# United States Court of Appeals for the Federal Circuit

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**MARK A. BARRY,**
*Plaintiff-Appellee*

**v.**

**MEDTRONIC, INC.,**
*Defendant-Appellant*

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2017-2463

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Appeal from the United States District Court for the Eastern District of Texas in No. 1:14-cv-00104-RC, Chief Judge Ron Clark.

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Decided: January 24, 2019

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DAVID CLAY HOLLOWAY, Kilpatrick Townsend & Stockton LLP, Atlanta, GA, argued for plaintiff-appellee. Also represented by COURTNEY DABBIERE; ADAM HOWARD CHARNES, Dallas, TX; ERWIN CENA, San Diego, CA; DARIO ALEXANDER MACHLEIDT, Seattle, WA; SEAN PAUL DEBRUINE, Law Office of Sean DeBruine, Menlo Park, CA.

SETH P. WAXMAN, Wilmer Cutler Pickering Hale and Dorr LLP, Washington, DC, argued for defendant-appellant. Also represented by BRITTANY BLUEITT AMADI; MARK CHRISTOPHER FLEMING, Boston, MA; MARY-OLGA

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LOVETT, Greenberg Traurig LLP, Houston, TX; JULIE PAMELA BOOKBINDER, SCOTT JOSEPH BORNSTEIN, ALLAN A. KASSENOFF, RICHARD CHARLES PETTUS, New York, NY.

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Before PROST, *Chief Judge,* MOORE and TARANTO, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* TARANTO.

Opinion dissenting in part filed by *Chief Judge* PROST.

TARANTO, *Circuit Judge.*

Dr. Mark Barry brought this action against Medtronic, Inc., alleging that Medtronic induced surgeons to infringe U.S. Patent Nos. 7,670,358 and 8,361,121, which Dr. Barry owns and which name him as the sole inventor. The jury found infringement of method claims 4 and 5 of the '358 patent and system claims 2, 3, and 4 of the '121 patent, rejected Medtronic's several invalidity defenses, and awarded damages. In post-trial rulings on the jury issues, *Barry v. Medtronic, Inc.*, 230 F. Supp. 3d 630 (E.D. Tex. 2017) (*Barry*), the district court upheld the verdict as relevant here—rejecting challenges as to induced infringement and associated damages for domestic conduct, *id.* at 640–47, 650–51, invalidity of the asserted '358 patent claims under the public-use and on-sale bars, *id.* at 653–59, and invalidity of all asserted claims due to another's prior invention, *id.* at 659–63. The district court then rejected Medtronic's inequitable-conduct challenge, *Barry v. Medtronic, Inc.*, 245 F. Supp. 3d 793, 823 (E.D. Tex. 2017) (*Inequitable Conduct Op.*), and, in a ruling not separately challenged on appeal, enhanced damages by twenty percent while denying attorney's fees to Dr. Barry, *Barry v. Medtronic, Inc.*, 250 F. Supp. 3d 107, 111, 119 (E.D. Tex. 2017) (*Enhancement Op.*). Medtronic appeals on numerous grounds, principally concerning the public-use and on-sale statutory bars, but also concerning prior

invention, inequitable conduct, and induced infringement and associated damages. We affirm.

## I

### A

Both patents at issue are entitled "System and Method for Aligning Vertebrae in the Amelioration of Aberrant Spinal Column Deviation Conditions." The patents claim methods and systems for correcting spinal column anomalies, such as those due to scoliosis, by applying force to multiple vertebrae at once. '358 patent, col. 2, line 63, through col. 3, line 6; '121 patent, col. 3, line 53, through col. 4, line 2. The '358 issued in 2010 from an application that Dr. Barry filed on December 30, 2004. The '121 patent issued in 2013 from an application—a continuation of an August 2005 application that was a continuation-in-part of the December 30, 2004 application—that Dr. Barry filed in 2010.

The asserted claims of the '358 patent are method claims 4 and 5. They depend ultimately on independent claim 1, which reads:

> 1. A method for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising the steps of:
>
> selecting a first set of pedicle screws, said pedicle screws each having a threaded shank segment and a head segment;
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> selecting a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having first handle means and a first group of pedicle screw engagement members which are mechanically linked with said first handle means, each pedicle screw engagement member being configured for engaging with, and transmitting manipulative forces applied to said first

handle means to said head segment of each pedicle screw of said first set of pedicle screws,

implanting each pedicle screw in a pedicle region of each of a first group of multiple vertebrae of a spinal column which exhibits an aberrant spinal column deviation condition;

engaging each pedicle screw engagement member respectively with said head segment of each pedicle screw of said first set of pedicle screws; and

applying manipulative force to said first handle means in a manner for simultaneously engaging said first group of pedicle screw engagement members and first set of pedicle screws and thereby in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae in which said pedicle screws are implanted to achieve an amelioration of an aberrant spinal column deviation condition;

selecting a first length of a spinal rod member; wherein one or more of said pedicle screws of said first set of pedicle screws each includes:

a spinal rod conduit formed substantially transverse of the length of said pedicle screw and sized and shaped for receiving passage of said spinal rod member therethrough; and

spinal rod engagement means for securing said pedicle screw and said spinal rod member, when extending through said spinal rod conduit, in a substantially fixed relative position and orientation;

extending said first length of said spinal rod member through said spinal rod conduits of one

> or more of said pedicle screws of said first set of pedicle screws; and
>
> after applying said manipulative force to said first handle means, actuating said spinal rod engagement means to secure said vertebrae in their respective and relative positions and orientations as achieved through application of said manipulative force thereto.

'358 patent, col. 6, lines 7–56. Claim 2, which depends on claim 1, adds steps requiring a second set of pedicle screws and a second derotation tool with a second group of engagement members and a second "handle means." *Id.*, col. 6, line 57, through col. 7, line 15. Claim 3, which depends on claim 2, adds steps requiring a second spinal rod. *Id.*, col. 7, line 16, through col. 8, line 11. Claim 4, which depends on claim 3, adds that the steps of applying "manipulative force" to the first and second handle means "are carried out substantially simultaneously to cooperatively achieve an amelioration of an aberrant spinal column deviation condition." *Id.*, col. 8, lines 12–17. Claim 5 adds the same requirement to claim 2 (on which it depends). *Id.*, col. 8, lines 18–23.

The asserted claims of the '121 patent are system claims 2–4. Claim 2, an independent claim, reads:

> 2. A system for aligning vertebrae in the amelioration of aberrant spinal column deviation conditions comprising:
>
> a first set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment; and
>
> a first pedicle screw cluster derotation tool, said first pedicle screw cluster derotation tool having a first handle means for facilitating simultaneous application of manipulative forces to

said first set of pedicle screws and a first group of three or more pedicle screw engagement members which are mechanically linked with said first handle means, said first handle means having a handle linked to each pedicle screw engagement member of the first group of three or more pedicle screw engagement members and a linking member to join together the handles linked to the pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member; wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said first set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said first handle means to said head segment of each pedicle screw of said first set of pedicle screws;

a second set of pedicle screws, each pedicle screw having a threaded shank segment and a head segment;

a second pedicle screw cluster derotation tool, said second pedicle screw cluster derotation tool having a second handle means for facilitating simultaneous application of manipulative forces to said second set of pedicle screws and a second group of three or more pedicle screw engagement members which are mechanically linked with said second handle means, said second handle means having a handle linked to each pedicle screw engagement member of the second group of three or more pedicle screw engagement members and a handle linking member to join together the handles linked to the

> pedicle screw engagement members, wherein the handle means is configured to move simultaneously each pedicle screw engagement member; wherein each pedicle screw engagement member is configured to engage respectively with said head segment of each pedicle screw of said second set of pedicle screws; and wherein each pedicle screw engagement member is configured to transmit manipulative forces applied to said second handle means to said head segment of each pedicle screw of said second set of pedicle screws;
>
> a cross-linking member that links the first handle means to the second handle means.

'121 patent, col. 7, line 57, through col. 8, line 45. The parties have highlighted the "cross-linking member" element in identifying the advance of the '121 patent claims over those of the '358 patent. Claim 3, which depends on claim 2, and claim 4, which depends on claim 3, add requirements that have had no material role in the arguments made to this court. *Id.*, col. 8, lines 46–58.

B

The following facts form the core of the background needed to understand the issues before us. Dr. Barry began working in late 2002 or early 2003 on trying to link derotation components (which grab screws in vertebrae to move the vertebrae) of devices for ameliorating spinal column deviation conditions. During 2003 he worked with a sales representative from the DePuy medical-device company, Mr. Pfefferkorn, to adjust standard DePuy tools for Dr. Barry's purposes and in accordance with Dr. Barry's ideas. Dr. Barry also spoke about his ideas with representatives from another company, SpineVision. By July 2003, Dr. Barry had a tool that allowed

him to link the screw-grabbing, vertebrae-moving wrenches together.

Dr. Barry used that tool in three surgeries—on August 4, August 5, and October 14. Dr. Barry testified, without contradiction by any evidence the jury had to credit, that the three surgeries represent the three most common types of scoliosis-caused spinal deviation conditions that surgeons typically see. Between August 2003 and January 2004, the patients in those surgeries returned to Dr. Barry several times for follow-up appointments. During the follow-up appointments, Dr. Barry viewed x-rays of the patients' spines, after they had been able to stand up and walk following the three-month acute phase of recovery, to determine if the curvature conditions had been successfully ameliorated by the surgery.

According to Dr. Barry's testimony at trial, it was only in January 2004, after the three-month follow-up for the October 14, 2003 surgery, that he felt confident that his invention functioned for its intended purpose and was ready to publicize it in a professional forum. J.A. 1161–65, 1195–96. He prepared an abstract summarizing the development of his methods and submitted it, by February 1, 2004, for inclusion in the materials to be presented at a July 2004 International Meeting of Advanced Spinal Techniques—the selection committee for which accepted it in April. On December 30, 2004, he filed the application for what issued as the '358 patent, making December 30, 2003, the critical date for that patent for purposes of the public-use and on-sale bar issues under 35 U.S.C. § 102(b) (2002).[1]

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[1] We refer throughout this opinion to the Title 35 provisions in effect before the changes made by the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-

Around the same time, Dr. Lawrence Lenke, a surgeon who works with Medtronic, was also working on a spinal derotation project. His work began in 2002. Medtronic contends that Dr. Lenke, through that work, was a prior inventor and that Dr. Barry's patents are therefore invalid under 35 U.S.C. § 102(g).

By 2006, Medtronic introduced its Vertebral Column Manipulation (VCM) kit, which is used in conjunction with Medtronic's CD Horizon Legacy and Solera spinal-surgery systems. Dr. Barry alleges that surgeons' use of that combination infringes the asserted claims of the two patents at issue and that Medtronic has induced such infringement through its extensive training materials and instructions relating to its VCM kit. As to the latter, instructions appear on the lid of each kit. Medtronic employees have trained surgeons in how to use the VCM kit. Medtronic has included instructions for using the VCM kit in surgical guides, which Dr. Barry's expert, Dr. Walid Yassir, testified Medtronic "put . . . out all of the time." J.A. 1782. And Dr. Lenke testified that he used the VCM kit when performing derotations, even after 2010, the year the '358 patent issued.

In this case, the jury found for Dr. Barry, and specifically did so on the key issues contested by Medtronic in this appeal—involving whether Dr. Barry's '358 invention was in public use or on sale before December 30, 2003; whether Dr. Lenke was a prior inventor for both patents; and whether, and to what extent, Medtronic induced infringement. As relevant here, the jury awarded Dr. Barry $15,095,970 for domestic infringement of the '358 patent and $2,625,210 for domestic infringement of the

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29, 125 Stat. 284 (2011), took effect. As the parties agree, the pre-AIA provisions apply here.

