United States Court of Appeals for the Federal Circuit

COLIBRI HEART VALVE LLC,
Plaintiff-Appellee

v.

MEDTRONIC COREVALVE, LLC,
Defendant-Appellant

2023-2153

Appeal from the United States District Court for the Central District of California in No. 8:20-cv-00847-DOC-JDE, Judge David O. Carter.

Decided: July 18, 2025

JEFFREY A. LAMKEN, MoloLamken LLP, Washington, DC, argued for plaintiff-appellee. Also represented by WALTER H. HAWES, IV, MICHAEL GREGORY PATTILLO, JR.; CATHERINE MARTINEZ, New York, NY; STEVEN DERRINGER, MEG E. FASULO, MATTHEW R. FORD, KATHERINE E. RHOADES, Bartlit Beck LLP, Chicago, IL; JOHN HUGHES, TAYLOR JAMES KELSON, Denver, CO.

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Piper LLP (US), Palo Alto, CA; STANLEY JOSEPH PANIKOWSKI, III, San Diego, CA.

Before TARANTO, HUGHES, and STOLL, *Circuit Judges*.

TARANTO, *Circuit Judge*.

U.S. Patent No. 8,900,294, owned by Colibri Heart Valve LLC, claims a method, for use in trying to implant an artificial heart valve to replace a defective valve, that furnishes a do-over opportunity to the installer to get the positioning right. In the claimed method, the replacement valve is only partially deployed from the delivery apparatus but recaptured within the delivery apparatus before full deployment if it looks like the positioning will be off. Colibri sued Medtronic CoreValve, LLC, a manufacturer of replacement heart valves, for infringement—alleging, as now relevant, that Medtronic was inducing surgeons to perform the claimed method with Medtronic's products. *See* 35 U.S.C. § 271(b).

The '294 patent, at the outset of prosecution, included two independent claims reciting the opportunity-for-do-over method of partial deployment: one claimed pushing out the valve from an outer sheath of the delivery apparatus, and one claimed retracting the outer sheath to expose the valve. During prosecution, the examiner rejected the latter claim for lack of written description, *see* 35 U.S.C. § 112, and Colibri cancelled it. The patent issued with an independent claim reciting partial deployment by pushing, and no claims expressly reciting partial deployment by retracting.

In the district court, Medtronic contended that the accused use of its product involved partial deployment by retracting, not pushing. At trial, Colibri dropped its assertion of literal infringement, relying solely on the doctrine of equivalents to establish infringement by accused direct infringers using the accused method with

Medtronic's products. The jury, besides rejecting Medtronic's invalidity challenge, found that Medtronic had induced infringement and awarded more than $106 million in damages to Colibri. Before and after the verdict, Medtronic sought judgment as a matter of law (JMOL) on the ground, among others, that Colibri's equivalents claim was barred by prosecution history estoppel, but the district court denied the motions.

On appeal, Medtronic argues, among other things, that the district court erred in denying JMOL of noninfringement. We now conclude that prosecution history estoppel, based on Colibri's cancelling of a claim to "retraction" for partial deployment of the replacement valve and Colibri's own recognition of the close linkage of the subject matter of the cancelled and retained claims, bars application of the doctrine of equivalents. We therefore reverse the district court's denial of JMOL of noninfringement. That is all we need decide to resolve this dispute over the now-expired patent.

I

A

The '294 patent, which expired in January 2022 and is titled "Method of Controlled Release of a Percutaneous Replacement Heart Valve," relates to artificial heart valves used to replace diseased or otherwise defective heart valves. '294 patent, title; *id.*, col. 2, lines 52–54. Blood flows through valves in the heart from areas of relatively high pressure to areas of relatively low pressure. *Id.*, col. 1, lines 31–33, 46–48. Each valve includes "leaflets" (sometimes called "cusps") spanning the passageway through which blood flows, with the opening and closing of the leaflets allowing blood to flow only in the proper direction through the circulatory system. *Id.*, col. 1, lines 48–56; *id.*, col. 2, lines 1–28.

The '294 patent describes a replacement heart valve (200) formed by folding biologically compatible material to form a tubular portion (210) and a leaflet portion (220), *id.*, col. 5, lines 1–7; *id.*, col. 6, lines 62–64, shown in figures 1 and 5.

