IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CR BARD INC. and BARD PERIPHERAL VASCULAR, INC., Plaintiffs/Counterclaim Defendants. vs. ANGIODYNAMICS, INC., Defendant/Counterclaim Plaintiff.	**CIV. NO. 15-218-JFB-SRF** **MEMORANDUM AND ORDER**

Following eight years of litigation, one-and-a-half jury trials, a trip to the Court of Appeals, and finally a blanket verdict of willful infringement and rejection of invalidity and infringement defenses in favor of Plaintiffs and patent owners CR Bard Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), this matter is before the Court on defendant AngioDynamics, Inc.'s motion for judgment as a matter of law. D.I. 572. Bard's claim reconstructions at trial would render the claims invalid either for recitation of ineligible subject matter or indefiniteness, whereas adherence to the original claim construction renders the claims anticipated. To the extent below, the motion is granted.

BACKGROUND

This case concerns the vascular access port, a small receptacle attached to a catheter implanted under a patient's skin to ease regular medical injection. More specifically, this case concerns Bard's purported patentable improvement of the vascular access port.

Doctors have used vascular access ports for decades to inject pharmaceutical drugs, such as chemotherapy. For most of this time, they injected these drugs a little at

a time—at low pressures and fluid flow rates, in the parlance of this case. Along the way, the development of the computed tomography, or "CT," scan expanded the value of the ports but added complications. Contrast fluid, a substance injected into patients to improve the visibility (and therefore efficacy) of a CT scan, proved too thick, or "viscous," for easy injection. And to get a good picture, the contrast fluid would need to be injected quickly into the patient. That just couldn't be done with traditional, usually manual, methods. So called "power-injection" machines entered the market, capable of pumping contrast media at pressures above 300 pounds per square inch (psi) and fluid flow rates beyond 1 milliliter (one thousandth of a liter) per second (mL/s)—well beyond what could previously have been done by hand. Solving one problem, though, power injection exposed another.

Previous ports hadn't been designed to accommodate such high pressures and fluid flow rates. Like overfilled balloons, some ports began bursting under power injection. Not always. And not even the first or first several times. But it happened enough that in 2004 the Food & Drug Administration warned doctors nationwide "of the potential for serious patient injury when vascular access devices not designed to tolerate high pressures are used for power injection of CT or MRI contrast media." The FDA reported over 250 different rupture events and stressed that doctors should "[c]heck the labeling of each vascular access device for its maximum pressure and flow rate" and not exceed those parameters. PX-508 (Reminders from FDA Regarding Ruptured Vascular Devices from Power Injection, July 2004).

Sensing the opportunity to market a port FDA-indicated, that is approved, for power injection, Bard got to work and eventually became the first to obtain approval to market a

power-injectable vascular access port. Bard's PowerPort entered the market in July 2006, followed by the PowerPort MRI (a plastic, as opposed to titanium, version) in March 2007. Others also sought FDA approval to market power-injectable ports, including AngioDynamics.

In the meantime, Bard had moved to protect its development, filing several applications with the United States Patent & Trademark Office. Ultimately, several patents issued, including the three at issue here, Patent No. 8,475,417, Patent No. 8,545,460, and Patent No. 8,805,478.[1] But rather than patenting the apparently new capability of the vascular access ports to withstand the heightened pressures and flow rates of power injection, the asserted patents instead focused on the labeling of such ports for that purpose. Claim 1 of the '460 patent fairly represents the lot:

> 1. A system for identifying a power injectable vascular access port, comprising:
>
> [a] a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;
>
> [b] a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature comprising a radiographic marker identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port; and
>
> [c] a second identifiable feature separated from the subcutaneously implanted access port, the second feature visually observable following subcutaneous implantation to confirm that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

Asserted claim 4 of the '460 patent adds the requirement that the "radiographic marker [be] selected from the group consisting essentially of an observable pattern, a symbol, a

[1] The three share a specification and trace either directly, by continuation, or division to application no. 11/380,124.

typographical character, an indicium, and combinations thereof." Asserted (dependent) claims 5[2] and 12[3] of the '417 patent recite the same substance in the form of "[a]n assembly for identifying a power injectable vascular access port," additionally requiring the "radiographic marker [to be] one or more radiographic letters." And asserted (dependent) claim 3[4] of the '478 patent recites the method of using such labeled vascular

[2] Claim 1 of the '417 patent reads:

An assembly for identifying a power injectable vascular access port, comprising:

[a] a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

[b] a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

[c] a second identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the second feature identifying the access port as suitable for accommodating a pressure within the cavity of at least 35 psi, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

[d] a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is both suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi.

[3] Independent claim 8 of the '417 patent reads:

An assembly for identifying a power injectable vascular access port, comprising:

[a] a vascular access port comprising a body defining a cavity, a septum, and an outlet in communication with the cavity;

[b] a first identifiable feature incorporated into the access port perceivable following subcutaneous implantation of the access port, the first feature identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port;

[c] a second identifiable feature incorporated into the access port separate from the first identifiable feature, the second feature perceivable following subcutaneous implantation of the access port to identify the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port, wherein one of the first and second features is a radiographic marker perceivable via x-ray; and

[d] a third identifiable feature separated from the subcutaneously implanted access port, the third feature confirming that the implanted access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port.

[4] Claim 1 of the '478 patent reads:

A method of performing a power injection procedure, comprising:

[a] taking an x-ray of a subcutaneously implanted access port in a patient to determine whether the access port includes a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second through the access port, the access port defining one or more fluid reservoirs, each fluid reservoir accessible through a cannula-penetrable septum;

[b] identifying the indicating radiographic feature on the x-ray; and

[c] flowing a fluid through the access port at a rate of at least 1 milliliter per second.

access port in a power-injection procedure, again also requiring the radiographic marker to be "a radiographic letter."

In 2015, Bard sued Angio for patent infringement. Following discovery and claim construction, D.I. 156, the parties proceeded to trial in March 2019. At the close of Bard's infringement case-in-chief, the Court granted judgment as a matter of law to Angio on noninfringement, but chiefly, on invalidity, finding the asserted claims invalid for recitation of patent ineligible print matter with no redeeming inventive concept. The asserted claims, the Court found, did not capture the technical developments in crafting a power injectable port but instead merely recited the labeling and instructions—print matter—of a port for such use. *C R Bard Inc. v. AngioDynamics Inc.*, 382 F. Supp. 3d 332 (D. Del. 2019); *see also*, *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208 (2014).

The Court of Appeals for the Federal Circuit agreed that the claims recited generally ineligible print matter but disagreed with this Court's ultimate conclusions. Specifically, an inventive concept could be discerned:

> When each claim is read as a whole, the focus of the claimed advance is not solely on the content of the information conveyed, but also on the means by which that information is conveyed. In particular, the claimed invention is described in the patents as satisfying a specific need for easy vascular access during CT imaging, and it is the radiographic marker in the claimed invention that makes the claimed port particularly useful for that purpose because the marker allows the implanted device to be readily and reliably identified via x-ray, as used during CT imaging.

Thus, the panel ruled, "the asserted claims are not patent ineligible under [35 U.S.C.] § 101 because the claims in their entireties are not solely directed to printed matter." The panel also cautioned this Court against granting judgment as a matter of law before Bard's rebuttal case on invalidity. *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1380,

1384 (Fed. Cir. 2020). With this guidance, the Court and the parties reconvened in November 2022.