'121 patent. J.A. 135.[2] The district court denied Medtronic's post-trial challenges regarding induced infringement, *Barry*, 230 F. Supp. 3d at 640–47; domestic in-infringement damages, *id.* at 650–51; invalidity under § 102(b), *id.* at 653–59; and invalidity under § 102(g), *id.* at 659–63. The district court also rejected Medtronic's charge of inequitable conduct by Dr. Barry in his interactions with the Patent and Trademark Office, based on an admitted mistake in identifying Figure 6 in both patents, finding absent the intent required for unenforceability on that ground in a case like this. *Inequitable Conduct Op.* at 797–98.

On appeal, Medtronic raises issues involving the § 102 statutory bars as to the '358 patent, Br. of Appellant at 26–41; inequitable conduct as to both patents, *id.* at 44–48; prior invention as to both patents, *id.* at 48–58; and induced infringement and associated damages as to both patents, *id.* at 58–67 (infringement), 67–69 (damages). We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

We review the denial of judgment as a matter of law de novo, and we review the denial of a new trial as well as rulings on jury instructions for abuse of discretion. *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 841 (Fed. Cir. 2010) (following Fifth Circuit law), *aff'd on other issues*, 564 U.S. 91 (2011). We review evidentiary rulings for an abuse of discretion. *Summit 6, LLC v. Samsung Elecs.*

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[2] The district court eliminated non-domestic infringement and damages from the judgment, a ruling not on appeal here. *Barry*, 230 F. Supp. 3d at 647–49. The court also enhanced the domestic damages by twenty percent (while denying Dr. Barry attorney's fees), a ruling not on appeal here. *Enhancement Op.* at 111, 119; *see* J.A. 309 (final judgment).

*Co.*, 802 F.3d 1283, 1294–95 (Fed. Cir. 2015) (following Fifth Circuit law).

A

We begin with Medtronic's argument for judgment as a matter of law that the '358 patent's asserted claims are invalid under § 102(b)'s statutory bar on patenting of inventions in "public use" in the United States more than one year before the application for the patent was filed. Here, the application was filed on December 30, 2004, so the critical date for an invalidating domestic public use is December 30, 2003. We reject Medtronic's challenge.

"The public use bar is triggered where, before the critical date, the invention is in public use *and* ready for patenting." *Polara Eng'g Inc v. Campbell Co.*, 894 F.3d 1339, 1348 (Fed. Cir. 2018) (emphasis added) (internal quotation marks omitted); *see also Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998); *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). "[T]he determination of whether a patent is invalid for public use is a question of law that we review *de novo*," but "the disputed facts found to support that determination are reviewed for substantial evidence." *Polara*, 894 F.3d at 1348; *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990). "We treat the jury's verdict of no invalidating public use as a resolution of all genuinely disputed underlying factual issues in favor of the verdict winner"—here, Dr. Barry. *Polara*, 894 F.3d at 1348 (internal quotation marks omitted).

We discuss "ready for patenting" first, then "in public use." We conclude that Medtronic's § 102(b) public-use challenge fails on two grounds, which are substantively related. First, the invention was not ready for patenting before the critical date. Second, there was no public use except for an experimental use, and "[p]roof of experimental use serves as a negation of the statutory bars," *Polara*, 894 F.3d at 1348 (internal quotation marks omit-

ted); *see New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1297–98 (Fed. Cir. 2002); *EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1352 (Fed. Cir. 2002).

We place our discussion of experimental use within our discussion of the "public use" element. This placement fits the facts that commercial exploitation may sometimes satisfy that element, *Invitrogen*, 424 F.3d at 1380, and "[t]he law has long recognized the distinction between inventions put to experimental use and products sold commercially," *Pfaff*, 525 U.S. at 64; *id.* at 64–65 (discussing *Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 133–37 (1877)). But this placement is not inevitable: we have observed that "evidence of experimental use may negate either the 'ready for patenting' or 'public use' prong [of the public-use-bar standard]" and "recogniz[ed] an overlap of the experimental use negation and the ready for patenting standard." *Invitrogen*, 424 F.3d at 1379–80 (citing *EZ Dock*, 276 F.3d at 1352). The overlap is reflected in the fact that the timing of knowledge that the invention will "work for its intended purpose" is important to both experimental use and readiness for patenting. *Polara*, 894 F.3d at 1348 (describing such an inquiry for both the "ready for patenting" and "experimental use" standards); *see EZ Dock*, 276 F.3d at 1356–57. In any event, whatever the best doctrinal organization, experimental use negates invalidity under the public use bar. We discuss both readiness for patenting and experimental use because they are related and because the dissent, agreeing with Medtronic about the first, addresses the second to complete its reasoning to support its conclusion of invalidity under § 102(b).[3]

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[3] The dissent proposes several changes to the legal standards stated in governing case law, such as a change to impose a (high) burden of persuasion on the patent owner to establish experimental use. Dissent at 14–19.

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The jury could reasonably find facts that support rejection of Medtronic's contention that Dr. Barry's '358 invention was ready for patenting before December 30, 2003. Medtronic's contention required it to prove that, before that date, the method was "'shown or known to work for its intended purpose.'" *Polara*, 894 F.3d at 1348 (quoting *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017), *cert. granted on a different issue*, 138 S. Ct 2678 (2018)); *see Electromotive Div. of Gen. Motors Corp. v. Transp. System Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1211 (Fed. Cir. 2005); *Manville*, 917 F.2d at 550–51. But there is substantial evidence that Dr. Barry's invention was not ready for patenting until January 2004 because the final follow-up from the October surgery was reasonably needed for the determination that the invention worked for its intended purpose.

This court has long held that "the Supreme Court's 'ready for patenting test'" from *Pfaff*, involving the on-sale bar, also "applies to the public use bar under § 102(b)." *Invitrogen*, 424 F.3d at 1379. Medtronic accepts in this appeal that, to show readiness for patenting, it had to show (a) a reduction to practice or (b) drawings or descriptions enabling an ordinarily skilled artisan to practice the invention. *Pfaff*, 525 U.S. at 67–68.[4] Here, Medtronic's

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Medtronic has not argued for such changes. We follow existing case law. We also note that we see nothing in the dissent's proposed changes that would alter our § 102(b) result—at the least on the sufficient ground that Medtronic failed to establish readiness for patenting.

[4] The dissent states that readiness for patenting might be shown in some other way. Dissent at 7–9. We have no such alternative before us. Reduction to practice and enabling drawings or descriptions are the sole bases on which Medtronic argues for readiness for patenting.

ability to support judgment as a matter of law in its favor under that test depends on its succeeding under the reduction-to-practice alternative.[5]

Under the test for a reduction to practice, the challenger must show that "the inventor (1) constructed an embodiment or performed a process that met all the limitations and (2) determined that the invention would work for its intended purpose." *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008) (internal quotations omitted). What testing was in order to determine whether an invention would work for its intended purpose is one of the subsidiary fact questions underlying a determination of whether an invention was in public use. *See Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007) ("Because the necessity and sufficiency of such testing [of an invention to determine if it will work for its intended purpose] are factual issues,

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Br. of Appellant at 29–34. The jury instructions, not challenged here, are similarly limited. J.A. 158–61.

[5] On appeal, Medtronic also points to drawings prepared in November 30, 2003, by a device company, SpineVision, based on conversations with Dr. Barry, and argues that the drawings show that "prior to the critical date the inventor [Dr. Barry] had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff*, 525 U.S. at 67–68 (footnote omitted). But Medtronic identifies no expert testimony making the necessary enablement showing. The jury could reasonably find that Medtronic failed to prove that descriptions by Dr. Barry (leading to the SpineVision-prepared drawings of devices), or even the drawings, enabled a person of ordinary skill in the art to practice the surgical-procedure claims. We therefore limit our discussion in text to Medtronic's argument based on reduction to practice.

substantial evidence . . . will suffice to support the jury's verdict."); *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1268 (Fed. Cir. 2002) ("[W]e leave to the fact finder the determination of whether testing was necessary . . . or whether the mere construction of the First Prototype, in and of itself, was enough to demonstrate to one of skill in the art that the invention would work for its intended purpose without any testing."); *Seal-Flex, Inc. v. Athletic Track & Court Const.*, 98 F.3d 1318, 1324 (Fed. Cir. 1996) ("The trier of fact must determine whether the invention was completed and known to work for its intended purpose . . . .").[6]

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[6] *Pfaff* supports the "intended purpose" standard in several ways. In a footnote, *see* 525 U.S. at 57 n.2, *Pfaff* quotes the statement in *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358, 383 (1928), that "[a] process is reduced to practice when it is successfully performed." What "successfully" means in *Corona* is achieving the purpose of accelerating the curing of rubber, as detailed extensively in *Corona* and summarized just before the "successfully performed" language—"It was the fact that it would work with great activity as an accelerator that was the discovery, and that was all, and the necessary *reduction to use* is shown by instances making clear *that it did so work*, and was a completed discovery," *id.* at 382–83 (emphasis added)—a summary that the Court quoted in *Pfaff*, 525 U.S. at 66 n.12. The "intended purpose" standard is also reflected in *Pfaff*'s reliance, in its rationale leading to the "ready for patenting" standard, on the statement in *Elizabeth* that a public use does not include an inventor's "*bona fide* effort to bring his invention to perfection, *or to ascertain whether it will answer the purpose intended,*" *Elizabeth*, 97 U.S. at 137 (emphasis added), which was quoted in *Pfaff*, 525 U.S. at 64–65. That reliance reflects the intertwining, as opposed to any

Here, Medtronic relied on the August and October 2003 surgeries as reductions to practice that immediately proved that the claimed invention of the '358 patent would work for its intended purpose. But the evidence allows a reasonable finding that Dr. Barry did not know that his invention would work for its intended purpose until January 2004, when he completed the follow-ups on those surgeries, which were on three patients who fairly reflected the real-world range of application of the inventive method.

We have already noted the evidence that the three surgeries involved "the three most common[] curve types of scoliosis" seen by surgeons, J.A. 1195, and that it was not until January 2004 that Dr. Barry completed the standard-practice follow-up on the third patient, at which point the three-month acute phase of recovery was over and the patient could stand up and walk. We also have noted Dr. Barry's testimony that only then did he conclude that the surgical method would work for its intended purpose, testimony confirmed by the fact that only then did he write up his development work for publication in a professional forum.

The record contains further supporting evidence. Dr. Lenke noted the range of scoliosis conditions. J.A. 2644. Evidence from several sources confirmed that, to evaluate the success of a spinal-deviation correction, it is important for the surgeon to evaluate the patient after some time has elapsed following the surgery, particularly once the patient can stand. *See* J.A. 1159–60, 1190–95, 1372, 5406, 5417, 13016. Dr. Barry's expert testified that "you know nominally if you have performed a correction of the

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clean separation, of experimental use and reduction to practice standards, which is further reinforced in a later footnote in *Pfaff*, 525 U.S. at 66 n.12.

spine"—agreeing to the "some amelioration" characterization by Medtronic's counsel only to that limited extent—and then immediately explained, starting in the same answer, that what happened afterward was crucial: "when the patient stands up, there are some changes that happen over time." J.A. 1959–60. As a result, he added, although "normally you can see the straightening" at the time of the surgery, "follow-up is absolutely required to determine that it lasts," J.A. 2906, and the follow-up appointments allowed Dr. Barry to conclude, "'[o]kay, this thing is holding up' and . . . '[n]ow I know I've got a method that works,'" J.A. 2899. Both Dr. Barry and his expert indicated that at least that amount of follow-up is not just prudent but consistent with standards for peer-reviewed publications reporting new techniques.