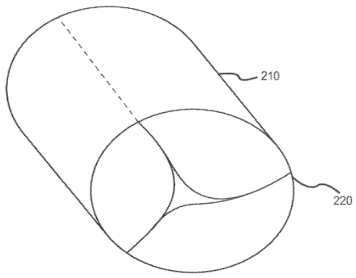


FIG.1

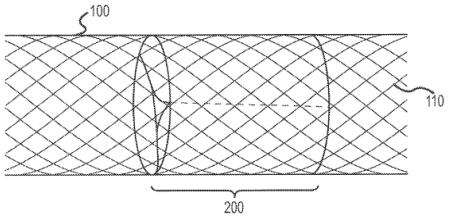


FIG.5

The leaflets (220) are formed from "a single, continuous, uncut layer" of material. *Id.*, col. 8, lines 54–60. The tubular portion (210) of the valve (200) is sutured to the interior of a cylindrical, self-expanding metal stent member (100), which provides a "semi-rigid" channel through the diseased valve upon implantation. *Id.*, col. 6, lines 57–67; *id.*, col. 7, lines 9–11, 27–29, 65–67.

The patent further describes a method of making the valve and, of key importance here, a method for use in implanting a replacement heart valve in which the valve is partially released and can be recovered if it looks like the positioning will be incorrect. *Id.*, col. 11, lines 51–62. Figure 8 depicts an implantation system used in the claimed method, with the distal end at the bottom and proximal end at the top, and with the components shown in an expanded view simply for display purposes. *Id.*, col. 11, lines 40–51.

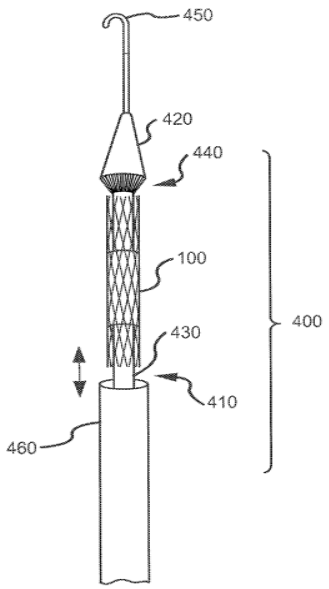


FIG.8

A flexible, hollow catheter (400) carrying the stent (100)—to which the replacement heart valve (200), not shown, is sutured—is inserted into a blood vessel of the patient, *e.g.*, the femoral artery, and advanced through the circulatory system to the location of the valve that is to be replaced. *Id.*, col. 11, lines 3–7, 40–48. The catheter (400) includes a pusher member (420), and, in some embodiments, a moveable sheath (460) that covers the stent (100) and valve (shown pulled down for display purposes). *Id.*, col. 11, lines 48–51; *id.*, col. 12, lines 11–14.

Once the catheter is in what seems the desired position, the pusher member (420) pushes the stent (100) and valve (200) towards the distal end of the catheter (410) such that the stent (100) only partially expands. *Id.*, col. 11, lines 51–55. At that stage, if the positioning seems incorrect, the valve can be "recaptured" (*i.e.*, recovered and returned to its original position within the catheter, with the stent re-squeezed) and re-deployed once the catheter's

overall location is adjusted. *Id.*, col. 11, lines 55–59. If no recapture is necessary, the catheter (400) is retracted slightly, and the pusher member (420) fully pushes out the stent (100) and valve from the catheter (400). *Id.*, col. 11, lines 59–62. In embodiments with a moveable sheath (460), the stent (100) and valve are released by pulling the moveable sheath towards the proximal end (440) of the catheter (400), "allowing the self-expending stent to achieve its full expansion." *Id.*, col. 12, lines 11–14, 24–27.

Claim 1 is representative and recites as follows:

> 1. A method of controlled release of a percutaneous replacement heart valve at a location of a native heart valve in a patient, the method comprising:
>
> obtaining a replacement heart valve device and a delivery and implantation system:
>
> the replacement heart valve device including:
>
> > a stent member that is collapsible, expandable and configured for percutaneous delivery; and
> >
> > a valve residing entirely within an inner channel of the stent member and attached to a proximal portion of the stent member, the valve including two to four individual leaflets made of fixed pericardial tissue;
>
> the delivery and implantation system including:
>
> > a pusher member and a moveable sheath, wherein the pusher member includes a guide wire lumen, and wherein the moveable sheath includes a lumen configured for receiving the pusher member;
>
> after the obtaining step, loading the replacement heart valve device into the lumen of the moveable sheath such that the replacement heart valve

> device is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath;
>
> after the loading step, advancing the delivery and implantation system transluminally over a guide wire within the patient to position the replacement heart valve device for deployment within the patient at the location of the native heart valve;
>
> **after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient by pushing out the pusher member from the moveable sheath to expose the distal portion of the replacement heart valve device;**
>
> after the partially deploying step, restraining the replacement heart valve device so that it does not pop out and is held for controlled release, with a potential that the replacement heart valve device can be recovered if there is a problem with positioning; and
>
> after the restraining step, recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient.

