No. 2023-2056

United States Court of Appeals for the Federal Circuit

C. R. BARD INC., BARD PERIPHERAL VASCULAR, INC.,

Plaintiffs-Appellants,

– v. –

ANGIODYNAMICS, INC.,

Defendant-Appellee.

Appeal from the United States District Court for the
District of Delaware, Case No. 1:15-cv-00218-JFB-SRF
Hon. Joseph F. Bataillon

BRIEF FOR DEFENDANT-APPELLEE ANGIODYNAMICS, INC.

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JANUARY 30, 2024

’417 Patent Claims 1, 5, 8, 12

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

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

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;

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

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.

5. The assembly according to claim 1, wherein the radiographic marker is one or more radiographic letters.

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

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

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;

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

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.

12. The assembly according to claim 8, wherein the radiographic marker is one or more radiographic letters.

’460 Patent Claims 1, 4

1. A system for identifying a power injectable vascular access port, comprising:

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

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

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.

4. The system according to claim 1, wherein the radiographic marker is selected from the group consisting essentially of an observable pattern, a symbol, a typographical character, an indicium, and combinations thereof.

’478 Patent Claims 1, 3

1. A method of performing a power injection procedure, comprising:

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; identifying the indicating radiographic feature on the x-ray; and flowing a fluid through the access port at a rate of at least 1 milliliter per second.

3. The method according to claim 1, wherein the identifying step comprises identifying a radiographic letter.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

THIRD AMENDED CERTIFICATE OF INTEREST

Case Number 2023-2056

Short Case Caption C.R. Bard, Inc. v. AngioDynamics, Inc.

Filing Party/Entity AngioDynamics, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 01/29/2024 Signature: /s/ Danielle Vincenti Tully

Name: Danielle Vincenti Tully

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
AngioDynamics, Inc.		AngioDynamics, Inc. is a publicly-held company. BlackRock, Inc. is a publicly-held company that owns 10% or more of AngioDynamics's stock.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☑ Additional pages attached

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

Addendum to Third Amended Certificate of Interest for AngioDynamics, Inc.

in Appeal No. 2023-2056

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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STATEMENT OF RELATED CASES

Appellee AngioDynamics, Inc. ("Angio") agrees with the Statement of Related Cases by C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") except that five other cases may be affected by this Court's decision: (a) *C.R. Bard, Inc. v. AngioDynamics, Inc.*, Case No. 1:20-cv-1544-CFC-SRF (Delaware); (b) *C.R. Bard, Inc. v. AngioDynamics, Inc.*, Case No. 1:21-cv-349-CFC (Delaware); (c) *C.R. Bard, Inc. v. Smiths Medical ASD, Inc.*, Case No. 1:20-cv-1543-CFC (Delaware); (d) *C.R. Bard, Inc. v. Medical Components, Inc.*, Case No. 2:12-cv-00032-JNP-DAO (Utah); and (e) *C.R. Bard, Inc. v. Medical Components, Inc.*, Case No. 2:17-cv-00754-HCN-DAO (Utah). The patents at issue in the above cases cover virtually the same subject matter as the Asserted Patents here, include many common inventors, and claim priority to Provisional Application No. 60/658,518, which the Asserted Patents incorporate by reference.

JURISDICTIONAL STATEMENT

This Court has jurisdiction under Rule 54(b). While Angio's inequitable conduct counter/cross claim remains unadjudicated, the district court found "no just reason to delay" this appeal and certified its judgment as final. Appx50.

INTRODUCTION

The district court had no choice but to grant JMOL. Bard claimed old ports and old labels. The only arguably new part of Bard's claims is printed matter. Throughout this case, Bard contested the applicability of the printed matter doctrine, asserting the claimed printed matter has patentable weight. Having lost these arguments at every turn, Bard has resorted to adding in unclaimed limitations to avoid the prior art. Bard's irrelevant evidence cannot support the jury's verdict, and the *only* competent evidence in the record supports the district court's decision.

The parties do not dispute that the claimed port structure—a body with a cavity/reservoir, a septum, and an outlet stem—long predates the Asserted Patents, or that Bard did not invent power injectors or power-injection procedures. Indeed, this Court previously recognized that "Bard's commercially marketed vascular port product was already structurally suitable for power injection" and "largely undisputed evidence" established that "certain prior art ports, and the use of those ports," meet the "power injectability" requirement. *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1375, 1384 (Fed. Cir. 2020). Bard cannot retract its admissions or use unclaimed limitations such as FDA indication or manufacturing tolerances to dispute that prior-art ports were power injectable.

Nor do the parties dispute that "identifiable features"—"radiographic markers" and "external" labels like stickers—existed in the prior art. Under the claim

construction, a "radiographic marker" is a "radiographic attribute that is *perceivable* via x-ray" and "identif[ies]" the port as power injectable.[1] Appx313. No party contests this construction, and the 2020 *Bard* decision did not change it or read out express embodiments. When the printed matter doctrine is fully applied, x-ray perceivability is the only part with patentable weight. That again leaves Bard to read in unclaimed limitations to distinguish the art—this time vague and unworkable concepts like uniqueness and undefined x-ray settings.

Against this backdrop, the district court did not revisit settled issues or invade the province of the jury. It instead faithfully adhered to the mandate and recognized that Bard's trial evidence and arguments flouted the claim construction and could not support the jury verdict. Based on uncontroverted evidence tracking the claim construction, anticipation was the only reasonable outcome. Alternatively, accepting Bard's "reconstructions" at trial, the district court correctly determined as a matter of law that the claims are invalid under §§101 and 112. The district court also properly held that Bard's evidence of willfulness was not even a "mere scintilla" and thus could not support the jury's verdict. And in recognition of Bard's flagrant disregard for the claim construction and repeated introduction of irrelevant evidence, the district court's conditional grant of new trial is proper.

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[1] All emphasis added unless otherwise stated.

The district court's judgment should be affirmed.

STATEMENT OF THE ISSUES

1. Whether the district court properly granted JMOL of anticipation based on the relevant undisputed evidence that: prior-art ports were structured for power injection, included x-ray perceivable, radiographic markers, and separated features like stickers, such that no reasonable jury could have found the claims not invalid under 35 U.S.C. §102.

2. Whether the district court properly held, in the alternative, Bard's claims patent ineligible under 35 U.S.C. §101 for being directed to the abstract idea of safety and reliability with no inventive concept.

3. Whether the district court properly held, in the alternative, Bard's claims invalid for indefiniteness under 35 U.S.C. §112 because they fail to inform skilled artisans about the scope of the invention in view of Bard's trial reconstructions.

4. Whether the district court properly granted JMOL of no willful infringement where Bard's evidence fails as a matter of law and Angio reasonably relied on competent opinions of counsel.

5. Whether the district court properly exercised its broad discretion in conditionally granting a new trial where: (i) Bard flouted the claim construction through improper testimony and argument at trial that no jury instruction could cure.

(ii) the verdict was against the clear weight of the evidence; and (iii) Bard unfairly influenced the jury's verdict including by presenting a damages number pulled out of thin air.

6. Whether the "extraordinary remedy" of reassignment, which courts "order sparingly," is warranted given the district court's demonstrated impartiality and its familiarity with this long-running complex patent case.

STATEMENT OF THE CASE

A. Bard Claimed Generic Port Components and "Identifiable Features" that Convey Printed Matter.

The claims recite basic structural components common to all prior-art ports. The apparatus claims of the '460 and '417 Patents recite a body, cavity/reservoir, septum, and outlet; the method claim of the '478 Patent recites a fluid reservoir and a septum. "Vascular access port" was construed to be any port "structured for" or "suitable for" power injection; the claims recite no new structure that makes a port "power injectable." Appx311; *see also* Appx310 (explaining at *Markman* that the claims are not about "how to make a power injectable vascular access port").

All claims recite printed matter: the information that the claimed port is power-injectable. The printed matter is conveyed by "identifiable features"—"separated" features like stickers and ID cards and "incorporated" features, at least one being an "attribute that is perceivable via x-ray." Appx313-314. Though the

former is read on paper and the latter is read on x-ray, both are perceived and understood by humans in the same way.

The method claim recites the routine steps (or medical standard of care) of using the claimed port: taking an x-ray of it; identifying information about the port when viewing a "radiographic feature," and flowing fluid at 1 ml/s.

1. Bard Did Not Invent a "Power-Injectable" Port or Claim a "Power-Injectable" Structure.

As this Court recognized, "Bard's commercially marketed vascular port product was already structurally suitable for power injection" and "largely undisputed evidence" established that "certain prior art ports, and the use of those ports," meet the "power injectability" requirement. *Bard*, 979 F.3d at 1375, 1384. Bard admitted that "testing data showed that Adult Titanium Ports that were tested were suitable for flowing fluid at a fluid flow rate of at least 1 milliliter/second, and suitable for accommodating cavity pressures of at least 35 psi with certain catheter configurations." Appx52586 (¶216, Bard Answer); *see also id.* ¶¶217–218. Bard also stipulated post-remand that at least some of its former vascular access port models were "structurally capable of withstanding the pressures and flow rates of power injection procedures." Appx5241 (stipulated facts). It likewise admitted that

implanted prior-art ports were power injected, both in this and the prior appeal. AppBr5-6; 2019AppBr5.[2]

Bard's files show doctors realized prior-art ports could be injected at the claimed pressures and flow rates using a machine called a power injector. Appx27415-27417. This use was "off-label," which meant doctors could use the prior-art ports for power injection but port manufacturers could not legally market this use. The lag between clinical practice and FDA indication presented Bard a tremendous business opportunity. Internally, Bard recognized that its existing ports needed no new "product technology to withstand the pressures" of power injection, and "other commercially available ports are capable of withstanding power injection, they just are not [FDA] indicated for it." Appx25501-25502. If Bard could be "first-to-market" with a port indicated for power injection, it could "target[]" competitors who had not yet obtained their own indications. *Id.*

Speed became Bard's goal. Rather than design a new port, Bard tested its prior-art Adult Titanium Port ("ATP") for power injection, submitted this testing to the FDA, and swore that the port it intended to market as power-injectable—PowerPort—was "identical" to ATP in all respects relevant to power injection.

[2] Citations to "AppBr" refer to Bard's opening brief, ECF No. 14. Citations to "2019AppBr" refer to Brief for Plaintiffs-Appellants, *Bard*, No. 2019-1756 (Fed. Cir. Sept. 27, 2019), ECF No. 37.

Appx24402, Appx24451-24452, Appx24457, Appx24484-24485, Appx4700-4706. Though Bard was first through the FDA, its competitors soon followed. Angio similarly proved to the FDA its prior-art Vortex Access ("Vortex") was power-injectable and represented that its indicated port, SmartPort, was the same in all respects relevant to power injection. Appx19713, Appx19725, Appx19755-19756, Appx19700-19701, Appx19706-19707 (FDA filings); Appx5428-5431 (Smith), Appx5781-5783 (Vogelzang).

Though Bard says "[e]xisting vascular access ports had not been designed, tested, and approved" for power injection, neither the claims nor claim construction require those concepts. AppBr5. Indeed, the prior art at issue here, Bard's ATP, Angio's Vortex, and Smiths's Port-A-Cath ("PAC"), were all structured for power injection:

- **ATP.** Per inventor Kevin Sheetz, ATP was "for sure" power-injectable. Appx5624; *see also* Appx5622. Inventor Kelly Powers, testified that at least some ATPs were power-injectable. Appx4508-4512, Appx4696, Appx4758-4759, Appx1006-1007; *see also* Appx2663 (¶37, PTO: Uncontested Facts), Appx5241 (stipulated facts). And Bard's power-injection testing—including testing submitted to the FDA—was specifically performed on ATPs. Appx4705-4706, Appx4590, Appx4598-4601, Appx5628-5630, Appx24452, Appx24484-24485, Appx24402, Appx24440.