That evidence suffices for the jury to have rejected Medtronic's contention that Dr. Barry is charged with knowing that the surgical technique worked for its intended purpose immediately upon completion of the surgical operation—at least the last operation, in October 2003. The evidence is not limited to Dr. Barry's own testimony, as just indicated. And credibility assessments, within a broad range, are for the factfinders, especially when they have seen the witnesses live, as the jurors in this case did. *See*, *e.g.*, *Cooper v. Harris*, 137 S. Ct. 1455, 1474 (2017); *Perry v. New Hampshire*, 565 U.S. 228, 237 (2012); *Kansas v. Ventris*, 556 U.S. 586, 594 n.* (2009); *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000); *Aetna Life Ins. Co. v. Ward*, 140 U.S. 76, 88 (1891); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1341 (Fed. Cir. 2016); *Comark Comm'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1192–93 (Fed. Cir. 2000). On the evidence in this case, the jury could readily credit the testimony of Dr. Barry—who has extensive medical experience and day-to-day professional responsibility for patient health and safety—about what evaluation was reasonably necessary for a prudent de-

termination that his technique worked for its intended purpose.

To the extent that Medtronic contends, and the dissent concludes, that the patent claims compel narrowing the "intended purpose" determination to a single surgery, or even two surgeries, assessed for success immediately upon its completion, we disagree. The claims do not limit the intended purpose in that way. They are not limited to a particular type of curvature correction. Nor do they indicate that the intended purpose is limited to observing a straightening at the completion of surgery, without regard to the correction lasting so as to improve the patient's health. To the contrary, the preamble to the independent claim calls for "the amelioration of aberrant spinal column deviation conditions," '358 patent, col. 6, lines 8–9, which Medtronic argues is the intended purpose, Br. of Appellant at 30. *See also* '358 patent, col. 3, lines 10–34 (specification statement of first four objects of the invention using materially the same language). In a ruling not disputed on appeal, the district court concluded that the phrase would be given its "normal, customary meaning," without further construction, and that no indefiniteness problem would result because, in this medical context, a skilled artisan, focused on "benefit to a patient," would understand the scope of the phrase. J.A. 33. That common-sense approach to identifying the intended purpose is rooted in the preamble claim language as well as the specification. And it is properly understood, consistent with the specification's background discussion of patients' conditions beyond the end of surgery, '358 patent, cols. 1–2 (discussing patient health over time), as looking past the time of a surgery to evaluate the improvement in patients' conditions and allowing the withholding of judgment about the technique reliably working until follow-up on a small but representative

range of "deviation conditions" surgeons would regularly encounter.[7]

The "intended purpose" need not be stated in claim limitations that define the claim scope. Even in this case, the claim language that Medtronic treats as identifying

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[7] The dissent suggests that at most two surgeries, not three, were needed for the plural "conditions." Dissent at 12–13. But Medtronic has not meaningfully presented, let alone supported, such a rationale for reversal. Only a single sentence in Medtronic's opening brief, where arguments must be made, is of even possible relevance. After reciting the district court's reliance on Dr. Barry's testimony that "he wanted to follow up with his patients three months after the surgery," citing J.A. 215, 1196, Medtronic said: "That reasoning fails even on its own terms: three months after surgeries on August 4 and 5, 2003, would mean reduction to practice in early November, which is still nearly two months before the December 30, 2003 critical date." Br. of Appellant at 30, lines 6–9. If the dissent's point is one about the claim preamble's plural language, Medtronic's sentence says nothing about that. If the dissent's point is a medical-judgment point about the need for three rather than two surgeries, Medtronic's sentence is doubly deficient. The testimony Medtronic says it is answering is not about three versus two, but merely about the length of follow-up time, as confirmed by the citations to J.A. 215, 1196. In any event, and decisively, a medical-judgment point must be supported by evidence, but Medtronic's sentence is unaccompanied by any citation to the record at all. Specifically, there is no citation to evidence contrary to Dr. Barry's testimony as a factual matter about the need for follow-ups of three surgeries, much less evidence that compelled a determination in Medtronic's favor on this point.

the "intended purpose" is preamble language that, it is undisputed here, is not limiting, *i.e.*, it does not state a requirement that must be proved to establish infringement. *See* J.A. 152 (unchallenged jury instruction). The case law cited by the dissent (at 10–11) looks to the claims and specification as a whole for guidance, without declaring strict requirements even as to those sources. We note that it is hardly surprising that intended purpose need not be stated in claim limitations, given that one typical way of claiming is simply to define the physical steps of the process, or the physical elements of a product, without building functional or purpose language into the claim limitations at all. *See*, *e.g.*, *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997) (explaining that "[a] patent applicant is free to recite features of an apparatus *either* structurally *or* functionally" but that the latter choice presents distinctive risks) (emphasis added).

Case law confirms this approach. For example, in *Corona Cord*, the Supreme Court, for its reduction-to-practice analysis, inferred the accelerate-curing purpose from the specification. And it described the main claims at issue (No. 1,411,231, claims 4, 8, and 12) as stating simple process steps without any reference to that purpose. 276 U.S. at 366.

In *Manville*, the patentee designed a light pole assembly that could be easily raised and lowered. 917 F.2d at 547–48. None of the claims included language about the light pole being durable in different weather conditions, but we determined that the patentee's testing of the invention "under wind, cold and corrosive atmospheric conditions" did not qualify as a public use because "[p]rior to its testing in the winter environment, there really was no basis for confidence by the inventor that the invention would perform as intended, and hence no proven invention to disclose." *Id.* at 550. It was not necessary for the patent to claim durability in order for durability to be part of the patent's intended purpose because a certain

function can be "inherent to the purpose of an invention," necessitating further testing even when that inherent purpose is not claimed. *Id.* at 551.

Similarly, in *Polara*, we agreed with Polara that it "needed to test the claimed invention at actual crosswalks of different sizes and configurations and where the prototype would experience different weather conditions to ensure that the invention would work for its intended purpose." 894 F.3d at 1349. The patent in that case was for a control system that would alert pedestrians when it was safe to cross the street. *Id.* at 1344. The claim language did not include limitations about the weather conditions or the size of the crosswalk, *id.*, but we determined that the inventor could not know if the invention worked for its intended purpose until it had been tested in a variety of settings where it would operate, *id.* at 1349. Testing an invention in practical situations was part of the determination of whether it was ready for patenting.

In *Honeywell International v. Universal Avionics Systems*, we likewise recognized that an invention might not be ready for patenting until the inventor ascertains how that invention will function in practical circumstances. *Honeywell Int'l Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982 (Fed. Cir. 2007). Honeywell was developing a terrain warning system for airplanes to address a problem in the prior art, whose ground proximity detectors could not detect sudden changes in terrain. *Id.* at 987. Honeywell's system "compare[d] the aircraft's position with an on-board digitized map of the earth's terrain and man-made obstacles." *Id.* at 987–88. Because there was evidence that Honeywell negotiated to sell its system to a customer, raising an issue under the on-sale bar, we had to determine if the invention was ready for patenting under the *Pfaff* test for that statutory bar. *Id.* at 997. We held that Honeywell's system was not ready for patenting before the critical date because the sale and integration of the system in real planes flown by human pilots "were a

part of Honeywell's program to determine that the invention worked for its intended purpose." *Id.* at 996. In short, Honeywell's determination that the system worked for its intended purpose was reasonably dependent on completion of a range of tests in a variety of real-world situations in which the system would be used.[8]

In *TP Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir. 1984), moreover, we confirmed the common-sense proposition that, for medical procedures, follow-up appointments can be necessary to determine when an invention is performing its intended purpose. The invention at issue was a means of correcting irregularities in teeth. *Id.* at 972. We determined that the inventor could not have immediately assessed after implantation whether the device was working for its intended purpose; therefore, it was reasonable for the doctor to continue to follow patients and test the invention on several patients before determining if it was working for the purpose intended. *Id.*

The three types of curvature addressed by Dr. Barry's three surgeries are analogous to the different weather conditions in *Manville* and *Polara*, the different crosswalk dimensions in *Polara*, and the different types of terrain in *Honeywell*. And Dr. Barry's reliance on follow-up appointments is analogous to the role of follow-up appointments in *TP Laboratories*. We therefore affirm the determination that the claimed '358 patent invention was not ready for patenting before the critical date.

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[8] In the related context of experimental use, we have likewise recognized that sometimes testing for a property can fall outside the statutory bars even if that property is not required by a claim limitation. *See Electromotive*, 417 F.3d at 1212 (first citing *Manville* as well as *EZ Dock*, 276 F.3d at 1353, then citing *Seal-Flex*, 98 F.3d at 1320).

2

Although the foregoing discussion suffices to affirm the rejection of Medtronic's invalidity challenge under § 102(b)'s public-use bar, we think it worthwhile to address Medtronic's contentions regarding the other element of the test of invalidity under the public-use bar: whether the invention was "in public use." We conclude that Medtronic also fails under this element.

Medtronic sought to establish this element by showing that the invention was accessible to the public and that it was commercially exploited. We conclude, however, that the evidence permitted a reasonable finding that Dr. Barry's '358 patent invention was not accessible to the public before the critical date. We also conclude that the asserted acts of commercial exploitation, namely, the August and October 2003 surgeries, come within the experimental-use exception.

i

In assessing accessibility to the public, we have focused on several underlying facts: "the nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there was any confidentiality obligation imposed on persons who observed the use." *Dey, L.P. v. Sunovion Pharm., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013). Here, the alleged public use consisted of Dr. Barry's surgeries. But there is substantial evidence that Dr. Barry's surgeries were not exposed or accessible to the public.

Unlike in the classic case of *Egbert v. Lippmann*, 104 U.S. 333, 335 (1881), the inventor here did not relinquish control of his invention. Dr. Barry was the only one who actually practiced the invention, *i.e.*, performed the surgery using the claim-required manipulation of linked derotators. And while other people were present in the operating room—an anesthesiologist, two assistant physi-

cians, a scrub technician, a neurophysiologist, a circulating nurse, and an equipment representative—there was sufficient evidence for the jury to find facts establishing that the technique was not accessible to the public through those people.

The evidence showed that very few of the people in the operating room had a clear view of the surgical field, where Dr. Barry was using his invention, because they were either not permitted near the sterile field or because there was a drape blocking the view. More dispositively, although sometimes (as in *Egbert*) even a limited disclosure can make an invention accessible to the public, *see Dey* 715 F.3d at 1355–56, an accessibility determination may be rejected where the evidence establishes a sufficient obligation of confidentiality, which can be implied rather than express. *Id.* at 1357; *Delano Farms Co. v. Cal. Table Grape Comm'n*, 778 F.3d 1243, 1249 (Fed. Cir. 2015) ("[D]emonstration of a prototype to 'friends and colleagues' was not invalidating because the evidence supported the existence of 'a general understanding of confidentiality.'"); *Invitrogen*, 424 F.3d at 1381 ("[T]his court has determined that a use before the critical period was not public even without an express agreement of confidentiality."). Here, the jury could find that those in the operating room were under an implied duty of confidentiality covering at least the tools and techniques used. *See* J.A. 1311, 1167–68, 1679, 2388–89. These confidentiality understandings suffice to support the jury's finding of no public accessibility.

ii

For commercial exploitation, as for public accessibility, Medtronic relies on the August and October surgeries. It rightly recognizes that "an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under § 102(b), barring him from obtaining a patent." *Woodland Tr. v. Flowertree Nursery, Inc.*, 148

F.3d 1368, 1370 (Fed. Cir. 1998); *see TP Labs.,* 724 F.2d at 972. And it points out, correctly, that Dr. Barry was compensated for the three surgeries in which he used his invention. It also cites precedents to support its contention that a determination of commercial exploitation would not be defeated simply because Dr. Barry charged his standard fee for the surgeries, not an extra amount reflecting use of the inventive method. *See*, *e.g.*, *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1369, 1370 (Fed. Cir. 2007); *In re Kollar*, 286 F.3d 1326, 1333 (2002) (citing *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001)) (relying on "[a]ctually performing the process itself for consideration"); *Application of Dybel*, 524 F.2d 1393, 1401 (CCPA 1975); *Application of Josserand*, 188 F.2d 486, 493–94 (C.C.P.A. 1951). *But cf. TP Labs.*, 724 F.2d at 968, 973 (finding no commercial exploitation, in part, because "the inventor[s] made no extra charge for fitting the three patients" with the invention and "followed 'their' regular practice of setting a fixed total fee").

