United States Court of Appeals for the Federal Circuit

MINERVA SURGICAL, INC.,
Plaintiff-Appellant

v.

HOLOGIC, INC., CYTYC SURGICAL PRODUCTS, LLC,
Defendants-Appellees

2021-2246

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-00217-JFB-SRF, Senior Judge Joseph F. Bataillon.

Decided: February 15, 2023

ROBERT N. HOCHMAN, Sidley Austin LLP, Chicago, IL, argued for plaintiff-appellant. Also represented by JULIA G. TABAT, CAROLINE A. WONG; VERA ELSON, Wilson, Sonsini, Goodrich & Rosati, PC, Palo Alto, CA.; OLIVIA M. KIM, EDWARD POPLAWSKI, Los Angeles, CA.

MATTHEW WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, argued for defendants-appellees. Also represented by MARC A. COHN, JENNIFER SKLENAR; AARON PATRICK BOWLING, Chicago, IL; RYAN CASAMIQUELA, San Francisco, CA; ASSAD H. RAJANI, Palo Alto, CA.

Before PROST, REYNA, and STOLL, *Circuit Judges*.

REYNA, *Circuit Judge*.

Minerva Surgical, Inc. sued Hologic, Inc. and Cytyc Surgical Products, LLC in the District of Delaware for infringement of U.S. Patent No. 9,186,208. After discovery, the district court granted summary judgment that the asserted claims are anticipated under the public use bar of pre-AIA 35 U.S.C. § 102(b). Minerva appeals.

We affirm. First, the patented technology was "in public use" because, before the critical date, Minerva disclosed fifteen devices having the technology at an event—the industry's "Super Bowl." Minerva's disclosure of these devices spanned several days and included Minerva showcasing them at a booth, in meetings with interested parties, and in a technical presentation. Minerva did not disclose the devices under any confidentiality obligations, despite the commercial nature of the event.

Second, at the time of the public use, the technology was "ready for patenting." Specifically, Minerva had created working prototypes and enabling technical documents describing the claimed technology.

The district court thus correctly granted summary judgment of invalidity because there are no genuine factual disputes, and defendants are entitled to judgment as a matter of law that the asserted claims are anticipated under the public use bar of § 102(b).

THE '208 PATENT

The application for U.S. Patent No. 9,186,208 (the "'208 patent") was filed on November 2, 2012, and claims a priority date of November 7, 2011. *Minerva Surgical, Inc. v. Hologic, Inc.*, 550 F. Supp. 3d 158, 161 (D. Del. 2021). Csaba Truckai and Akos Toth are the listed inventors.

The '208 patent is directed to surgical devices for a procedure called "endometrial ablation," which stops or reduces abnormal uterine bleeding. '208 patent at Abstract. The procedure generally involves inserting a device having an energy-delivery surface into a patient's uterus, expanding the surface, energizing the surface to "ablate" or destroy the endometrial lining of the patient's uterus, and removing the surface. *See id.* at 1:31–2:67, 6:12–60.

The patented device contains a frame having "inner" and "outer" elements, also called flexures or struts, as seen in the following figure:

Op. Br. at 11 (annotating Fig. 9 of the '208 patent). The elements expand to bring the energy-delivery surface into contact with the walls of the uterine cavity. *Minerva Surgical*, 550 F. Supp. 3d at 161. Once in place, the energy-delivery surface is used to apply energy sufficient to destroy the uterine lining. *Id.*

