BSC and BSSI allege that Defendants infringe U.S. Patent Nos. 8,685,048 (“the ’048 Patent”), 8,974,371 (“the ’371 Patent”), and 9,271,731 (“the ’731 Patent”) (collectively “the Patents-in-Suit”).

PARTIES

2. Plaintiff BSC is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 300 Boston Scientific Way, Marlborough Massachusetts 01752. BSC is a leading developer, manufacturer, and supplier of medical

devices, including endoscopic products for the treatment of diseases of the digestive system.

3. Plaintiff BSSI is a corporation organized and existing under the laws of the state of Minnesota with a principal place of business at One Scimed Place, Maple Grove, MN 55311. BSSI is a wholly owned subsidiary of BSC. Among other things, BSSI develops and manufactures endoscopic products for the treatment of diseases of the digestive system, including hemostatic clips, that BSC distributes. BSSI is the owner by assignment of the '048, '371, and '731 Patents.

4. On information and belief, Defendant Cook Group Incorporated is a corporation organized and existing under the laws of the State of Indiana with a principal place of business at 750 N. Daniels Way, Bloomington, Indiana 47404.

5. On information and belief, Defendant Cook Medical LLC is a limited liability company organized and existing under the laws of the State of Indiana with a principal place of business at 1025 West Acuff Road, Bloomington, Indiana 47404.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States, Title 35 of the United States Code.

7. This Court has subject matter jurisdiction over the causes of action asserted herein pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over each of Defendants. On information and belief, Defendants, either collectively or individually, have had systematic and continuous contacts with this District, regularly transact business within this District, and regularly avail themselves of the benefits of this District. On information and belief, Defendants, directly or through intermediaries (including sales agents and others), use, offer for sale, sell, import and/or

distribute to others for such purposes, endoscopic products for the treatment of diseases of the digestive system, including hemostatic clips, in the United States and this District.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b)–(c) as, among other reasons, Defendants are subject to personal jurisdiction in this District and a substantial part of the events giving rise to the claims occurred in this District.

BACKGROUND

10. Plaintiffs BSC and BSSI are leading developers, manufacturers, and suppliers of medical devices dedicated to helping medical care professionals deliver superior healthcare to their patients. One such medical product that BSSI developed and BSC distributes is the Resolution™ Clip, an endoscopic hemostasis clip that is intended to, among other things, stop bleeding in the gastrointestinal tract. The novel design (*e.g.*, reversibly operable clip arms and locking mechanism) of the Resolution™ Clip allows medical care professionals to more precisely position the clip and securely lock the clip in place so that medical care professionals may quickly stop gastrointestinal bleeding.

11. BSSI has made significant investments into the research, development, and testing of the design of hemostatic clips, including the technology embodied by the Resolution™ Clip.

12. BSC has made significant investments into bringing the product to market.

13. To protect these investments, BSSI applied for and obtained a number of patents, including the '048, '371, and '731 Patents.

14. On information and belief, Defendants have been directly competing with BSC and BSSI since at least 2013 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use the Instinct™ Endoscopic Hemoclip. A true and correct copy of the data sheet for the Instinct™ Endoscopic Datasheet dated 2013 and obtained from

Defendants' website (<https://www.cookmedical.com/data/resources/productReferences/ESC-WM-50044-EN-201301.pdf?905860>) is attached as Exhibit A.

15. On information and belief, Defendants have been directly competing with BSC and BSSI since at least 2021 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use the Instinct Plus™ Endoscopic Clipping Device. A true and correct copy of the data sheet for the Instinct Plus™ Endoscopic Clipping Device Datasheet dated 2021 and obtained from Defendants' website (https://www.cookmedical.com/data/resources/ESC-D59445-EN-F_M3_1613141746664.pdf) is attached as Exhibit H.