An eventful retrial followed. Bard's first witness, named-inventor Kelley Powers, admitted on direct examination that the novelty of the PowerPort lay neither in creating a power-injectable port nor in making one radiographically visible, but instead in crafting a reliable radiographic label and in tightening the manufacturing tolerances of an existing port design such that it would endure repeated power injection, each to a satisfactory degree of safety.

Then, in a surprise twist, Bard's damages expert, Dr. Cox, admitted that in his reasonable royalty calculations he had not apportioned the value imparted by each discrete aspect of the allegedly infringing products, but simply picked a royalty rate based upon the entire revenue of the products that seemed "fair" to his mind. Under long-standing guidance from the Federal Circuit, *see, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 977 (Fed. Cir. 2018), this Court had no choice but to strike Dr. Cox's testimony in full. Aiming to salvage at least an untainted infringement and validity verdict, though, the Court bifurcated the trial, giving Bard a chance to redeem its damages case at a later date.

As will be detailed below, throughout the trial, Bard's witnesses, both percipient and expert, flouted the Court's claim construction order, construing newly-material terms for the first time. Remedial attempts evidently failed. After five hours of deliberation, the Tuesday before Thanksgiving, the jury returned a blanket verdict for Bard: direct infringement, induced infringement, willful infringement, novelty, nonobviousness, and

rejecting AngioDynamics' prior use defense. D.I. 565. Angio now moves for judgment as a matter of law of invalidity, noninfringement, and nonwillfullness. D.I. 576.

LEGAL STANDARD

Judgment as a matter of law may disturb a jury verdict if, and only if, a party has been fully heard on an issue *and* "the record is critically deficient of the minimum quantum of evidence upon which a jury could reasonably base its verdict." *C R Bard Inc.*, 979 F.3d at 1378; *Pitts v. Delaware*, 646 F.3d 151, 155 (3d Cir. 2011) (cleaned up). In invoking this "sparingly" used remedy, the Court must view the record in the light most favorable to Bard, giving it the advantage of every fair and reasonable inference, and refrain from substituting its own view of the facts. *Marra v. Philadelphia Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge"—though a court should disregard evidence, even favorable to Bard, that the jury is not required to believe. *Reeves v. Sanderson Plumbing Prod., Inc.*, 530 U.S. 133, 150–51 (2000).

Judgment as a matter of law may be appropriate, however, when based on a legal determination not itself premised on a rejection of the jury's findings. *Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 211 (3d Cir. 2009). After all, claim construction, along with its "evidentiary underpinnings," remains "exclusively" the Court's realm. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (2015).

DISCUSSION

This case highlights the danger in construing claim terms during discovery, without the context of infringement and invalidity cases. At claim construction, D.I. 156, the Court

understood the claimed port descriptors "suitable" for power injection and "identifiable" as such as characteristics present or not—as though flipping a light switch—in a port. Five-and-a-half years on, trial testimony reveals otherwise.

As Mr. Powers detailed, Bard's task lay not in crafting a power-injectable port from a blank slate, but in modifying the manufacturing tolerances of then-existing ports to make them "suitable" for power injection. Previous ports, such as Bard's Adult Titanium which had been on the market since 2003, *had* successfully endured power-injection procedures, and those that had failed had not necessarily done so in the first instance. This makes sense—vascular access ports facilitate not just one but *repeated* injections, such as multiple CT scans over time to track a course of treatment. '460 pat. at 2:35–8. The repeated cycles of power-pressurization and depressurization, like a balloon blown up and deflated or a paper clip folded back and forth, over and over, wear the port until it fails. A power-injectable vascular access port may be designed for five cycles, ten, twenty, or thirty, before the device must be replaced. D.I. 580 at 163 (Tr. 2-380:24–83:6, Tr. 2-389:13–90:18) (Powers); D.I. 581 at 206 (Tr. 3-747:8–14), D.I. 582 at 49 (Tr. 4-872:3–10) (Dr. Clark); D.I. 584 at 178 (Tr. 6-1652:23–53:16) (Dr. Johnson); PX-69 at 143–44, 174 (letter dated July 14, 2006 from Chiu Lin, PhD., FDA, to Susan Scott, Bard Access Systems, Inc., re Section 510(k) Premarket Notification No. K060812); PX-488. The question was not then whether a vascular access port was suitable for power injection, but *how* suitable.

So too, as Mr. Powers explained, the distinct shape, patient records, and radiographic markers served the reliability of port identification. Removal of the features would not render a port invisible once implanted. It could still be seen and felt under a

patient's skin and viewed under X-ray. The radiographic "CT" granted doctors certainty. D.I. 580 at 166 (Tr. 2-383:4–6, Tr. 2-395:20–96:7, Tr. 2-404:17–05:7) (Powers). Again, the question was not whether a vascular-access port was identifiable as power injectable, but *how* identifiable.

It should go without saying that Bard's new trial constructions of "suitable" and "identifiable" and the failure of the jury instructions to adequately account entitles AngioDynamics to a new trial—defendants being entitled to a properly instructed jury.[5] *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1352–53 (3d Cir. 1991); *E.E.O.C. v. State of Del. Dep't of Health & Soc. Servs.*, 865 F.2d 1408, 1413 (3d Cir. 1989); Fed. R. Civ. P. 59(a). Yet a simpler path than retrial appears. Under Bard's new constructions, imbued variously with the medical standard of care or safety to the FDA's satisfaction, the claims recite patent-ineligible subject matter. Stripped of such of considerations of safety and reliability—under the constructions Bard litigated for years—Bard's own Adult Titanium port, among others, anticipates the asserted claims. And construing the terms anywhere in between these bounds renders the claims indefinite.

Before diving in, however, it's worth noting some running themes. First, noted yet largely inchoate through trial and post-trial briefing, this case spans the ken of two federal agencies. While the PTO governs the patents, *the FDA governs* the marketing of the ports themselves. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); 21 C.F.R. § 807.87(e). The FDA asks whether a device is safe and effective for its intended purpose. The patentability inquiry asks what a device teaches. Unsurprisingly, the ultimate-structural capacities, potential

[5] This order does not address the remainder of Bard's alleged claim reconstructions.

uses, and teachings of a medical device fall, often enough, beyond what the FDA would consider safe and effective use. So, as will be seen throughout, Bard's continual reliance on labels or FDA "indication" does not actually answer Angio's reliance on test data to prove the prior-art ports' capabilities.

Second, "the rule of law embodies evenhandedness . . . sauce for the goose is normally sauce for the gander." *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. ___, 138 S. Ct. 2361, 2385 (2018) (Breyer, J., dissenting). In patent, this timeless tenet of the common law takes a simple form: a patent owner's infringement and invalidity cases *must* conform. *CommScope Techs. LLC v. Dali Wireless Inc.*, 10 F.4th 1289, 1299 (Fed. Cir. 2021); *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1449 (Fed. Cir. 1984). Time and again, then, the testimony of Bard's validity expert, Dr. Johnson, must be discarded because Bard's infringement expert, Dr. Clark, testified otherwise.

Third, with the patent owner's privilege to act as lexicographer, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005), comes the price that it will be held to that use of the term. As corollary to the previous, obviously, terms must take the same construction for infringement and validity. Most dispositive, as will be seen, will be Bard's definition of "power injection." Use of the phrase by others need not convey the specific claimed flow rate and pressure parameters. But, having defined "power injection" in the patents and in this case to mean those specific parameters, Bard's own use, or incorporation without clarification, of the phrase necessarily conveys that meaning. Introductory matter complete, this order turns to the merits.