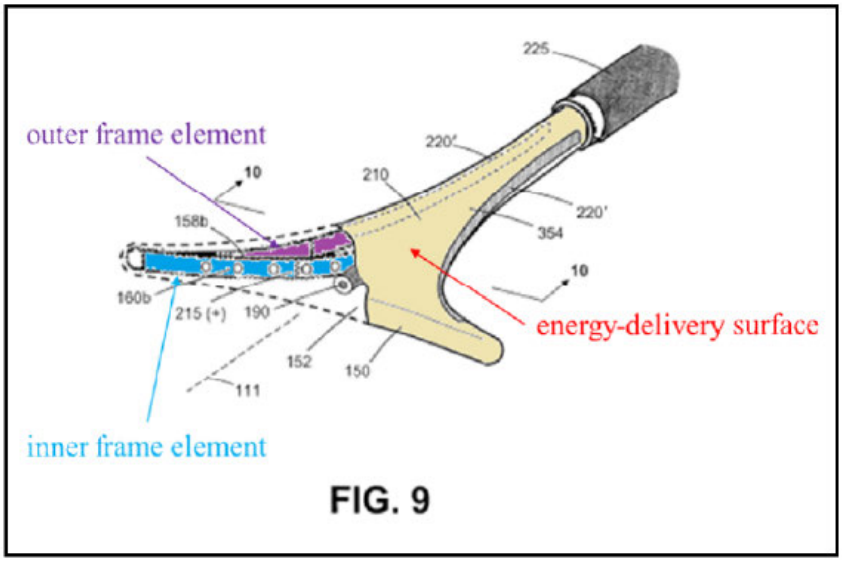

FIG. 9

Independent claim 13, representative for the purposes of this appeal, recites:

> A system for endometrial ablation comprising:
>
> > an elongated shaft with a working end having an axis and comprising a compliant energy-delivery surface actuatable by an interior expandable-contractable frame;
> >
> > the surface expandable to a selected planar triangular shape configured for deployment to engage the walls of a patient's uterine cavity;
> >
> > wherein the frame has flexible outer elements in lateral contact with the compliant surface and flexible inner elements not in said lateral contact, wherein the inner and outer elements have substantially dissimilar material properties.

'208 patent at 22:34–45 (emphasis added).

This appeal focuses on the claim term, "the inner and outer elements have substantially dissimilar material properties," ("SDMP" term) which was construed by the court to mean that the "inner and outer frame elements have different thickness and different composition." *Minerva Surgical*, 550 F. Supp. 3d at 162. The parties do not appeal that construction. The parties also do not dispute that the SDMP frame is intended to result in: (1) An increase to the device's flexibility—facilitating the device's ability to contact the uterine lining; (2) An increase to the device's durability—preventing deformation while the device is being used and removed; and (3) A reduction in the device's diameter. *See id.* at 164–65; Op. Br. at 3–4, 15; Resp. Br. at 8–10; J.A. 6334.

DISTRICT COURT PROCEEDINGS

In 2017, Minerva accused Hologic, Inc. and Cytyc Surgical Products, LLC (collectively "Hologic") of infringing the '208 patent. J.A. 116. After discovery, Hologic moved for summary judgment of invalidity, arguing that the asserted '208 patent claims were anticipated under the public use bar of pre-AIA 35 U.S.C. § 102(b).[1] *Minerva Surgical*, 550 F. Supp. 3d at 160. According to Hologic, on November 16–19, 2009—more than a year before the '208 patent's priority date—Minerva brought a device called "Aurora" to the 38th Global Congress of Minimally Invasive Gynecology sponsored by the American Association of Gynecologic Laparoscopists ("AAGL 2009"). Hologic asserted that the Aurora device disclosed every limitation of the asserted claims and that the asserted claims were therefore invalid as anticipated by Minerva's own device.

The story of the Aurora device starts in 2008, when Minerva began its development. Op. Br. at 9. By early 2009, Minerva had begun developing prototypes, but these lacked a frame, an "inner flexure," "lateral symmetry," and the SDMP technology. J.A. 6644–45. Minerva was, however, searching for the "right combination of parameters to be able to open the device wide enough and cover a large enough surface area, deliver energy and then be able to collapse" so the device could be withdrawn, i.e. problems the SDMP technology resolved. *Id*.

By mid-2009, Minerva had prototypes that could be inserted into uteri, could deliver energy necessary to perform the surgery, and could be withdrawn after the procedure, but the prototypes' frames were "deforming too much."

---

[1] "A person shall be entitled a patent unless . . . the invention was . . . in public use . . . in this country, more than one year prior to the date of the application for patent in the United States." Pre-AIA 35 U.S.C. § 102(b).

J.A. 6645. By July or August 2009, Minerva had recognized that the deformation was caused by the prototypes having "a very simple frame structure . . . [with] the same properties." J.A. 6646; *see also* J.A. 6621 (Inventor Truckai testifying that conception of the SDMP term occurred "somewhere between" July 23, 2009, and November 25, 2009).

In July 2009, Minerva began testing the Aurora device on extirpated (surgically-removed) human uteri. Op. Br. at 55–56. A report analyzing tests conducted on October 1, 2009, and November 14, 2009, describes that "[a]ll Minerva devices (n=13) were successfully deployed and conformed to the uterus," and "[a]ll devices were removed successfully post-ablation." J.A. 12175–76. These results align with the benefits that the SDMP technology is intended to achieve. The report concludes that "the Minerva device would be considered acceptable for clinical use in pre-hysterectomy cases"—i.e., in live patients. J.A. 12176.

Undated pages from a lab notebook show the Aurora device having a frame with an inner element using 440A stainless steel and an outer element using 17-4 PH stainless steel. J.A. 12227. These two steels have different thicknesses and compositions, and thus disclose the SDMP term. *Minerva Surgical*, 550 F. Supp. 3d at 163. While these pages are undated, subsequent pages are dated November 25, 2009. J.A. 12250.

The undated lab notebook pages include two CAD drawings dated August 2009 that also disclose the SDMP term. J.A. 12234; *Minerva Surgical*, 550 F. Supp. 3d at 163. The first CAD drawing shows an outer element made of 0.010" thick 17-4 PH stainless steel. *Id.* The second drawing shows an inner element made of 0.018" thick 420 stainless steel. *Id.* Inventor Toth testified that prototypes using 420 stainless steel "were performing quite fine" but "Minerva didn't stop developing the [Aurora] device even though the frame was like perfect." J.A. 6668. He

explained that Minerva later found materials that were "a little better." J.A. 6669.

On October 23, 2009, Minerva pitched the Aurora device to a potential acquiror. J.A. 11883, 12090. The presentation slide deck includes several photos of the device and touts that the Aurora device had a "small insertion diameter" and improved "[f]lexibility to conform" to the uterus—the benefits of the SDMP technology. J.A. 11899–900.

By October 2009, Minerva was preparing for AAGL 2009, an industry related event dubbed "the Super Bowl of [the] industry" by Inventor Truckai. J.A. 9128. AAGL 2009 attendees were from various industry groups, competitors, investors, and phyisicians. J.A. 11294 (slide deck describing that around 70 device companies had exhibits at AAGL 2009), 11914, 12090–91.

Inventor Truckai—who was Minerva's CEO at the time—asked Minerva's research and development team to have "15 full[y] functional" devices ready to bring to AAGL 2009. J.A. 14643; *Minerva Surgical*, 550 F. Supp. 3d at 164. Minerva obtained a booth at AAGL 2009 to demonstrate the Aurora devices. J.A. 12115, 11298–99. A Minerva employee manning the booth reported in an email that the "[b]ooth has been busy. Lots of interested [doctors] including several potential investigators. . . . Devices have been working well. One frame broke but I swapped it out undetected." J.A. 12189. A Minerva document summarizes "comments from AAGL . . . meetings" and provides feedback that Minerva received on its Aurora device from sophisticated attendees, such as phyisicians. J.A. 11914. One comment states that the Aurora device's "[f]rame flexibility lends possibility of better conformity to varying architectures of the uterine cavity," which, again, is a purpose of the SDMP technology. *Id.*

On November 19, 2009, Dr. Andrew Brill, the Chairman of Minerva's Medical Advisory Board, gave a presentation at AAGL 2009 discussing the Aurora device.

A brochure, distributed at AAGL 2009, explains that the presentation would include discussion of "[t]he disposable device's ability to conform to the uterus [to] enable treatment of uterine cavities with deformities and variable volumes." J.A. 13444.

An "Investigator's Brochure" dated November 20, 2009—a day after AAGL 2009—provided a detailed description of the Aurora device and identified that its frame elements were made of "Stainless steel (420 and 17-4)," which is consistent with the August 2009 CAD drawings. J.A. 12169. Similarly, a Bill of Materials from November 24, 2009, lists the same frame elements. Resp. Br. at 18 (citing J.A. 11917); Op. Br. at 18–19 (conceding that the Bill of Materials "sets forth the specifications for a frame with flexures having different thicknesses and different compositions of steel"). These documents, therefore, all disclose the SDMP term. Inventor Toth testified that the device referenced in the Bill of Materials was "[l]ikely" the Aurora device shown at AAGL 2009. J.A. 6689.

In view of the forgoing record, the district court granted summary judgment that the asserted claims are anticipated under the public use bar. *Minerva Surgical*, 550 F. Supp. 3d at 169–70. The court found no genuine dispute that the display and demonstration of the Aurora device at AAGL 2009 constituted public use more than a year before the '208 patent's priority date and that those devices disclosed embodied claim 13 of the '208 patent. *Id.* The court also explained that the prototypes and technical documents showed that the invention of the '208 patent was ready for patenting at the time of AAGL 2009. *Id.*

Minerva timely appeals, and we have jurisdiction under 28 U.S.C. § 1295(a)(1).

STANDARD OF REVIEW

We review a district court's grant of summary judgment under the law of the regional circuit, in this case the Third Circuit. *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, 661 F.3d 1378, 1381 (Fed. Cir. 2011). The Third Circuit reviews a grant of summary judgment de novo. *Id.* Summary judgment is appropriate when, drawing all justifiable inferences in the nonmovant's favor, there exists no genuine issue of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). "Whether a patent is invalid for public use is a question of law based on underlying facts." *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1267 (Fed. Cir. 2008).

DISCUSSION

Minerva argues that the court erred in granting summary judgment of invalidity based on the public use bar. We disagree.

Pre-AIA 35 U.S.C. § 102(b)

Under the public use bar, "[a] person shall be entitled a patent unless . . . the invention was . . . in public use . . . in this country, more than one year prior to the date of the application for patent in the United States." Pre-AIA 35 U.S.C. § 102(b). "The public use bar is triggered 'where, before the critical date, the invention is [(1)] in public use and [(2)] ready for patenting.'"[2] *Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1348 (Fed. Cir. 2018) (citing *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005)).

---

[2] The parties agree that the critical date for the '208 patent is November 7, 2010.

The "in public use" element of the bar is met if the invention "was accessible to the public or was commercially exploited"[3] by the inventor. *Delano Farms Co. v. California Table Grape Comm'n*, 778 F.3d 1243, 1247 (Fed. Cir. 2015) (citation omitted); *see also Dey, L.P. v. Sunovion Pharms., Inc.*, 715 F.3d 1351, 1355 (Fed. Cir. 2013) (same with minor modifications). "An invention is in public use if it is shown to or used by an individual other than the inventor under no limitation, restriction, or obligation of confidentiality." *Am. Seating*, 514 F.3d at 1267. To determine whether this occurred, the court considers, "*inter alia*, the nature of and public access to activities involving the invention [and] confidentiality obligations imposed upon observers." *Id.*; *Delano Farms*, 778 F.3d at 1247.

"Ready for patenting"—the second element of the public use bar—may be shown in at least two ways. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998). The first way is "by proof of reduction to practice before the critical date." *Id.* "Reduction to practice occurs if the claimant had possession of the subject matter of the [claim] and . . . it was shown or known to work for its intended purpose." *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1372 (Fed. Cir. 2017) (citation omitted). "Possession" of the subject matter may be shown by the existence of a working prototype. *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1379 (Fed. Cir. 2013). The "intended purpose" of an invention should be considered in light of the claims and specification. *Manning v. Paradis*, 296 F.3d 1098, 1102–04 (Fed. Cir. 2002).

The second way the "ready for patenting" element may be shown is "by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the

---

[3] Because we find that the invention "was accessible to the public," we do not resolve whether it was also "commercially exploited." *Delano Farms*, 778 F.3d at 1247.

invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff*, 525 U.S. at 67–68. For example, we have found "CAD drawings" and related descriptions sufficiently enabling. *Hamilton Beach Brands*, 726 F.3d at 1378.

Minerva has three main arguments. First, Minerva asserts that disclosure of the Aurora device at AAGL 2009 was not "in public use" because Minerva "merely displayed" the device. Op. Br. at 59–65. Second, Minerva argues that there was no disclosure of the "invention" of claim 13 of the '208 patent because the Aurora device disclosed at AAGL 2009 lacked the SDMP term. *Id*. at 42–53. Third, Minerva argues that the invention was not "ready for patenting" because Minerva was still improving the SDMP technology at the time of AAGL 2009, so the device did not function for its intended purpose of ablating "live human" tissue. *Id*. at 53–59. We address each of these arguments in turn.