16. Defendants are a major competitor of BSSI and BSC in the endoscopic hemostatic clip market.

COUNT I

(Defendants' Infringement of the '048 Patent)

17. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

18. On April 1, 2014, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '048 Patent, entitled "Device and Method for Through the Scope Endoscopic Hemostatic Clipping," to Mark L. Adams, Russell F. Durgin, Vincent Turturro, Justin Grant, Norman May, and Roy H. Sullivan as inventors. A true and correct copy of the '048 Patent is attached as Exhibit B.

19. BSSI is the assignee and lawful owner of all right, title, and interest in and to the '048 Patent.

20. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with

respect to products that they manufacture and sell under the '048 Patent.

21. Defendants have had knowledge of the '048 Patent since at least October 27, 2015, when BSC filed the Original Complaint (Dkt. 1) in this action and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device would infringe one or more claims of the '048 Patent.

22. On information and belief, Defendants have infringed and continue to infringe, literally and/or through the doctrine of equivalents, the '048 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products, services, methods, or processes that are covered by at least claims 3, 4, 7, and 14 of the '048 Patent. On information and belief, such devices include, but are not limited to, the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device.

23. On information and belief, Defendants have indirectly infringed and continue to indirectly infringe the '048 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendants' customers directly infringe at least claims 3, 4, 7, and 14 of the '048 Patent by using the claimed apparatus. On information and belief, Defendants have knowingly induced infringement and have had a specific intent to induce infringement of the '048 Patent by their activities relating to the marketing, sales, support, and distribution of the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device, including, for example without limitation, providing through Defendants' website video and print instructions to use the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device in a manner that infringes one or more claims of the '048 Patent. On information and belief,

Defendants have contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '048 patent and not a staple article or commodity of commerce suitable for substantial noninfringing use. A true and correct copy of the Instinct™ Endoscopic Hemoclip Quick Reference Guide is attached as Exhibit C.

(*See also* [https://www.cookmedical.com/products/f8ea2847-62e8-4d31-852e-](https://www.cookmedical.com/products/f8ea2847-62e8-4d31-852e-3d2b01440236/#tab=resources)

[3d2b01440236/#tab=resources](https://www.cookmedical.com/products/f8ea2847-62e8-4d31-852e-3d2b01440236/#tab=resources).) A true and correct copy of the Instinct Plus™ Endoscopic Clipping Device Quick Reference Guide is attached as Exhibit I. (*See also*

https://www.cookmedical.com/data/resources/ESC-D55576-EN-F_M3_1608740596201.pdf.)

24. On information and belief, Defendants' infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

25. As a result of Defendants' infringement of the '048 Patent, Plaintiffs have suffered and continue to suffer damages.

26. Defendants' infringement of the '048 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

27. Claim charts indicating that the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device include each of the limitations found in claims 3, 4, 7, and 14 of the '048 Patent were filed on June 15, 2021. Dkt. 421, Ex.2, Attach. A, C (filed under seal at Dkt. 422).

COUNT II

(Defendants' Infringement of the '371 Patent)

28. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

29. On March 10, 2015, the USPTO duly and legally issued the '371 Patent, entitled "Through the Scope Tension Member Release Clip" to Russell F. Durgin, William C. Mers Kelly, Lance Alan Wolf, Brian Keith Wells, Vasily P. Abramov, and Gregory R. Furnish as inventors. A true and correct copy of the '371 Patent is attached as Exhibit E.

30. BSSI is the assignee and lawful owner of all right, title, and interest in and to the '371 Patent.

31. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that it manufactures and sells under the '371 Patent.

32. Defendants have had knowledge of the '371 Patent since at least October 27, 2015, when BSC filed the Original Complaint (Dkt. 1) in this action and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device would infringe one or more claims of the '371 Patent.

33. On information and belief, Defendants have infringed and continue to infringe, literally and/or through the doctrine of equivalents, the '371 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products that are covered by at least claim 13 of the '371 Patent. On information and belief, such devices include, but are not limited to, the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device.