- **Vortex.** Angio's testing—including an "unchallenged lab notebook," Appx40, and testing provided to the FDA—established that its P5455/P5355 Vortex model was power-injectable. Appx29222-29225, Appx19725-19728, Appx19755-19756. An internal Bard document signed by inventors Powers, Sheetz, Burnside, and Beasley also identifies Vortex as one of the "commercially available ports" capable of power injection, explaining that a prominent doctor at the Hospital of the University of Pennsylvania confirmed

Vortex's power-injectability and was using it for this purpose. Appx25497, Appx25501, Appx25535 n.17.

- **PAC.** Two prior-art articles, Gebauer and Carlson, established PAC's power injectability. Appx28337-28356, Appx27709-27713. Bard's files, including a 1999 protocol from Wayne Memorial Hospital solicited by Bard, also showed the routine use of PACs in a hospital for power injection. Appx27415-27417.

The USPTO did not have Bard's and Angio's internal evidence on power injectability, including their power-injection testing and the Wayne Memorial Hospital protocol.

2. Bard Claimed Printed Matter Conveyed Radiographically, Not a New Type of Radiographic Marker.

As Bard admitted, it did not invent radiographic markers. Appx5241-5242 (stipulated facts), Appx5956-5958 (Johnson). Nor did Bard invent or claim an improved radiographic marker, let alone one that "reliably and accurately identif[ies] a port as structured for power injection." AppBr5.

Instead, Bard claimed a "radiographic marker"—any "attribute that is perceivable via x-ray." Appx313-314. Only x-ray visibility matters—not unclaimed uniqueness or some amorphous level of differentiation from "existing ports" with "substantially similar geometries." AppBr6. Reflecting the term's breadth, the specification says "*any...indicium* that may be visually perceivable or otherwise perceptible may be used." Appx105 (col.26:53-57).

It follows that the radiographic marker need not be something *added* to the port. It can be a port's "physical attributes," including "e.g." its "size" and "shape."

Appx105 (col.25:35-41, 63-67). The specification also "contemplates that any of the identification features or attributes" in Bard Provisional Application 60/658,518 "may identify an access port as being structured for power injection." *Id.* (col.25:42-46). That application expressly identifies "square" shaped ports, ports with a "rounded or arcuate exterior," and port "suture" holes as radiographic markers that can identify power injectability. Appx19326-19336 (¶¶41,50,52,60,67; claims 2,6); Appx19365 (¶¶6,8).

Bard also claimed printed matter: the mental step of observing something "(e.g., visually, by palpation, ultrasonically, radiographically, etc.)" and correlating it to "information" contained in an observer's mind. Appx105 (col.25:35-41). How that mental correlation step occurs depends on the individual. A radiologist, for example, would be better than a layperson at perceiving details from a port's x-ray and drawing conclusions from them using his/her experience and knowledge. The crux of the invention is thus not anything special about the radiographic marker, but a routine mental process that occurs every time a trained clinician perceives radiographically-transmitted information.

That led to the error at the heart of this case: the patents issued only because the USPTO wrongly believed printed matter was entitled patentable weight. Appx7225, Appx7222 ('417 File History: OA response relying on printed matter to overcome obviousness rejection), Appx10943-10944, Appx10925-10926 ('460 File

History: same), Appx15607, Appx15687, Appx18923-18924 ('478 File History: same; Notice of Allowance identifying printed matter as the reasons for allowance).

B. On Remand, the District Court Faithfully Adhered to this Court's Mandate and Properly Granted JMOL in Angio's Favor.

The 2019 trial ended with a victory for Angio on invalidity, infringement, and willfulness. On appeal, this Court sided with Angio on printed matter, but "reverse[d]-in-part" on patent ineligibility, "vacate[d]-in-part" on all other invalidity grounds, and vacated on infringement and willfulness. *Bard*, 979 F.3d at 1382, 1385.

On remand, Bard attempted to recant its prior concessions about not inventing a power-injectable port. *E.g.*, Appx1006-1007 (testifying in 2019 that ATP was power-injectable by "dumb luck"), Appx1224 (testifying it was "serendipitous" that Vortex was too); *see* 2019AppBr5. It strategically created a "claim construction debacle" to avoid the prior art, Appx34-35, asserting that the claimed port requires numerous unclaimed limitations:

- catheters, needles, and undefined septum dimensions, tolerances, and puncture life, *e.g.*, Appx4366-4367 (Bard's opening), Appx4885-4886, Appx5042-5047, Appx5068-5069 (Clark), Appx5961-5962 (Johnson), Appx4509-4513, Appx4756-4757 (Powers), Appx6188 (Bard's closing);

- FDA approval or knowledge of power injection capability, *e.g.*, Appx4361, Appx4365-4366, Appx4381, Appx4383 (Bard's opening), Appx4745-4750 (Powers/sidebar), Appx4893-4894, Appx4931-4933, Appx5037-5041 (Clark), Appx5913-5916, Appx5928-5929, Appx5930-5931, Appx5945-5947 (Johnson), Appx6141, Appx6145-6147 (Bard's closing);

- an unspecified amount of testing and reliability to show power-injectability, *e.g.*, Appx4547-4548, Appx4612-4613, Appx4744-4745 (Powers), Appx4885, Appx4893-4894 (Clark);

- an injection fluid of an unspecified viscosity, *e.g.*, Appx4359-4361, Appx4365 (Bard's opening), Appx4733, Appx4756-4757 (Powers), Appx4906, Appx4915 (Clark), Appx5906-5909 (Johnson).

The district court repeatedly admonished Bard for flouting the constructions. *E.g.*, Appx4344-4346, Appx4748-4750, Appx5081-5084, Appx5929, Appx5994-6009, Appx6025-6027. Bard's validity expert also admitted he had to "look" beyond the claims to recant his prior sworn testimony that Bard *did not* invent power-injectable ports:

> [F]ive years ago, I didn't know whether Bard had invented power-injectable ports because *I was asked to look at the claims*, and that was—the claims included a power-injectable port. *Now from what I've seen in this testimony, I believe that they did*.

Appx5959-5960 (Johnson); *see* Appx5050-5053 (Bard's other technical expert, Clark, also relying on unclaimed safety and reliability to dispute power injectability). Bard even acknowledged the confusion it created, telling the jury in closing: "what the invention is" had "gotten a little bit muddy." Appx6136-6137.

On damages, Bard's expert presented a number pulled "out of the air" that was untethered from the claims, damages law, and his expert report. Appx5316. That forced the district court to bifurcate damages, strike his testimony, and attempt a curative instruction. Appx5309-5316, Appx6275-6276, Appx3950-3951. But the jury heard hours of improper and unfounded damages testimony, *e.g.*, Appx5121-

5122, Appx5137-5140, Appx5166-5167, and Angio had no opportunity to present any rebuttal. The damage was done.

Angio timely moved for JMOL on anticipation, obviousness, patent ineligibility, no willfulness, and non-infringement under Rule 50(a); Angio also raised Bard's flouting "of the Court's claim construction." Appx5317-5324; Appx6053-6073; Appx3842-3865. Angio renewed these grounds under Rule 50(b), the issues were fully-briefed, and the parties presented oral argument. Appx3972-4018, Appx4020-4067, Appx6335-6360, Appx6365-6445.

Anticipation. As this Court explained, Angio "presented largely undisputed evidence that certain prior art ports"—including Bard's commercially available port—"and the use of those ports, satisfied most of the remaining elements of the asserted claims, including power-injectability and the presence of external identifiers." *Bard*, 979 F.3d at 1384. One issue remained on remand: whether certain "features" of prior-art ports were "radiographically discernible" and could be used for identification. *Id.* at 1384–85. Bard seizes on this Court's language to argue that for a port feature to qualify, it must be "unique...among all prior art ports"—an unworkable standard divorced from the claims, written description, and the law on anticipation. Appx4042 (Bard's JMOL Opp'n Br.); AppBr40, AppBr46-48, AppBr50.

The claims and construction require x-ray perceivability and nothing more. Appx313-314. Bard stipulated post-remand that "[t]itanium vascular access ports were radiographically visible on x-ray before April 27, 2004." Appx5241, Appx2663 (¶35, PTO: Uncontested Facts). Its validity expert likewise conceded that the various attributes of titanium ports, such as shape and suture holes, are x-ray perceivable. Appx5965-5966 (Johnson). Now on a complete record, it is thus undisputed that the prior-art ports—all of which are titanium—have x-ray perceivable attributes meeting the patents' express disclosures.

Additionally, *Bard* held the claimed flow rate and pressure information to be unpatentable printed matter. 979 F.3d at 1384. On remand, the district court applied this ruling to *all the claimed information and mental steps*, including letters and the mental step of identifying power injectability. Appx6032-6035; *see also* Appx3959-3960 (final jury instructions). The district court's ruling thus recognizes that information and mental steps cannot distinguish prior art that otherwise meets the patents' express embodiments of the "radiographic marker."

The district court thus properly granted JMOL on anticipation. Appx34-47.

Patent Ineligibility. *Bard* decided a narrow ineligibility issue: whether the claims were ineligible for being "solely" directed to printed matter. *Bard*, 979 F.3d at 1375. The panel did not rule on any other ineligibility grounds, let alone hold that the claims are *de facto* eligible when reversing "in part." *Id.* at 1385.

At *Alice* step one, the district court ruled that the claims are directed to the abstract idea of safety and reliability. Appx27-28. At *Alice* step two, on a complete trial record, the undisputed facts show that using well-known radiographic markers to identify old ports was not inventive. Appx28-31; *see* Appx5241-5242 (stipulated facts), Appx5285-5287, Appx5288-5289, Appx5298-5300 (Eliasen), Appx5445-5446 (Smith), Appx5583 (Girard), Appx5873-5874 (Vogelzang), Appx5956-5958 (Johnson), Appx29474 (¶38, Eliasen Decl.). The district court thus properly granted judgment of patent ineligibility in the alternative. Appx31.

Indefiniteness. Bard created a "claim construction debacle" by presenting evidence and argument premised on unclaimed and undefined limitations, which the district court termed "reconstructions." Appx12, Appx34. These reconstructions are subjective and turn on "the vagaries of Bard's whim[.]" Appx34. The district court thus alternatively granted judgment of indefiniteness based on Bard's reconstructions. *Id.*

Willfulness. The 2019 willfulness ruling was vacated. The evidence in 2019 was not "materially identical" to the record here. For example, it included none of the evidence showing Angio's repeated reliance on independent and competent opinions of counsel. Appx47. Bard's evidence failed as a matter of law on specific intent, shape- and letter-based radiographic markers existed in the prior art, and Angio merely adapted them to convey unpatentable information.

New Trial. The district court properly recognized that no jury instructions could cure Bard's "claim construction debacle." Appx20, Appx34. The same goes for the testimony and theory presented by Bard's damages expert—it polluted the record and could not be cured by bifurcation, particularly where the jury was instructed only that the parties had "worked this out." Appx6275; *see also* Appx3950-3951 (final jury instructions).