In Public Use

The district court correctly determined that disclosing the Aurora device at AAGL 2009 constituted the invention being "in public use" for the purposes of § 102(b) because the invention was "shown to . . . individual[s] other than the inventor under no limitation, restriction, or obligation of confidentiality." *Am. Seating*, 514 F.3d at 1267.

First, "the nature of and public access to activities involving" the Aurora device at AAGL 2009 indicate public use. *Id*. AAGL 2009 was the "Super Bowl" of the industry and was open to the public. It included attendees who were critical to Minerva's budding business—such as potential investors and physicians—and Minerva had every incentive to showcase the Aurora devices to these attendees as best as it could. The record shows that Minerva brought "15 full[y] functional" Aurora devices to AAGL 2009. J.A. 14643. And Minerva's disclosure of these fifteen devices spanned several days and included Minerva showcasing them at a booth, in meetings with interested parties, and

in a technical presentation. J.A. 9091, 11296, 12115, 12189 (describing the booth as being "busy," with "[l]ots of interested [doctors,] including several potential investigators," stopping by). Demonstrations of the Aurora device at the exhibition booth involved using the device on a "transparent uterine model with saline" and resulted in "[h]ighly visible plasma [being] generated only where saline contacted" the energy-delivery surface of the device. J.A. 11299. On the last day of the show, Minerva sponsored a presentation by Dr. Andrew Brill, Chairman of Minerva's Medical Advisory Board, who among other things highlighted the Aurora device's "ability to conform to the uterus [that] may enable treatment of uterine cavities with deformities and variable volumes." J.A. 9096–97; *see also* J.A. 9018, 9073, 9096–97, 12035.

Citing *Motionless Keyboard*, Minerva argues that its "mere display" of the Aurora device at AAGL 2009 does not rise to the level of "public use." Op. Br. at 60–61 (citing *Motionless Keyboard Co. v. Microsoft Corp.*, 486 F.3d 1376 (Fed. Cir. 2007)). We disagree.

In *Motionless Keyboard*, the inventor disclosed his patented keyboard to various third parties. *Motionless Keyboard*, 486 F.3d at 1385. But these disclosures "only provided a visual view of the new keyboard design without any disclosure of the" claimed technology, which involved "enter[ing] data into a system." *Id.*

Minerva's disclosure at AAGL 2009 went well beyond that at issue in *Motionless Keyboard*. At AAGL 2009, as evidenced by the records of the event (such as the feedback Minerva documented), Minerva pitched the Aurora device to various sophisticated industry members, who were allowed to scrutinize the Aurora device closely and see how it operated. For example, the "Product Comments" Minerva received from the "AAGL & MAB [Medical Advisory Board] Meetings November 16–19, 2009" praised the "ergonomic design of the handle" as "comfortable and easy to

use" for physicians and highlighted the "[f]rame flexibility" and "[f]lexibility of [the] shaft" as beneficial for patients. J.A. 11914; *see also* J.A. 11907–09, 12116. *See generally* 3 Matthews Annotated Patent Digest § 17:145 (collecting cases) ("Displaying a product at a trade show by demonstrating to observers the product in its normal operation, or a simulation thereof, generally constitutes a 'public use' of the displayed product."); *Art+Com Innovationpool GmbH, v. Google LLC*, 712 F. App'x 976, 984 (Fed. Cir. 2017) (invalidity finding where evidence showed that the "system was publicly demonstrated at two technical conferences to attendees with knowledge of the art and without any restriction or effort to maintain confidentiality"); *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1319–21 (Fed. Cir. 2002) (affirming a district court's conclusion that the inventor's "demonstration of the claimed invention" to two experts "without any obligation of confidentiality was a public use"). Minerva's own employee reported that the Aurora devices were "working well" but were showcased so thoroughly that "[o]ne frame broke." J.A. 12189.

Minerva also disputes the district court's finding that attendees "observed or handled" the device because "there is no evidence even suggesting that Minerva had a prototype at its AAGL booth that could be handled." Op. Br. at 63–64 (citing *Minerva Surgical*, 550 F. Supp. 3d at 169). Regardless of whether the Aurora devices were closely observed or physically handled, our standard for disclosure rising to the level of public use is not predicated on a device being physically handled by the public. *See Am. Seating*, 514 F.3d at 1267. Rather, public use may also occur where, as here, the inventor used the device such that at least one member of the public without any secrecy obligations understood the invention. *See Netscape*, 295 F.3d at 1321. The inescapable conclusion of the detailed feedback Minerva received on the Aurora device is that Minerva allowed knowledgeable individuals to scrutinize the

invention enough to recognize and understand the SDMP technology Minerva later sought to patent. *See, e.g.*, *Dey*, 715 F.3d at 1355–56 (collecting cases) ("Even limited disclosure to those who are skilled enough to know, understand, and easily demonstrate the invention to others, may mean that there was no reasonable expectation of secrecy and that the invention was therefore in public use.").

Second, the record shows that there were no "confidentiality obligations imposed upon" those who observed the Aurora device. *Am. Seating*, 514 F.3d at 1267. Minerva does not dispute the district court's determination that the attendees were not required to sign non-disclosure agreements. J.A. 6689 (Inventor Toth stating his belief that AAGL 2009 participants were not required to sign NDAs). Nor does Minerva allege that AAGL 2009 implemented the type of informal confidentiality obligations we have recognized in prior cases. *See, e.g.*, *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1380–81 (Fed. Cir. 2004) (vacating a district court decision finding an invalidating public use where the district court failed to consider that "access was tightly controlled," "there was an industry-wide understanding [of confidentiality]," "a breach of confidence could have serious consequences for an attendee," and "there was no effective means for the attendees to divulge the designs they viewed at [the event] because no photographs or sketches . . . were permitted"). Instead, Minerva asserts that its "company policy is not to disclose proprietary information to people until Minerva files for a patent." Op. Br. at 64 (cleaned up). While that may be true, the record establishes that Minerva did not follow this policy at AAGL 2009.[4]

---

[4] Minerva also cites *Delano Farms* and *Dey* for its argument that the AAGL 2009 disclosure was not "in public use." *See* Op. Br. at 59–65. But there was evidence in those cases that the disclosure was confidential, unlike in this

Third, we agree with the district court that there is no genuine factual dispute that the Aurora devices shown at AAGL 2009 disclosed the SDMP term of claim 13. *Minerva Surgical*, 550 F. Supp. 3d at 169. The inventors conceived the SDMP technology before AAGL 2009. *See, e.g.*, J.A. 6646; *see also* J.A. 12234. Minerva's documentation about the Aurora device from before and shortly after the event expressly discloses the Aurora device having the SDMP term or touts benefits that are derived from the device having the SDMP technology. This includes Minerva's July 2009 extirpated uteri studies, the lab notebook with August 2009 CAD drawings, the October 23, 2009 acquiror presentation, the November 20, 2009 Investigator Brochure, and the November 24, 2009 Bill of Materials.

Further, the record establishes that it was this device disclosing the SDMP technology that Minerva brought to AAGL 2009. As discussed, Minerva brought "full[y] functional" devices to AAGL 2009. J.A. 14643. The feedback Minerva received at AAGL 2009 described features Minerva attributes to the SDMP term. J.A. 11914. Even Inventor Toth could not dispute that the device disclosed at AAGL 2009 "[l]ikely" had the SDMP term when confronted with the evidence. J.A. 6689.

We therefore agree with the district court there was no genuine issue of material fact that the invention of claim

---

case. *See Delano Farms*, 778 F.3d at 1248 ("When Jim Ludy gave [his cousin] the plants, Jim Ludy explicitly told his cousin to 'keep [knowledge of the plants] to ourselves' and expected the fact of their possession of the plants to remain private."); *see also Dey*, 715 F.3d at 1356 (material dispute existed where there was evidence of "precautions [that] were taken to exclude members of the public from obtaining information about the" at-issue drug).

13 was "in public use" prior to the critical date of the '208 patent.

Ready for Patenting

We conclude that the district court correctly determined that the Aurora device was ready for patenting. The Aurora device was ready for patenting for two reasons: (1) Minerva reduced the invention to practice and (2) Minerva had enabling documentation describing the invention of claim 13.

First, the record shows that the invention was ready for patenting because Minerva reduced the invention to practice by creating working prototypes that embodied claim 13 and worked for the intended purpose of performing endometrial ablations. *See Hamilton Beach Brands*, 726 F.3d at 1379. The evidence establishing this includes inventor testimony explaining the prototypes and their implementation of the SDMP technology, the extirpated uteri studies, and the documents describing the prototypes.

Minerva asserts that there is a factual dispute as to reduction to practice because Minerva was still working to improve the Aurora device at the time of AAGL 2009. Minerva insists that the Aurora device did not function for its intended purpose of performing ablations on "live human" uteri. Op. Br. at 55. This argument is unsupported by law and the evidence in this case.

Contrary to Minerva's argument, our case law does not require imposing the "live human" requirement here. Minerva points to nothing in the intrinsic record indicating that the '208 patent is limited to devices only usable on live human tissue. *See, e.g.*, Op. Br. at 54–55, 58; Reply Br. at 5–12; *see Manning*, 296 F.3d at 1102–04. Further, that Minerva was ultimately able to find materials that were "a little better" for the SDMP term does not preclude a reduction to practice finding. J.A. 6668. This instead amounts to mere "later refinements" or "fine tuning," which are

more than reduction to practice requires. *See Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1367 (Fed. Cir. 2008) ("[I]t is improper to conclude that an invention is not reduced to practice merely because further testing is being conducted."); *Hamilton Beach Brands*, 726 F.3d at 1379 ("'Fine-tuning' of an invention after the critical date does not mean that the invention was not ready for patenting."). Likewise, Minerva's contention fails because it is essentially that the disclosed Aurora device was not ready for FDA approval, which is also beyond that required. *Helsinn Healthcare*, 855 F.3d at 1372–73 (explaining that FDA approval is much stricter than the "ready for patenting" standard); *see* Op. Br. at 56–57 (arguing that the inventors did not know whether the Aurora device would have a failure rate lower than the five or ten percent required for a successful commercial device).

Even if we applied Minerva's heightened "live human" requirement, however, this would not preclude a reduction to practice finding. As discussed, the extirpated uteri studies concluded that "the Minerva device would be considered acceptable for clinical use in pre-hysterectomy cases," in other words that the Aurora device would be considered acceptable for use in clinical trials on live humans. J.A. 12176. And Inventor Toth similarly testified that the disclosed versions of the Aurora device were nearly "perfect." J.A. 6668.

Aside from being reduced to practice, the invention was ready for patenting for a second reason: there was documentation "sufficiently specific to enable a person skilled in the art to practice the invention" of the disputed SDMP term of claim 13. *Pfaff*, 525 U.S. at 67–68. This documentation includes the drawings and detailed descriptions in the 2009 lab notebook pages disclosing a device with the SDMP term. *See* J.A. 12227, 12234; *see also* J.A. 11899–900 (the October 23, 2009, acquiror presentation having images and details of the device); *Hamilton Beach Brands*, 726 F.3d at 1378 (explaining that "CAD drawings and

descriptions . . . [were] more than enough to enable a person of ordinary skill in the art to practice the claimed invention").

We thus agree with the district court there was no genuine issue of material fact that the invention of claim 13 was "ready for patenting" before the critical date of the '208 patent.[5]

CONCLUSION

The district court correctly determined that Minerva's disclosure of the Aurora device constituted the invention being "in public use" and that the device was "ready for patenting." We therefore affirm the district court's grant of summary judgment because there are no genuine factual disputes, and Hologic is entitled to judgment as a matter of law that the '208 patent is anticipated under the public use bar of § 102(b). We have considered Minerva's remaining arguments and do not find them persuasive.

AFFIRMED

COSTS

No costs.

---

[5] Minerva also appeals the district court's exclusion of Minerva's expert testimony on the doctrine of equivalence. Because the asserted claims are invalid as anticipated, we do not reach this moot issue.