1. According to Bard, "Suitable" and "Identifiable" Mean Safely So

Undisputedly (as will be detailed later), Bard's precursor to the PowerPort, the Adult Titanium could endure power injection—albeit only those batches built closer to design specification. D.I. 580 at 197 (Tr. 2-414:23–17:17, Tr. 2-495:10–19, Tr. 2-503:15–06:7); D.I. 581 at 26 (Tr. 3-567:9–68:12, Tr. 3-620:21–21:6) (Powers); D.I. 583 at 252 (Tr. 5-1405:5–7) (Kevin Sheetz); PX-69 at 142, 174 (FDA 510(k) Premarket Notification Letter); DX-41 (Bard Document P57279, Rev. 000, *PowerPort Equivalency to the Titanium Adult Port Protocol* (Oct. 2005)). The problem for Bard's engineers to solve was safety. Mr. Powers testified:

> Q. Okay. Now when you said before that the current ports weren't structured for power injection, would it have been dangerous from your perspective to hook up the power injector to your existing ports in 2002?
>
> A. Absolutely. It would be Russian roulette to do that.
>
> Q. By Russian roulette, what do you mean?
>
> A. Well, what I mean is [that] it might work one time. It might work ten times. You might damage the device, and it could fail another time, or it could fail outright or not fail. So unless you knew for sure, *it wasn't safe*. The consequences of failing are too serious.

D.I. 580 at 165 (Tr. 2-382:17–83:6). Mr. Powers continued:

> [Prior ports] weren't structured [for power injection] because it is important that if a device is used for something like that and there—every condition, under every—for the first stick or the hundredth stick, after two days or after two years, *that it performs safely* for that entire period.
>
> * * *
>
> [T]hey *have to be safe* under all conditions. . . you can't tolerate one in a million.
>
> * * *
>
> [I]t had to be a port structurally capable of handling all the extremes of this application.
>
> * * *

> The definition of "power injectable" means that *it is safe* under—safely used under all the use conditions.
>
> * * *
>
> [P]ower injectable to me means that *it has to be safe with high certainty* under all the conditions. Not just some of the time, all of the time.

D.I. 580 at 164 (Tr. 2-381:3–8, Tr. 2-390:9–18, Tr. 2-432:9–13); D.I. 581 at 54 (Tr. 3-595:4–6, Tr. 3-618:25–19:3).[6]

> Bard's infringement expert, Dr. Clark, agreed:
>
> [I]t was known at the time to those of us in the field that if you power injected a port, you were placing the patient at risk. It might work at times. At other times, it could result in a catastrophic complication. Most of us didn't do it because there was no product available to be able to do that.

D.I. 581 at 206 (Tr. 3-747:8–14, Tr. 3-756:10–14).

And so did Bard's validity expert, Dr. Johnson. "[T]he problem at the time, was people who had these patients, like me, didn't know *whether it was safe* to [power inject]."

D.I. 584 at 171 (Tr. 6-1645:22–24, Tr. 6-1651:2–8).

> Testing, however, revealed the solution. Mr. Powers again:
>
> Q. You said you tested [the] Adult Titanium Port, and sometimes it would pass and sometimes it would fail?
>
> A. Yes.
>
> * * *
>
> The nominal dimension is sort of the target, but everything you manufacture has certain natural variation as part of the process.
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> * * *
>
> So what we found was the variation in all of these component parts, when you added them all up into this assembly, was too much. And on the boundaries, it would fail. In the center, it wouldn't. That was really important information . . . [W]e needed to control these dimensions.

D.I. 580 at 196 (Tr. 2-413:23–17:17). In other words, the problem wasn't designing the first port capable of power injection—it was modifying the design of the Adult Titanium

[6] Emphasis added throughout unless noted.

port to ensure safety and reliability in power injection. And the solution, Bard engineers determined, was to tighten the Adult Titanium's manufacturing tolerances. On this demonstration of safe and reliable use for power injection, the FDA approved Bard's Power Port. PX-69 (FDA 510(k) Premarket Notification Letter).

Beside touting its own achievement as one of safety, Bard imbued its asserted claim with this notion of safety to avoid the admittedly-power-injectable prior art. Sometimes it stated that outright. For example, Dr. Clark overtly invoked safety to distinguish power injection with a Vortex port: "Q. . . . Dr. Clark. Prior to 2006, did you consider any Vortex ports to be power injectable? A. I did not. Q. Why not? A. It's not safe to do so. It could result in catastrophic failure and hurt the patient." D.I. 581 at 253 (Tr. 3-794:22–95:17); D.I. 580 at 163 (Tr. 2-380:2–83:6), D.I. 581 at 66 (Tr. 3-607:12–24) (Powers); D.I. 584 at 194 (Tr. 6-1668:4–69:25) (Dr. Johnson). Often Bard relied on product labeling or FDA indication to imply it. For example, Mr. Powers described Bard's endeavor to obtain FDA approval for the PowerPort:

> A. . . . [W]e [we]re creating a new—a new port family with the ability to—it [was] structured for these kinds of things and also indicated for these procedures.
>
> Q. Okay. When you say "indicated," does that mean the FDA?
>
> A. It means, yeah, the FDA agreed. We supported it with data.
>
> * * *
>
> [T]hey expect us to understand the use environment and simulate the use environment for all of our engineering so it's not just a matter of engineering in a vacuum. It has to be safe and effective for its intended use, and as I said, even for sometimes unintended use, so they expect us to confirm that and ask us to support it.

D.I. 580 at 234 (Tr. 2-451:5–52:4); *see also*, D.I. 584 at 196 (Tr. 6-1670:14–71:11) (Dr. Johnson quoting port label). Thus, under Bard's own telling at trial, a port "suitable" for power injection is one safe for it.

Bard likewise construed "identifiable." Mr. Powers: "[A] big challenge for this product would be if we structured the product to handle all of the strains of power injection, how could you tell in a patient with *extreme certainty and never misidentify it*? How could you do that?" D.I. 580 at 178 (Tr. 2-395:20–25, Tr. 2-396:1–5).

He continued:

> [I]t has to be foolproof . . . [I]t was critical not—to not just have a port that was structured for power injection but also have one that you could, with great certainty, discern—a clinician can discern in patients and not make a mistake.
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> * * *
>
> [W]e needed a way that would be recognizable to everybody who might potentially try to identify it.
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> * * *
>
> [I]it had to be identified with great certainty by a number of different people.
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> * * *
>
> And so our goal here is to have a really foolproof identification that—because it's a—because it will affect patient safety.
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> * * *
>
> [I]t had to be reliably discernable from everything else that was in the market at the time so that clinicians could recognize it with great certainty, make a decision about it to—make a decision to use it for power injection.
>
> * * *
>
> [I]f they [mistook] a port that wasn't structured for power injection and they power injected it at these levels that were routine, they could have a failure.

D.I. 580 at 187 (Tr. 2-404:20–05:7, Tr. 2-431:12–16, Tr. 2-432:9–13, Tr. 2-434:19–35:9); D.I. 581 at 77 (Tr. 3-618:1–12).

> Again, Dr. Clark agreed:
> You had no means for being able to reliably and accurately identify a port as structured for power injection.
>
> * * *
>
> That's fundamental to the inventiveness of the technology. So again, it's to ensure that the ports structure[d] for power injection can be absolutely reliably identified with a hundred percent certainty every time.

* * *

> [The] [r]adiographic marker is something that you can visualize after the port has already been implanted into the patient and that it can be seen with X-ray, either scout scan or chest X-ray or some other form of X-ray, with a highly characteristic shape that's not going to confuse it with another structure that isn't a power injector.
>
> * * *
>
> [Bard's instructions] provide further assurance that the ports can be safely identified as being structured for power injection and then used for that purpose.