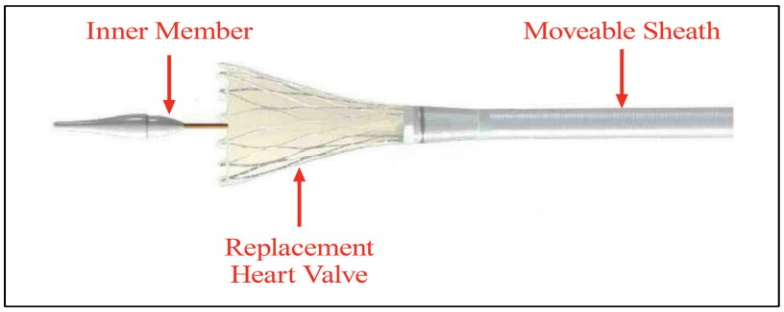
Id., col. 13, line 38 through col. 14, line 37 (emphasis added).

B

Medtronic sells replacement heart valves, broadly referred to as the "Evolut" line of products. The Evolut products include a self-expanding metal stent and a replacement heart valve with three leaflets sutured to a cylindrical "inner skirt." J.A. 26579, 26676, 28875.

Importantly here, the Evolut products can be "recaptured" during implantation, if necessary. *See*, *e.g.*, J.A. 26514–15 (describing recapture process).

The implantation of the Evolut products involves advancing a catheter containing the replacement heart valve through the patient's circulatory system. J.A. 26580–81. The catheter includes an inner member disposed inside the replacement heart valve and stent, and a moveable sheath (also called a capsule) that covers the replacement heart valve and stent. J.A. 22866–68. It is illustrated in the record as follows (with the distal end to the left):



J.A. 27612. A deployment knob (located on a portion of the catheter outside the patient's body) controls the position of the moveable sheath relative to the replacement heart valve and stent: Rotating the deployment knob in one direction retracts the moveable sheath and uncovers (*i.e.*, partially or fully deploys) the replacement heart valve and stent, while rotating in the other direction re-covers (*i.e.*, recaptures) the replacement heart valve and stent. J.A. 22867–68; *see also* J.A. 21133, line 1 through J.A. 21135, line 7 (Colibri's witness discussing deployment mechanism).

II

A

In May 2020, Colibri sued Medtronic for infringement of the '294 patent in the United States District Court for the Central District of California. Complaint at 16–21,

Colibri Heart Valve LLC v. Medtronic CoreValve LLC, No. 20-cv-00847 (C.D. Cal. May 4, 2020), ECF No. 1 (*Complaint*); *see also* First Amended Complaint at 16–22, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal. June 12, 2020), ECF No. 30 (*First Amended Complaint*).[1] Colibri asserted direct infringement (literally and under the doctrine of equivalents) under 35 U.S.C. § 271(a), contributory infringement under § 271(c), and inducement of infringement under § 271(b). *Complaint* at 18–19; *First Amended Complaint* at 18–19. Colibri later abandoned its allegations of direct and contributory infringement, proceeding only with its allegations of inducement of infringement. Medtronic raised affirmative defenses of invalidity and prosecution history estoppel in its answer. Answer at 10, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal. Apr. 13, 2021), ECF No. 114.

A special master appointed by the district court, after conducting claim-construction proceedings, issued a recommendation to the court on February 11, 2021. Report and Recommendation on Claim Construction at 1, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847, 2021 WL 4437737, at *1 (C.D. Cal. Feb. 11, 2021), ECF No. 97 (*Claim Construction*). The parties disputed the construction of one term relevant here: "pushing out the pusher member from the moveable sheath." *Id.* at *20–22. Colibri proposed that the phrase meant a "pushing force is applied to the pushing member in a direction outwards from the moveable sheath," and Medtronic proposed the phrase meant "pressing against the pusher member with a

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[1] Colibri also asserted infringement of U.S. Patent No. 9,124,739. *Complaint* at 16–17; *First Amended Complaint* at 16–18. The district court granted summary judgment of noninfringement of the '739 patent, and Colibri did not cross-appeal.

force that moves the pusher member out of the moveable sheath." *Id.* at *20. The special master recommended that the district court adopt Medtronic's proposed construction, reasoning that the claimed "pushing out" limitation is not just a matter of the force's direction but "requires movement of the pusher member such that the replacement heart valve moves outward from the sheath to at least some degree." *Id.* at *26. The district court adopted the recommended claim construction. Order at 1, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847, 2021 WL 4439091, at *1–2 (C.D. Cal. May 19, 2021), ECF No. 119.