34. On information and belief, Defendants have indirectly infringed and continue to indirectly infringe the '371 Patent in violation of 35 U.S.C. ¶ 271. On information and belief, Defendants' customers directly infringe at least claim 13 of the '371 Patent by using the claimed apparatus. On information and belief, Defendants have knowingly induced infringement and have had a specific intent to induce infringement of the '371 Patent by their activities relating to the marketing, sales, support, and distribution of the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device, including, for example without limitation, providing video and print instructions to use the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device in a manner that infringes one or more claims of the '371 Patent. On information and belief, Defendants have contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Instinct™ Endoscopic Hemoclip and the Instinct Plus™ Endoscopic Clipping Device knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '371 patent and not a staple article or commodity of commerce suitable for substantial noninfringing use. A true and correct copy of the Instinct™ Endoscopic Hemoclip Quick Reference Guide is attached as Exhibit C. (*See also* <https://www.cookmedical.com/products/f8ea2847-62e8-4d31-852e-3d2b01440236/#tab=resources>.) A true and correct copy of the Instinct Plus™ Endoscopic Clipping Device Quick Reference Guide is attached as Exhibit I. (*See also* https://www.cookmedical.com/data/resources/ESC-D55576-EN-F_M3_1608740596201.pdf.)

35. On information and belief, Defendants' infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

36. As a result of Defendants' infringement of the '371 Patent, Plaintiffs have suffered and continue to suffer damages.

37. Defendants' infringement of the '371 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

38. Claim charts indicating that the InstinctTM Endoscopic Hemoclip and the Instinct PlusTM Endoscopic Clipping Device include each of the limitations found in claim 13 of the '371 Patent were filed on June 15, 2021. Dkt. 421, Ex.2, Attach. B, D (filed under seal at Dkt. 422).

COUNT III

(Defendants' Infringement of the '731 Patent)

39. Plaintiffs repeat and reallege each and every allegation set forth in the preceding paragraphs as if fully set forth herein.

40. On March 1, 2016, the USPTO duly and legally issued the '731 Patent, entitled "Device and Method for Through the Scope Endoscopic Hemostatic Clipping," to Mark L. Adams, Russell F. Durgin, Vincent Turturro, Justin Grant, Norman May, and Roy H. Sullivan as inventors. A true and correct copy of the '731 Patent is attached as Exhibit F.

41. BSSI is the assignee and lawful owner of all right, title, and interest in and to the '731 Patent.

42. Plaintiffs have complied with the notice requirements of 35 U.S.C. § 287 with respect to products that it manufactures and sells under the '731 Patent.

43. Defendants have had actual knowledge and notice of U.S. Patent Application Publication No. 2014/0257342 ("the '342 Publication"), the published patent application giving rise to the '731 Patent, since at least November 17, 2015, when counsel for BSC and BSSI sent a

letter to Defendants in care of Defendants' outside counsel pursuant to 35 U.S.C. § 154(d). A true and correct copy of the November 17, 2015 Letter is attached as Exhibit G.

44. On information and belief, Defendants have had knowledge of the '731 Patent since it first issued on March 1, 2016, because Defendants have had actual knowledge and notice of the '342 Publication since November 17, 2015.

45. Defendants have had knowledge of the '731 Patent since at least the filing of the First Amended and Supplemental Complaint (Dkt. 19) on March 9, 2016 and knew or should have known that the sale, offer for sale, use, manufacture, and/or importation of the Instinct Plus™ Endoscopic Clipping Device would infringe one or more claims of the '731 Patent.

46. On information and belief, Defendants have infringed and continue to infringe, literally and/or through the doctrine of equivalents, one or more claims of the '731 Patent in violation of 35 U.S.C. § 271 by making, using, selling, offering to sell, and/or importing into the United States for subsequent sale or use products that are covered by at least claims 5 and 19 of the '731 Patent. On information and belief, such devices include, but are not limited to, the Instinct Plus™ Endoscopic Clipping Device.