But regardless of the foregoing, the August and October surgeries come within the experimental-use exception. An inventor's use, while public in one sense, will not be considered a statutory public use if the use was experimental. *Electromotive*, 417 F.3d at 1211; *City of Elizabeth*, 97 U.S. at 134–35 ("The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as [a public] use. . . . [Testing an invention in a building even with the doors open] is not a public use, within the meaning of the statute, so long as the inventor is engaged, in good faith, in testing its operation. He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary."). "[I]n the context of a public use bar, evidence of experimental use may negate either the 'ready

for patenting' or 'public use' prong." *Invitrogen*, 424 F.3d at 1379–80. "A use may be experimental if its purpose is: '(1) [to] test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose—itself a requirement of patentability.'" *Polara*, 894 F.3d at 1348; *see Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317, 1327 (Fed. Cir. 2009).

This court has identified a host of factors that can be relevant to assessing whether a use is experimental, including:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

*Id.*; *see Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002). Many of those considerations are factual, but "[e]xperimental use is a question of law to be analyzed based on the totality of the surrounding circumstances." *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1426 (Fed. Cir. 1996).

In this case, the evidence—including the evidence already discussed when addressing "ready for patenting"—shows that many of the above-recited factors point toward a conclusion of experimental use. Dr. Barry was not sure that the device would work on different types of scoliosis, so he performed surgeries on the three main types. He

was not confident that the new procedure was effective until the January 2004 follow-up appointment for the third of those surgeries. In the context of this medical patent, as we have discussed, it is reasonable, to truly determine whether a method works, to engage in such testing for a brief time on a small but representative range of expected circumstances of use and to rely on follow-up. *See TP Labs.*, 724 F.2d at 972. Dr. Barry earned no more from the surgeries than he would have earned had he used prior-art methods; and there is no basis for finding that he attracted the three customers because of the new technique—indeed, Medtronic insists that they did not even know it was being used.[9] In addition, Dr. Barry was the only one to perform the method using his device. More generally, he did not surrender control of the claimed invention before the critical date. J.A. 1312. He kept control through the expectation of secrecy binding the other medical professionals present at the surgeries and the other circumstances that, as explained above, support the jury's determination of no public accessibility. And other people were aware that he was experimenting, including one doctor, one of the nurses in the operating room, and a representative of the DePuy medical-device firm who was helping with the

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[9] Contrary to the dissent (at 21–22), this fact reduces the "degree of commercial exploitation," *Clock Spring*, 560 F.3d at 1327, in the sense at the heart of the § 102(b) policy of preventing an overlong period of commercial exploitation of an invention. Though earning his normal fees from the three surgeries, Dr. Barry did not "exploit" his invention as a means to attract the three patients for those surgeries or to charge more because he used his new technique. The jury could find that he would have gotten the same business, and earned the same fee, even if he had not planned to use or used the inventive process.

instrumentation. *See* J.A. 1370, 1178–79, 1733–35. These are all facts that the jury could reasonably find; considered together, not in isolation from each other, they weigh in favor of a determination of experimental use.

Medtronic relies centrally on two factors as pointing against a finding of experimental use: that Dr. Barry charged his patients for the surgeries; and that Dr. Barry did not inform his patients that he was engaged in testing of his particular technique. The first factor is not by itself weighty in this case. Receipt of payment, if sufficiently incidental to an experiment, is not automatically disqualifying. *See*, *e.g.*, *Int'l Tooth Crown Co. v. Gaylord*, 140 U.S. 55, 62–63 (1891); *Allen*, 299 F.3d at 1354. The evidence permitted the jury to find that Dr. Barry earned no more from the surgeries than he would have earned from using prior-art methods and did not attract his three patients based on use of the inventive method. On these facts, his fee can be viewed as merely incidental to experimental work—a very limited number of tests, "reasonably necessary" to the experimental purpose, *Int'l Tooth Crown*, 140 U.S. at 63—if the surgeries are otherwise experimental.

Medtronic must rely, therefore, on the second factor, at least when present together with the first. Both circumstances were present in *Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494 (Fed. Cir. 1992), *overruled on other grounds by Pfaff*, 525 U.S. 55 (1998), on which Medtronic heavily relies. Dr. Sinskey was working on an intraocular lens that would be "implanted in the human eye to restore or improve the visions of patients who ha[d] had their natural lens removed because of damage or disease." *Id.* at 496. Between January and February 1980—before the critical date of February 24, 1980—Dr. Sinskey implanted the lens in eight patients. *Id.* at 497. He followed standard hospital procedures and was paid for the surgery. *Id.* We determined that the "objective evidence . . . cut[] heavily against experimental use." *Id.* at 499. We noted that he "charged his usual surgical fee

for the operation and a standard price for the implants." *Id.* And we relied on the fact that he "did not inform the patients that they were being treated with a 'new' or 'experimental' lens." *Id.*

The facts in *Sinskey* differ from the facts here in ways that we think are crucial. First, there was evidence here that not just Dr. Barry, but others, understood the surgeries to be experimental. In *Sinskey*, there was no such objective confirmation; and Dr. Sinskey himself, during his deposition, had stated that he did *not* consider his prior uses to be experimental. *Id.* at 497–98. Second, the nature of the invention and conduct is critically different in the two cases. Whereas Dr. Barry's invention is of a method, Dr. Sinskey's patent was for a physical product, *i.e.*, a lens. *Id.* at 496 ("The patent is directed to an intraocular lens."). And when Dr. Sinskey implanted the lens in a patient, he was surrendering control of his invention, whereas Dr. Barry did not surrender control of his invention when he performed the derotation surgeries.

The experimental-use inquiry asks whether the inventor's conduct would lead the "'public' to reasonably believe the invention was in the public domain," *Manville*, 917 F.2d at 550, and in particular whether there has been "any use of that invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor," *In re Smith*, 714 F.2d 1127, 1134 (Fed. Cir. 1983). When Dr. Sinskey surrendered control of the invention to another, without explaining that the device was experimental, the public was entitled to believe that the device was in the public domain. That conclusion answered the statutory question at least in the absence of any objective evidence supporting Dr. Sinskey's litigation claim of experimental use.

This court stated the principle in *LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n*: "When sales are made in an ordinary commercial environment and the goods are

placed outside the inventor's control, an inventor's secretly held subjective intent to 'experiment,' even if true, is unavailing without objective evidence to support the contention. Under such circumstances, the customer at a minimum must be made aware of the experimentation." 958 F.2d 1066, 1072 (Fed. Cir. 1992) (citation omitted). That statement ties a demand for a warning of experimentation to at least two premises (which were present in *Sinskey* and *LaBounty*) beyond the "ordinary commercial environment"—there was no other objective evidence of experimentation, but merely a subjective inventor belief; and "the goods [were] placed outside the inventor's control." *Id.* But both of those premises are missing in the present case. There is objective evidence of experimentation, not just a purely subjective intent of Dr. Barry. And there was no loss of control—a factor that this court has stressed "is critically important." *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed. Cir. 1996). No person left the operating room with the (method) invention, and no person learned the method without an obligation of confidentiality. In these circumstances, there was no placing of the invention in the public domain that is inconsistent with experimentation.

Medtronic cites several of our opinions that contain language that, taken out of context, might be read as making a necessary requirement for experimental use that the experimenter inform patients or customers of the experimental nature of the product. But the statements should not be taken out of context. Like *LaBounty*, which expressly tied the inform-customers statement to placing a product invention outside the inventor's control, every one of those cases in fact involved a device placed into a patient's or customer's control, and out of the inventor's control. *See*, *e.g.*, *Electromotive*, 417 F.3d at 1213 (focusing on the importance of customer awareness when the invention is put squarely in the hands and in the control of the customer); *Paragon Podiatry Lab., Inc. v. KLM*

*Labs., Inc.*, 984 F.2d 1182, 1186–87 (Fed. Cir. 1993) (discussing the importance of communicating with customers the experimental nature of orthotic devices placed in the customer's shoes); *Sinskey*, 982 F.2d at 499 (discussing how Mr. Sinskey fitted the patients with a new kind of lens); *LaBounty*, 958 F.2d at 1069–70, 1072 (discussing the need to inform customers who used the scrap metal shears that the shears were experimental); *In re Dybel*, 524 F.2d at 1394–95, 1401 (discussing how the inventor's failure to disclose the experimental nature of his "load sensing piezoelectric transducer" when he sold it to a customer was fatal to the inventor's experimental-use argument). We have not applied the inform-customer principle in a context, like the present, involving a method kept within the inventor's control. The underlying logic of the principle does not justify its extension here: explaining to patients (or their parents or insurers) that the procedure was experimental was not vital to keeping it from the public domain.

The experimental-use exception is properly applied in light of the recognized mix of § 102(b) policies—permitting experimental testing, protecting existing public domain knowledge, limiting extension of the statutory period of gaining revenues due to the invention, and encouraging prompt disclosure. *See*, *e.g.*, *Lough*, 86 F.3d at 1119–20. Here, on all the facts the jury could properly find, we conclude that the surgeries fall within the experimental-use exception.[10]

B

The second asserted § 102(b) ground of invalidity of the asserted claims of the '358 patent is the on-sale bar.

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[10] We discuss Medtronic's new-trial challenge to a jury instruction regarding experimental use in our discussion of the on-sale bar next.

"A person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States[.]" 35 U.S.C. § 102(b) (2002). To be rendered invalid under the on-sale bar, an invention "must be the subject of a commercial offer for sale" in the United States and it "must be ready for patenting." *Pfaff*, 525 U.S. at 67; *see Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, No. 17-1229, slip op. at 1, 6 (U.S. Jan. 22, 2019). But experimental use negates applicability of the on-sale bar, as it does the public-use bar. *Polara*, 894 F.3d at 1348.

We have already concluded, in discussing the public-use bar, that the '358 patent's invention was not ready for patenting before the critical date and that the August and October 2003 surgeries come within the experimental-use exception. Those conclusions leave only one aspect of Medtronic's on-sale-bar challenge that requires discussion.[11]

Medtronic argues on one ground for a new trial regarding experimental use. It challenges a jury instruction that informed the jury that "there is a difference between 'experimental use' in the context of patent law and the way that the word 'experiment' is used in the context of medicine." J.A. 160. We reject this challenge.

Although underlying questions of patent law are matters of this court's law, we generally apply regional-circuit law on the overall standards for setting aside a verdict because of asserted error in jury instructions. *See Kinetic*

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[11] We need not discuss whether certain pre-critical-date communications between Dr. Barry and two device makers, DePuy and SpineVision, would constitute offers for sale under "traditional contract law principles." *Allen Eng'g*, 299 F.3d at 1352.