B

After claim construction, both parties moved for summary judgment: Colibri for partial summary judgment of no invalidity, and Medtronic for summary judgment of invalidity and noninfringement. Medtronic argued, among other things, that Colibri's assertion of infringement of claim 1 under the doctrine of equivalents was barred by prosecution history estoppel. In particular, it argued that Colibri's cancelling during prosecution of then-claim 39—while retaining then-claim 34 (which issued as claim 1)—"precludes Colibri from asserting that, under the [doctrine of equivalents], partial deployment and recovery of the valve is performed *by retracting* the sheath." J.A. 3164 (emphasis added). Cancelled claim 39 recited:

> A method of controlled release of a percutaneous replacement heart valve in a patient where a bioprosthetic heart valve is indicated, comprising:
>
> providing a replacement heart valve device and a delivery and implantation system;
>
> the replacement heart valve device including:
>
> > a stent member that is collapsible, expandable and configured for percutaneous delivery; and

> a valve attached to the stent member. the valve including two to four individual leaflets;
>
> the delivery and implantation system including:
>
> a pusher member and a moveable sheath, wherein the pusher member includes a lumen for receiving a guide wire, wherein the moveable sheath includes a lumen configured for receiving the pusher member, and wherein the replacement heart valve device is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in a collapsed configuration by the moveable sheath;
>
> after the providing step, advancing the delivery and implantation system over the guide wire within the patient to position the replacement heart valve device for deployment within the patient;
>
> **after the advancing step, partially deploying the replacement heart valve device within the patient by retracting the moveable sheath to expose a portion of the replacement heart valve device; and**
>
> after the partially deploying step, recovering the portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient.

J.A. 23140–41 (emphasis added).

The special master recommended that the court reject Medtronic's prosecution-history-estoppel argument. Report and Recommendation on Summary Judgment at 33–

38, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal. July 26, 2021), ECF No. 202; *see also* Redacted Report and Recommendation at 33–38, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal. Aug. 10, 2021), ECF No. 220-1 (*Summary Judgment Recommendation*). The special master reasoned that cancelled claim 39 "was an independent claim separate from" retained claim 34 (issued claim 1) and Medtronic "d[id] not show that . . . [Colibri] cancelled claim 39 in favor of purs[u]ing a limitation that already appeared in [claim 1] . . . or that [Colibri] added or amended any claims directed to this limitation." *Summary Judgment Recommendation* at 37. In other words, cancelled claim 39 and retained claim 34 (issued claim 1) were clearly different, *i.e.*, separate and distinct. The special master also distinguished Colibri's "asserted equivalent" as "not merely retraction" but instead a combination of pushing and retracting, so "[t]he asserted equivalent . . . differs from what was set forth in the cancelled claim." *Id.* at 37–38. The district court adopted the special master's recommendation regarding the "pushing out" limitation and denied summary judgment. Order at 12–13, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal. Nov. 15, 2021), ECF No. 275.

C

A jury trial on the issues of invalidity and infringement began on January 31, 2023. Mid-trial, Colibri abandoned its theory that Medtronic literally infringed the '294 patent, arguing instead that, under the doctrine of equivalents, Medtronic's partial-deployment method (applying a force to hold the stent in place while retracting the moveable sheath) is equivalent to the claimed partial-deployment method (applying a force to push the stent out of the moveable sheath). During the jury trial, Medtronic filed two motions for JMOL, *see* Fed. R. Civ. Pro. 50(a), seeking, among other things, judgment of no equivalents infringement on

the ground of prosecution history estoppel. The district court did not rule on the Rule 50(a) motions.

The jury found that Medtronic induced infringement of claims 1–3 of the '294 patent and that Medtronic had not proven that those claims were invalid, and it awarded more than $106 million in damages to Colibri. J.A. 20–23. After the jury issued its verdict, Medtronic filed a renewed motion for judgment as a matter of law under Fed. R. Civ. P. 50(b) and a motion for new trial under Fed. R. Civ. P. 59. The district court denied the motions on June 8, 2023, rejecting Medtronic's prosecution history estoppel argument "for the same reasons set forth by the Court during summary judgment proceedings." J.A. 4.

The district court entered final judgment on June 16, 2023, J.A. 16–17, and Medtronic timely appealed, J.A. 205. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

III

Medtronic challenges four rulings of the district court: (1) the denial of JMOL of invalidity, Medtronic Opening Br. at 30–40; (2) the denial of JMOL of noninfringement, *id.* at 41–53; (3) the denial of JMOL of no active inducement, *id.* at 53–58; and (4) the denial of Medtronic's motion for a new trial on damages, *id.* at 59–71. It is undisputed that, if we reverse the denial of JMOL of noninfringement, we need not reach Medtronic's other challenges, including the invalidity challenge to this expired patent. Oral Arg. at 2:23–2:45, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=23-2153_05052025.mp3.