SUMMARY OF THE ARGUMENT

I.A. Clear-and-convincing evidence established that Bard's ATP, Angio's Vortex, and Smiths's PAC were each power-injectable, comprised a radiographic marker, had separated identifiable features, and disclosed each method step. Bard's evidence and arguments to the contrary are premised on claims it does not have, claim constructions that do not exist, and printed matter.

Power-Injectable Port. The claims recite no structure that renders a port power-injectable, the claim construction requires only that the port be "structured for power injection," and the construction has remained unchanged since 2017. As *Bard* recognized in 2020, "Bard's commercially marketed vascular port product was already structurally suitable for power injection" and "largely undisputed evidence showed that certain prior art port, and the use of those ports" satisfied the limitations about "power injectability." *Bard*, 979 F.3d at 1375, 1384. That same evidence and

more came in at the 2022 trial. Bard cannot recant its prior admissions, its evidence and arguments attempting to do so are premised on unclaimed limitations.

Radiographic Marker. Bard does not contest that the prior art discloses "separated" features. That leaves the "radiographic marker," which has been construed as an attribute "perceivable on x-ray" that "identif[ies]" the port as power injectable. Appx313. Bard stipulated post-remand that titanium ports have been visible on x-ray before the priority date. Across party lines, the experts also admitted that port features, such as shape and suture holes, were visible on x-ray. ATP, Vortex, and PAC each unquestionably have these features. The printed matter—the information identifying the port as power injectable—need not be shown, and each port's radiographic markers track the specification's express embodiments. And uncontested evidence shows that each could be and was used to perform the claimed method step.

I.B. The grant of JMOL of anticipation was procedurally proper and consistent with the mandate. The district court properly disregarded evidence and argument premised on Bard's "claim construction debacle." Appx34. Far from assessing credibility, weighing evidence, or drawing inferences from the facts, the district court properly considered the uncontroverted and unimpeached relevant evidence. Considering only the relevant evidence and disregarding evidence inconsistent with the claims and the claim construction, the district court had no choice but to grant

JMOL of anticipation. *Bard* did not foreclose that ruling—it did not change the claim construction, read in unclaimed limitations like uniqueness, or read out express embodiments of the radiographic marker. *Bard*'s procedural posture also meant that neither party was fully heard on the issue of invalidity and the issue was not conclusively decided.

II.A. The district court also correctly held, in the alternative, that the claims are patent ineligible. Bard asserts it claimed a technological solution for achieving safety and reliability, but the claims include no technical detail for achieving this abstract idea. They do not recite a new or improved port or a new or improved radiographic marker. Indeed, undisputed evidence showed that each claim element was uninventive, and that identifying an old port with old labels lacked an inventive spark.

II.B. *Bard* and *Medcomp* addressed a narrow ineligibility issue: whether the claims are "solely" directed to printed matter. They do not address the abstract idea of safety and reliability, let alone enter *de facto* judgment of eligibility. Indeed, Bard's view would subvert *Alice*'s prohibition against abstract claiming, transforming the printed matter doctrine from a shield against overreach into a sword facilitating preemptively broad claims. Angio properly raised the ground of ineligibility on Rule 50(a) and Rule 50(b), and the district court could reach this issue as a matter of law.

II.C. On JMOL, Bard chose only to address patent ineligibility on procedural grounds. It cannot address the merits for the first time on appeal. It has thus waived this issue.

III.A. The claims are indefinite under Bard's claim "reconstructions." Appx12. Bard sought to avoid anticipation by injecting unclaimed limitations that access ports must be sufficiently identifiable as being "safely" and "reliably" power injectable. But these concepts turn on subjective judgment and "the vagaries of Bard's whim." Appx34.

III.B. Bard ambushed Angio and the district court at trial with reconstruction-based evidence, perpetrating a "claim construction debacle." Appx34. Angio repeatedly objected, the district court repeatedly admonished Bard—giving notice to Bard that its reconstructions would render the claims impermissibly subjective—and Bard's reconstructions were again a focus at JMOL. Bard cannot now advance procedural excuses to profit from its misconduct. Nor is this Court precluded from affirming the district court's alternative holding on indefiniteness, which is a pure matter of law.

IV. Angio presented its rebuttal on willfulness for the first time on remand. The unrebutted evidence showed that Angio obtained opinions of counsel on which it reasonably relied—Bard offered no evidence that these opinions were in any way incompetent or not reasonable to rely on. Nor did Bard present any legally competent

evidence on specific intent or otherwise meet its evidentiary burden. This Court's prior vacatur and remand was not a *de facto* holding of willful infringement, and the *Bard* mandate was no procedural impediment to JMOL.

V. The district court did not abuse its discretion in conditionally granting a new trial. Bard's trial presentation caused extreme prejudice, including a "claim construction debacle" and improper damages testimony. Appx34. The district court provided its honest assessment that "[r]emedial attempts evidently failed" and "a *properly* instructed jury" did not decide the case. Appx17, Appx34 (emphasis in original). Nothing could have unrung the bell for the jury, and its verdict went against the clear weight of the evidence. Far from waiving, Angio properly requested a new trial due to the extreme prejudice Bard caused and because the jury's verdict went against the clear weight of the evidence.

VI. The extreme remedy of reassignment would not be warranted. The district court gained significant institutional knowledge over the past seven years, demonstrated impartiality, and thoughtfully addressed complex legal issues like printed matter. Bard abused the district court's leeway at trial by flouting the claim construction and presenting impermissible evidence. Bard's dissatisfaction with the district court's opinion does not support reassignment.

STANDARD OF REVIEW

Under applicable Third Circuit law, a district court must grant JMOL if "the record is critically deficient of the minimum quantum of evidence" from which the jury might reasonably afford relief. *Eshelman v. Agere Sys.*, 554 F.3d 426, 433 (3d Cir. 2009) (cleaned up); *The Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1348–49 (Fed. Cir. 2008) ("Substantial evidence is more than a mere scintilla and is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."). The question is not whether some evidence may support the nonmovant, "but whether there is evidence upon which the jury could properly find a verdict for that party." *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993) (cleaned up). The district court need not reject the jury's findings, but may determine those factual findings do not support the required legal determination. *Unidisco, Inc. v. Schattner*, 824 F.2d 965, 967–68 (Fed. Cir. 1987) (reversing district court's denial of judgment notwithstanding the verdict where "[t]he facts of the case d[id] not support the jury's [legal] conclusion" of patent infringement).

An "abuse of discretion" standard applies as to the appropriateness of a new trial. *Wagner v. Fair Acres Geriatric Ctr.*, 49 F.3d 1002, 1017 (3d Cir. 1995). Under this standard, the trial judge may consider the improper conduct of attorneys and "need not view the evidence in the light most favorable to the verdict winner." *Amgen, Inc. v. Hospira, Inc.*, 336 F. Supp. 3d 333, 341 (D. Del. 2018). Where

conduct by counsel is involved, the appellate court defers to the district court's assessment of the prejudicial impact. *See Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 207 (3d Cir. 1992).

ARGUMENT

I. THE DISTRICT COURT'S GRANT OF JMOL ON ANTICIPATION WAS PROPER AND SHOULD BE AFFIRMED.

Angio met its clear-and-convincing burden on anticipation for ATP, Vortex, and PAC. The claims require a prior-art port structure and a prior-art "identifiable features" that conveys printed matter. The claim construction tracks this simplicity. It requires that the port be "structured for power injection," and that one of the identifiable features be an "attribute that is perceivable via x-ray." Appx313-314. Given the claims, claim construction, printed matter doctrine, and relevant evidence, the district court had no choice but to grant JMOL of anticipation.

Bard highlights irrelevant evidence about unclaimed limitations—including FDA indication and the "uniqueness" of the radiographic markers—to support the verdict. The 2020 *Bard* decision provides Bard no sanctuary—it did not change or modify the claim construction, read unclaimed concepts like uniqueness and discernibility into the radiographic marker, or exclude express embodiments of the radiographic marker like port shape and suture holes. Bard's evidence and arguments depend on its erroneous claim interpretations and were properly rejected by the district court.

This Court should affirm the judgment on all grounds. However, to the extent it holds any one of the prior-art ports anticipatory, it "need not reach" any other ground raised in the judgment. *See, e.g.*, *Centocor Ortho Biotech, Inc. v. Abbott Lab'ys*, 636 F.3d 1341, 1344 (Fed. Cir. 2011) (holding claims invalid and not reaching other issues).

A. The Grant of JMOL on Anticipation Was Necessary Under the Proper Claim Construction.

Bard concedes, as it must, that the prior art discloses "separated" features. *See* Appx36 (citing Appx5783-5784 (Vogelzang)), Appx5958 (Johnson). That leaves two primary issues: (1) whether the prior-art ports were power injectable, and (2) whether their x-ray perceivable attributes are "radiographic markers." *See* AppBr44-45. Considering only evidence relevant to the district court's claim construction—including stipulations and testimony from Bard's own witnesses—Angio met its burden that ATP, Vortex, and PAC each anticipate.

1. The Claims Recite Known Port Structure, Known "Identifiable Features," and Printed Matter.

Power-Injectable Port. The district court construed "[v]ascular access port" and "access port" to be "[a] port structured for power injection." Appx311. Ports "structured for power injection" are those "'suitable for flowing fluid at a fluid flow rate of at least [1 ml/s] through the access port' and 'suitable [as well] for accommodating a pressure within the cavity of at least 35 psi.'" Appx311. Nothing

more is required: not the "vagaries of safety and efficacy," unclaimed "needle and catheter dimensions," or "labels and instructions," all of which cannot "counter actual test data of a port's capacity." Appx36-37. As explained at *Markman*, the patents are not about "how to make a power injectable vascular access port." Appx310.

Radiographic Marker. The district court construed the "radiographic marker" of the '417 Patent and the "radiographic feature" of the '460 and '478 Patents as a "radiographic attribute" that "identif[ies] an access port as being structured for power injection" and "is perceivable via x-ray." Appx313-314. Bard does not contest this construction.

The specification is clear that any attribute of a port, such as its shape or suture holes, could be a radiographic marker—it need not be something *added* to or *changed* about a port. *See, e.g.*, Appx105 (col.25:35-41, 63-67). In fact, the radiographic marker need only be an "indicium that indicates the access port is structured for accommodating a particular flow rate, pressure, or both"—anything "that may be visually perceivable or otherwise perceptible may be used." Appx105 (col.26:47-57). Relevant here, x-ray perceivable square shapes, round shapes, and suture holes are exemplary "identification features or attributes" that "may identify an access port as being structured for power injection." Appx105 (col.25:42-46)

(incorporating '518 Provisional); Appx19326-19336, Appx19365 ('518 Provisional).

Though Bard seeks to disqualify certain shapes as non-unique, it represented to the district court that, generally, "the *shape* of the port can be a radiographic attribute under the Court's construction[.]" Appx50000 n.1 (emphasis in original). Its expert did too at trial. Appx4905, Appx4908-4912, Appx5061 (Clark) (discussing square and notched shapes). Bard's interpretation is also inconsistent: it says triangular shapes—but not square shapes—qualify as "radiographic markers" without showing the supposed uniqueness of triangles. AppBr50-51. The patents do not support this distinction.

Printed Matter. This Court held that identifying the port as "suitable for [power] injection" was printed matter not entitled to patentable weight. *Bard*, 979 F.3d at 1382. Post-remand, the district court applied this ruling to all claimed information, including mental steps and letters. Appx6032-6035; *see also* Appx3959-3960 (final jury instructions). The prior art need not teach unpatentable printed matter, leaving the requirement that the "radiographic attribute" be "perceivable via x-ray" as the only part of the radiographic marker limitation with patentable weight. *See In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004). To require anything more would expand the invention beyond the claims and vitiate the printed matter doctrine.