*Concepts, Inc. v. Blue Sky Med. Grp., Inc.*, 554 F.3d 1010, 1021 (Fed. Cir. 2009); *Voda v. Cordis Corp.*, 536 F.3d 1311, 1328 (Fed. Cir. 2008). The Fifth Circuit asks whether "the 'charge as a whole leaves [the court] with substantial and ineradicable doubt whether the jury [was] properly guided in its deliberations' and the challenged instructions, separately or collectively, 'affected the outcome of the case.'" *Janvey v. Dillon Gage, Inc. of Dallas*, 856 F.3d 377, 388 (5th Cir. 2017).

The district court's instruction was not an abuse of discretion. In light of Medtronic's suggestions regarding the impropriety of medical experimentation without informed consent, it was reasonable for the court to address potential confusion about borrowing, for § 102(b), legal standards that govern experiments in quite different legal contexts. And what the court said on the subject was both modest and consistent with our holdings. This court has explained, specifically with regard to testing, that legal standards in other contexts do not control in the patent-validity context. *Pennwalt Corp. v. Akzona Inc.*, 740 F.2d 1573, 1580 (Fed. Cir. 1984) ("The fact that a sale or use occurs under a regulatory testing procedure, such as a FIFRA15 experimental use permit, does not make such uses or sales per se experimental for purposes of 35 U.S.C. § 102(b)." (footnote omitted)); *see also Helsinn*, 855 F.3d at 1373 (explaining that the standards for FDA experimentation are different from patent law's "ready for patenting" standards); *Clock Spring*, 560 F.3d at 1328 (explaining that actions and regulations by the Department of Transportation did not impact the analysis of whether the inventor's use was experimental). The district court's jury instruction in this case reasonably made that point to reduce the potential for a confused application of § 102(b)'s standards.

C

Medtronic's final invalidity challenge, applicable to both patents at issue here, is that Dr. Lenke invented the claimed matter before Dr. Barry, rendering the asserted claims invalid under 35 U.S.C. § 102(g). "A person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2) (2002). "[P]riority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice." *Z4 Techs.*, 507 F.3d at 1352.

Reduction to practice requires that the inventor prove that "(1) he constructed an embodiment or performed a process that met all the limitations . . . and (2) he determined that the invention would work for its intended purpose." *Id.* Medtronic had the burden of showing by clear and convincing evidence that Dr. Lenke reduced to practice first. *See id.* Reduction to practice is a mixed question of law and fact. *Id.* "[W]e must sustain the jury's conclusion unless the jury was not presented with substantial evidence to support any set of implicit findings sufficient under the law to arrive at its conclusion." *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1362 (Fed.Cir.2004).

We uphold the jury's rejection of Medtronic's § 102(g) challenge because there is substantial evidence to support a finding that Dr. Lenke did not reduce the claimed inventions to practice before February 2006, after Dr. Barry did so (for both patents at issue here). Weaknesses in Medtronic's evidence, including credibility issues, allowed the jury to reject Medtronic's assertion that Dr. Lenke, having worked on linked derotators since 2002, reduced the Barry-claimed inventions to practice before

Dr. Barry did so in 2004. *See Barry*, 230 F. Supp. 3d at 659–63. At the same time, substantial evidence supports Dr. Barry's account of his invention and reduction to practice before February 9, 2006, including his 2003 surgeries and follow-up appointments, his securing of assistance from device makers, and his continued work in 2004.

D

Medtronic asserted in the district court that the two patents are unenforceable because Dr. Barry engaged in inequitable conduct during patent prosecution in the PTO. The district court found no such inequitable conduct. We affirm that determination.

"Inequitable conduct is an equitable issue committed to the discretion of the trial court and is, therefore, reviewed by this court under an abuse of discretion standard." *Energy Heating, LLC v. Heat On-The-Fly, LLC*, 889 F.3d 1291, 1299 (Fed. Cir. 2018). Inequitable conduct here requires a showing of both materiality and intent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). "[W]e review the district court's findings of materiality and intent for clear error." *Regeneron Pharm., Inc. v. Merus N.V.*, 864 F.3d 1343, 1351 (Fed. Cir. 2017) (quotation marks omitted).

The basis of the charge of inequitable conduct is Figure 6 of both patents, which Dr. Barry initially described incorrectly. Both patents describe Figure 6 as displaying "a three frame x-ray view showing 'before and after' views of a scoliosis patient who was treated in an investigational procedure using the system and method of the present invention." '358 patent, col. 4, lines 38–41; '121 patent, col. 4, lines 44–47. In January 2008, during the initial prosecution, the examiner requested clearer drawings than those originally submitted, including the x-rays that make up Figure 6. J.A. 5077 ("Figures 1-4 and 6-7 are objected [to] as they are unclear and do not distinctly

show features which are pertinent to the understanding of the disclosed device. New corrected drawings are required."). In September 2008, Dr. Barry's counsel submitted a different set of x-rays for Figure 6. The evidence in this case indicates that counsel was not aware that, contrary to the description, the subject of the submitted x-rays actually was not a patient treated with the inventive methods, but instead was a patient treated on June 23, 2003, using a method that was not the invention claimed in the '358 patent (or the '121 patent's follow-on invention).

In March 2016, Dr. Barry sought to correct the description during this litigation. For the '121 patent, the PTO allowed the correction, issuing a Certificate of Correction in August 2016. Dr. Barry simultaneously requested the same correction of the '358 patent, but the '358 patent was the subject of an inter partes review proceeding at the time, so he withdrew the request in April 2016. Dr. Barry then filed a motion to correct under 37 C.F.R. § 1.323. The Patent Trial and Appeal Board denied the motion, expressing uncertainty about why the mistake had happened and why Dr. Barry had taken as long as he did to ask for the correction. When Dr. Barry again requested a certificate of correction from the PTO on May 25, 2017, the PTO granted the request and issued a Certificate of Correction in June 2017.

The district court found that there was no intent to deceive the PTO on the part of Dr. Barry and his counsel. *Inequitable Conduct Op.*, 245 F. Supp. 3d at 804–06. The district court found that both Dr. Barry and his counsel were credible in explaining why the errors occurred, without any intent to deceive, and why the errors were not discovered until this litigation. *Id.* We see no clear error in the court's finding that the intent required for inequitable conduct is absent here. We need not reach the issue of materiality.

E

Medtronic challenges the jury's finding that Medtronic directly infringed the patents and that it induced others to infringe. "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). "[I]nducement liability may arise if, but only if, [there is] . . . direct infringement." *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014) (internal quotation marks omitted). "The patentee must also show that the alleged infringer possessed the requisite intent to induce infringement, which we have held requires that the alleged infringer knew or should have known his actions would induce actual infringements." *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (internal quotation marks omitted). "Circumstantial evidence can support a finding of specific intent to induce infringement." *Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1129 (Fed. Cir. 2018); *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 824 F.3d 1344, 1347 (Fed. Cir. 2016). "[I]nducement can be found where there is [e]vidence of active steps taken to encourage direct infringement, which can in turn be found in advertising an infringing use or instructing how to engage in an infringing use." *Vanda*, 887 F.3d at 1129 (internal quotation marks omitted). Direct infringement and inducement are issues of fact. *Sanofi v. Watson Labs., Inc.*, 875 F.3d 636, 645 (Fed. Cir. 2017); *01 Communique Lab., Inc. v. LogMeIn, Inc.*, 687 F.3d 1292, 1296 (Fed. Cir. 2012).

1

Substantial evidence supports the jury's finding of underlying direct infringement by surgeons. Dr. Barry presented the results of a survey—the Neal Survey—that asked spine surgeons questions about the spine derotation

surgeries they had performed in the last two years. *See* J.A. 5449–57.[12] In particular, the survey asked doctors whether they had performed surgeries that included the following steps:

> Insert 2 spinal rods through pedicle screws on multiple vertebrae (at any stage of the procedure)[.] Attach derotators to pedicle screws on 2 or more vertebrae. Mechanically link 2 or more derotators. Link 2 or more different derotators attached to screws in a second group of 2 or more vertebrae (the 2 groups may have vertebrae in common). Both sets of linked derotators are moved simultaneously[.] Engage pedicle screw locking mechanism to hold vertebrae in derotated position[.]

J.A. 5454.

Medtronic argues insufficiency, or even inadmissibility, of the Neal Survey because it did not specifically name the accused Medtronic VCM kit in asking doctors what they did. We do not think, however, that Medtronic has shown error in the admission of or reliance on the survey as reasonably indicating the amount of activity by surgeons that would infringe.

The steps recited in the survey's inquiry track the claim language in the patent. The patent claim language includes: "implanting . . . each pedicle screw in a pedicle region of each . . . first group of multiple vertebrae of a spinal column," '358 patent, col. 6, lines 22–23; "a first group of pedicle screw engagement members which are

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[12] The parties have not specified precisely when the Neal Survey was conducted. But the district court said that it was not completed when Dr. Barry filed a motion concerning non-VCM products, a motion filed in late February 2016. J.A. 15168 n.8.

mechanically linked with said first handle means" of the "first pedicle screw cluster derotation tool, *id.*, col. 6, lines 13–17; "in a single motion simultaneously rotating said vertebrae of said first group of multiple vertebrae," *id.*, col. 6, lines 33–35; and "actuating said spinal rod engagement means to secure said vertebrae in their respective and relative positions," *id.*, col. 6, lines 53–55. On the record before us, we cannot say, as a matter of law, that a survey like this one had to itemize every single claim element: some claim elements might, for example, be essentially universal accompaniments of the steps included in the questions, making their inclusion pointlessly complicating. To establish the inadequacy of the survey, Medtronic had to show with specificity that the absence of some inquiry made the questions asked and answers given an unreliable indicator of the occurrence of activity that constitutes direct infringement. It has not done so. And if the identification of substantive steps in the survey was adequate, the omission of the "VCM" name makes no difference.

The Neal Survey asked not only about specific steps but also about surgeons' use of Medtronic's Horizon System. J.A. 5451. According to Dr. Barry's expert, moreover, any use of the Horizon System to derotate a spine would have used the VCM kit. The jury could accept that testimony. Although Medtronic has argued that use of certain tube derotators might not infringe yet would have been captured by the Neal Survey about what surgeons actually used, the jury could reject that contention. There was evidence indicating that such derotators would not have worked as the claims require. Medtronic has also argued, in this court and in its post-trial motion, that the Neal Survey would have captured use of its SmartLink product, which it says would be non-infringing; but all evidence of SmartLink was excluded from the trial, with Medronic's agreement, so such evi-

dence cannot support Medtronic's challenge to the verdict. *Barry*, 230 F. Supp. 3d at 642 n.9.

The Neal Survey is not the only evidence of direct infringement. The jury could find that Dr. Lenke himself used the accused VCM kit. Dr. Lenke testified that when he performed derotations, the technique involving the VCM kit "would be the technique . . . that [he] would use" and continued to use after 2010 (the year the '358 patent issued). J.A. 2706–08. He also continued to educate other surgeons on this technique after 2010.

Medtronic also makes an argument directed specifically to infringement of the '121 patent. It points to the requirement, stated in that patent's claim 2 as quoted above, of a cross-linking member connecting two handle means, each of which links three screw engagement members (for simultaneous manipulation). Medtronic contends that there was insufficient evidence, from the Neal Survey or otherwise, of surgeons' using such a three-by-three linking step with the VCM kit. We disagree. The Neal Survey asked about surgeons' using "6 or more derotators linked by lateral and transverse connections and moved simultaneously," J.A. 5454, and Dr. Barry's expert testified that the three-by-three linking step would be carried out by surgeons following the instructions on the VCM kit's lid. *See Barry*, 230 F. Supp. 3d at 644–45.