We follow the Ninth Circuit's de novo standard for review of the district court's JMOL decision. *See TEK Global, S.R.L. v Sealant Systems International, Inc.*, 920 F.3d 777, 783 (Fed. Cir. 2019) (citing *Wechsler v. Macke International Trade, Inc.*, 486 F.3d 1286, 1290 (Fed. Cir. 2007)). The JMOL standard itself, regarding fact issues, requires deference to the factfinder: JMOL is not to be granted unless

"the evidence, construed in the light most favorable to the nonmoving party, permits only one reasonable conclusion, and that conclusion is contrary to the jury's verdict." *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017) (quoting *Harper v. City of Los Angeles*, 533 F.3d 1010, 1021 (9th Cir. 2008)). Prosecution history estoppel, however, is a matter of law, not of fact, and it is decided de novo on appeal under our own circuit's law on this patent-law issue. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367–68 (Fed. Cir. 2003) (en banc).

Although Medtronic challenged the district court's denial of JMOL of noninfringement on several grounds, we address and decide only on one of those grounds—prosecution history estoppel. We conclude that Colibri's cancellation during prosecution of claim 39, which recited "retracting the moveable sheath," bars Colibri from asserting infringement under the doctrine of equivalents under the theory that a combination of applying a pushing force to the pusher member while retracting the moveable sheath (what Medtronic's device does) is equivalent to, *i.e.*, not substantially different from, "pressing against the pusher member with a force that moves the pusher member outward from the moveable sheath" (what claim 1 requires). Medtronic Opening Br. at 46–51; *see Claim Construction* at *26; *see also* Colibri Response Br. at 47 (discussing equivalence theory). That conclusion suffices for reversal.

A

As an initial matter, we reject Colibri's assertion that we should not consider Medtronic's prosecution-history-estoppel argument because Medtronic waived it before the district court. Colibri Response Br. at 45. Colibri's waiver argument rests on Medtronic's statement in a pre-trial memorandum filed on January 3, 2022, under the heading "Abandonment of Issues," that "Medtronic is not pursuing the Fifth Affirmative Defense of Prosecution History

Estoppel." J.A. 13659. Medtronic filed this pre-trial memorandum in accordance with Local Rule 16-4.6 of the Central District of California, which requires that the parties "identify any pleaded claims or affirmative defenses which have been abandoned." In the circumstances of this case, we do not deem Medtronic to have waived the JMOL argument based on prosecution history estoppel, an argument the district court itself reached on the merits in denying JMOL without suggesting that there was a waiver.

First, Medtronic's statement, though poorly worded, can reasonably be understood to be saying only what it was not pursuing at *trial*, *i.e.*, that Medtronic would not repeat its prosecution-history-estoppel argument before the jury, as this argument had already been rejected at summary judgment and involved a question of law on which no facts needed to be proved at trial. Indeed, Medtronic in the same pre-trial memorandum disclaimed waiver, stating: "The [c]ontentions below are based on Medtronic's current understanding of the parties' claims in light of the Technical Special Master's Reports and Recommendations on Summary Judgment . . . . Medtronic's inclusion of the [c]ontentions below does not constitute a waiver or concession of any aspect of Medtronic's objections or arguments made in connection with those orders, not does it constitute a waiver of Medtronic's right to appeal the same." J.A. 13637. Medtronic made a similar disclaimer in its trial brief. J.A. 18581–82.

Second, when Medtronic later made a Rule 50(a) motion for JMOL during trial, Medtronic explicitly made its prosecution-history-estoppel argument. J.A. 18727. And Colibri, responding, did not assert that Medtronic had abandoned the argument, instead urging the court to reject the argument solely on the merits. J.A. 18751. That response by Colibri comes within the principle that a waiver argument may be forfeited "by addressing the claim on the merits without also making a waiver argument." *Norwood v. Vance*, 591 F.3d 1062, 1068 (9th Cir. 2010).

Third, Colibri asserted waiver for the first time in its opposition to Medtronic's Rule 50(b) motion, even though it had the opportunity to do so when responding to Medtronic's Rule 50(a) motions. Colibri's Opposition to Medtronic's Renewed Motion for Judgment as a Matter of Law at 8, *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 20-cv-00847 (C.D. Cal. May 11, 2023), ECF No. 479 ("The Court should hold Medtronic to its voluntary abandonment of its prosecution history estoppel defense and find this issue waived."). But even then, Colibri did not establish any prejudice from the pretrial statement followed by the raising of this issue of law in seeking JMOL. And the district court, in then ruling on the Rule 50(b) motion, did not agree with Colibri's waiver contention. Instead, it directly addressed the merits, with no suggestion that the estoppel argument had been waived. *See* J.A. 4. Whether that course reflected the district court's reading of the pre-trial statement, reliance on Colibri's failure to raise waiver in opposing the Rule 50(a) motion, or exercise of any available discretion to reach the merits in the absence of any prejudice in these circumstances, we see no justification for us now to reject Medtronic's prosecution-history-estoppel argument as waived by its pre-trial statement.