D.I. 581 at 205 (Tr. 3-746:21–23, Tr. 3-749:21–25, Tr. 3-750:7–14, Tr. 3-766:14–20).

And again, Bard distinguished prior art on the grounds that it wasn't reliably identifiable enough. D.I. 584 at 191 (Tr. 6-1665:14–17, Tr. 6-1670:5–10, Tr. 6-1671:24–73:24, Tr. 6-1689:10–15) (Dr. Johnson). In sum, again under Bard's telling at trial, a port "identifiable" as power-injectable is one safely and reliably identified as such.

2. The Asserted Claims Recite Ineligible Subject Matter

But Bard's reframing of the asserted claims invalidates them. Patents don't cover natural phenomena or abstract ideas, absent some transformative addition. *Alice Corp. Pty.*, 573 U.S. at 216; *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66 (2012).[7]

"[A] claimed invention must embody a concrete solution to a problem having the specificity required to transform a claim from one claiming only a result to one claiming a way of achieving it." *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1343 (Fed. Cir. 2018) (quotation omitted). "An improved result, without more stated in the claim" does not "confer eligibility to an otherwise abstract idea . . . To be patent-eligible, the claims

[7] Angio renews its argument that recitation of print matter accompanied by a trial record revealing no transformative concept renders the asserted claims invalid. Bound by the Federal Circuit's prior ruling, the argument is preserved for appeal.

must recite a specific means or method that solves a problem in an existing technological process." That bears repeating—the claim itself must "sufficiently capture the inventors' asserted technical contribution to the prior art by reciting how the solution specifically improves the function of prior art . . .." *Koninklijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143, 1150–51 (Fed. Cir. 2019) (emphasis added); *see also Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019); *Vanda Pharms. Inc. v. W.-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1121, 1134 (Fed. Cir. 2018); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016).

With due care to neither oversimplify the invention, *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1347 (Fed. Cir. 2017), nor fall draftsman's prey, *Mayo*, 566 U.S. at 72, *by Bard's own word* the "focus" of the asserted claims and their "character as a whole" lies in the concept of safety, *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). By "suitable" for power injection, Bard claims merely the degree of safety and reliability necessary to secure FDA approval. And by "identifiable" as such, Bard claims merely the medical standard of care—recognition of a port such that doctors would be comfortable power injecting. Both standards comprise human judgments of risk tolerance, and thus, Bard claims an abstract solution to human, not technical, problems.

The technical solutions Bard didn't patent prove telling. Bard patented neither power injection, nor the design parameters of a power-injection capable port, nor the process to manufacture a power-injectable port. The claims omit any reference to the tightened tolerances. Bard claimed neither discovery of nor improvement to x-ray, radio-opacity, or radiographic letters. It does not purport to have invented the identification of subcutaneous medical devices via x-ray, with or without radiographic marking. Bard did

not patent improved radiographic marking, or an improved process for radiographic marking, such as better etching or film inlays. Nor did Bard claim an improved arrangement of radiographic makers to make a port recognizable. The focus of the claims, distilled from the prior art, according to Bard, is that it designed a port the FDA deemed safe and reliable for power injection and safely and reliably "identifiable" as such to doctors. Safety and reliability, however, are unquestionably abstract ideas. *See Mayo*, 566 U.S. at 77–79.

Nor do the claims recite a redeeming inventive concept, transforming the claims into a patent-eligible application of the underlying abstract concept. *Alice*, 573 U.S. at 221. "[A]n inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces." *Bascom Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). Though "the components must involve more than performance of well-understood, routine, conventional activit[ies] previously known to the industry." *In re TLI Commc'ns LLC Pat. Litig.*, 823 F.3d 607, 613 (Fed. Cir. 2016) (quotes omitted). Generally, "[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact" which may involve extrinsic evidence or testimony. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). The present matter, however, lacking dispute of material fact, is appropriate for the Court's disposition.

A transformative concept regarding the claimed "suitability" for power injection can be easily dismissed. No one, let alone the asserted claims which wholly ignore the topic, even pretends that the effort to refine the existing structure of the Adult Titanium port into the PowerPort contained an inventive spark. Nor could they—structural testing and the

narrowing of manufacturing tolerances being the bread and butter of mechanical engineering.

This lapse alone condemns the asserted claims to invalidity. But, given the effort expended on the patentability of the radiographic indicia throughout this case, it is worth evaluating their transformativeness. Following trial, it is indisputable that medical devices with radiographic markers and lettering were known in the prior art, as the witnesses agreed across party lines. D.I. 582 at 243 (Tr. 4-1066:24–67:4 (stipulated facts), Tr. 4-1110:14–11:7) (Kenneth Eliasen); D.I. 583 at 122 (Tr. 5-1275:20–76:3) (former-Angio engineer Anthony David Smith); D.I. 584 at 69 (Tr. 6-1537:6–43:20 (Dr. Vogelzang), Tr. 6-1696:6–97:20 (Dr. Johnson)); *e.g.*, DX-539 (U.S. Pat. 6,287,239 to Jones, *et al.*); DX-540 (U.S. Pat. 4,863,470 to Carter). Indeed, as former-Bard-engineer Mr. Eliasen told the PTO in a different proceeding, any skilled artisan would have known how to do it:

> Because (i) the housing base provides the largest outside surface to place the radiopaque indicia, (ii) locating the indicia on the housing base has the least impact on the functionality of the port, and (iii) placing the radiopaque markings on the outside surface of the housing base (i.e., the bottom of the port) requires relatively simple manufacturing processes, the outside surface of the housing base location would have been obvious to try, as evidenced by the fact that nearly every port has a lot number and/or company logo printed, embossed, engraved, etc. on the bottom of the housing base, i.e., one of ordinary skill in the art in the 2006 timeframe would have immediately thought to put the radiopaque markings on the housing base.

DX-977 at ¶ 38 (Eliasen Declaration). And, it should go without saying, there's nothing inventive about using the abbreviation "CT" to convey suitability for use in conjunction with a, wait for it, CT scan. Simply put, no *technical* hurdle prevented application of radiographic indicia indicating suitability for power injection to a port.

Instead, Bard simply discovered that doctors and medical professionals liked the radiographic marker and felt confident enough to perform power injections after seeing

the markers via x-ray. D.I. 580 at 227 (Tr. 2-444:13–25), D.I. 581 at 44 (Tr. 3-585:15–86:8, Tr. 3-599:2–22, Tr. 3-617:6–18:12; 3-626:9–15) (Powers). In fact, having initially launched the titanium PowerPort *without* the "CT" label, Bard *added* it after seeing how popular it was on the plastic PowerPort MRI. As Mr. Powers explained: "[W]e launched this as the plastic PowerPort, and the CT marker radiopaque feature was so preferred and popular that we decided to do it with the titanium also." D.I. 580 at 282 (Tr. 2-449:3–12); *see also*, D.I. 581 at 61 (Tr. 3-602:7–24). Indeed, as Bard proclaimed, medical professionals' preference for the specific label (and thus its incorporation into medical standard of care) drove Angio to incorporate it—and at this point would prevent them from removing it. D.I. 580 at 273 (Tr. 2-490:11–20) (Powers); D.I. 581 at 222 (Tr. 3-763:11–12), D.I. 582 at 35 (Tr. 4-859:2–3) (Dr. Clark), *see also, e.g.*, PX-123 at 1 (Erin Young, AngioDynamics, mem. re Infusion Nurses Society Annual Meeting (Aug. 14, 2007)); PX-271 (Danny Garrison, Market Summary Report (August 2007)).