While Bard argues that letters are not printed matter, it previously took the opposite position. Appx50000. Letters are a canonical example of printed matter. *See In re Jie Xiao*, 462 F. App'x 947, 951 (Fed. Cir. 2011) (concerning letters and symbols on a lock); *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161 (Fed. Cir. 2018) (concerning "dice markings"). They are understood to be letters—as opposed to, say, numbers—because of their "communicative content." *Bard*, 979 F.3d at 1381. Thus, all courts applying *Bard* have concluded that letters are unpatentable printed matter and rejected Bard's "information-conveying means" loophole.[3] AppBr60.

Finally, since the jury was instructed to give letters no patentable weight, Appx3959-3960, the record includes no "presumed finding" about letters. AppBr60.

2. No Reasonable Jury Could Have Found the Claims Valid Under §102.

Bard's evidence and arguments ignore the claims and claim construction and are properly disregarded.

[3] *See* Order at 3–4, *C.R. Bard, Inc. v. AngioDynamics, Inc.*, C.A. No. 20-1544 (D. Del. Jan. 10, 2024), ECF No. 637; *C.R. Bard, Inc. v. Med. Components, Inc.*, No. 17-cv-754, 2020 WL 6902367, at *18–21 (D. Utah Nov. 24, 2020); *C.R. Bard, Inc. v. Med. Components, Inc.*, 550 F. Supp. 3d 1202, 1215–20 (D. Utah 2021), *rev'd in part, vacated in part*, No. 2022-1136, 2023 WL 2064163 (Fed. Cir. Feb. 17, 2023).

On power injectability, Bard presented evidence directed to unclaimed limitations at trial, including FDA indication, knowledge via testing, infinite repeatability, extreme performance, needles, and catheters. *E.g.*, Appx5037-5047, Appx5928-5929 (Clark), Appx4361, Appx4365 (Bard's opening statement), Appx4612-4613, Appx4756-4757 (Powers), Appx5909 (Johnson). That approach necessarily fails—"prior art cannot be distinguished on the ground that it lacks features that are not claim limitations." *Melchior v. Hilite Int'l, Inc.*, 665 F. App'x 894, 899 (Fed. Cir. 2016); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1337 (Fed. Cir. 2016) (holding jury's verdict of no anticipation to be unsupported by the substantial evidence where evidence related to an unclaimed limitation was "irrelevant to the [invalidity] analysis").

Neither regulatory approval from the FDA, subjective design intent, nor marketing makes a port power-injectable. Appx311, Appx37. Nor is a port retroactively deemed not power-injectable because, like every medical device, it fails after repeated use. Appx19. Similarly, needles, catheters, and injection fluid viscosities are unclaimed and have no bearing on whether the claimed *port* is structured for power injection. Appx36-37, Appx311.

As for the "radiographic marker," when Bard argues it must possess some unknown quality that can "distinguish or identify the device or its functionality," AppBr44 (quoting *Bard*, 979 F.3d at 1385), Bard really means that Angio must show

a prior-art radiographic marker "unique...among all prior art ports," Appx4042. That view flouts the claim construction and ignores that anticipation depends on the teachings of *one* prior-art reference, not the collective teachings of all. *See Power Integrations*, 843 F.3d at 1337; *Melchior*, 665 F. App'x at 899. At any rate, distinguishing/identifying is also a mental step—unpatentable printed matter—that cannot distinguish the prior art. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1033–34 (Fed. Cir. 2018). In short, Bard cannot grant itself claims it does not have, subvert the law of anticipation, or resuscitate unpatentable printed matter.

a. ATP Anticipates.

Bard disputes ATP's power injectability using unclaimed manufacturing tolerances and FDA indication. AppBr51. On the radiographic marker, Bard does not contest the x-ray visibility of ATP's shape and suture holes; it instead argues ATP does not meet an unclaimed and unknowable standard of uniqueness. AppBr50.

Power-Injectable Port. Bard repeatedly admitted that ATP was structured for power injection in its sworn statements; witness testimony; documentary evidence; testing; and prior representations to this Court, the FDA, and the district court. Bard admitted to the district court that "testing data showed that Adult Titanium Ports that were tested were suitable for flowing fluid at a fluid flow rate of at least 1 milliliter/second, and suitable for accommodating cavity pressures of at least 35 psi

with certain catheter configurations." Appx52586 (¶216, Bard Answer); *see also id.* ¶¶217–218. It did not challenge that ATP was power injectable at summary judgment. *Compare* Appx52319-52320 and Appx52326-52341 (Bard's SJ briefing), *with* Appx50029 and Appx50691-50692 and Appx50709 (Angio's SJ briefing). And this Court previously deemed ATP's power-injectability undisputed. *Bard*, 979 F.3d at 1375, 1385. Bard cannot recant.

Yet at trial, Bard presented a new story premised on unclaimed limitations. Appx38-39. Its witnesses repeatedly testified that ATP was not power injectable because it was not endlessly power-injectable; ATP lacked FDA-indication for power injection; the ATPs that passed power-injection testing were "cherry-picked" from manufacturing; and changes were made to PowerPort's needles and catheters. *E.g.*, Appx5928-5929, Appx5909 (Johnson), Appx4756-4757, Appx4590, Appx4598-4601, Appx4612-4613 (Powers). None of that is claimed or relevant, and the jury could not have reasonably relied on it.

On appeal, Bard retreats to unclaimed tolerances and dimensional variation, arguing that PowerPort and ATP had the same "nominal dimensions," but Bard changed PowerPort's manufacturing process to make its dimensions "tighter, more precise." AppBr51-52. That is a distraction: ATP matters, not PowerPort's manufacturing process. It is also futile: Powers conceded that a subset of ATPs—those falling within the later-determined "tightened" tolerance—would "pass"

power-injection testing without leaking. Appx23 (citing Appx4508-4512). As the district court recognized, "[i]mperfect practice is enough." Appx38-39; *see Power Integrations*, 843 F.3d at 1337 (prior art that "sometimes" embodies the claims invalidates).

Bard also argues that, because Angio and the FDA recognized the PowerPort as the first port to receive FDA indication for power-injectability, the jury could ignore the clear-and-convincing evidence of ATP's power-injectability. AppBr51. But FDA indication is not claimed and cannot undermine ATP's uncontested evidence. *See Power Integrations*, 843 F.3d at 1337; *Melchior*, 665 F. App'x at 899. It is also a fallacy to conclude that ATP lacked some essential structure because PowerPort happened to be the first FDA-cleared device. After all, Bard relied on testing performed on ATP in seeking FDA indication and swore that ATP has the "[s]ame basic port" design as the PowerPort and claimed that the "[s]eptum, reservoir and connection [were] unchanged." Appx24402, Appx24440 (PowerPort 510(k)), Appx4692-4693 (Powers); *see also* Appx24422, Appx24429 (PowerPort 510(k)), Appx5773-5774 (Vogelzang).

Bard's new story must yield to the uncontroverted evidence. Bard stipulated: "[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." Appx5241. Bard

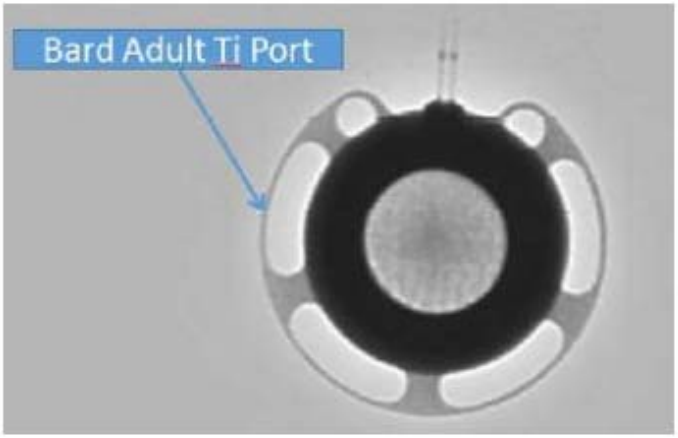
engineer and named inventor Kevin Sheetz, admitted ATP was "for sure" power-injectable. Appx5624, Appx5774-5775. Kelly Powers, Bard's main inventor and primary witness, likewise admitted at the 2019 trial that ATP was power-injectable, testifying that it was "pure dumb luck" that ATP had the "construction" necessary to "tolerate the pressures and flow [rates] required for power injection." Appx1006-1007; *see* Appx888. Bard also represented to this Court that, "[a]t the time of Bard's inventions, some existing ports could tolerate the flow rates required for power-injection in CT scans," citing Mr. Powers' 2019 trial testimony on ATP as support. 2019AppBr5.

These admissions track Bard's own uncontroverted data that it "submitted to the FDA"—showing that *30 ATPs*, power injected 36 times each at a flow rate of 5 ml/s, withstood the power injections without failure for a total of *1,080 power injections*. Appx38, Appx24484-24485, Appx4704-4706; *see also* Appx24452 (Bard swearing to the FDA that ATP and PowerPort were "identical in all aspects that would affect test results"). As Powers confirmed, the tested ATPs "were representative of the final design" of the PowerPort; "would have been in the mix of products that would have been available to the public;" and "were equivalent to other [ATPs]" "sold to the public at that time." Appx4694-4696, Appx4705-4706.

Last, Bard ignores Herts, an independent study from 2001 that Bard provided to the FDA to show the safety and efficacy of power injection but withheld from the

USPTO. Appx24454 n.32, Appx24588-24589 (¶¶7,32), Appx24601-24607 (Herts in PowerPort 510(k)), Appx2663 (¶¶39–40, PTO: Uncontested Facts), Appx5242 (stipulated facts). Herts demonstrates power injection of contrast media for CT examinations through implanted BardPorts at flow rates above 1 ml/s, *without failure*. Appx24928-24932, Appx5774-5775 (Vogelzang). "BardPorts" are ATPs. *E.g.*, Appx24565-24584 (Bard identifying BardPort labeling/Instructions for Use ("IFU") as predicate device (ATP) labeling in PowerPort 510(k) submission), Appx27728-27729 ("BardPort" IFU featuring ATP). The district court identified Herts as "objective, documentary evidence" of prior use, Appx45, which Bard does not contest on appeal.

Radiographic Marker. Bard does not contest that Angio's evidence shows ATP had x-ray perceivable attributes. Both sides' experts also agreed that ATP's shape, suture holes, and orientation holes are x-ray visible. Appx5784-5785 (Vogelzang), Appx5965-5966 (Johnson). In fact, Bard's own expert created the below x-ray of ATP:



Compare Appx25785, *with* Appx25813. All of this tracks Bard's stipulation that titanium ports are visible on x-ray. Appx5241.

Whether Bard's experts could "conclude anything about the port" when viewing ATP on x-ray, AppBr50, is a mental step and irrelevant under the printed matter doctrine. *Bard*, 979 F.3d at 1382. Nevertheless, Angio's expert explained that, once a practitioner knows what the physical attributes of ATP look like on x-ray, any could be used to identify the port. Appx5760-5762, Appx5785 (Vogelzang). That testimony is uncontroverted, unimpeached, and reflects how all humans engage in pattern recognition. Indeed, Bard's own expert agreed. *See* Appx43-44 (citing Clark).