B

On the merits of prosecution history estoppel, Medtronic argues that the district court erred by concluding that Colibri's asserted equivalent is quite distinct and separate from what was recited in cancelled claim 39 and that Colibri's cancellation of claim 39 was not a narrowing amendment. Medtronic Opening Br. at 47–48. We agree with Medtronic on those two related points, relying on Colibri's own recognition, in its affirmative case for finding equivalents, of the substantive linkage between the cancelled and retained claims. And because Colibri makes no argument against prosecution history estoppel except that the presumption of estoppel is inapplicable at the

threshold, *i.e.*, it makes no argument that this case comes within an exception when the presumption of estoppel applies or that the scope of particular narrowing does not justify estoppel, we hold that estoppel bars equivalents infringement here.

1

We begin with the district court's conclusion that the asserted equivalent (*i.e.*, the implantation method of Medtronic's Evolut system) differs distinctly from what was recited in cancelled claim 39. Colibri asserts that claim 39 did not require pushing the inner member—only retracting the moveable sheath—whereas Medtronic's Evolut devices require both pushing and retracting. Colibri Response Br. at 47; *see also id.* at 47–48 ("Pushing while retracting is not 'precisely what was recited in claim 39.' Pushing appears nowhere in claim 39."). The district court agreed with Colibri that, because Colibri's "asserted equivalent is not *merely* retraction," the "asserted equivalent . . . differs from what was set forth in the cancelled claim." *Summary Judgment Recommendation* at 37–38 (emphasis added).

Colibri's own affirmative theory of equivalence, however, hinges on what Colibri calls "simple physics," Colibri Response Br. at 11, 38, and "basic physics," *id.* at 56, requiring that opposing forces (*i.e.*, pushing and retracting) be applied to deploy the valve and stent from the moveable sheath. Colibri repeatedly asserted, before both this court and the district court, that the relevant artisan would understand that pushing necessarily accompanies retracting: "[B]ecause of the radial force the stent exerts on the inside of the sheath, there's '[a]bsolutely' no way to deploy the replacement heart valve without 'applying opposing forces.'"[2]

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[2] We do not rely on Medtronic's argument based on the "comprising" language of cancelled claim 39. *See* Medtronic Opening Br. at 47–48.

Id. at 59 (second alteration in original) (quoting J.A. 21292, lines 20–24); *see also* J.A. 21077, lines 3–18 (Colibri's witness explaining that, because the stent is self-expanding, "we have to have something that's going to contact and take hold of that stent so that we can move it").

Claim language present in both retained claim 34 (issued claim 1) and cancelled claim 39 further indicates that the relevant artisan would know that pushing necessarily accompanies retraction—that, in Colibri's words, "basic physics require pushing." *See* Colibri Response Br. at 56. Both claims recite that "the replacement heart valve device . . . is restrained in the collapsed configuration by the moveable sheath." '294 patent, col. 14, lines 12–15 (claim 1); J.A. 23140 (claim 39). This language indicates that the stent is held in place by the moveable sheath and will move with the moveable sheath in the absence of a pushing force on the stent (or something holding the stent, like the pusher member).

We conclude, accordingly, that the district court and special master were incorrect that Colibri's asserted equivalent distinctly "differs from what was set forth in" claim 39 such that the substance dropped when cancelling claim 39 is quite separate from the substance of retained claim 34 (issued claim 1). *Summary Judgment Recommendation* at 38. Colibri's assertions before this court and the district court, coupled with the surrounding claim language, make clear that pure retraction of the moveable sheath would result in retraction of the stent and valve as well—the only way to deploy (*i.e.*, separate) the stent and valve from the moveable sheath is to simultaneously exert a pushing force on the inner member holding the stent and valve. A countervailing pushing force is therefore necessary to both Colibri's asserted equivalent and the deployment method described by claim 39.

2

We similarly agree with Medtronic's second argument, which is closely related to the first—that Colibri's cancelling of claim 39 in favor of pursuing limitations that already appeared in retained claim 34 (issued claim 1) was a narrowing amendment giving rise to prosecution history estoppel. Medtronic Opening Br. at 47–48. Narrowing is a prerequisite to prosecution history estoppel: "If the amendment was not narrowing, then prosecution history estoppel does not apply." *Festo*, 344 F.3d at 1366. But the required narrowing is not a purely formal matter of altering a single claim's terms; it can exist, and we conclude here does exist, as a substantive matter based on cancelling a closely related claim involving such intertwined terminology that cancelling one claim necessarily communicated that the scope of the other claim had narrowed.