In sum, the jury could properly find that there was direct infringement of both patents at issue here, of a scope indicated by the Neal Survey.

2

Substantial evidence also supports the finding that Medtronic induced infringement after issuance of Dr. Barry's two patents. On appeal, Medtronic focuses on the timing of its inducing actions to contend otherwise, arguing that there was insufficient proof of inducement after the patents' issuance. We reject the contention, agreeing

with the district court. *See Barry*, 230 F. Supp. 3d at 245–46.

VCM was on the market four years before the '358 patent issued and seven years before the '121 patent issued. The Neal Survey asked whether surgeons "received any information or training (formal or informal) regarding derotation of multiple vertebrae using linked derotators from that source," without asking the dates of the information received. J.A. 5455. There was extensive evidence about the training materials provided by Medtronic and its sales representatives. Importantly, every VCM kit that went out had instructions on it, and the Medtronic sales force was constantly teaching surgeons the nuances of and techniques for using the devices. Dr. Lenke also testified that he was still instructing surgeons on using the VCM kit after 2010. On the evidence of record, we conclude, the jury could permissibly find inducement in the period after patenting.

F

Medtronic challenges the jury's damages award. But the challenge is dependent on our accepting Medtronic's challenges to use of the Neal Survey to establish infringement, which we have rejected. We add here only that the district court carefully considered Medtronic's challenges to the methodology of the Neal Survey and denied Medtronic's motion to exclude the survey, concluding that Medtronic's criticisms went to the weight of the evidence, not its relevance and reliability. *Barry*, 230 F. Supp. 3d at 641. We see no abuse of discretion in that evidentiary ruling.

III

For the foregoing reasons, we reject Medtronic's challenges on appeal and affirm the judgment of the district court.

Costs to Dr. Barry.

**AFFIRMED**

# United States Court of Appeals for the Federal Circuit

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**MARK A. BARRY,**
*Plaintiff-Appellee*

**v.**

**MEDTRONIC, INC.,**
*Defendant-Appellant*

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2017-2463

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Appeal from the United States District Court for the Eastern District of Texas in No. 1:14-cv-00104-RC, Chief Judge Ron Clark.

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PROST, *Chief Judge*, dissenting in part.

I join the majority's opinion regarding the '121 patent. I respectfully dissent, however, from its conclusion regarding the '358 patent.

The facts are simple. More than one year before filing for the '358 patent, Dr. Barry successfully performed his claimed surgical method on three different patients, charging each his normal fee. Dr. Barry's method was

thus *prima facie* "on sale" or in "public use" before the critical date under 35 U.S.C. § 102(b).[1]

The majority concludes otherwise based on Dr. Barry's litigation testimony. Dr. Barry testified that, even though he charged his patients and successfully performed the claimed method three times before the critical date, he was not truly satisfied with his method until a follow-up after the third surgery—a follow-up that occurred just after the critical date. Never mind that Dr. Barry appreciated that his method worked as of a surgery's completion. And never mind that successful follow-ups for the first two surgeries occurred *before* the critical date. Dr. Barry testified that he needed that third follow-up to be satisfied. On this basis, the majority concludes Medtronic failed to show that the asserted claims of the '358 patent are invalid under § 102(b)'s statutory bars.

Both the Supreme Court's and our precedent require invalidating the asserted claims under § 102(b) as a matter of law on this record. For this reason, I dissent.

## I

### A

Whether an invalidating sale or public use has occurred is a question of law reviewed de novo, based on underlying facts reviewed for substantial evidence following a jury verdict. *Leader Techs., Inc. v. Facebook, Inc.*, 678 F.3d 1300, 1305 (Fed. Cir. 2012).

The § 102(b) on-sale bar applies when, before the critical date, the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting.

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[1] All citations to sections of Title 35 are to their pre-AIA version.

*Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998).[2] Medtronic needed to prove the facts underlying these two conditions by clear and convincing evidence. *See, e.g.*, *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002).

This case mostly concerns *Pfaff*'s ready-for-patenting prong. This prong may be satisfied "in at least two ways": by proof of reduction to practice before the critical date; or by proof that before the critical date the inventor had prepared enabling drawings or other descriptions. 525 U.S. at 67–68. And to establish a reduction to practice, we have held that a patent challenger must show that the inventor "(1) constructed an embodiment or performed a process that met all the [claim] limitations and (2) determined that the invention would work for its intended purpose." *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008) (internal quotation marks omitted) (quoting *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007)).

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[2] I focus the rest of my discussion on § 102(b)'s on-sale bar as opposed to its public-use bar, though my ultimate conclusion is the same for each. The public-use bar applies when, before the critical date, the claimed invention was (1) in public use; and (2) ready for patenting. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). The ready-for-patenting prong is the same for both bars, and the public-use prong is met if the purported use was accessible to the public or commercially exploited. *Id.* at 1379–80. The claimed inventions were commercially exploited for essentially the same reasons that they were the subject of a commercial sale or offer for sale. I see no material difference between the two bars in this case or in the way that evidence of experimental use would affect their application.

Even if a patent challenger makes out a *prima facie* case of the on-sale bar, a patentee may negate the bar's application with evidence that the sale was primarily for experimental purposes. *See Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co.*, 417 F.3d 1203, 1210 (Fed. Cir. 2005) (proceeding in a "stepwise fashion," analyzing first whether there were any pre-critical-date sales and then whether any such sales were negated by experimentation); *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed. Cir. 2002) ("To establish that an otherwise public use does not run afoul of [§] 102(b), it must be shown that the activity was substantially for purposes of experiment." (internal quotation marks omitted)); *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971–72 (Fed. Cir. 1984).

B

The majority provides two bases for its conclusion that the asserted claims are not invalid under § 102(b) and *Pfaff*. Majority Op. 11–12. First, it says that the claimed methods were not ready for patenting before the critical date because they did not satisfy this court's reduction-to-practice test before that date. Majority Op. 13–18. Second, it says that the three pre-critical-date surgeries were for experimental purposes, thus negating application of a § 102(b) bar. Majority Op. 24–31.

Part II below concerns how Medtronic met *Pfaff*'s two-prong test. Specifically, Part II.A shows that *Pfaff*'s commercial-sale prong was satisfied. Part II.B shows that *Pfaff*'s ready-for-patenting prong was satisfied because our reduction-to-practice test was satisfied. Part II.C shows that, regardless of whether the claimed methods were "reduced to practice," they were ready for patenting.

Part III concerns how the majority misapplies our reduction-to-practice test. This part also addresses a confusing aspect of our case law that the majority's opinion

perpetuates. Part IV concerns the experimental-use doctrine.

## II

The key facts are undisputed. The '358 patent's critical date is December 30, 2003. Dr. Barry performed three pre-critical-date surgeries that practiced all the limitations of the asserted '358 patent claims. These surgeries occurred on August 4, 2003; August 5, 2003; and October 14, 2003. Dr. Barry charged his normal fee for them.

### A

The foregoing evidence establishes *Pfaff*'s commercial-sale prong for each of the three pre-critical-date surgeries. *See Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1163 (Fed. Cir. 2006) ("[P]erforming the patented method for commercial purposes before the critical date constitutes a sale under § 102(b)."); *In re Kollar*, 286 F.3d 1326, 1333 (Fed. Cir. 2002) ("[P]erforming the process itself for consideration would . . . trigger the application of § 102(b)."). Therefore, absent sufficient evidence that these surgeries were done for primarily experimental purposes, they would satisfy the first *Pfaff* prong as a matter of law.

### B

Medtronic also established that the inventions were reduced to practice no later than the second surgery's completion, and therefore were ready for patenting by then. *Pfaff*, 525 U.S. at 67–68 (identifying reduction to practice as a basis for establishing the ready-for-patenting prong).

Reduction to practice is a question of law we review de novo. *DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991). To establish a reduction to practice, we have held that a patent challenger must show that the inventor (1) constructed an

embodiment or performed a process that met all the claim limitations and (2) determined that the invention would work for its intended purpose. *In re Omeprazole*, 536 F.3d at 1373. It is undisputed that each of the three pre-critical-date surgeries met all the claim limitations. The only question is when Dr. Barry determined that his methods worked for their intended purpose.

The claims state the inventions' intended purpose: "the amelioration of aberrant spinal column deviation conditions." '358 patent col. 6 ll. 7–8. Dr. Barry testified that such amelioration happened during surgery:

> Q. And there is a term that is used in the patent that is not a term that is familiar to me as a lay-person, but it's "amelioration." Does that mean correction?
>
> A. Yes.
>
> Q. Okay. So, it happens right there in the operating room, on the spot, true?
>
> A. The surgical correction of the rotated vertebrae back to the midline, yeah, happens with that maneuver. Yes.

J.A. 1369–70. Dr. Barry's expert testified similarly. J.A. 1960 ("Q. And at least for the vertebrae, that derotation problem, you'll know if there was at least some amelioration when the surgery is over. A. Fair enough.")

Once this amelioration happened, Dr. Barry secured the derotated vertebrae in place with rods and screws, as the claims require:

> Q. And can you explain for the jury, please, what happens once you get the vertebrae derotated into the proper alignment? How do you hold it there?
>
> A. Well, as mentioned, you have screws up and down throughout that area of that curve. Once

> those vertebrae are rotated back into the midline and *you have the correction that you are happy with, you are comfortable with*, you lock down the screws to the two rods. . . . So, that's at the end of the procedure where all of the implants—screws, rods, and the setscrews—are all tightened down, locked down.

J.A. 1158–59 (emphasis added); *see* '358 patent col. 6 ll. 52–56.

Thus, by no later than the second surgery's completion, Dr. Barry appreciated that his invention worked for its intended purpose—to ameliorate aberrant spinal column deviation conditions.[3] His inventions were reduced to practice by then as a matter of law.

C

Though sufficient, reduction to practice is not necessary for § 102(b)'s on-sale bar to apply. *Pfaff*, 525 U.S. at 66 (concluding that it is unnecessary "to engraft a reduction to practice element into the meaning of the term 'invention' as used in § 102(b)"). Rather, the standard is whether the invention was "ready for patenting"—that is, whether the inventor "could have obtained a patent." *Id.* at 67–68; *see id.* at 62–63.

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[3] Because the claims' preamble refers to the amelioration of "aberrant spinal column deviation conditions" (plural), and because Dr. Barry testified that his patients had different types of conditions, I place the time of reduction to practice at the completion of the second surgery—not the first. Given that both of the first two surgeries (and their respective follow-ups) occurred before the critical date, the difference is immaterial here.

The record demonstrates that, regardless of when his inventions were reduced to practice, Dr. Barry could have obtained a patent before the critical date. By August 5, 2003, he had already performed the claimed methods on what he contends were two different types of aberrant spinal column deviation conditions. There was at least some amelioration of those conditions by the end of the surgeries. At this point, Dr. Barry could have satisfied the enablement and written-description requirements of § 112 and credibly claimed utility under § 101. *See Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189–90 (Fed. Cir. 2014) (noting that "a patent does not need to guarantee that the invention works for a claim to be enabled" and that "[t]here is no requirement that the disclosure contain either examples or an actual reduction to practice" (internal quotation marks omitted)); *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1339 (Fed. Cir. 2003) (describing the relationship between enablement and utility and concluding that, "[b]ecause the preamble term 'cleaning' means only 'removal of contaminants,' not removal of all contaminants or removal of contaminants according to [a] commercial standard, the inventor shows utility and enables the invention by disclosing 'removal of contaminants'").

By focusing only on reduction to practice, the majority misses *Pfaff*'s point—readiness for patenting is broader than reduction to practice and is meant to answer whether the inventor could have obtained a patent on his or her invention. This court captured a similar insight even before *Pfaff*. We noted that "the thrust of the on-sale inquiry is whether the inventor thought he had a product which could be and was offered to customers, not whether he could prevail under the technicalities of reduction to practice appropriate to determining priority of invention under interference law." *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1187 n.5 (Fed. Cir. 1993); *cf. Pfaff*, 525 U.S. at 60–61 (observing that neither § 100

nor § 101 mentions "reduction to practice" and that the statute's only specific reference to that term is in § 102(g), which concerns resolving priority disputes between two competing claimants to a patent).

The same insights apply here. Regardless of whether Dr. Barry satisfied our reduction-to-practice test as of the second surgery's completion, his inventions were ready for patenting by then.

III

The majority disagrees that Dr. Barry's inventions were ready for patenting before the critical date. The concept of an "intended purpose" is central to the majority's analysis and conclusion.

First, the majority reasons that Dr. Barry's claimed methods were not ready for patenting until they were reduced to practice, and that they were not reduced to practice until Dr. Barry knew that they would work for their intended purpose. The majority accepts that Dr. Barry needed the third follow-up to determine that the inventions worked for their intended purpose. Majority Op. 13; *see id.* at 14–19. This is error, because the majority asks more of the "intended purpose" than what the claims and specification define it to be.

Second, the majority finds support in cases where we have discussed "intended purpose" in the context of the experimental-use doctrine. But that doctrine contemplates a broader conception of "intended purpose" than what is required to show reduction to practice. Statements in our case law that loosely refer to an "intended purpose" are, regrettably, confusing. But the majority perpetuates the confusion in reaching its result. And its approach threatens to render superfluous a substantial body of law starting with the Supreme Court's seminal *City of Elizabeth* case.

I discuss these two problems in turn.

A

To know whether and when the inventor determined that the invention would work for its intended purpose for reduction to practice, we must first know what the "intended purpose" is. Although the testing necessary to determine whether an invention would work for its intended purpose is a factual question, *z4 Techs.*, 507 F.3d at 1352, defining the intended purpose is a legal question based on the claims and specification, *see Manning v. Paradis*, 296 F.3d 1098, 1102–04 (Fed. Cir. 2002).

Here, the claims define the intended purpose as "the amelioration of aberrant spinal column deviation conditions." '358 patent col. 6 ll. 7–8. As both Dr. Barry and his expert testified, that amelioration is apparent and appreciated during a surgery when the surgeon rotates and straightens the vertebrae and then locks them into place. *See supra* Part II.B. That testimony, along with the undisputed fact that the pre-critical-date surgeries met all the claim limitations, should end the reduction-to-practice inquiry.

To conclude otherwise, the majority must conceive of a more exacting intended purpose—one that, based on Dr. Barry's testimony, includes clearing a follow-up at a certain time and working across three different types of conditions (not just two). In doing so, the majority legally errs by looking beyond the claims and the specification to effectively define the "intended purpose" for reduction to practice.[4] *Conner v. Joris*, 241 F.2d 944, 947 (CCPA 1957)

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[4] The majority also references Dr. Barry's expert's testimony as supporting Dr. Barry. Majority Op. 16–17. But much of that testimony concerns what the expert thought Dr. Barry was thinking, J.A. 2899, which adds very little to an objective, patent-based assessment of

("In going beyond both the [claim] and the specification to glean [an inventor's] intended purpose the [B]oard has gone far beyond any position supported by the cases cited or any that we have been able to find."); *see Land v. Regan*, 342 F.2d 92, 98–99 (CCPA 1965) (criticizing going beyond the claims and specification to glean an invention's intended purpose); *cf. z4 Techs.*, 507 F.3d at 1352 (finding error in the district court's definition of intended purpose as "stop[ping] piracy" because the claim language indicated a purpose only of *reducing* piracy).

To be sure, the majority suggests that the '358 patent describes follow-up time and the three-surgery requirement as part of the inventions' intended purpose. *See* Majority Op. 18–19 (referencing a "common-sense approach to identifying the intended purpose [that] is rooted in the preamble claim language as well as the specification"). I am unpersuaded.

The claims say nothing about follow-up time. They say, "the amelioration of aberrant spinal column deviation conditions." '358 patent col. 6 ll. 7–8. The district court concluded that "amelioration" would be accorded its customary meaning, which a person of ordinary skill in the art would understand as "to improve." J.A. 33–34. Both Dr. Barry and his expert testified that the aberrant spinal column deviation conditions were ameliorated, or

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what the inventions' intended purpose is. And, insofar as the majority relies on standards for peer-reviewed publications as they relate to follow-up time, Majority Op. 17, I am not convinced that those standards are, or should be, relevant to reduction to practice or readiness for patenting under the U.S. patent laws. For instance, Dr. Barry's expert testified that such publications require two years' follow-up time, J.A. 2900, but Dr. Barry successfully filed for a patent well before that.

improved, as of a surgery's completion. And Dr. Barry testified that he appreciated as much at the time. *Supra* Part II.B.

The specification also says nothing relating follow-up time to the inventions' intended purpose. The majority references two portions of the specification in its discussion, but neither supports its position. First, it cites the background section. Majority Op. 18–19 (citing '358 patent cols. 1–2). This section discusses prior-art treatment regimens and problems from untreated scoliosis; it says nothing about follow-up criteria as it relates to the intended purpose of Dr. Barry's inventions. Second, the majority refers to the four "objects of the invention" articulated in the summary of the invention. Majority Op. 18 (citing '358 patent col. 3 ll. 10–34). Again, these objectives say nothing about follow-up time. Quite the contrary; they describe what happens in the operating room—for example, (1) "facilitat[ing] *the application of significant derotational forces to individual vertebra*, with substantially reduced risk for fracture thereof *upon application of such forces*," '358 patent col. 3 ll. 23–25 (emphasis added); and (2) "facilitat[ing] *the application of forces to vertebrae of affected spinal column segments en bloc*, thereby distributing otherwise potentially injurious forces in a manner for safely achieving over-all spinal column correction or derotation," *id.* at col. 3 ll. 30–33 (emphasis added).

Nor does the intended purpose contemplate working across three different types of curvatures, as opposed to just two. The claims' body requires amelioration of "*an* aberrant spinal column deviation condition," '358 patent col. 6 ll. 35–36 (emphasis added), and the preamble mentions only "amelioration of aberrant spinal column deviation conditions," *id.* at col. 6 ll. 7–8. The majority identifies nothing in the patent itself—whether in the claims or specification—that explains how working across three, not just two, curvatures is part of the inventions'

intended purpose. Therefore, even if I were to accept that the '358 patent's language made follow-up time relevant to the inventions' intended purpose, I would still fail to understand the legal relevance of Dr. Barry's alleged need for the *third* surgery's follow-up, as opposed to just the first two, to determine whether his invention worked for its intended purpose (so as to establish reduction to practice).

The majority suggests that Medtronic "has not meaningfully presented, let alone supported" the argument that follow-ups on two surgeries (covering two conditions) were enough to establish reduction to practice. Majority Op. 19 n.7. I disagree. The majority acknowledges that Medtronic's opening brief argued that the two follow-ups from the August surgeries were enough. *Id.* Dr. Barry responded that he needed to test his invention on "different anatomies" and that it was only after the third follow-up that he knew whether he had successfully treated the "three most common[] curve types." Dr. Barry's Resp. Br. 25–26 (alteration in original). Medtronic replied:

> [A]n invention works for its intended purpose as long as there is *some* demonstration of the workability or utility of the claimed invention. A demonstration of its use in two patients certainly qualifies. After all, the claims are not confined to methods that ameliorate *every* patient's spinal deviation condition.

Medtronic's Reply Br. 8 (citation and internal quotation marks omitted); *see id.* at 8–9 (citing Dr. Barry's testimony regarding the surgeries, their follow-ups, and the patients' curve types). This straightforward argument is before us. Not even Dr. Barry has urged otherwise.

If Dr. Barry wanted to claim or describe his inventions' intended purpose differently—for example, with reference to satisfying a standard of care that contemplates a certain amount of follow-up time, or versatility

across more than two curvature types—he could have done so. But his claims and specification say nothing of the sort. Given his testimony that before the critical date he practiced his invention (as he later claimed it) and achieved its purpose (as he later described it), his invention was reduced to practice before then as a matter of law.

B

To find Dr. Barry's inventions not ready for patenting, the majority analogizes to several cases it says support its view of the inventions' intended purpose. Majority Op. 20–22. Its analysis of *Pfaff*'s ready-for-patenting prong reflects some confusion in our case law regarding the relationship among reduction to practice, an invention's intended purpose, and the experimental-use doctrine.

Again, reduction to practice requires proof that the inventor determined that the invention would work for its intended purpose. *In re Omeprazole*, 536 F.3d at 1373. Therefore, showing readiness for patenting (at least, via reduction to practice) requires proof that the inventor determined that the invention would work for its intended purpose. Yet we have also said that a use may be experimental if it is to "determine whether an invention will work for its intended purpose." *Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1348 (Fed. Cir. 2018) (quoting *Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317, 1327 (Fed. Cir. 2009)). But if that determination has not already been made, then the invention would not be ready for patenting in the first place. Therefore, any consideration of whether a use was experimental would be superfluous, as there would be no *prima facie* case of a § 102(b) bar to begin with. This is how the majority resolves the case. *See* Majority Op. 23.

I am skeptical, however, of an approach that would render the experimental-use doctrine superfluous based upon the same considerations of an "intended purpose"

being considered elsewhere.[5] Instead of rendering this doctrine superfluous, the better and more accurate view is that the considerations of an "intended purpose" are not really the same as between reduction to practice and experimental use.

The experimental-use doctrine exists to afford an inventor the ability to experiment with his or her invention via what would *otherwise* constitute a barring sale or public use. The focus is on the inventor's intent in making the sale or using the invention publicly; if it is for primarily experimental purposes, we do not consider the sale or use barring. *See Electromotive Div.*, 417 F.3d at 1211. Several factors have emerged to evaluate that intent—e.g., the amount of control the inventor maintained, whether there was a secrecy obligation, the degree of commercial exploitation, and whether customers were aware the inventor was experimenting. *Id.* at 1212–14. Such factors are unrelated to how far along the invention is in terms of reduction to practice. Rather, they bear on the inventor's intent.

Given these differences, a subjective, expansive understanding of an invention's "intended purpose"—one that accommodates the good-faith, perfectionist inventor—is considered as part of the experimental-use inquiry. This is the way the Supreme Court addressed the issue in the *City of Elizabeth* pavement case:

> Durability was one of the qualities to be attained. [The inventor] wanted to know whether his pavement would stand, and whether it would resist decay. Its character for durability could not

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[5] I am all the more skeptical given that *Pfaff* explicitly reaffirmed the continued vitality of the experimental-use doctrine. 525 U.S. at 64–65, 67.

> be ascertained without its being subjected to use for a considerable time. He subjected it to such use, in good faith, for the simple purpose of ascertaining whether it was what he claimed it to be.

*City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 136 (1877); *id.* at 137 (justifying, on policy grounds, delaying filing for a patent when the delay is "occasioned by a *bona fide* effort to bring [the] invention to perfection, or to ascertain whether it will answer the purpose intended").

In fact, most of the cases the majority analogizes to in its not-ready-for-patenting discussion actually analyze this subjective, outside-the-patent-language "intended purpose" as part of experimental use. Majority Op. 20–22; *see Polara*, 894 F.3d at 1349 ("The jury could have properly based its finding of experimental use on the need for testing to ensure the durability and safety of the claimed [invention]."); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550 (Fed. Cir. 1990) ("Because [the inventor] . . . did not offer to sell the [invention] to anyone else until after it was tested in the cold, rain, snow, and wind—an environment in which it was designed to operate—we must agree with the district court that experimentation, and not profit, was the primary motive behind [the use]."); *TP Labs.*, 724 F.2d at 972.

Thus, if an inventor's pre-critical-date sale or public use is to test an unclaimed or undescribed, yet inherent, feature of an invention (e.g., durability, safety), such testing may support the inventor's overall claim of experimental use and thereby avoid invalidity. *See Electromotive Div.*, 417 F.3d at 1211–12. But neither this testing nor the inventor's assertions regarding his or her subjective desire for such testing should control the ready-for-patenting inquiry. *Pfaff*'s "ready for patenting" does not mean whenever the inventor was ready to file for a patent.

## IV

Given my conclusion that Medtronic made a *prima facie* showing of both *Pfaff* prongs, I must address whether Dr. Barry presented enough evidence that he conducted the three surgeries with experimental purpose sufficient to negate an on-sale bar. Although the majority does not address the parties' respective burdens in this context, I address them briefly. I then address the evidence.

### A

The Supreme Court addressed the burdens issue in *Smith & Griggs Manufacturing Co. v. Sprague*:

> In considering the evidence as to the alleged prior use for more than two years of an invention, which, if established, will have the effect of invalidating the patent, and where the defense is met only by the allegation that the use was not a public use in the sense of the statute, because it was for the purpose of perfecting an incomplete invention by tests and experiments, *the proof, on the part of the patentee*, the period covered by the use having been clearly established, *should be full, unequivocal, and convincing*.

123 U.S. 249, 264 (1887) (emphasis added). The Court reiterated the rule in *Root v. Third Avenue Railroad Co.*, 146 U.S. 210, 226 (1892).

Over forty years later, the Second Circuit interpreted and applied this language. With Judge Learned Hand writing, the court concluded that, on the issue of experimental purpose, "the patentee has the burden, once the [prior] use is proved, and he must establish it by stronger proof than in ordinary civil suits." *Aerovox Corp. v. Polymet Mfg. Corp.*, 67 F.2d 860, 861 (2d Cir. 1933) (Hand, J.). The court noted that the First, Third, and Seventh Circuits all read *Smith & Griggs* the same way. *Id.* (collecting cases). Indeed, the court "should have

supposed this settled" but for contrary language in a Sixth Circuit case, *Austin Machinery Co. v. Buckeye Traction Ditcher Co.*, which said that "the legal and heavy burden of proof as to all the elements involved continues until the end upon one who attacks the patent grant." 13 F.2d 697, 700 (6th Cir. 1926). Although Judge Hand saw merit in both positions, he concluded that the majority view was authoritative "until the Supreme Court decides otherwise." *Aerovox*, 67 F.2d at 861. The Supreme Court has not decided otherwise.

This court has, though. In *TP Laboratories, Inc. v. Professional Positioners, Inc.*, the court addressed the burdens applicable to a patent challenger's § 102(b) defense and a patentee's corresponding assertion of experimental use. It followed *Austin* and held that "the burden of proof [is] upon the party attacking the validity of the patent, and that burden of persuasion does not shift at any time to the patent owner." 724 F.2d at 971; *id.* at 971 n.3 (citing *Austin*, 13 F.2d at 700). Although the court acknowledged *Smith & Griggs* in a footnote, it saw no conflict there. 724 F.2d at 971 & n.3.

The *TP Laboratories* court further opined that, even if *Smith & Griggs* expressed a contrary view—i.e., one that "impose[d] the ultimate burden of persuasion on the patent holder rather than merely the burden of going forward with countering evidence"—the Supreme Court's view would not be "tenable" in light of the subsequently enacted statutory presumption of validity in 35 U.S.C. § 282. 724 F.2d at 971 n.3. This reasoning was questionable even at the time. As several commentators noted, the presumption of validity long predated the 1952 Patent Act.[6] The court's reasoning has not improved with age.

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[6] *E.g.*, William C. Rooklidge & Stephen C. Jensen, *Common Sense, Simplicity and Experimental Use Nega-*

*See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 102 (2011) ("[B]y the time Congress enacted § 282 and declared that a patent is 'presumed valid,' the presumption of patent validity had long been a fixture of the common law." (citing *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1 (1934))).

Thus, in *TP Laboratories*, the patentee's burden of persuasion on experimental use became a burden of production: "[I]f a *prima facie* case is made of public use, the patent owner must be able to point to or *must come forward with convincing evidence* to counter that showing." 724 F.2d at 971 (emphasis added). And while *TP Laboratories* at least required a patentee to come forward with "convincing" evidence of experimental use, we later held that this does not imply a heightened standard, such as one akin to "clear and convincing." *Lisle Corp. v. A.J. Mfg. Co.*, 398 F.3d 1306, 1316 (Fed. Cir. 2005). *But cf. In re Dybel*, 524 F.2d 1393, 1401 (CCPA 1975) (holding that, in light of a *prima facie* case of an on-sale bar, the applicant "had the burden of establishing by clear and convincing evidence that such sales were for experimental purposes").

B

Even under the burden-of-production approach set forth in *TP Laboratories*, I conclude that Dr. Barry's

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*tion of the Public Use and On Sale Bars to Patentability*, 29 J. Marshall L. Rev. 1, 44–45 (1995) (cited favorably in *Pfaff*, albeit for a different proposition); *see also* 2A Chisum on Patents § 6.02[8], p. 6-292 n.41 (2017) (noting that "[t]he court's basis for this holding is questionable" given that "[t]he enactment of [§] 282 on the presumption of validity in 1952 was generally thought to have codified prior law").

evidence of experimental purpose was insufficient as a matter of law to negate a bar.

Most of Dr. Barry's evidence of experimental purpose as to the three pre-critical-date surgeries is just his own after-the-fact testimony. *See* Majority Op. 26–27 (referencing Dr. Barry's testimony).[7] "[C]ertain things are settled. Significantly, an inventor's subjective intent to experiment cannot establish that his activities are, in fact, experimental." *Electromotive Div.*, 417 F.3d at 1212. Indeed, we have repeatedly noted the minimal evidentiary value of an inventor's after-the-fact, litigation-inspired testimony as to experimental intent. *E.g.*, *LaBounty Mfg., Inc. v. ITC*, 958 F.2d 1066, 1071 (Fed. Cir. 1992) ("An inventor's protestation of an intent to experiment, expressed for the first time during litigation, is of little evidentiary value, at best."); *see also Sinskey v. Pharmacia Ophthalmics, Inc.*, 982 F.2d 494, 499 (Fed. Cir. 1992) ("[A]fter-the-fact testimony of an inventor's subjective 'experimental intent' is entitled to minimal

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[7] The majority suggests that other people were aware that Dr. Barry was experimenting, Majority Op. 27–28, but its record citations do not withstand scrutiny. Dr. Barry's doctor colleague testified that she understood him to be working on a technique sometime "in the 2002–2004 time frame." J.A. 1733. This testimony is vague and says nothing about these particular surgeries, much less their experimental purpose. Dr. Barry's nurse colleague said that it was "exciting when [the] team uses [the] levers to correct the curve," but said nothing about whether she understood the procedure to be experimental. J.A. 1370. And testimony concerning the DePuy medical-device representative relates only to the development of surgical tools, not these particular surgeries or whether they were experimental. J.A. 1178–79.

weight."), *abrogated on other grounds by Pfaff*, 525 U.S. 55 (1998); *TP Labs.*, 724 F.2d at 972 (similar).

Rather, we generally look to objective evidence to determine whether a sale was for experimentation. *Electromotive Div.*, 417 F.3d at 1212–13 (listing various objective indicia); *see Lough v. Brunswick Corp.*, 86 F.3d 1113, 1121 (Fed. Cir. 1996); *In re Smith*, 714 F.2d 1127, 1135 (Fed. Cir. 1983). The record is thin on objective evidence indicating such a purpose.

To begin, Dr. Barry kept no records reflecting any experimental intent as to these surgeries. We have observed that the absence of such records weighs against a finding of experimental use. *See Lough*, 86 F.3d at 1121 (finding the lack of recordkeeping important even with an inventor less sophisticated than Dr. Barry); *see also Clock Spring*, 560 F.3d at 1328; *Netscape*, 295 F.3d at 1322.

Dr. Barry also charged his normal fee for the surgeries. The majority concludes that this fact points toward a conclusion of experimental use. Majority Op. 27–28. Yet I cannot see how charging one's normal fee makes the sale look like anything other than a normal sale. *See Electromotive Div.*, 417 F.3d at 1217; *Sinskey*, 982 F.2d at 499. Had Dr. Barry charged a premium, a claim of experimental purpose would be difficult to maintain. Had he charged less, it might suggest experimental purpose—or it might not. *Compare EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1352 (Fed. Cir. 2002) (citing, in support of a conclusion of experimental use, fact that customer did not pay full market price for the product and received free equipment and free installation), *with Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1428 (Fed. Cir. 1996) (finding evidence of a discount not determinative because a patentee "may have created an on-sale bar despite *losing* money on a sale" (citation omitted)). Either way, I disagree with the majority's conclusion that charging the normal fee permits an inference of experimental use.

Majority Op. 27–28. At best, this fact is neutral for Dr. Barry. But the more natural inference is one of a sale for commercial purposes.

The majority places weight on the fact that Dr. Barry maintained control over his method, but I find it hard to do the same. Control can be a useful objective indicator of experimental intent when it serves to distinguish between a commercial sale and one that is experimental. For example, if an inventor sells his or her inventive product but retains some control over its use, that scenario looks different from a normal sale—thus, more likely experimental. Similarly, if an inventor sells his or her product but forgoes an opportunity to retain some control, that scenario looks more like a normal sale. In this case, however, the nature of the inventor (a practicing surgeon) and his invention (a surgical method) means the inventor was likely going to retain sole control over the method for as long as he was practicing it. Although Dr. Barry's control over his method is consistent with experimental intent, given these circumstances, I cannot place much weight on this consideration.

Dr. Barry also did not inform his patients that he was performing his surgical method for experimental purposes. The majority dedicates considerable discussion to minimizing the importance of this fact. It carefully parses a statement in one of our prior cases, *LaBounty*, and finds that informing a customer of experimental intent is only relevant or necessary if at least two premises exist: (1) the absence of other objective evidence of experimentation; and (2) the placement of the invention outside of the inventor's control. Majority Op. 29–30. Respectfully, I believe the majority's two-necessary-premises requirement over-reads *LaBounty* and overcomplicates what should be a simple observation: if an inventor tells his or her customer that the invention is for experimental purposes, it is more likely that the inventor's intent was experimental; if he or she does not, it is less likely. Re-

gardless, even if I were to accept that informing customers of experimental intent is *more* important when control is lost, that would not mean it is irrelevant when control is maintained. It remains useful as an objective indicator of the inventor's contemporaneous intent.

In Dr. Barry's case, all of the foregoing considerations—the lack of records indicating experimentation, the normal fee charged, the control exercised, and the failure to inform customers of experimental purpose—would look the same if the surgeries were for commercial purposes. The only thing that affirmatively suggests these surgeries were experimental is that Dr. Barry said they were—after the fact, during litigation. As a matter of law, that is insufficient to show experimental purpose.

* * *

The record in this case shows that Dr. Barry waited too long to file for the '358 patent and that the on-sale bar applies. I respectfully dissent from the majority's contrary conclusion.