47. On information and belief, Defendants have indirectly infringed and continue to indirectly infringe the '731 Patent in violation of 35 U.S.C. § 271. On information and belief, Defendants' customers directly infringe at least claims 5 and 19 of the '731 Patent by using the claimed apparatus. On information and belief, Defendants have knowingly induced infringement and have had a specific intent to induce infringement of the '731 Patent by their activities relating to the marketing, sales, support, and distribution of the Instinct Plus™ Endoscopic Clipping Device, including, for example without limitation, providing video and print instructions to use the Instinct Plus™ Endoscopic Clipping Device in a manner that infringes one

or more claims of the '731 Patent. On information and belief, Defendants have contributed to infringement by selling and/or offering to sell within the United States, or importing into the United States, the Instinct Plus™ Endoscopic Clipping Device knowing the same to be especially made or especially adapted for use in the infringement of one or more claims of the '731 Patent and not a staple article or commodity of commerce suitable for substantial noninfringing use. A true and correct copy of the Instinct Plus™ Endoscopic Clipping Device Quick Reference Guide is attached as Exhibit I. (*See also* https://www.cookmedical.com/data/resources/ESC-D55576-EN-F_M3_1608740596201.pdf.)

48. On information and belief, Defendants' infringement has been and continues to be willful, making this an exceptional case under 35 U.S.C. § 285 and entitling Plaintiffs to treble damages under 35 U.S.C. § 284.

49. As a result of Defendants' infringement of the '731 Patent, Plaintiffs have suffered and continue to suffer damages.

50. Defendants' infringement of the '731 Patent has caused and will continue to cause Plaintiffs irreparable injury for which there is no adequate remedy at law, unless this Court enjoins such infringing acts.

51. Claim charts indicating that the Instinct Plus™ Endoscopic Clipping Device includes each of the limitations found in claims 5 and 19 of the '731 Patent were filed on June 15, 2021. Dkt. 421, Ex.2, Attach. E (filed under seal at Dkt. 422).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs BSC and BSSI respectfully request that this Court grant the following relief:

1. Judgment in favor of Plaintiffs BSC and BSSI, and against Defendants Cook

Group Incorporated and Cook Medical LLC, that Defendants have and continue to directly infringe and induce infringement of one or more claims of the '048 Patent;

2. Judgment in favor of Plaintiffs BSC and BSSI, and against Defendants Cook Group Incorporated and Cook Medical LLC, that Defendants' infringement of the '048 Patent has been and continues to be willful;

3. Judgment in favor of Plaintiffs BSC and BSSI, and against Defendants Cook Group Incorporated and Cook Medical LLC, that Defendants have and continue to directly infringe and induce infringement of one or more claims of the '371 Patent;

4. Judgment in favor of Plaintiffs BSC and BSSI, and against Defendants Cook Group Incorporated and Cook Medical LLC, that Defendants' infringement of the '371 Patent has been and continues to be willful;

5. Judgment in favor of Plaintiffs BSC and BSSI, and against Defendants Cook Group Incorporated and Cook Medical LLC, that Defendants have and continue to directly infringe and induce infringement of one or more claims of the '731 Patent;

6. Judgment in favor of Plaintiffs BSC and BSSI, and against Defendants Cook Group Incorporated and Cook Medical LLC, that Defendants' infringement of the '731 Patent has been and continues to be willful;

7. A preliminary and permanent injunction against Defendants Cook Group Incorporated and Cook Medical LLC for infringement of the Patents-in-Suit;

8. Judgment awarding Plaintiffs BSC and BSSI damages adequate to compensate for Defendants Cook Group Incorporated and Cook Medical LLC's infringement of the Patents-in-Suit in an amount to be proven at trial, together with pre-judgment and post-judgment interest and costs, as fixed by the Court;

9. Judgment enhancing the damages due to Defendants Cook Group Incorporated and Cook Medical LLC's willful infringement, pursuant to 35 U.S.C. § 284;
10. Judgment declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs BSC and BSSI attorney fees and costs incurred in prosecuting its claims; and
11. Such other relief as this Court deems just and proper.

JURY DEMAND

Plaintiffs BSC and BSSI demand a trial by jury in this action on all issues so triable.

DATED: August 17, 2021

/s/ David J. Hensel
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