As just explained, Colibri cancelled claim 39, which recited partial deployment by retracting and necessarily involved applying a pushing force to the inner member in order to achieve that retraction. That cancellation bears on what can be covered under the doctrine of equivalents by claim 1 because a relevant artisan would understand the close basic-physics relationship of the cancelled and retained claims. The portions of the two claims that recite the partial-deployment step in question are substantially similar—both recite exposing the valve, the only difference is that then-claim 34 (issued claim 1) recites doing so by "pushing" while claim 39 recites "retracting":

> after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient ***by pushing out the pusher member from the moveable sheath*** to expose the distal portion of the replacement heart valve device

'294 patent, col. 14, lines 21–25 (emphasis added) (claim 1); *see* J.A. 23140 (then-claim 34).

> after the advancing step, partially deploying the replacement heart valve device within the patient ***by retracting the moveable sheath*** to expose a portion of the replacement heart valve device;

J.A. 23141 (emphasis added) (claim 39).

The district court's reasons for rejecting such a relationship between the cancelled subject matter and claim 1 rely on formalities: that then-claim 34 (issued claim 1) and then-claim 39 were separate independent claims, and that Colibri did not "add[] or amend[] any claims directed to" the pushing limitation. *Summary Judgment Recommendation* at 37. That rationale, however, makes an entirely formal point, requiring a formal claim relationship between the cancelled and allowed claims (*e.g.*, independent and dependent). If formalities are not determinative, however, the rationale does not justify denying estoppel here. As already indicated, the relevant artisan would understand that claim 1 (reciting only pushing) and claim 39 (reciting only retracting) are not unrelated to each other but, in fact, are closely related as a substantive matter, so giving up one communicates a narrowing message about the one retained.

Governing law precludes making formalities determinative, to the exclusion of substantive relationships that would be understood by relevant readers. "Estoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'" *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002) (quoting *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220–21 (1940)). That principle by its terms does not limit estoppel to situations in which the issued, asserted claim itself was amended, though the claim in *Festo* itself had been amended. *See Festo*, 344 F.3d at 1371–72 (discussing patentee's narrowing by adding limitations). And the Court in *Festo* used additional language not strictly limiting

estoppel to the amendment of a particular claim, but instead tailoring the inquiry to the scope of the claims of the patent as a whole, pre- and post-amendment. *See*, *e.g.*, *Festo*, 535 U.S. at 736 ("Estoppel arises when an amendment is made to secure the patent and the amendment narrows the *patent's* scope." (emphasis added)); *id.* at 740 ("Where the original application once embraced the purported equivalent but the patentee narrowed his *claims* to obtain the patent or to protect its validity, the patentee cannot assert that he lacked the words to describe the subject matter in question." (emphasis added)).[3]

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[3] The Supreme Court in *Festo* relied on the reasoning of *Schriber-Schroth*, which explained the underlying rationale of prosecution history estoppel in a validity context not directly involving that doctrine. For example, the Court in *Schriber-Schroth* said: "Where the patentee in the course of his application in the patent office has, by amendment, cancelled or surrendered claims, those which are allowed are to be read in the light of those abandoned and an abandoned claim cannot be revived and restored to the patent by reading it by construction into the claims which are allowed." 311 U.S. at 218; *see also id.* at 220–21 ("It is a rule of patent construction consistently observed that a claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent." (citation omitted)). In *Schriber-Schroth*, the patentee had cancelled claims reciting a "flexible web" feature and subsequently argued that claims not reciting the feature should be construed to include it (to escape invalidation by prior art). *Id.* at 219–20. The Supreme Court rejected the patentee's argument and explained that "the patentee, having acquiesced in the[] rejection [of claims reciting the

We rejected a formalistic approach to the narrowing inquiry in *Honeywell International Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1141–44 (Fed. Cir. 2004) (en banc). In that case, following the patent office's rejection of the original independent claims for obviousness, the patentee cancelled those independent claims and simply rewrote two dependent claims into independent form. *Id.* at 1141. The rewritten claims were subsequently allowed. *Id.* at 1137–38, 1141. Honeywell later asserted infringement under the doctrine of equivalents of the rewritten claims. *Id.* at 1138.