And as Dr. Clark admitted, the remaining method limitations, directing an x-ray to identify the port and performing the power injection, describe merely the ordinary use of the port under the medical standard of care. D.I. 581 at 236 (Tr. 3-777:6–83:8); *see also* D.I. 584 at 57 (Tr. 6-1531:4–34:15) (Dr. Vogelzang concurring). Obviously enough, recitation of a natural phenomenon with the bare command, "apply it," does not transform an abstract idea into a patentable application. *Mayo*, 566 U.S. at 77–78.

At bottom, vascular access ports were already power injectable, so that step wasn't patentable. Radiographic indica were known; that addition wasn't patentable. And medical preference for radiographic indicia is just the standard of care; so, it's also not patentable. Which leads us, yet again, to the crux of the case. The supposed invention

here is Bard's application of a radiographic indicia to a port to convey to medical professionals that the port is power injectable. The hurdle Bard had to overcome to achieve that development was the FDA. That is, manufacturers may only apply to a port a radiographic label indicating suitability for power injection *because the FDA lets them*. It hardly needs be said; obtaining FDA approval to market is routine in the medical device industry.

Under Bard's own telling at trial, then, the asserted claims recite patent-ineligible subject matter.

3. The Asserted Patents Are Invalid for Indefiniteness.

Even assuming the recitation of safety does not render the asserted claims ineligibly abstract, they would remain invalid, for a claim must delineate its bounds with "with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

If not to the FDA's satisfaction, just what rates a port as safe for power injection? Beyond the obvious avoidance of port rupture, the patents do not say. The only statements on point,

> Further, an access port may be identified by a maximum rate at which fluid may safely be infused.
>
> * * *
>
> In one embodiment, at least one physical attribute (e.g., size, shape, etc.) of an access port may identify the access port as suitable for power injection or may identify a maximum flow rate or pressure that may be safely accommodated by the access port.

fail to define the terms, leaving the meaning to those skilled in the art, that is, the medical standard of care. '460 pat. 25:54–55, 63–67.

To be sure, no one would call the medical standard of care "purely subjective." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). Patient wellbeing and some degree of communal consensus would seem to provide an "objective baseline." *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1378 (Fed. Cir. 2017). Yet the standard varies according to the subjective judgment of each professional based upon their individual training, experience, risk tolerance, and circumstance. And while perhaps this variation alone would not render the claims indefinite, *Interval*, 766 F.3d at 1370, the trial record reveals a marked disjoint.

Some doctors considered prior ports safe for power injection. Dr. Vogelzang, considering Bard's test data, Bard-witness testimony, and independent-published test data, considered the Adult Titanium suitable for injection at the claimed parameters. D.I. 584 at 39 (Tr. 6-1513:1–15:18). Considering hospital protocols and two sets of independent and published test data, Dr. Vogelzang concluded the Port-A-Cath suitable for power injection. D.I. 584 at 43 (Tr. 6-1517:8–19:14). And considering Angio test data and submissions to the FDA, Dr. Vogelzang considered the Vortex port suitable for power injection. D.I. 584 at 46 (Tr. 6-1520:11–22:7). Other doctors, including Dr. Scott Trerotola at the University of Pennsylvania, agreed. D.I. 584 at 48 (Tr. 6-1522:13–23:1). Dr. Johnson disagreed. D.I. 584 at 195 (Tr. 6-1669:2–6, 6-1671:7–11, 6-1675:13–19).

Some doctors recognized, or trusted their recognition of, the shape and characteristics of the various ports under x-ray. Dr. Vogelzang thought the Adult Titanium, Port-A-Cath, and Vortex ports readily identifiable in his own experience and according to his training. D.I. 584 at 26 (Tr. 6-1500:23–02:9, 6-1525:2–18) (Adult Titanium), (Tr. 6-1516:1–2, 24–25, 6-1527:14–21, 6-1528:15–18) (Port-A-Cath), (Tr. 6-

1529:1–11) (Vortex). Notably, *Bard's* Dr. Clark agreed that similar features identified ports under x-ray. D.I. 581 at 226 (Tr. 3-767:15–23, 3-770:24–71:3, 3-774:12–16, 3-778:19–23 (Bard's Power Port), 4-837:4–13 (Angio's SmartPort). Dr. Johnson disagreed. D.I. 584 at 187 (Tr. 6-1661:2–4, 6-1663:13–15, 6-1665:10–17, 6-1670:6–9, 6-1672:5–73:20, 6-1676:5–22).

The issue here is not an evidentiary discrepancy between experts—that would be a question for the jury. It is instead that equally qualified and respected doctors, in the exercise of their medical judgment, reach different conclusions. The Court discerns, and Bard cites no, evidence upon which the jury could reasonably have disregarded Dr. Vogelzang's testimony that *he* could recognize each of the prior art ports and deemed them safe for power injection, or that Dr. Trerotola found the Vortex port safe for power injection, or that Dr. Clark found various ports identifiable based on shape. Dr. Johnson's testimony that, in *his* judgment, the ports were not sufficiently identifiable is to not the contrary. Nor is his and Dr. Clark's testimony that, in *their* judgment, the ports would not have been safe for power injection. Whether or not an *identical* medical device infringes (or anticipates) a patent cannot depend on which doctor, according to their own unchallenged medical judgment, uses it. *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 635 (Fed. Cir. 2015).

This aside, the asserted claims are also indefinite because, as the trial record shows, vascular access ports are not designed for endless use but are designed with a specific life span—in the Bard PowerPort's case, twenty-one power injections. PX-69 at 173–44 (FDA 510(k) Premarket Notification Letter). The limiting factor is material fatigue, the cyclic wear of the device after repeated pressurization and depressurization; a port

becomes less "suitable" for power-injection with *every use*. And so, without indication a port that *looks* suitable, becomes unsuitable. PX-488 (FDA - Caution on Power Injection of MRI and CT Contrast Media (October 2005)); D.I. 580 at 165 (Tr. 2-382:25–83:3, 2-389:13–23) (Powers); D.I. 581 at 206 (Tr. 3-747:8–14) (Dr. Johnson). Naturally, the claims do not purport to cover a port suitable for unlimited power injection—Bard has not invented that. *E.g.* *O'Reilly v. Morse*, 56 U.S. 62, 113–14 (1853). Yet, as Dr. Clark confirmed, the asserted claims recite no port-lifespan. D.I. 582 at 49 (Tr. 4-872:3–10). Read in light of the specification (which fails to mention the matter), the claims fail to denote whether they capture a port suitable merely for twenty-one injections—as Bard developed—or for twenty-two injections, let alone thirty, forty, or as Mr. Powers referenced at trial, one hundred. D.I. 580 at 164 (Tr. 2-381:3–8). That is, only the vagaries of Bard's whim tell the skilled competing artisan whether the asserted claims cover a longer-lasting port. *Dow*, 803 F.3d at 635.

4. Bard's Own Existing Port Anticipates the Asserted Claims

Assuming the Court were to reject Bard's reinterpretation of the claims and return to the construction under which Bard has litigated for years, D.I. 156, the trial record leaves no room for a reasonable jury to conclude but that several prior art references each anticipate the asserted claims, reciting each and every limitation. *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1306 (Fed. Cir. 2019).