On appeal, Bard argues ATP's radiographic attributes do not count because they are not "uniquely discernible from other ports." AppBr50. But the specification is clear that "at least one *physical attribute (e.g., size, shape, etc.)* of an access port may identify the access port[.]" Appx105 (col.25:63-67). Nowhere does the

specification exclude any port shapes. *See id.*; Appx107 (col.30:42-45), Appx4889-4890 (Clark). Nor can Bard read out express embodiments like suture holes and round shapes. Appx19329-19336 (¶¶52,60,67,74; claims 2,6), Appx19365 (¶8). Indeed, Bard's own expert in another proceeding swore under oath that ATP's orientation holes *are radiographic identifiers*. Appx29513-29514.

As for letters, they are printed matter and need not be shown in the prior art. Appx3959-3960 (final jury instructions). Nevertheless, they too are shown by the uncontroverted evidence. *Compare* Appx25785 (ATP photo), *with* Appx25813 (ATP x-ray). Any argument that they are faint, blurry, or partially obscured is irrelevant. They are perceivable, and no standard of visibility is claimed or described. Appx5760-5762, Appx5785 (Vogelzang).

b. Vortex Anticipates.

Bard disputes Vortex's power injectability with unclaimed FDA indication and Angio's marketing practices. AppBr47. Bard applies the same approach for the "radiographic marker," conceding Vortex's x-ray visibility but injecting vague notions of uniqueness that read out express embodiments. AppBr45-47.

Power-Injectable Port. Uncontroverted evidence shows that Angio tested P5455/P5355 Vortex ports for power injection and represented to the FDA that no changes were made to the non-indicated ports to "add the power injection claim." Appx5416-5419, Appx5429-5430, Appx19725, Appx19755-19756. An

"unchallenged" lab notebook showed an engineer power-injected "stock" prior-art Vortex ports at flow rates of 5 ml/s "at a machine pressure of 305 psi." Appx40, Appx29222-29225; *see* Appx5429-5431, Appx19755-19756. Also unchallenged is Bard's admission that Vortex was power-injectable, as recognized in an internal document signed by inventors Powers, Sheetz, Beasley, and Burnside. Appx25497. That document memorializes that Dr. Trerotola conducted power-injection testing on prior-art Vortex ports and confirmed that his hospital used Vortex ports in clinical settings for power injection. Appx46 (discussing Appx25535 n.17); *see also* Appx4717-4719. Though the district court addressed all of this uncontroverted evidence, Appx46, Bard ignores it on appeal.

At trial, Bard's expert backtracked on his 2019 trial admission that Vortex was power-injectable, Appx5050-5053, and testified instead that it was not "safe" to power inject Vortex because it lacked FDA indication for power injection. Appx4931-4933; *see also* Appx40. Bard doubles-down on appeal by pointing to a non-technical sales training document that lists the "Vortex family" as non-power-injectable. AppBr47. That "mudd[ies] the waters with irrelevant labels and safety considerations." Appx40. The Vortex ports Angio sells are not indicated for power injection, preventing Angio from legally marketing this non-indicated use or training its salespeople to do so. Appx41; *cf.* Appx5432-5434 (Smith discussing Appx29265). The way Angio markets Vortex says nothing about its structural

capability. Bard's expert's "conclusory" suggestion that it does is "insufficient to sustain a jury's verdict." *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1172 (Fed. Cir. 2015).

Also irrelevant is Bard's argument about alleged "extensive material changes" to SmartPort. AppBr47. Only Vortex matters, and Bard's focus on SmartPort is a calculated distraction. At any rate, uncontested and unimpeached evidence shows that Vortex was rebranded as the accused SmartPort product and, as certified to the FDA, no changes were made to the port to make it power-injectable. Appx28614, Appx19725, Appx19713, Appx5429-5430, Appx5391-5392.

Equally misplaced are Bard's arguments about the FDA's initial non-concurrence in the lead-up to Angio's launch of SmartPort. The FDA explained that it needed additional test data on the prior-art Vortex port before it would issue its indication. Appx5420-5422. After Angio submitted this data—representing it made "no changes" to tested ports—the FDA concurred, permitting Angio to launch SmartPort. Appx28614, Appx28612 (FDA approval), Appx5421-5422 (Smith). During its case-in-chief, Bard's infringement expert testified that he relied *on this very same testing of Vortex* to prove that the accused SmartPort products were power-injectable. Appx4928-4930 (discussing Appx19755-19756), Appx5050 (same). Bard cannot "twist [its] claims, like a nose of wax, in one way to avoid [invalidity]

and another to find infringement." *Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021) (cleaned up).

Radiographic Marker. Uncontroverted and unimpeached evidence shows that Vortex's notched shape, suture hole orientation, and tangential outlet stem are all perceivable on x-ray and can identify the port. Appx5061 (Clark discussing notched shape), Appx5394, Appx5397-5399, Appx5760-5762, Appx5788-5789.

That leaves Bard with the same argument the district court properly rejected: Vortex has the "same round shape, suture holes, and tangential outlet stem" as SmartPort and thus they are not unique enough to identify. AppBr45-46. But the claims require only that Vortex's attributes be x-ray *perceivable*, not "unique." Excluding Vortex's suture holes, shape, and other attributes would also read out express embodiments—"physical attribute[s] (e.g., size, shape, etc.)." Appx105 (col.25:63-67); Appx19332-19336 (¶¶60,67, claim 6), Appx19365 (¶8) (suture holes).

Bard's interpretation also leads to absurd results: an attribute's status as a radiographic marker could be destroyed if it ever becomes non-unique. For example, if a competitor launches a non-power-injectable triangular port, triangles would no longer be unique and PowerPort's triangular shape could no longer be a "radiographic marker." The scope of the claims cannot be a moving target.

Finally, it is irrelevant that Angio added "CT" and scallops to identify the port as power-injectable. *See* AppBr46-47. That gives weight to printed matter. It also depends on the fallacy that no port attributes existing before these additions could meet the broad claim language. And it reads in the unclaimed requirement that the "radiographic marker" be something intentionally *added* to or *changed* about the port to facilitate the claimed mental step. *See* Appx105 (col.25:63-67).

c. PAC Anticipates.

Bard concedes PAC could withstand the claimed flow rate but argues it is not power injectable because Angio's evidence does not show the claimed 35 psi measured in the cavity of the port. AppBr48-49. It does not contest PAC's x-ray visibility, arguing only that its square shape, which tracks an express embodiment, is "generic." AppBr47-48.

Power-Injectable Port. Bard did not present *any* relevant evidence at trial to rebut PAC's power injectability. Instead, it attempted to confuse the jury with unclaimed viscosity, needle pressure, testing repeatability, and catheter lengths. Appx5902-5904, Appx5917-5918, Appx5975. Bard jettisons these arguments on appeal, instead focusing on the pressure in the cavity. AppBr48-49.

But the Gebauer study shows that the pressure at the power injector was 325 psi, which the specification states would *necessarily* correlate to more than 35 psi in the cavity. Appx28344-28346, Appx97 (col.9:62-col.10:4), Appx64 (Fig. 7); *see also*

Appx39-40. Bard's expert even testified that, for the purposes of infringement, 300 psi at the injector corresponds to "*at least* 35 psi" in the cavity. Appx4899, Appx4912-4913. Bard represented the same to this Court. 2019AppBr35.

As the district court explains, it is irrelevant that the pressure limit threshold of 325 was eventually reached *at the power injector*. Appx39-40; *see* Appx28344-28346. No ports failed, nor did this "lead *in any case* to a disconnection or rupture of a port catheter." Appx28341-28346. Again, Bard advances irrelevancies and distractions.

The district court identified both the Wayne Memorial Hospital protocol and Carlson as "objective, documentary evidence" of prior use, which Bard does not contest here. Appx45-46. Bard's sole argument about them is on cavity pressure. AppBr49. But its supporting expert testimony is conclusory and properly disregarded, particularly because the claims equate cavity pressures of 35 psi with flow rates of 1 ml/s. *See MobileMedia*, 780 F.3d at 1172.

Radiographic Marker. The clear and convincing evidence showed that PAC comprises attributes, such as a square shape and suture hole arrangement, that are perceivable on the x-ray reproduced below. Appx5760-5761, Appx5776, Appx5787, Appx29545, Appx29288.

Appx29545.

Again, Bard retreats to unclaimed limitations that would read out an express embodiment, arguing PAC's square shape and suture holes are not identifiers because they did not "distinguish[] it radiographically or identif[y] anything about its functionality[.]" AppBr47-48. Yet Bard's expert admitted that a "square shape" could be a radiographic marker. Appx5061. And Bard's incorporated-by-reference provisional application explicitly lists "square" shape and suture "apertures" as a radiographically identifiable feature. Appx105 (col.25:42-46), Appx19332-36 (¶¶60,67, claims 2,6), Appx19365 (¶¶6,8). Bard's conclusory expert testimony ignores these express embodiments and cannot sustain the verdict. Appx5936-37; *MobileMedia*, 780 F.3d at 1172.

d. The Method Claim Is Anticipated.

The only method step Bard argues Angio did not show in the prior art—"identifying the indicating radiographic feature" or "identifying a radiographic letter"—is a mental step that under the printed matter doctrine is not entitled

patentable weight. *See Praxair*, 890 F.3d at 1033–34; Appx3959-3960 (final jury instructions). Regardless, "identifying" is likewise shown by Angio's clear and convincing evidence.

Bard's other argument—that Angio must show actual use of the claimed method in the prior art—is doubly flawed. On the law, clear-and-convincing evidence does not require actual use. *See Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) ("[A]nticipation does not require actual performance of suggestions in a disclosure" but only "that those suggestions be enabling to [a POSA]," which can be established through additional references); *Iovate Health Scis., Inc. v. Bio-Engineered Supplements & Nutrition, Inc.*, 586 F.3d 1376, 1381 (Fed. Cir. 2009) (holding printed publication anticipated method claim). Indeed, the district court correctly pointed out the "irony" of Bard's position where it relied on the same type of evidence for infringement that Angio relied on for invalidity. Appx46.

Regardless, on the facts, Angio demonstrated actual use. Uncontroverted and unimpeached evidence shows that each prior-art port was power-injected with fluid at or above 1 ml/s. *E.g.*, Appx24928-24932 (2001 Herts disclosing power injections through ATPs), Appx27416-27417 (2004 Bard survey response attaching 1999 Wayne Memorial Protocol, disclosing power injections through PAC), Appx27710-27713 (1992 Carlson disclosing same), Appx29222-29225 (Vortex testing); *see also*

Appx25535 n.17, Appx4718-4719, Appx5782-5783 (disclosing Dr. Trerotola's hospital was power-injecting Vortex in 2005). Bard even admits that prior-art ports were being power injected. AppBr6; 2019AppBr5.

Uncontroverted and unimpeached evidence also shows the "taking an x-ray" and identifying steps. While Bard argues that the evidence showing the claimed invention steps post-dates Bard's invention, it admits that prior to its alleged invention technicians would perform "routine scout scans" to visualize the implanted port prior to "CT procedures." AppBr7-8; 2019AppBr8. Tracking this admission, both sides' experts agreed that—without qualification—as part of every CT procedure, technologists always take a scout scan x-ray which involves port visualization. Appx45 (citing Appx4917, Appx4919 (Clark), Appx5791-5794 (Vogelzang)). Each of the prior-art ports' IFUs also instruct practitioners to radiographically view the implanted port prior to use, *e.g.*, to "ensure that the catheter is not being pinched." Appx24570-24571 (ATP), Appx29269, Appx29278 (PAC), Appx28965, Appx28975 (Vortex). The catheter could not be visualized on x-ray without also visualizing the port to which it was connected. Appx5791-5792 (Vogelzang).

Last, though Bard claims the district court applied inherency, AppBr56, it instead held each limitation expressly disclosed. *See* Appx44-46.

B. Bard's Procedural Attacks Fail.

1. The District Court Properly Considered the Relevant Evidence Comporting with the Claim Construction, Disregarding the Rest.

Unable to distinguish the prior art, Bard resorted to "reconstructions," adding unclaimed repeatability, safety, and port dimensions into the power-injectable port limitation. Appx18-26, Appx34. Its evidence and arguments on the radiographic marker also ignored the claims, construction, and printed matter ruling. Appx41-44. Uniqueness and vague notions of discernibility are not claimed, nor can they be used to read out express embodiments. So too for unclaimed x-ray settings and radiation exposure. AppBr53. Neither is described anywhere in the specification, and Bard certainly presented no evidence about the radiation or x-ray standards used to show the accused radiographic markers in its infringement case. Bard's irrelevant arguments and evidence were thus properly disregarded. *See Power Integrations*, 843 F.3d at 1337; *Melchior*, 665 F. App'x at 899.

Doing so is not tantamount to drawing inferences against Bard nor inconsistent with *Reeves*. *See* AppBr52 (citing *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133 (2000)). The district court was clear that it did not assess credibility, weigh evidence, or draw inferences from the facts. Appx18. Instead, it simply rejected irrelevant evidence that was inconsistent with the claim construction. *Id*. Because that left only "uncontroverted and unimpeached" evidence establishing

anticipation by clear-and-convincing evidence, the grant of JMOL was both proper and required. *Galena v. Leone*, 638 F.3d 186, 208, 213 (3d Cir. 2011).

2. Bard's "Foreclosure" Argument Is Erroneous.

Bard did not reverse on invalidity, yet Bard treats it as a *de facto* judgment of validity. But its statement that "a genuine dispute of material fact" existed did not change the claim construction, read out express embodiments, or resuscitate printed matter. AppBr39-40; *see E-Pass Techs., Inc. v. 3Com Corp*, 473 F.3d 1213, 1215–18 (Fed. Cir. 2007) (holding prior remand of a summary judgment ruling signaled that judgment "in favor of either party" was still possible "depending on the evidence and argument" on remand). The case was instead remanded for further proceedings, allowing—for the first time—a complete record to be developed and the printed matter doctrine to be applied in full.

Bard's post-remand admissions highlight the flaws in its procedural attack. The summary judgment record in *Bard* had disputed facts that have since become uncontested. For example, Bard stipulated that titanium ports are visible on x-ray, Appx5241; its experts admitted that a "square shape" (PAC's shape) could meet the radiographic marker limitations, Appx5061; and its experts admitted that ATP's shape, suture holes, and other features were all attributes "perceivable via x-ray," Appx5965-5966. On remand, the district court applied the printed matter ruling to all of the claimed information, including mental steps and letters. Appx6032-6035;

see also Appx3959-3960 (final jury instructions). That leaves Bard to argue vague notions of uniqueness/discernibility—unclaimed concepts that cannot exclude express embodiments.

Bard's reliance on *Uniloc USA, Inc. v. Microsoft Corporation*, 632 F.3d 1292 (Fed Cir. 2011), is misplaced. *See* AppBr41-42. Unlike the prior reversal at issue in *Uniloc*, 632 F.3d at 1300, *Bard* vacated-in-part on invalidity after affirming on printed matter. *Uniloc* does not stand for the proposition that judges are powerless to act after the jury was misled into reading out express embodiments. And law of the case does not apply because anticipation was not "already conclusively decided" in *Bard*. *Momenta Pharms., Inc. v. Teva Pharms. USA Inc.*, 809 F.3d 610, 620 (Fed. Cir. 2015).

Bard's foreclosure argument also hinges on the legal fallacy that because "Rule 56's genuine-dispute inquiry 'is the same' as Rule 50's reasonable-jury inquiry," the outcome must be "the same." AppBr41. "Rule 50 provides that JMOL against a party is only appropriate once the party 'has been fully heard on an issue.'" *Bard*, 979 F.3d at 1380 (quoting Fed. R. Civ. P. 50). No such requirement exists for Rule 56. Prior to *Bard*, neither party had fully presented invalidity arguments at trial, and this Court's opinion relied on an undeveloped summary judgment record. *Id.* at 1380–81. By remanding "for further proceedings consistent with [its] opinion," this

Court signaled that a judgment in favor of Angio could be supported by the evidence. *Bard*, 979 F.3d at 1385; *see also E-Pass*, 473 F.3d at 1215–18.

II. THE DISTRICT COURT'S ALTERNATIVE HOLDING OF INELIGIBILITY WAS PROPER AND SHOULD BE AFFIRMED.

A. The District Court Properly Held the Asserted Claims Ineligible Under Bard's "Reframing" of the Claims.

At *Alice* step one, the district court correctly held that, "[u]nder Bard's own telling at trial," the focus of the claims is a port that "the FDA deemed safe and reliable for power injection" and one that doctors could "safely and reliably" identify as such. Appx27-28, Appx31; *see Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217–18 (2014). This is consistent with this Court's recognition that "the radiographic marker" "allows the implanted device to be readily and reliably identified" which "makes the claimed port particularly useful[.]" *Bard*, 979 F.3d at 1375, 1384. The district court also correctly recognized that the method steps of x-raying, identifying, and flowing fluid "describe merely the ordinary use of the port under the medical standard of care." Appx30.

At trial, safety and reliability was the focal point of Bard's attempts to avoid the prior art: its inventor referred to power injecting the prior-art ports as "Russian roulette" because a device "might work one time" but "fail another time[.]" Appx4477-4478 (Powers). Its experts did not consider Vortex power injectable because it was "not safe to do so," Appx4932-4933 (Clark), and ATP was not power

injectable because, while some were "capable of it," "the entire line of titanium ports was not" absent tolerance tightening, Appx5928-5929 (Johnson). Likewise, Bard distinguished prior-art radiographic markers as not reliably identifiable. Those markers failed for not being: "foolproof," "recognizable to everybody," "identified with great certainty," Appx4499-4500, Appx4526-4527 (Powers); "reliably identified with a hundred percent certainty every time," Appx4887 (Clark); and distinguishable from other ports, Appx5931-5932 (Johnson).

Bard argues "the claims focus on a technological solution to achieve safety and reliability." AppBr30; *see Simio, LLC v. Flexsim Software Prods., Inc.*, 983 F.3d 1353, 1359 (Fed. Cir. 2020) (holding that step one looks to "what the patent asserts to be the focus of the claimed advance over the prior art" (cleaned up)). But the claims recite no "technological solution," let alone one that transcends this abstract idea. They instead recite a generic port—not improved power-injectable port structure, design parameters, or the process of making a port—and amorphous "identifiable features" given meaning by mental steps. Appx27-28. As the district court recognized, the "medical standard of care" of power injecting safely is an "abstract solution to human, not technical, problems." Appx27.

The specification provides Bard no quarter. It does not describe how to make a port power-injectable or radiographically identifiable. Appx4594-4596 (Powers), Appx105 (col.25:35-41, 63-67), Appx107 (col.30:42-45). Indeed, power-injectable

ports long existed in the art. *Bard*, 979 F.3d at 1375, 1384. So did "radiographic" features. Appx5241-5242 (stipulated facts). And the specification does not limit what features can be a radiographic marker. Appx105 (col.26:46-57), Appx107 (col.30:42-45); *see also* Appx52413-52414 (court recognizing at *Markman* that the specification is "pretty unlimiting" in terms of the radiographic marker).

For these reasons, Bard's "claimed advance" over the prior art is not new technology or functionality but the abstract idea itself. *Simio*, 983 F.3d at 1359. The "broad claim language" reflects this reality. *ChargePoint, Inc. v. Sema-Connect, Inc*., 920 F.3d 759, 769–70 (Fed. Cir. 2019). "Even if" the specification "had provided...a technical explanation," the claims would be preemptive because they recite no structure for making a port power injectable; nearly all ports, particularly titanium ones, have x-ray perceivable attributes; and ports are generally sold with separated features. *Id.*

At *Alice* step two, the district court correctly held that the claims do not recite an inventive concept. Appx28. Bard argues that its claims are not ineligible because it chose "to claim a combination of inventive features." AppBr30-31. But the radiographic marker need not be something added to the port—it can be *any* attribute of the port. This Court in *Bard* never held, as a matter of law, that the combination of a radiographic marker and a port was inventive. AppBr31. On a limited record,

this Court instead held that the evidence did not prove that "radiographic marking was routine and conventional" at step two. *Bard*, 979 F.3d at 1384.

On a complete record after remand—where Bard stipulated to formerly disputed facts, and "witnesses agreed across party lines" that "medical devices with radiographic markers and lettering were known in the prior art"—it was indisputable that "no *technical* hurdle prevented" using a marker to identify a port. Appx29. Nor can the printed matter—conveying that the port is power-injectable—provide an inventive concept at step two. *See Guldenaar*, 911 F.3d at 1162 (holding claims ineligible where "the only arguably unconventional aspect" of the claims was printed matter).

Far from turning step two into an obviousness inquiry, the district court based its holding on undisputed, relevant evidence—including Bard's pre-trial stipulations—showing that power-injectable ports and radiographic markers were well-understood prior to the priority date. Appx29-30. This undisputed evidence included:

- the patents' recognition that any feature of port, including size and shape, could comprise a radiographic marker, Appx107 (col.30:36-45);
- stipulated facts that radiographic markers and lettering were known, and that titanium ports were already radiographically visible, Appx5241-5242;
- admissions from Bard's expert, Dr. Johnson, that Bard did not invent radiographic features, labels, or letters, Appx5956-5958;

- 30(b)(6) testimony from Bard witness Kenneth Eliasen about the triviality of engraving a radiographic marker on a port, Appx5285-5287;

- testimony from Angio witnesses Anthony David Smith and Dr. Vogelzang stating the same, Appx5494-5495, Appx5797-5803; and

- multiple prior art references describing prior art radiographic markers, *e.g.*, Appx28362-28369, Appx28370-28373.

See Appx29.

Thus, the claims recite only "generic features" that cannot provide an inventive concept. *Free Stream Media Corp. v. Alphonso Inc.*, 996 F.3d 1355, 1366 (Fed. Cir. 2021) (recognizing that claims that "simply recite the use of generic features, as well as routine functions, to implement the underlying idea" are ineligible). Their "ordinary use" in performing the "standard of care" method is likewise uninventive. Appx29-30; *see Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 77-78 (2012).

Nor is there an inventive concept based on an ordered combination of generic components. AppBr29. Here, the combination of generic ports and markers does not lead to new or improved port functionality. Indeed, a radiographic marker does not "physically transform" the port into a power-injectable port, Appx5057 (Clark); it simply allows doctors to more safely and reliably use the port. *See ChargePoint*, 920 F.3d at 774–75 (holding no inventive concept at step two because the "generic networking capabilities" did "nothing to improve how charging stations function").

But that is the abstract idea itself, which cannot provide an inventive concept that saves the claims. *Id.*; *see also Free Stream*, 996 F.3d at 1366.

B. The District Court Properly Reached Ineligibility.

Bard seeks to create a glaring loophole in the *Alice* doctrine—patentees can insulate themselves from *Alice* scrutiny by pursuing abstract claims with a printed matter limitation as long as the claims are not directed "solely" to that limitation. That would undermine *Alice*'s prohibition against abstract claiming and transform the printed matter doctrine from a shield against overreach into a sword facilitating preemptively broad claims.

Beyond this flaw, Bard's procedural attacks on ineligibility fail. *First*, *Bard* and *Medcomp* addressed a narrow issue: whether the "claims in their entireties" were ineligible for being "solely" directed to printed matter. *C.R. Bard, Inc. v. Med. Components, Inc.*, No. 2022-1136, 2023 WL 2064163, at *2 (Fed. Cir. Feb. 17, 2023); *Bard*, 979 F.3d at 1383–84. In holding they were not, this Court did not consider ineligibility under any other theory, nor did it hold the patents broadly eligible. Another court has adopted this interpretation. *See C.R. Bard, Inc. v. AngioDynamics*, *Inc.*, C.A. No. 20-1544, 2024 WL 36015, at *1 (D. Del. Jan. 3, 2024) (rejecting Bard's same procedural arguments). Indeed, declaring patents valid or eligible is not the province of the Court. *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 994 (Fed. Cir. 2009) ("[C]ourts do not declare

patents to be valid," they "only declare that [patents] have not been proved to be invalid"). The Court's mandate cannot foreclose judgment on unaddressed issues. *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 137 F.3d 1475, 1477–78 (Fed. Cir. 1998) (holding prior reversal of literal infringement did not preclude a new trial on infringement under doctrine of equivalents). At no point did Angio "concede[]" that *Medcomp* was dispositive, and Angio's statements made before that opinion issued are not relevant. *See* AppBr25.

Second, there is no requirement that a purely legal issue such as patent ineligibility be decided by a jury. *See Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1325 (Fed. Cir. 2020) ("The issue of patent eligibility under §101 is a question of law that we review without deference."). Nor does Bard identify any facts supporting its eligibility case that it did not present at trial.

Indeed, courts hold claims ineligible at all stages of litigation, including at the Rule 12 stage, the Rule 50 stage, and on appeal. *See SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1166 (Fed. Cir. 2018)*; iLife Techs., Inc. v. Nintendo of Am., Inc.*, Civ. A. No. 13-cv-4987, 2020 WL 13281800, at *5 (N.D. Tex. Jan. 17, 2020), *aff'd*, 839 F. App'x 534 (Fed. Cir. 2021).

In *iLife*, for example, ineligibility was not presented to the jury, but Nintendo still moved for JMOL of ineligibility, which the district court granted. *iLife*, 2020 WL 13281800, at *1, *5. This Court affirmed. *iLife Techs., Inc. v. Nintendo of Am.,*

Inc., 839 F. App'x 534, 538 (Fed. Cir. 2021); *see also Prism Techs. LLC v. T-Mobile USA, Inc.*, 696 F. App'x 1014, 1016, 1018 (Fed. Cir. 2017) (reversing denial of JMOL on ineligibility and holding the claims ineligible even though the issue was not presented to the jury). Same here: the district court properly deemed Bard's patents ineligible despite the absence of a jury charge.

Third, Bard stretches *Kutner* too far, arguing that the grant of JMOL must be overturned because the district court's analysis of ineligibility was not *verbatim* what Angio argued in its Rule 50 motions on ineligibility. AppBr27-29 (citing *Kutner Buick, Inc. v. Am. Motors Corp.*, 868 F.2d 614, 617 (3d Cir. 1989)). In *Kutner*, the district court granted JMOL of no damages and the Third Circuit reversed because the movant's ground—that "[plaintiff] failed to make out a prima facie case on the existence of a contract"—did not track failure for lack of damages proof. *Kutner*, 868 F.2d at 617.

Here, however, Angio raised the issue of patent eligibility at the Rule 50(a) and 50(b) stages, and the district court granted JMOL on that ground. Appx6068-6070; *see also* Appx3849-3853, Appx3999-4005. The grounds on which Angio moved and the district court granted are the same: ineligibility based on *Alice*'s abstract idea framework, and Angio's motions at the Rule 50(a) and 50(b) stages complied with *Kutner*'s "same grounds" requirement.

Regardless, even if "the issue of patent eligibility was not properly preserved below," this Court retains discretion to address and resolve that legal issue. *Ericsson*, 955 F.3d at 1323–24 (holding claims ineligible on appeal after the issue was denied at JMOL).

C. Bard Addresses the Merits for the First Time on Appeal and Thus Waived the Issue.

At the district court, Bard neglected the merits and argued only that this Court's ruling in *Medcomp* precludes a determination that the claims are ineligible. Bard's merits arguments have thus been waived. *Hylete LLC v. Hybrid Athletics LLC*, 931 F.3d 1170, 1175 (Fed. Cir. 2019).

III. THE DISTRICT COURT'S ALTERNATIVE HOLDING OF INDEFINITENESS WAS PROPER AND SHOULD BE AFFIRMED.

A. Bard's Claims Are Indefinite as a Matter of Law.

Subjective limitations that "improperly allow[] the scope to vary from day-to-day and from person-to-person" render claims indefinite. *IQASR LLC v. Wendt Corp.*, 825 F. App'x 900, 907 (Fed. Cir. 2020); *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

During trial, Bard ambushed Angio and the district court with witness testimony and attorney argument flouting the claim construction "to avoid the admittedly-power-injectable prior art." Appx24. Angio repeatedly objected, and the district court repeatedly admonished Bard. *E.g.*, Appx4342-4346, Appx4746-4749, Appx4894-4896, Appx5928-5931, Appx5994-6009. Yet Bard charged ahead, with

witness after witness testifying that the prior-art ports do not anticipate because they (i) are not sufficiently identifiable as being "safe" for power injection, and (ii) have not been shown to be safe after an undefined number of injections. Appx22-26 (citing, *e.g.*, Appx4931-4933 (Clark), Appx4475-4478, Appx4744-4745 (Powers), Appx5928-5929 (Johnson)). But the Asserted Patents provide no guidance for determining when a port is safely and reliably power-injectable, or how many times a port must be capable of power injection to be "power-injectable." Appx31-34.

Bard says its claims are "precise about the structural elements and properties a power injectable vascular access port must possess," citing to claim limitations requiring a body, a cavity, a septum, an outlet stem, and a radiographic marker perceivable via x-ray. AppBr35. Yet each prior-art port here had this structure, and though not FDA-indicated for power injection, each could withstand power injections. Bard thus departed from its claims, telling the jury "[t]here was no [prior art] product that you could be assured that you could consistently, safely, and reliably inject[.]" Appx4893-4894 (Clark); *see also* Appx4932-4933 (Clark), Appx22-24. Bard meant, however, there were no FDA-cleared ports and that a port must be power-injectable for some indeterminate number of cycles. Appx33. But FDA indication is not claimed, and "only the vagaries of Bard's whim [would] tell the skilled competing artisan whether the asserted claims cover a longer-lasting port." Appx34.

The district court noted that POSAs disagreed whether prior-art ports met Bard's unclaimed safety and reliability requirements. Appx32-33. These included not only the parties' experts, but other doctors in the record who had been using prior-art ports for power injection procedures, including Dr. Trerotola, whose success power injecting was documented in Bard's files. Appx32-33, Appx5782-5783 (Vogelzang), Appx25535 n.17 (disclosing Dr. Trerotola's hospital was power-injecting Vortex).

The disagreement highlights that each POSA must determine whether a port is sufficiently safe and reliable based on his or her "individual training, experience, risk tolerance, and circumstance." Appx32. That human subjectivity renders the claims indefinite—whether two identical products meet the claim language cannot "vary from day-to-day and from person-to-person, providing a moving target that may change over time". *IQASR*, 825 F. App'x at 907 (cleaned up); *see Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1373–74 (Fed. Cir. 2014).

This case is unlike *BASF* because here, the district court referred to the specification and other evidence and determined that there was no objective way to determine the scope of the unclaimed lifespan limitation. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367–68 (Fed. Cir. 2017). Further distinguishing this case from *BASF*, Bard fails to cite to any portion of the specification that would provide reasonably certainty on this unclaimed term. Nor does Bard adequately

address the other evidence cited by the district court. Appx33-34. *Nevro* is similarly distinguishable. *Nevro Corp. v. Bos. Sci. Corp*., 955 F.3d 35, 41 (Fed. Cir. 2020).

The district court therefore properly held these claims invalid as indefinite.

B. The District Court Properly Reached Indefiniteness.

Bard seeks to avoid the consequences of its "claim construction debacle," asserting that the district court could not rule on indefiniteness. AppBr33-34; Appx34. This argument fails for three reasons.

First, "indefiniteness is a question of law and in effect part of claim construction." *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517 (Fed. Cir. 2012). Bard's argument that indefiniteness needed to go to the jury fails; unlike *Halliburton* and *Bombardier*, Bard identifies no disputed factual issues, the resolution of which would be determinative on indefiniteness. AppBr34 (citing *BJ Servs. Co. v. Halliburton Energy Servs., Inc*., 338 F.3d 1368, 1372 (Fed. Cir. 2003), *Bombardier Recreational Prods. Inc. v Arctic Cat Inc*., 785 F. App'x 858, 867 (Fed. Cir. 2019)). The POSAs' disagreement instead highlights the impermissible subjectivity of Bard's reconstructions, which is not dependent on fact-finding. Appx33. Indeed, indefiniteness is typically resolved without a jury and may be considered at the Rule 50 stage of litigation. *See, e.g.*, *iLife*, 2020 WL 13281800, at *1 n.2 (noting ineligibility and indefiniteness had not been tried to the jury because they were "matters of law").

Second, equity prevents Bard from using procedure to escape the consequences of its own misconduct. Rule 50 has a "notice-giving purpose" intended to ensure no party is ambushed on an unexpected topic. *Holt v. Pennsylvania*, 683 F. App'x 151, 156 (3d Cir. 2017). But here, it was Angio and the district court that were ambushed with new theories at trial, not Bard. Bard itself created this issue and cannot now assert that it had no notice of the indefiniteness of its reconstructions. *HP* and *Kutner* are distinguishable on this basis. *See Hewlett-Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1322 (Fed. Cir. 2003); *Kutner*, 868 F.2d at 617.

Bard says it "addressed different issues" than claim construction, "like the problem that Bard inventors were trying to solve or the scope and content of the prior art." AppBr33. But its arguments and witness testimony were clearly intended to differentiate prior art based on safety and reliability. *See*, *e.g.*, Appx22-26. And, despite previously acknowledging under oath that Bard did not invent power-injectable ports, Bard's expert changed his testimony in 2022 by "look[ing]" beyond the claims and crediting testimony premised on Bard's reconstructions. Appx5955-5960 (Johnson).

Third, Angio repeatedly raised Bard's improper reconstructions during trial. Angio raised this issue again during its JMOL motion, explaining that Bard's witnesses were impermissibly reconstruing the claims and altering their scope. Appx5317-5319, Appx6054-6057, Appx3981-3994, Appx4014-4017. Bard

responded to these charges, including during an hour-long JMOL argument. *See, e.g.*, Appx6382-6383 (Angio arguing that Bard's attempt to construe "identifiable feature" as "unique feature" created ambiguity because "[i]t's actually not even clear what would constitute a unique shape...[Bard's] patents certainly don't define it"), Appx6416-6417 (Bard's response). Bard was thus on notice that the reconstructions rendered the claims fatally subjective, and had an opportunity to respond.

IV. THE DISTRICT COURT'S JMOL OF NO WILLFUL INFRINGEMENT WAS PROPER AND SHOULD BE AFFIRMED.

Bard failed to meet its burden to prove willfulness. Angio's evidence that it reasonably relied on competent opinions of counsel is unrebutted, and Bard's willfulness arguments are based on misapprehensions of law.

Bard did not present evidence to contradict the testimony that Angio's legal department and senior engineers reasonably relied on competent opinions of counsel. Appx5108-5115 (King discussing Appx20413-20884, Appx20885-23143, Appx23144-23727), Appx5582-5587 (Girard discussing Appx29283, Appx29284, Appx29285). That they might differ from Angio's trial theories is irrelevant since opinions need only be competent and reliable when rendered. *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 944–45 (Fed. Cir. 1992); *see also SRI Int'l Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019). Indeed, competent opinions of counsel demonstrate a *lack* of an intent to infringe, and Angio "formed a good-faith belief that [Bard's patents were] invalid" on the basis of these unchallenged opinions of

counsel. *Sunoco Partners Mktg. & Terminals L.P. v. U.S. Venture, Inc.*, 32 F.4th 1161, 1177–78 (Fed. Cir. 2022).

Bard's view would turn the law of willfulness on its head, transforming a good-faith opinion into evidence of bad faith and subverting the public policy favoring opinions. *See Ortho Pharm.*, 959 F.2d at 944–45. Indeed, Bard premises willfulness on the opinions, claiming they show the "pre-issuance knowledge" of Angio's former IP director. AppBr62 (citing Appx5109 (Clark)). But "knowledge of [an] asserted patent" is alone insufficient to establish a "specific intent to infringe at the time of the challenged conduct[.]" *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 987–88 (Fed. Cir. 2021). Nor is pre-issuance knowledge of the applications alone competent evidence of a specific intent to infringe the patents. *See Bioverativ Inc. v. CSL Behring LLC*, C.A. No. 17-914, 2020 WL 1332921, at *2 (D. Del. Mar. 23, 2020) (recognizing the "generally limited relevance" of "pre-patent issuance conduct"). Further, the district court correctly noted that "a finding of willfulness should have a start date," but Bard presented no evidence that Angio possessed a specific intent to infringe at *any* point in time. Appx47; *Bayer*, 989 F.3d at 987–88.

Far from "copying Bard's *patented* technology," AppBr9, the letters "CT" are *unpatentable* printed matter, and Bard cites no case holding that copying ineligible subject matter can be evidence of willful infringement. *See Praxair*, 890 F.3d at 1032–35 ("[N]o patentable weight means no patentable weight."). Bard also admits

that radiographic labeling, including through the use of radiographic letters, existed in the prior art. *E.g.*, Appx2663 (¶38, PTO: Uncontested Facts), Appx5956-5958 (Johnson); *see also* Appx5241-5242 (stipulated facts). Angio's use of these prior-art techniques cannot be evidence of willfulness.

Bard's procedural arguments are flawed. This Court "vacate[d] the judgment of...no willful infringement" and "remand[ed] the case for further proceedings consistent with this opinion." *Bard*, 979 F.3d at 1385. A vacated decision does not mandate a contrary holding on remand. *See, e.g.*, *E-Pass*, 473 F.3d at 1215–18. The district court was instead free to "act on matters left open by the mandate." *Laitram Corp. v. NEC Corp.*, 115 F.3d 947, 951 (Fed. Cir. 1997) (cleaned up).

For the first time at the 2022 trial, both sides presented their entire cases, including new evidence and rebuttal on willfulness. That evidence included testimony from Angio's senior engineers that they reasonably relied on the opinions of counsel. Appx5582-5587 (Girard discussing Appx29283, Appx29284, Appx29285). This new evidence, combined with Bard's complete lack of evidence on specific intent, means that no reasonable jury could find willful infringement.

Thus, the district court's grant of JMOL should be affirmed.

V. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN CONDITIONALLY GRANTING A NEW TRIAL.

Because "[t]he trial judge observes the witnesses and follows the trial in a way that [the appellate court] cannot replicate by reviewing a cold record," the Third

Circuit applies an abuse of discretion standard, giving "considerable deference" to the decision to grant a new trial. *Williamson v. Consol. Rail Corp*., 926 F.2d 1344, 1348, 1353 (3d Cir. 1991) (cleaned up). An "abuse of discretion within the meaning of the rule" exists only "when the action of the trial judge is clearly contrary to reason and not justified by the evidence." *Vizzini v. Ford Motor Co*., 569 F.2d 754, 760 (3d Cir. 1977) (cleaned up). Here, the district court did not abuse its discretion in holding that a new trial was warranted.

Bard's argument that the district court abused its discretion, AppBr62-63, avoids its many improper and prejudicial arguments and testimony throughout trial, including when Bard impermissibly "flouted the Court's claim construction order, construing newly-material terms for the first time." Appx17; *see, e.g.*, Appx4342-4346, Appx4746-4749 (Powers), Appx4894-4896 (Clark), Appx5929 (Johnson). In granting a new trial, the district court provided its honest assessment that the jury was, *inter alia*, not "properly instructed...given the claim construction debacle," Appx34, and recognized that "[r]emedial attempts evidently failed," Appx17. Indeed, Angio could not have waived objections where the district court itself acknowledged that the jury instructions did not and could not "adequately account" for Bard's gamesmanship. Appx20.

"No party may contradict the court's construction to a jury." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1321 (Fed. Cir. 2009). Yet, when Bard began

questioning its validity expert regarding whether the ATP was "structured for power injection," the district court sustained Angio's objection regarding improper claim construction, noting that "[t]he case is not about inventing a PowerPort that can withstand 35 psi. This case is about, and I quote, 'an assembly for identifying a power-injectable vascular access port[.]'" Appx5929. Bard also claimed at trial that "the radiographic marker wasn't construed" when, indeed, it explicitly was. Appx5843-5844. Bard even recognized that its misconduct and manipulation of the claim construction "mudd[ied]" the issues for the jury. Appx6136-6137.

On damages, Bard presented a fabricated damages theory "pulled out of the air," forcing the district court to strike Bard's expert testimony, bifurcate damages from the trial, and attempt a curative instruction. Appx5315-5316, Appx6275, Appx3950-3951. That too created extreme prejudice.

Bard's misconduct undeniably pervaded the proceedings such that it is reasonably probable that the verdict was the product of prejudice, and the court's evaluation of that misconduct is entitled to substantial deference. *Fineman*, 980 F.2d at 207 ("Because the trial judge was present and able to judge the impact of counsel's remarks, we defer to his assessment of the prejudicial impact.").

This Court can also "affirm on any basis supported by the record, even if it departs from the district court's rationale." *TD Bank N.A. v. Hill*, 928 F.3d 259, 270 (3d Cir. 2019); *see also Laurel Gardens, LLC v. Mckenna*, 948 F.3d 105, 116 (3d Cir.

2020) (recognizing "appellee may urge affirmance on such a ground even if the district court overlooked it or it involves an attack on the district court's reasoning").

Here, a new trial is also warranted because the jury's verdict is against the clear weight of the evidence, and a new trial must be granted on all issues to prevent a miscarriage of justice. *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1185–86 (Fed. Cir. 2002) (affirming district court's grant of a new trial where the "jury's verdict...was against the weight of the evidence" and expert testimony was "general and vague"); *see also Roebuck v. Drexel Univ.*, 852 F.2d 715, 736–37 (3d Cir. 1988) (affirming district court's grant of new trial on similar grounds).

VI. THERE IS NO BASIS FOR REASSIGNMENT.

Reassignment is an "exceptional remedy" courts "weigh seriously and order sparingly." *United States v. Kennedy*, 682 F.3d 244, 258 (3d Cir. 2012). Such requests are evaluated to see if "a reasonable person, with knowledge of all the facts, would conclude that the judge's impartiality might reasonably be questioned." *See Arrowpoint Cap. Corp. v. Arrowpoint Asset Mgmt., LLC*, 793 F.3d 313, 329 (3d Cir. 2015) (cleaned up). This standard has not been met here. To the contrary, the district court's significant expenditure of judicial resources; the institutional knowledge it has gained over the past seven years; the court's demonstrated (and repeated)

impartiality towards all parties; and its thoughtfulness in evaluating the complex legal issues like printed matter, all counter against Bard's exceptional request.

The district court was thoughtful in evaluating each side's legal arguments and impartial throughout its time overseeing this case. It issued a 37-page opinion with detailed analysis and explanation. Appx12-48. It also gave Bard every benefit of the doubt at trial, assuming that Bard would litigate in good faith. Instead, Bard disregarded the claim construction, creating a "debacle" that sowed confusion and allowed Bard to convince the jury its patents were novel and non-obvious. Appx17-18, Appx34. The district court also afforded Bard the benefit of the doubt on its tenuous damages theory. Appx4083-4087, Appx4317. But Bard again took advantage, forcing the district court's hand. *E.g.*, Appx5138-5140, Appx5165-5167, Appx5176-5187, Appx5315-5316, Appx6275, Appx3950-3951.

Bard's authority, which is factually and legally distinguishable, explains that reassignment is an "extraordinary remedy" which often must derive from an "extrajudicial source...meaning something above and beyond judicial rulings or opinions formed in presiding over the case." *United States v. Bergrin*, 682 F.3d 261, 282–84 (3d Cir. 2012) ("reluctantly" granting reassignment due to judge's "repeated expressions of discomfort" with RICO charges); *Kennedy*, 682 F.3d at 258, 260 (reassigning case where the district court repeatedly questioned "the propriety of the prosecution"; "castigated the Government for" its charging decisions;

"[i]nsinuat[ed] additional prosecutorial misconduct"; and frequently referred to the charges and sentence as "Draconian"); *TriMed Inc., v. Stryker Corp.*, 608 F.3d 1333, 1344 (Fed. Cir. 2010) (reassigning case where district court engaged in "disfavored" and "regrettable practice" in twice adopting the prevailing party's "proposed statement of law and facts" wholesale). Nothing similar occurred here.

Bard's dissatisfaction with the district court's JMOL decision is not sufficient. *Arrowpoint*, 793 F.3d at 330. The district court previously implemented and faithfully adhered to this Court's order and mandate upon remand, and it is speculative and improper of Bard to infer it would not do so again. There is simply no basis for the extraordinary order of reassignment, and such order would unnecessarily waste judicial and party resources. No "reasonable person, with knowledge of all the facts, would conclude that the district court's impartiality might reasonably be questioned." *Id.* at 329.

CONCLUSION

The Court should affirm the district court's judgment.

Dated: January 30, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by CADWALADER WICKERSHAM & TAFT, LLP, attorneys for the Appellee, to print this document. I am an employee of Counsel Press.

On the **30th Day of January, 2024** counsel has authorized me to electronically file the foregoing **Brief For Defendant-Appellee AngioDynamics, Inc.** with the Clerk of Court using the CM/ECF System, which will serve via email a notice of such filing upon all of the following counsel registered as CM/ECF users at the time of filing:

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CERTIFICATE OF COMPLIANCE

In compliance with Fed. R. App. P. 32(g), I certify that:

This brief complies with the type-volume limitations of Fed. Cir. R. 32(b) because it contains 13,983 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2), as determined by the word-counting feature of Microsoft Word 2019.

This brief complies with the typeface requirement of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface, including serifs, using Times New Roman 14-point font.

January 30, 2024 /s/ Danielle Vincenti Tully

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