Honeywell argued that rewriting a dependent claim into independent form does not give rise to the presumption of prosecution history estoppel "because the scope of the rewritten claims themselves has not been narrowed." *Id.* at 1141. After all, the original dependent claims, by statutory directive, already contained all the independent claims' elements, 35 U.S.C. § 112(d) ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."); the rewritten claims simply made the incorporation express, changing nothing of substance. But we rejected that argument, reasoning that the Supreme Court had already rejected it in *Festo*. *Id.* at 1141–42. In particular, we observed that the Supreme Court had explained in *Festo* that this type of argument "conflates the patentee's reason for making the amendment with the impact the amendment has on the subject matter." *Id.* at 1141–42 & n.7 (citing *Festo*, 535 U.S. at 736–37). "[T]he fact that the scope of the rewritten claim has remained unchanged will not preclude the application of prosecution history estoppel if, by canceling the original independent claim and rewriting the dependent

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flexible web feature], is no longer free to gain the supposed advantage of the rejected claims by a construction of the allowed claims as equivalent to them." *Id.* at 221–22.

claims into independent form, the scope of subject matter claimed in the independent claim has been narrowed to secure the patent." *Id.* at 1142.

The focus in *Honeywell* on the scope of what was abandoned, even when a particular claim was not altered in scope, is reflected in other decisions of this court as well. *See Glaxo Wellcome, Inc. v. Impax Laboratories, Inc.*, 356 F.3d 1348, 1356 (Fed. Cir. 2004) ("[S]ubject matter surrendered via claim amendments during prosecution is also relinquished for other claims *containing the same limitation*." (emphasis added)); *Deering Precision Instruments, L.L.C. v. Vector Distribution System, Inc.*, 347 F.3d 1314, 1325–26 (Fed. Cir. 2003) (applying presumption of prosecution history estoppel to "all claims containing the [cancelled limitation], regardless of whether the claim was, or was not, amended during prosecution"). In our non-precedential decision in *Mycogen Plant Science, Inc. v. Monsanto Co.*, we summarized a key aspect of governing law: "Among the rules from the original *Festo* en banc decision that were unchanged by the Supreme Court and reaffirmed by this court . . . was our holding that cancellation of claims for reasons related to patentability in favor of claims with a narrower literal scope has the same presumptive effect on claim limitations as amending the claims directly." 91 F. Appx. 666, 668 (Fed. Cir. 2004) (non-precedential) (referring to *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc), which was vacated in *Festo*, 535 U.S. 722 (2002), which in turn was followed by *Festo*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc))).

When evaluating prosecution history estoppel, we do not address each claim in isolation, considering only whether that asserted claim was amended. If that were the proper approach, this court in *Honeywell*, for example, would have rejected the application of prosecution history estoppel when dependent claims were amended to be put in independent form, because the scope of those particular claims did not change by amendment. Instead, this court

concluded that the cancellation of a prior, broader independent claim may give rise to prosecution history estoppel in relation to a narrower claim, depending on the relationship between the scopes of those claims. *Honeywell*, 370 F.3d at 1144.

This court in *Honeywell* also cited favorably to *Keith v. Charles E. Hires Co.*, 116 F.2d 46 (2d Cir. 1940), in which the Second Circuit held that prosecution history estoppel applied where, as with the claims at issue here, the patentee filed two independent claims and cancelled one after its rejection. *Honeywell*, 370 F.3d at 1142 n.8 (discussing *Keith*, 116 F.2d at 48). The Second Circuit rejected the proposition that, for estoppel to apply, the patentee must have amended the claim that ultimately issued. *Keith*, 116 F.2d at 47–48. Because the patentee "ha[d] already filed a claim which contains the necessary differentia" from the rejected subject matter, maintaining that claim while cancelling another, broader claim abandoned coverage of "the element by which that claim differs from the cancelled claim." *Id.* at 48.

For those reasons, we reject Colibri's contention that claim 1 itself had to be amended for prosecution history estoppel to apply. The close substantive relationship between the cancelled and retained claims, by Colibri's own basic-physics logic for its affirmative assertion of equivalence, is enough to cross the estoppel threshold. A skilled artisan reading the prosecution history would understand that some narrowing had occurred through cancelling claim 39. In that situation, in the absence of further arguments about the scope of narrowing or exceptions to the presumption of estoppel, the doctrine of equivalents became unavailable to Colibri for the issued claim 1. If Colibri wished to capture territory involving retraction that was outside the literal scope of claim 1, it could have filed a continuation application (and there sought to show written-description support). Within the confines of the '294 patent, the public-notice function of prosecution

history estoppel is served by barring infringement under the doctrine of equivalents.

IV

Having determined that Medtronic was entitled to judgment as a matter of law of noninfringement of the '294 patent, we reverse the district court's denial of such a judgment. That reversal moots the remaining aspects of Medtronic's appeal (*i.e.*, those relating to invalidity, the remaining noninfringement arguments, and damages).

The parties shall bear their own costs.

REVERSED