A step not to be taken lightly—especially as *Angio*, not Bard, bears the burden of proof on this front—judgment as a matter of law probes not just the sufficiency of the evidence, but its overwhelming effect. And while it can hardly be said that a *properly* instructed jury has decided the case, given the claim construction debacle, nevertheless,

to find the asserted claims anticipated, "[t]he Court must be able to say not only that there is sufficient evidence to support the finding, even though other evidence could support as well as contrary finding, but additionally that there is insufficient evidence for permitting any different finding." *Bayer Healthcare LLC v. Baxalta Inc.*, 407 F. Supp. 3d 462, 469 (D. Del. 2019) (citing *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976)) (cleaned up).

Angio offers three anticipatory prior-art ports: Bard's own Adult Titanium marketed since 2003; the Port-A-Cath, manufactured in various corporate iterations by Pharmacia Deltec, Smiths Medical, and now ICU Medical, marketed since at least 1992; and the Vortex Access port, manufactured by Horizon Medical Products (then RITA Medical Systems, now Angio) since at least 2002. DX-77 (Bard Access Systems, Inc. Product Brochure (2003)); DX-81 (Carlson, *et al.*, *Safety Considerations in the Power Injection of Contrast Media Via Central Venous Catheters During Computed Tomography Examinations*, 27 INVEST. RADIOL. 337 (1992)); DX-509 (Horizon Medical Products, *2002 Product Catalog*). Given the patents' critical date of April 25, 2005, no one disputes that these ports constitute prior art under 35 U.S.C. § 102.[8] Review of the trial record, guided by the governing law and proper claim construction, reveals that the jury had *no sufficient basis* to reject that Bard's Adult Titanium, the Port-A-Cath, and the Vortex ports each anticipate the asserted claims.

Taken together, as Bard told the jury, the asserted claims of the '460 and '417 patents recite: (1) a vascular access port suitable for power injection; (2) a palpable feature; (3) a radiographic feature comprising an observable pattern or symbol or the like;

[8] For what it's worth, the pre-America Invents Act version of the statute governs here.

and (4) an external feature, including an ID card, key ring, bracelet, or similar identifier carried by the patient. No one contests that prior art ports included both palpable features—as Dr. Clark admitted, port shape is palpable through the skin—and external features—every vascular access port includes instructions. D.I. 581 at 232 (Tr. 3-773:22–74:14 (Dr. Clark)); D.I. 584 at 49 (Tr. 6-1523:25–24:16 (Dr. Vogelzang)). The remaining, indisputably on this record, may each be found in the three ports.

The jury lacked sufficient basis to reject the power-injectability of the three prior-art ports

As construed by the Court, the asserted claims recite a port's capacity to withstand 35 psi in the chamber and suitable for a flow rate of at least 1 mL/s. Again, highlighting the dangers of claim construction divorced from a patent owner's infringement case, a few points require resolution. First, the vagaries of safety and efficacy would invalidate the claims under Section 101 or 112 and play no part in the analysis here.

Second, while various witnesses testified to the effects of needle and catheter dimensions on port pressures, and the (in)propriety of inferring port pressure based upon pressure measurements elsewhere in the power-injection system, throughout its *infringement case* Bard interpreted the pressure requirement as being satisfied by a showing of 300 psi or more at the power-injector machine. As Dr. Clark repeatedly testified:

> Q. What does that mean in terms of the internal pressure inside the port cavity when it's operating at the flow rate and 300 psi pressure setting on the power injection machine?
>
> A. That corresponds to a pressure inside the cavity of at least 35 psi.
>
> * * *
>
> [Bard's PowerPorts] are structured to accommodate power injector pressure of 300 psi, which we know corresponds to pressure of at least 35 psi in the cavity.

* * *

Q. Dr. Clark what type of procedures are the AngioDynamics SmartPorts structured to be used in?

A. They're structured to be used for injection of contrast [media] up to 5 milliliters per second and up to 300 psi on the injector, which corresponds to a pressure inside the cavity of over 35 psi.

* * *

Q. What type of procedures are the Xcela ports designed or marketed for, Dr. Clark?

A. These are for doing power-injected CT scans, so power injection with rates of contrast injection up to 5 milliliters per second and pressure ratings on the injector up to 300 psi, which corresponds to a pressure inside the port of 35 psi.

* * *

Q. Dr. Clark, are the Xcela Plus Power-Injectable Ports indicated for power injection procedures involving 5 milliliters per second flow rate and 300 psi on the power injection machine?

A. Yes.

Q. What does that tell you about how the internal cavity port is structured during these procedures?

A. As with the other ports, capable of going up to 300 psi on the power injector machine. That tells us that the pressure inside the cavity itself is in excess of 35 psi.

D.I. 581 at 220 (Tr. 3-761:17–22, 3-775:1–4, 3-789:8–14, 3-804:5–12, 3-809:3–15). Bard doesn't get to choose one claim interpretation for infringement because (placing the cart before the horse) "Angio designed the ports to infringe" and pick another for validity because "those products weren't designed to infringe." The same construction applies to both cases. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1449 (Fed. Cir. 1984).

Third, and the running theme of this case, while the PTO governs the patents, *the FDA governs* the marketing of the underlying medical devices. Labels and instructions do not counter actual test data of a port's capacity.

Turning to those capacities, no great inquiry is required for Bard's Adult Titanium port; Bard itself admitted that at least some of these ports were structurally capable of the claimed flow conditions:

> [A]t least some of Bard's current and former vascular access port models that have not been marketed as being power injectable are structurally capable of withstanding the pressures and flow rate of power injection procedures.
>
> * * *
>
> At least as early as 2005, Bard's commercially marketed vascular port product, the Adult Titanium port, was structurally suitable for power injection, although it had not yet been approved for such use.
>
> * * *
>
> Q. What Bard ports were capable of withstanding the pressures of power injection?
>
> A. The Adult Titanium Port, for sure.

D.I. 530-1, Ex. 1 ¶ 37, Ex. 1a ¶ 8 (statements of undisputed facts); D.I. 583 at 252 (Tr. 5-1405:5–7 (Kevin Sheetz)). After all, Bard used hand-picked Adult Titanium ports to prove up the power-injectability of its patent-practicing PowerPort. D.I. 580 at 278 (Tr. 2-495:10–19; 2-503:15–06:7); D.I. 581 at 26 (Tr. 3-567:9–68:12 (Powers)).

Setting aside the admitted facts, and the data submitted to the FDA, one might quibble that some of Bard's witnesses only ever admitted its Adult Titanium suitable for "power injection," and never specified the pressure and flow rate parameters. But recall that, as lexicographer, Bard has defined the meaning of "power injection" here as the claimed pressure and flow rates, has actively wielded that definition to distinguish prior art, and may not selectively recant.

That only a subset of Adult Titanium ports proved structurally capable of power injection is of no consequence. Imperfect practice is enough. *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003). And the repeatedly invoked

various (unclaimed) changes between the Adult Titanium and the PowerPort served safety and reliability, not satisfaction of the basic claim requirement.

The Adult Titanium alone would be enough, yet evidence confirmed that the Port-A-Cath too could sustain a flow rate of 1 mL/s and injection-machine pressure of 300 psi. Regardless of the port labeling, in 2005, Gebauer *et al.* successfully achieved flow rates in a Port-A-Cath of 2.3, 4.2, 6.2, and 8.2 mL/s, at machine pressures of 191, 333, 352, and 371 psi, respectively, without rupture or disconnection. DX-529 (translated copy of Gebauer, *et al.*, *Contrast Media Power Injection Using Central Venous Port Catheters—Results of an In Vitro Study*, 177 RÖFO 1417 (Oct. 2005)).

Dr. Johnson quibbles with the *duration* of those pressures because, as the study notes, the higher pressures triggered the power-injector machine pressure limit of 325 psi, prompting the machine to either back off to safe pressures or shut down entirely (the study describes both scenarios but does not specify which happened in each test). D.I. 584 at 183 (Tr. 6-1657:4–8). But this misconstrues the claim language as requiring a fluid flow rate of 1 mL/s *at* a chamber pressure of 35 psi throughout. Not so. The claims and specification confirm these to be separate requirements:

> In addition, the housing and septum may be structured for accommodating a flow rate through the reservoir of at least about 1 milliliter per second. In another embodiment, an access port may include a housing and septum, as described above, wherein the housing and the septum are structured for accommodating a pressure developed within the reservoir of at least about 35 psi.

'460 pat. at 3:32–39. Certainly, the flow rate element implies a duration necessary to complete a power-injection, "the access port [i]s suitable for *flowing fluid at a fluid flow rate of at least 1 milliliter per second* through the access port." But the pressure element includes no such language, requiring only that the port be capable of "accommodating a

pressure within the cavity of at least 35 psi." '417 pat. claim 1[c]–[d]. And so, nothing requires these elements be proven in the same go around.

This all makes intuitive sense. The claimed flow rate describes function; the pressure requirement ensures safety. A port might simply be designed, as the Port-A-Cath unquestionably is—to achieve the required flow rate at a lower pressure. In effect, Dr. Clark criticizes Gebauer *et al.* for, having proven the flow-rate capabilities, searching for the pressure failure point and, finding none, triggering instead the *power-injector machine* safety feature. Regardless, as claimed, the Port-A-Cath supports power-injection at 1 mL/s or greater and can accommodate injector-machine pressures well above 300 psi, which Bard confirms indicates a chamber pressure above 35 psi.

Test data also confirms the Vortex's power-injectability. On April 27, 2005—according to his *unchallenged* lab notebook—Angio (then-RITA) engineer Anthony David Smith successfully achieved a flow rate of 5 mL/s at a machine pressure of 305 psi with a stock, already marketed, Vortex port, model No. P5355K. DX-687 at 6 (Smith Laboratory Notebook); DX-509 at 17 (HMP 2002 Catalog); D.I. 583 at 43 (Tr. 5-1196:10–1200:4). Whether or not the FDA thought this data sufficient does not matter here. Bard's best bet might be to note that Mr. Smith's testing came two days *after* the patent critical date of April 25, 2007. But, as Mr. Smith's uncontroverted testimony and the documents make clear, the tested ports had been on the market since 2002.

Bard can neither retract admissions that its own prior port was power-injectable nor challenge the test data, instead continually muddying the waters with irrelevant labels and safety considerations. In sum, the jury had no substantial evidence upon which to reject the objective capabilities of the prior-art ports.

Nor had the jury any sufficient basis to reject the radiographic identifiability of the prior-art ports

As construed, the recited radiographic identifier need be no more than an "attribute . . . perceivable via x-ray." D.I. 156 at 5. And as far as one could "[r]ecogniz[e] that the radiographic attribute on the x-ray identifies an access port as being structured for power injection," *id.* at 6, the patent explains that "identification . . . means the ability to correlate selected information of interest with a perceivable feature," '460 pat. at 25:37–41. Again, considerations of safety and reliability in identifying a port would invalidate the asserted claims and play no part in this analysis.

Now unquestionably, no prior-art port bore a label or instruction for power injection. Nor, without FDA signoff, could they. Of course, as the Federal Circuit held previously in this case, the actual identification of a port as suitable for power injection is printed matter not entitled to patentable weight. 979 F.3d at 1382. The matter must be considered—"we do not strike out the printed matter and analyze a 'new' claim"—but it will not distinguish the claim from the prior art. *In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015); *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). And, as the Court determined at trial, the recitation that the radiographic markers be a letter ('417 pat. claims 5 and 12, '478 pat. claim 3) also rates as print matter. A letter, after all, intrinsically conveys its typographical meaning, and Bard has pointed to no technical hurdle traversed by the asserted claims in making the radiographic marker a letter as opposed to any other indicia. Here then, the analysis asks whether the prior-art ports possessed radiographic attributes by which one skilled in the art could identify the port and, with reference to the label or instructions, determine its parameters of use and, by extension, its suitability for power injection. They did, and the jury had no sufficient basis to reject that fact.

As above, Dr. Vogelzang found each prior-art port readily identifiable in his own experience and according to his training.

> Q. Now let's move to the ports . . . [w]hat do we see here?
>
> A. . . . These are radiographs of the ports to illustrate a basic principle that I was espousing, which is pattern recognition. These are radiographs, and each one has a distinctive, characteristic look that's readily identifiable. The Adult Titanium Port obviously has a certain shape. It has some suture holes and orientation holes. The Port-A-Cath is square. Vortex Access has a distinctive shape as well as the outlet stem. So they are distinctive in and of themselves under a radiograph.
>
> Q. [And] there's a reference up there to the ports being "Aunt Minnie." What does that refer to?
>
> A. Now, "Aunt Minnie" is an interesting term that we used for years in radiology and was taught to radiology residents . . . this concept which has
>
> been widely known and is taught to radiology residents in the first year. It's essentially pattern recognition, and the description is how do I know my Aunt Minnie when I see her across the street? Because I know what she looks like. And the same thing is true in pattern recognition for certain diseases and other anatomy. *That's what these ports are, they are Aunt Minnie in the sense that once I'm told what they are, I know what they are*.

D.I. 584 at 26 (Tr. 6-1500:15–02:9). Regarding Bard's Adult Titanium:

> The radiograph is provided by Bard's expert, Dr. Johnson, and I used this to show the radiographic features which would be present and available and visible on a radiograph, which is the characteristic shape, the so-called "Aunt Minnie" shape, as well as the suture holes, distinctive, as well as the circular holes which they describe as orientation holes, all visible under X-ray.

D.I. 584 at 51 (Tr. 6-1525:2–18). Port-A-Cath:

> Q. What are the radiographic incorporated features of the Port-A-Cath that you've identified here?
>
> A. I've done the same thing, this time, the physical specimen on the left, the radiograph on the right. It's obvious it's different, and we can see it. It has a different, unique square shape and Aunt Minnie, square shape with suture holes at the corners. Obviously, very distinctive, as well as etching, which is present on the physical specimen.

D.I. 584 at 53 (Tr. 6-1527:14–21). And Vortex:

> Q. Let's move to Vortex Access . . . [w]hat are the identifiable incorporated radiographic features you found here?
>
> A. Again, we've arranged them—I arranged them in the physical on the left and the radiograph on the right. The typical Aunt Minnie shape is unique. It has suture holes in a specific outline around the periphery and in this case the tangential outlet stem, which is part of the Vortex technology. It also has that notch at the bottom near the outlet stem which would be very visible.

D.I. 584 at 54 (Tr. 6-1528:23–29:11). And—it cannot be overstated—Bard's infringement expert, Dr. Clark, agreed that port shape and basic features would be among the usual identifiable attributes via x-ray:

> Q. And can you walk us through some of the key steps in the instructions in the CT guidelines?
>
> A. Yes. So[,] it begins with identification to verify that the port is, in fact, a PowerPort.
>
> Q. Okay. And that identification step, that might include looking at the CT marker; is that correct?
>
> A. Yes.
>
> Q. How would that identification be made when looking at the CT marker?
>
> A. Well, the CT marker is visible on scout scan, so the CT technologist or radiologist or combination of the two will look at the image and verify that the triangular shape, that . . . is one radiographic marker and the CT letter is present as the second radiographic marker.

D.I. 581 at 225 (Tr. 3-766:21–67:14). Perhaps grasping the admission in real time, Bard's counsel appeared to attempt a retraction, yet the doctor doubled down:

> Q. I think you misspoke. The triangular shape was a radiographic marker. Were you saying the CT is the radiographic marker?
>
> A. Well, the radiographic lettering is the CT, but the triangular shape is radiographically visible. It's a characteristic.
>
> Q. So you can make out the shape of the triangle—
>
> A. Yes.

Q. —under X-ray, and that's a radiographically made identification?

A. Yes.

D.I. 581 at 226 (Tr. 3-767:12–23); *see also*, D.I. 581 at 229 (Tr. 3-770:24–71:3, 3-774:12–16, 3-778:19–23, 3-779:5–8). The patent specifications naturally agree, '460 pat. at 26:10–45, though Dr. Clark's testimony alone leaves Dr. Johnson without a leg to disagree on. *Kimberly-Clark*, 745 F.2d at 1449.

Yet again, the trial record left the jury with no basis to reject the radiographic identifiability of the prior-art ports.

And the jury lacked sufficient basis to reject anticipation of the method steps

The asserted method claim recites the taking of an x-ray, identification of the port (and by extension its capabilities), and flow of fluid. Again, no radiographic indication of power injectability need be found, nor need medical professionals have searched for such indication. As above, it suffices as a matter of law, that medical professionals looked for radiographic identifying attributes, identified the port, and determined the corresponding pressure and flow-rate parameters. It is also worth noting that while claim 1 (and by extension asserted claim 3) of the '478 patent requires a port capable of specific fluid-flow and chamber-pressure parameters, the third recited step requires its *use* only at the specified flow rate—"flowing a fluid through the access port at a rate of at least 1 milliliter per second"—not at the recited pressure.

But for this fluid-flow-rate requirement, Dr. Johnson admitted that each step would be performed in standard medical practice with an access port, usually by a CT technologist: "[A]n X-ray technologist with further training in performing CT scans and in current era, that includes the identification of ports structured for power injection, accessing those ports, and then flowing contrast [fluid] through those power-injectable

ports to perform contrast and CT scans." D.I. 581 at 239 (Tr. 3-780:23–81:4). First and second, an x-ray to identify the port:

> [T]he patient arrives to the CT scanner. They are positioned on the table of the CT scanner. The CT technologist does this preliminary, quick scan, scout scan, and that image is reviewed to look for the CT lettering and/or the shape of the port.
>
> * * *
>
> A. [A] scout scan is performed 100 percent of the time.
>
> Q. Okay. How do you know that?
>
> A. That is known to everyone who's a practicing radiologist.
>
> Q. As a radiologist, would you find it safe or okay to not do a scout scan prior to a power injection?
>
> A. I would not.

D.I. 581 at 238 (Tr. 3-779:3–8, 3-781:15–23). And third, injection and fluid flow:

> Through accessing the port with a cannula or needle that goes through the skin and into the central reservoir and flowing the X-ray contrast or contrast media at the prescribed settings that you've set on the CT power injector up to 300 psi up to 5 milliliters per second and performing the study.

D.I. 581 at 238 (Tr. 3-779:17–23). Dr. Vogelzang agreed. D.I. 584 at 57 (Tr. 6-1531:10–16, 6-1532:19–24, 6-1534:8–15).

Dr. Clark contested that the prior-art ports would have necessarily been used at the claimed flow rate. D.I. 582 at 64 (Tr. 4-887:20–889:9). But objective, documentary evidence confirmed doctors already had. D.I. 584 at 57 (Tr. 6-1531:4–34:23). Herts, *et al.*, flowed contrast media through dozens of patients' Adult Titanium ports at 1.5 mL/s before February 2001. PX-95 (Herts, *et al.*, *Power Injection of Contrast Media Using Central Venous Catheters: Feasibility, Safety, & Efficacy*, 176 AM. J. ROENTGENOLOGY 447 (Feb. 2001)). Carlson, *et al.*, flowed 1.0 mL/s through five patients' Port-A-Caths in early 1991. DX-81 (Carlson, 27 INVEST. RADIOL. 337). Additionally, Bard survey data from Wayne Memorial Hospital in Goldsboro, North Carolina reports injections of up to 1.2

mL/s with the Port-A-Cath. DX-11 (Wayne Memorial Hospital, *Protocol for Using Port-A-Caths For CT Scans* (1999)). So too, Dr. Treretola reported his power injection of a Vortex port. PX-246 at 39 n. 17 (C.R. Bard Inc., Doc. 56636, Rev. 0, *PowerPort Product Opportunity Appraisal* (July 2005)). And by Dr. Clark's own explication of standard medical practice, these doctors scout scanned and identified the ports "100 percent of the time." None of Bard's objections compel.

Bard notes that Dr. Trerotola does not specify the fluid flow rate. But Bard obviously believed the report enough to describe it as "power injection." Again, that use, without clarification, binds Bard to the definition it gave to the phrase. And so, as a matter of law, Dr. Trerotola injected at a sufficient flow rate.

Similar to the discussion above regarding indefiniteness, the question here isn't one of balancing evidence. The question is whether the jury had any evidence to disbelieve that these professionals did what they said they did. Bard introduced no such evidence, so the jury did not.

More seriously, Bard faults Angio for failing to introduce direct testimony from a CT technologist who performed the method steps and instead relying on testimony of standard medical practice. But one cannot miss the irony in Bard rejecting such reliance on general medical practice for validity where it relies on precisely the same to prove the necessary-direct infringement by Angio's customers, underlying the charge of induced infringement. D.I. 582 at 19 (Tr. 4-842:4–43:15); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920–21 (2014). Sauce for the goose, after all . . .

* * *

In sum, Bard left the jury with no evidentiary basis to reject the anticipation of its asserted claims. Bard's own admissions, along with uncontroverted test data, identify *three different* prior-art ports capable of withstanding at least a flow rate of 1 mL/s and chamber pressure of 35 psi. Dr. Clark admitted the identifiability of the radiographic features present on each prior-art port, and that the method steps would naturally be performed in standard medical use of any port. This overwhelming evidence leaves but one supportable conclusion: Bard's own Adult Titanium port, Port-A-Cath, and Vortex all anticipate the asserted claims.

5. The Willfulness Verdict Lacks Substantial Evidence

Leaving aside all the foregoing and skipping to the end, a final failure plagues Bard's verdict. A jury determination of willful infringement requires "no more than deliberate or intentional infringement." *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 14 F.4th 1323, 1327 (Fed. Cir. 2021). Yet willfulness at one point does not poison the entirety of a defendant's course of conduct; culpability is "measured against the actor's knowledge at the time of the challenged conduct." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 579 U.S. 93, 106 (2016). So, a finding of willfulness should have a start date. *SRI Int'l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019).

The time-unbounded willfulness verdict here lacks substantial evidence. Bard blurs together a range of Angio's conduct across a span of years—both before and after patent issuance. This judges Angio's culpability based on what it knew *at some other point*. Having both declined either to ask the jury to specify a start date or to provide one in post-trial briefing, Bard has also waived the matter.

CONCLUSION

More than enough forgoing to adjudge the asserted claims invalid at a matter of law, the Court reserves the matters of obviousness and noninfringement by dint of prior use, on the latter specifically declining to embark on an unnecessary course of statutory interpretation.

THEREFORE, IT IS ORDERED THAT AngioDynamic's motion for judgment as a matter of law, D.I. 572, is granted in part as specified above. Judgment to follow.

Dated this 1st day of June, 2023.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge