**No. 23-2056**

# 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, No. 1:15-cv-00218-JFB-SRF, Judge Joseph F. Bataillon

## REPLY BRIEF OF C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.

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MAY 6, 2024

# CERTIFICATE OF INTEREST

Counsel for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case.

C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

2. **Real Parties in Interest.** 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.

3. **Parent Corporations and Stockholders.** 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.

Bard Peripheral Vascular, Inc. is a wholly-owned subsidiary of C. R. Bard, Inc. C. R. Bard, Inc. is a wholly-owned subsidiary of Becton, Dickinson and Company. No publicly held company owns 10% or more of Becton, Dickinson and Company's stock.

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.

MORRISON & FOERSTER LLP: Vincent J. Belusko, Nicole M. Smith, Jonathan McNeal Smith, Ashleigh K. Landis, John Raleigh O'Donnell (all no longer with firm); and Rose S. Lee.

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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, see separately filed notice.

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).

Not applicable.

Dated: May 6, 2024

/s/ Deanne E. Maynard
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## INTRODUCTION

AngioDynamics's response confirms that this Court's prior decision in this same case dictates this appeal's outcome. At both *Alice* steps, that decision rejected JMOL and summary judgment of ineligibility. *C. R. Bard v. AngioDynamics*, 979 F.3d 1372, 1384 (Fed. Cir. 2020). This Court held Bard's claims "are patent eligible." *Id.* at 1375. The Court similarly rejected JMOL and summary judgment of anticipation, concluding instead that there was sufficient evidence for a reasonable jury to find otherwise. *Id.* at 1384-85. The Court also rejected as "procedurally improper" the district court's approach of *sua sponte* raising and deciding issues under Rule 50. *Id.* at 1380.

AngioDynamics tries to relitigate each of those holdings, betraying the extent to which the district court violated the mandate and failed to follow this Court's decision. AngioDynamics asks the Court to reconsider ineligibility, redecide anticipation, and embrace the district court's use of Rule 50 to again raise and decide new issues, including indefiniteness. But straightforward application of the mandate rule and this Court's prior decision resolves those issues, requiring reversal or vacatur of all the invalidity judgments.

Reversal would be required even without that prior decision. As this Court recognized, Bard's claims are directed to improved vascular access ports—actual medical devices—not an abstract idea. On issue after issue, AngioDynamics slogs

through piles of competing evidence. It asks the Court to decide for itself, by drawing inferences favorable to AngioDynamics, factual issues like the scope and content of the prior art. But that is not this Court's role, nor was it the district court's. The jury was tasked with resolving the invalidity issues AngioDynamics actually preserved; it reasonably resolved them against AngioDynamics. That too requires reversal or vacatur.

Whether the invalidity judgments should be reversed or vacated is all this Court need decide. Although the initial briefs address additional issues, the parties have since narrowed their dispute. As Bard notified the Court, the parties have agreed to a conditional settlement, which provides for a license and substantial payment contingent on reversal or vacatur of the invalidity judgments. ECF No. 39. Bard thus focuses on those issues.

## ARGUMENT

### I. ON INELIGIBILITY, ANGIODYNAMICS CANNOT OVERCOME THIS COURT'S MANDATE, PRECEDENT, OR THE RECORD

#### A. AngioDynamics's Mandate-Defying Attempt To Relitigate Subject-Matter Eligibility Should Be Rejected

This Court's prior decision squarely addressed and rejected AngioDynamics's ineligibility challenge. *Bard*, 979 F.3d at 1381, 1384-85. The Court reversed invalidity and held that "the asserted claims are not patent ineligible under § 101." *Id.* In doing so, this Court created no "loophole in the *Alice* doctrine" (Angio.Br.50);

rather, it rightly refused to expand the printed-matter doctrine far beyond its traditional role in prior-art invalidity. *Id.* Regardless, in re-arguing ineligibility, AngioDynamics (like the district court) wrongly gives this Court's controlling mandate short shrift.

AngioDynamics abandons the district court's flawed rationales, including the notion that this Court "only ruled on half of the 101 defense not the second half." Appx6068-6070. Bard explained that is factually and legally wrong: this Court addressed both *Alice* steps; regardless, AngioDynamics's failure at either is dispositive. Bard.Br.26. AngioDynamics has no response. Angio.Br.50-53.

AngioDynamics instead pivots to a new argument, just as flawed. It argues this Court's prior decision addressed ineligibility under only one "theory," leaving AngioDynamics free to challenge ineligibility "under any other theory." Angio.Br.50. But the mandate rule forecloses "alternative argument[s]" parties "could have argued" but did not. *Yankee Atomic Elec. v. United States*, 679 F.3d 1354, 1361 (Fed. Cir. 2012). In *Yankee*, this Court rejected the government's attempt on remand to "rewind the clock to pursue a new litigation approach" based on an alternative contract interpretation after this Court had rejected the government's original interpretation. *Id.* (analogizing to improper attempt to raise new patent "anticipation defense on remand"). AngioDynamics's similar attempt to undo this Court's prior decision fails for the same reason.

AngioDynamics cannot avoid that conclusion by invoking the maxim that "courts do not declare patents to be valid" but only not "proved to be invalid." Angio.Br.50-51 (citation/alteration omitted). That maxim cannot help AngioDynamics, for two independent reasons. First, whatever may be the general principle for other parties, AngioDynamics's failure to prove Bard's claims invalid under Section 101 in this very case precludes *AngioDynamics's* second apple bite on remand. This Court's prior holding is the final word on that issue here, as *Yankee* makes clear. Allowing otherwise would undermine the mandate rule's purpose of ensuring litigation "ha[s] an end." *In re Nwogu*, 570 F. App'x 919, 922 (Fed. Cir. 2014).

Second, because this Court interpreted Bard's claims and held "the focus of the claimed advance" directed to patent-eligible matter at *Alice* step one, this Court's decision was the final word on Section 101 for these claims, for AngioDynamics and others. *Bard*, 979 F.3d at 1384. Such a decision "effectively entered judgment of validity." *Ericsson v. TCL Commc'ns Tech. Holdings*, 955 F.3d 1317, 1321 (Fed. Cir. 2020). Indeed, a different panel so recognized, holding this Court's prior decision required reversal of a district-court decision deeming materially similar Bard claims ineligible. *C.R. Bard v. Med. Components*, No. 22-1136, 2023 WL 2064163, at *2 (Fed. Cir. Feb. 17, 2023). Throughout this case, including in its failed rehearing petition in this Court, AngioDynamics repeatedly acknowledged

these decisions conclusively resolved eligibility at step one, belying its contrary assertions now. Bard.Br.13-14, 25.

The mandate rule alone dooms the ineligibility judgment.

### B. AngioDynamics Never Contests Ineligibility Was Not Tried, Another Reason To Reverse Or Vacate

This Court already held that "Rule 50 provides that JMOL against a party is only appropriate once the party 'has been fully heard'" at trial because JMOL depends on what "a reasonable jury" could conclude from trial evidence. *Bard*, 979 F.3d at 1378. As AngioDynamics never disputes, subject-matter eligibility was not tried; the district court expressly excluded it pretrial (Appx2309); neither party identified it as a disputed factual or legal issue in the pretrial order (Appx2681-2686); and neither party requested, and the district court never gave, an ineligibility jury instruction (Appx3189-3323). Bard.Br.27-28 (explaining same). Because Bard was never heard at trial on ineligibility, JMOL could not be granted on it. *Bard*, 979 F.3d at 1380.

AngioDynamics's only response is that "there is no requirement that a purely legal issue such as patent ineligibility be decided by a jury." Angio.Br.51-52. That response fails many times over. It fails because Rule 50 was the only basis the district court and AngioDynamics invoked, yet Rule 50 authorizes judgment only for issues presented "during a jury trial." Fed. R. Civ. P. 50; *Bard*, 979 F.3d at 1380. And like the district court, AngioDynamics repeatedly relies on trial testimony and

evidence as the basis for purported ineligibility, making clear no other mechanism exists for its belated ineligibility arguments. Appx22-31; Angio.Br.45-50; *see Berkheimer v. HP*, 881 F.3d 1360, 1365 (Fed. Cir. 2018) (eligibility "may contain underlying issues of fact"). AngioDynamics's "purely legal" characterization also contradicts its own narrative that this Court supposedly ruled on ineligibility "[o]n a limited record" while the district court acted "[o]n a complete record after remand." Angio.Br.47-48.

AngioDynamics's decisions undermine its position. Angio.Br.51-53. In *iLife*, a summary-judgment motion had been deferred until after trial; here, no summary-judgment motion was pending on remand. *iLife Techs. v. Nintendo of Am.*, 839 F. App'x 534, 536 (Fed. Cir. 2021); *id.*, No. 3:13-cv-4987, 2020 WL 13281800, at *1 n.2 (N.D. Tex. Jan. 17, 2020) (noting ineligibility summary-judgment motion "carried" forward to after trial). Likewise, the *Prism* district court had resolved cross-motions for summary judgment, and the *Ericcson* district court had resolved ineligibility before trial. *Prism Techs. v. T-Mobile USA*, 696 F. App'x 1014, 1016 (Fed. Cir. 2017); *Ericsson*, 955 F.3d at 1323-24. No decision suggests parties can skip pressing an issue altogether and then raise it in a Rule 50 motion or on appeal. Angio.Br.52-53.

Even were Rule 50 available, AngioDynamics still has no answer for the district court's *sua sponte* raising of a ground different from the one AngioDynamics

belatedly raised. AngioDynamics never disputes that the district court based its Rule 50 grant on its own rationale that Bard's claims are purportedly directed to the "abstract solution" of "safety and reliability." Appx27-28. Instead, AngioDynamics argues both it and the district court identified the same ground because both addressed "ineligibility based on *Alice*[]." Angio.Br.52. But specifying the ground at that level of generality conflicts with Rule 50's text, which requires identifying "the law *and facts*" supporting judgment. Fed. R. Civ. P. 50 (emphasis added). Because the district court granted JMOL on a ground not "specifically advanced" by AngioDynamics, reversal or vacatur is required. *Kutner Buick v. Am. Motors*, 868 F.2d 614, 617 (3d Cir. 1989) (reversing JMOL).

### C. Regardless, AngioDynamics Fails To Justify JMOL Of Ineligibility

AngioDynamics cannot get past *Alice* step one, as Bard's claims are directed to a non-abstract invention: a vascular access port with a "radiographic marker" that "makes the claimed port particularly useful"; and non-abstract methods of using such ports. *Bard*, 979 F.3d at 1384. AngioDynamics parrots the district court that "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." Angio.Br.45-50. But AngioDynamics points to nothing in the claims supporting that assertion, ignoring this Court's repeated rejection of "describing the claims at such a high level of abstraction and untethered from the language of the claims." *Enfish*

*v. Microsoft*, 822 F.3d 1327, 1337 (Fed. Cir. 2016). Even in AngioDynamics's telling, the focus of the claims is still non-abstract: a "port" that delivers certain benefits, not the idea of abstract benefits. Angio.Br.45-50.

AngioDynamics's step-two arguments fare no better. It repeatedly labels disputed evidence "undisputed." Angio.Br.48-50. For example, it says Bard's patents recognize "that any feature of [a] port, including size and shape, could comprise a radiographic marker." Angio.Br.48 (citing Appx107(col.30:36-45)). Not so. The cited passages merely acknowledge that the claimed port itself may have different "sizes and shapes," not that either is a "radiographic marker." Appx107(col.30:36-45).

AngioDynamics (like the district court) also points to disputed evidence about whether individual claim elements "were known." Angio.Br.47-49 (citing Appx29). But the step-two hurdle is higher: "[w]hether a particular technology is well-understood, routine, and conventional goes beyond what was simply known." *Berkheimer*, 881 F.3d at 1369. And even if individual elements were known, that would not establish lack of an inventive concept in their "ordered combination." *Id.* at 1366 (citation omitted). On that issue, AngioDynamics acknowledges that the claimed combination of power-injectable ports with identifying radiographic markers "allows doctors to more safely and reliably use the port." Angio.Br.49-50.

That concession is fatal: it shows the claimed combination improves port functionality and is not just "the abstract idea itself." *Contra* Angio.Br.49-50.

Finally, Bard's challenge to the merits of the ineligibility ruling is preserved for appeal. *Contra* Angio.Br.53 (citing *Hylete v. Hybrid Athletics*, 931 F.3d 1170 (Fed. Cir. 2019)). "[A] party may raise on appeal any issue that was raised *or* actually decided below." *Lifestyle Enter. v. United States*, 751 F.3d 1371, 1377 (Fed. Cir. 2014) (Court's emphasis). That rule applies with even greater force here, where no party pressed the ineligibility ground the district court decided—distinguishing *Hylete*, where the appellant had "notice" of the issue in the reviewed tribunal. 931 F.3d at 1174-75.

* * * * *

Because the mandate, rules, and record each independently foreclose the ineligibility judgment, the Court should reverse or vacate it.

## II. ON INDEFINITENESS, ANGIODYNAMICS CANNOT OVERCOME THE DISTRICT COURT'S PROCEDURAL AND SUBSTANTIVE ERRORS IN *SUA SPONTE* GRANTING JMOL

### A. It Is Undisputed That The Rule 50 Order *Sua Sponte* Raised And Decided Indefiniteness, Requiring Reversal Or Vacatur

Neither AngioDynamics nor Bard even broached indefiniteness in pretrial filings, trial, or post-trial filings, as AngioDynamics never disputes. Angio.Br.56-58. Nor does AngioDynamics identify anywhere that Rule 50 motions raised indefiniteness. The Rule 50 order's *sua sponte* raising and deciding of

indefiniteness thus reflects a clear-cut violation of settled procedure. *Hewlett-Packard v. Mustek Sys.*, 340 F.3d 1314, 1322 (Fed. Cir. 2003); *Kutner*, 868 F.2d at 617; Bard.Br.32-34 (explaining same, citing additional authority).

AngioDynamics responds by pointing to different issues it raised, such as rejected *Daubert* motions, noninfringement, prior-art invalidity, and a new-trial request for purported "prejudice." Angio.Br.57-58 (citing Appx3981-3994, Appx4014-4017, Appx5317-5319, Appx6054-6057). But that just highlights what is missing: compliance with the basic Rule 50 prerequisites, including timely pre- and post-verdict motions raising indefiniteness and providing Bard notice and an opportunity to respond. *Kutner*, 868 F.2d at 617.

AngioDynamics is wrong that Rule 50's strictures can be ignored because indefiniteness need not be decided by a jury. Angio.Br.56. As with its similar argument on eligibility, AngioDynamics ignores that Rule 50 was the only basis the district court invoked, and that both it and the district court rely heavily on trial testimony the jury purportedly could not "reasonably have disregarded" and what "the trial record shows" about purported indefiniteness. Appx31-34; Angio.Br.53-56; *supra* pp. 5-6. Also as with eligibility, no other procedural mechanism exists: no indefiniteness summary-judgment motion was pending; nor did the district court give "notice and a reasonable time to respond," as required. Fed. R. Civ. P. 56(f).

Because AngioDynamics cannot reconcile the district court's order with basic procedural norms, AngioDynamics resorts to generalized notions of "equity"—arguing Bard purportedly presented "new theories" and created a "claim construction debacle," so "equity prevents Bard from using procedure" to avoid the consequences. Angio.Br.56-57. But Bard neither presented "new theories" nor created a "debacle." Rather, it merely did what all patentees do: for invalidity, it disputed whether the prior art satisfied the claim constructions, and for infringement, whether AngioDynamics practices them. Bard.Br.36-37 (explaining and walking through same).

In suggesting otherwise, AngioDynamics points to only a handful of transcript pages. But those passages involve what was known in the art (not claim construction), and AngioDynamics's attempt to impeach a Bard witness. Angio.Br.57 (Appx5955-5960). The jury heard that testimony and rejected the invalidity issues AngioDynamics actually presented. Nor does AngioDynamics have legal support for its misguided view of "equity," which ignores that Rule 50's protections have constitutional dimensions, including protecting the non-movant's Seventh Amendment jury-trial right. *Orlando v. Billcon Int'l*, 822 F.2d 1294, 1298 (3d Cir. 1987).

As Bard showed, the district court's failure to abide by Rule 50's requirements alone requires reversal or vacatur on indefiniteness. Bard.Br.32-34; Angio.Br.56-58 (never contesting this relief if error).

### B. Regardless, AngioDynamics Confirms The Indefiniteness Judgment Is Untethered From Law And Fact

Even were the Court to reach the merits, AngioDynamics's arguments reveal the district court's error.

*First*, AngioDynamics points to unclaimed limitations—such as arguing there is allegedly "no objective way to determine the scope of the unclaimed lifespan limitation." Angio.Br.53-56 (no "reasonabl[e] certainty on this unclaimed term"; similar for safety/reliability).

But the definiteness standard requires only that the "claims, read in light of the specification" inform skilled artisans "with reasonable certainty" about the invention's scope. *Nautilus v. Biosig Instruments*, 572 U.S. 898, 901 (2014); 35 U.S.C. § 112. The claims do that here, identifying the exact structures and features forming the invention. Bard.Br.34-36. Nothing required Bard's patents to address "unclaimed" features, nor does Bard's anticipation appeal turn on such features. *Infra*, Part III.

*Second*, AngioDynamics stretches to analogize Bard's claims to ones with highly "[s]ubjective limitations." Angio.Br.53-55 (citing *IQASAR v. Wendt Corp.*, 825 F. App'x 900, 905-06 (Fed. Cir. 2020) (claiming "magnetic fuzz," described as

"difficult to substantially identify"); *Interval Licensing v. AOL*, 766 F.3d 1364, 1367-68 (Fed. Cir. 2014) (requiring displaying content "in an unobtrusive manner that does not distract")). AngioDynamics identifies no similar terms of unidentifiable degree or subjective opinion in the claims as construed here, which merely require a port with specific physical properties, such as "a body defining a cavity" and being "structured for" power injection at recited parameters. Appx107-108(col.30:51-col.31:6); Appx309-315.

AngioDynamics, like the district court, also improperly draws inferences against Bard. For example, AngioDynamics cites evidence about a non-testifying witness, Dr. Trerotola, who tested "power injection" of the prior-art Vortex port. Angio.Br.55 (citing Appx5782-5783; Appx25535 n.17). In deciding invalidity, the jury was not required to credit that evidence, which does not address the claims' undisputedly objective requirements of power injection at specific flow rates and cavity pressures. Appx5782-5783; Appx25535 n.17. AngioDynamics omits these and other claim requirements when it baldly asserts that the "prior-art ports" included every claim element and that Bard distinguished the prior art only by "depart[ing] from its claims." Angio.Br.54. In actuality, as the routine factual disputes between the parties on anticipation show (Part III, *infra*), the prior-art issues turn on objective claim requirements that skilled artisans understand, making this case like *BASF* and *Nevro*. *BASF v. Johnson Matthey*, 875 F.3d 1360, 1367-68 (Fed.

Cir. 2017); *Nevro Corp. v. Boston Sci.*, 955 F.3d 35, 41 (Fed. Cir. 2020); *contra* Angio.Br.55-56.

AngioDynamics tries to inject subjectivity into the claims because Bard's witnesses disagreed with AngioDynamics's about whether prior-art ports were structured for power injection at specific flow rates and cavity pressures or included the required radiographic markers. Angio.Br.53-55 ("POSAs disagreed"). But as Bard explained and AngioDynamics never rebuts, that is a dispute about the scope and content of the prior art, not claim scope. Bard.Br.36-37; Angio.Br.53-56. Under AngioDynamics's flawed view, essentially every patent dispute about prior-art invalidity and infringement would be an indefiniteness battle. No statute or precedent supports that result; precedent holds otherwise. *Nevro*, 955 F.3d at 41 (rejecting similar argument that "would render nearly every claim term indefinite").

* * * * *

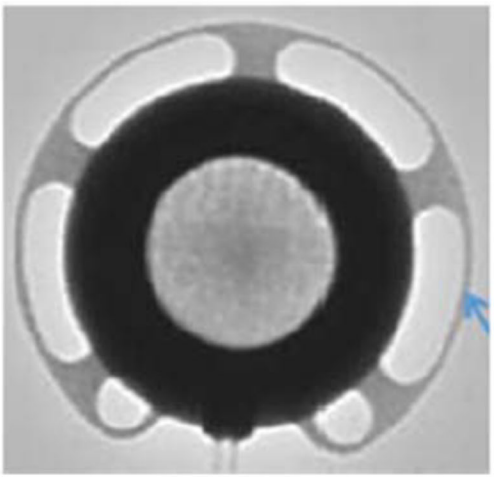
The district court's procedural and substantive errors, alone or combined, compel reversal or vacatur on indefiniteness.

## III. ON ANTICIPATION, ANGIODYNAMICS CANNOT OVERCOME THIS COURT'S PRIOR DECISION OR THE RECORD

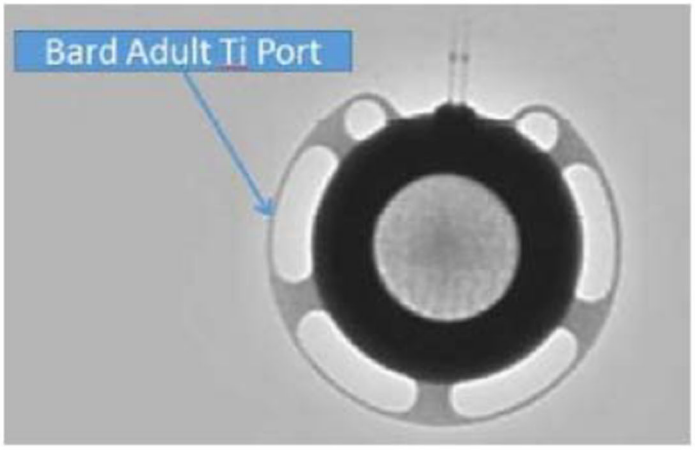
### A. AngioDynamics's Arguments Show It Is Re-Litigating The Same Issue It Litigated And Lost In The Prior Appeal, Which Is Prohibited

AngioDynamics's response feels like déjà vu. Four years ago, AngioDynamics told this Court a reasonable jury would be compelled to find that

prior-art ports anticipated Bard's claims, arguing among other things that the prior-art Adult Titanium port includes the claimed radiographic marker in the form of "a flange with suture slots and orientation holes," "etching," and "a perceivable shape." 19-1756, ECF 43, at 64. Back then, AngioDynamics pointed to the below images:

*Id.* AngioDynamics now repeats the same arguments based on the same evidence: the Adult Titanium Port allegedly includes a radiographic marker because its "shape, suture holes, and orientation holes are x-ray visible." Angio.Br.31. AngioDynamics relies on identical images (with different cropping/orientation; Angio.Br.32):

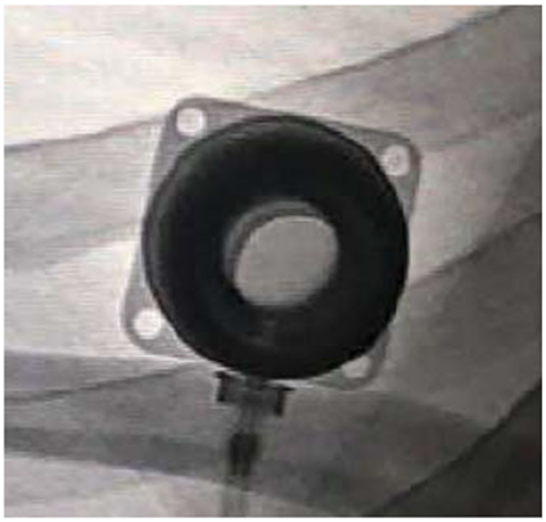


Four years ago, AngioDynamics argued the prior-art Port-A-Cath included the claimed radiographic marker because it has "a square geometric shape" and "a unique quadrilateral suture hole configuration," pointing to the below images:


Standard Picture

X-Ray

19-1756, ECF 43, at 68-69. AngioDynamics now recycles the same arguments with the same evidence. Port-A-Cath allegedly anticipates because it has "a square shape and suture hole arrangement" that "are perceivable on the x-ray reproduced below":



Angio.Br.38-39 (again, with different cropping/orientation).

Four years ago, AngioDynamics argued evidence about different port shapes sufficed because allegedly "[a]ll shapes are identifiable," which is all Bard's claims purportedly require. 19-1756, ECF 43, at 68-69 (citation omitted). AngioDynamics now rehashes the same theory: the claims are purportedly met if "any attribute of a port, such as its shape or suture holes" is "x-ray perceivable." Angio.Br.23, 23-39 (claims met if features x-ray "perceivable"). AngioDynamics makes materially identical arguments based on materially similar evidence for the Vortex port, pointing to features like generic "shape" and "suture hole orientation" as anticipatory and arguing "the claims require only that Vortex's attributes be x-ray *perceivable*." Angio.Br.36 (AngioDynamics's emphasis).

These arguments confirm that the anticipation JMOL violated this Court's prior, binding decision. This Court already rejected the arguments accepted by the district court on remand and repeated by AngioDynamics here. Presented with materially identical evidence and arguments, this Court held that a reasonable jury could uphold Bard's claims because the claims require more than just x-ray visibility—they require features that are "radiographically discernible" and that "distinguish or identify the device or its functionality." *Bard*, 979 F.3d at 1384-85. Now that the jury reached that conclusion on remand, this Court's holding precludes

AngioDynamics's attempt to relitigate issues it already lost. *Uniloc USA v. Microsoft*, 632 F.3d 1292, 1308 (Fed. Cir. 2011).

AngioDynamics acknowledges, without contesting, that "'Rule 56's genuine-dispute inquiry is the same as Rule 50's reasonable-jury inquiry.'" Angio.Br.44. It argues instead that the remand allowed for "a complete record to be developed," asserting there were purportedly facts that were no longer disputed and additional evidence. Angio.Br.43-45. Not so: the remand record was materially the same as the one this Court considered. The district court was express that there would be no "new discovery, amended contentions, nor updated expert reports" because the "invalidity cases" are "set." Appx3066-3067. The parties would merely "retry to a new jury the case they presented (or would have presented)" at the first trial. Appx3067. Indeed, AngioDynamics's examples of purportedly new evidence and admissions confirm that the remand record was just like that presented in the last appeal, such as evidence about "shape, suture holes, and other features" that are "attributes 'perceivable via x-ray,'" and evidence that a square shape "could" be a radiographic marker. Angio.Br.43 (citing Appx5061, Appx5241, Appx5965-5966).

AngioDynamics cannot reconcile its position now with this Court's prior holding that a reasonable jury could reject materially identical evidence.[1]

Trying to avoid this Court's holding, AngioDynamics argues that only the district court, and not this Court, "applied in full" the "printed matter doctrine." Angio.Br.43, 2, 13. But before the prior appeal, the district court had applied the printed-matter doctrine and held a reasonable jury could find only anticipation. *Bard*, 979 F.3d at 1377-78. Bard appealed and this Court decided that issue: applying the "printed matter doctrine[] when evaluating the novelty" of the claims, the Court held "conflicting evidence created a genuine dispute of material fact." *Id.* at 1384-85.

AngioDynamics also attacks strawmen. Bard is not asserting that this Court's prior decision was "a *de facto* judgment of validity" or that it foreclosed a jury from ruling for AngioDynamics. *Contra* Angio.Br.43-45. Bard's point is that this Court already held that a materially identical record would support a reasonable jury's finding for Bard and rejecting anticipation; on remand, the jury so found. *Bard*, 979 F.3d at 1384-85. This Court's prior holding thus precluded the district court from

[1] That Bard contested additional issues that had been unaddressed at summary judgment, such as the power-injectability of prior-art ports (Angio.Br.27-28), simply further supports the jury's verdict. *Infra* pp. 26-31.

setting aside that verdict on the ground that no reasonable jury, after hearing that materially identical evidence, could so find.

AngioDynamics never contests that ruling for Bard on this issue requires reversal or vacatur of the anticipation judgment for all claims.

### B. Regardless, The Record Supports The Jury's Verdict

Even without this Court's prior decision, reversal of JMOL is required because substantial evidence supports the no-anticipation verdict.

#### *1. AngioDynamics, like the district court, applies the wrong standard*

Bard described the high bar AngioDynamics faces in trying to overturn the jury verdict on an issue on which AngioDynamics bore a clear-and-convincing burden. Bard.Br.42-43. Giving Bard the advantage of every fair inference and disregarding all evidence favorable to AngioDynamics that the jury was not required to believe, AngioDynamics must show "the record 'is critically deficient of that minimum quantum of evidence from which a jury might reasonably'" have reached its verdict. *Dawson v. Chrysler*, 630 F.2d 950, 959 (3d Cir. 1980). And it must do all that through the prism of the "heavy burden of persuasion" AngioDynamics bore. *Microsoft v. i4i Ltd.*, 564 U.S. 91, 102 (2011).

Without disputing this standard, AngioDynamics ignores it. Like the district court, AngioDynamics largely ignores the evidence favorable to Bard, including from its own documents and witnesses admitting that prior-art ports were not power-

injectable or lacked radiographic identifying features. Bard.Br.45-54. AngioDynamics instead marches through evidence it believes favors invalidity and repeatedly asks the Court to reject inferences favoring Bard and draw inferences favoring AngioDynamics. As just a few examples:

- AngioDynamics insists that any evidence that a prior-art port was "power injectable," without mention of flow rates or cavity pressures, must mean the port was structured for power injection at the flow rate and pressure required by Bard's claims. *E.g.*, Angio.Br.29 (citing Appx5241) Angio.Br.30 (citing Sheetz and Powers at Appx1006-1007, Appx5624, Appx5774-5775), Angio.Br.34 (citing Appx25497; Trerotola at Appx25535 n.17).

- AngioDynamics simultaneously asks the Court to disregard its own internal training documents identifying its prior-art ports as non-power-injectable, dismissing these documents as mere "marketing." Angio.Br.34-35 (primarily citing district court rather than evidence).

- AngioDynamics argues the Court must infer that statements that devices are the "same" for purposes of establishing "substantial equivalence" for FDA approval mean they are the same for purposes of comparing to Bard's claims. *E.g.*, Angio.Br.29-30 (citing Appx24440, Appx24402, Appx24422, Appx24429), Angio.Br.33-34 (citing, *e.g.*, Appx5416-5419, Appx19755-19756).

- AngioDynamics simultaneously says the Court can infer nothing from other evidence and statements related to the FDA, such as the FDA's requiring "extensive" material changes to a prior-art port before it could be marketed as power injectable (Appx5518-5520). Angio.Br.33-34 (dismissing "unclaimed FDA indication").

AngioDynamics thus commits the same error as the district court, which expressly stated it was "disregard[ing] evidence, even favorable to Bard, that the

jury is not required to believe." Appx18. This failure to apply the correct standard is alone fatal.

#### *2. AngioDynamics's cherry-picked evidence at most shows factual disputes, which the jury reasonably resolved for Bard*

Under the correct standard, the outcome is clear. Although AngioDynamics asserts it need only show "any one of the prior-art ports" "anticipatory" (Angio.Br.22), it never contests it must run the table on both the requirement for an identifying "radiographic marker" or "radiographic feature" and the requirement for a port structured for power injection for all claims (including the method and radiographic-letter ones). Bard.Br.45; Angio.Br.25-39. The jury's reasonable conclusion on either limitation for each prior-art port defeats anticipation.

##### *a. AngioDynamics's overarching arguments on the identifiable-feature limitation show reversal or vacatur is required on all claims*

Although Bard walks through each prior-art port in subsection b *infra*, the Court can decide this issue on all ports based on AngioDynamics's overarching arguments on the identifiable-feature limitation. This Court already decided which portion of this limitation is unpatentable printed matter and which is not. *Bard*, 979 F.3d at 1381-82. Applying that ruling to anticipation, this Court held that AngioDynamics would have to show a prior-art port with a feature that is "radiographically discernible" *and* can "be used to distinguish or identify the device or its functionality." *Id.* at 1385. Contrary to AngioDynamics's repeated assertions,

this neither creates an unworkable "unique" identifier requirement nor amounts to an unpatentable "mental step." *E.g.*, Angio.Br.27. Rather, it requires a port with a specific physical feature.

Yet AngioDynamics's invalidity theory, adopted by the district court, expressly depends on ignoring half of this Court's requirement. AngioDynamics argues the only "requirement" is "that the 'radiographic attribute' be 'perceivable via x-ray.'" Angio.Br.24, 2, 13; *see* Angio.Br.31 (Adult Titanium Port: features are "x-ray visible"), Angio.Br.36 (Vortex: "perceivable on x-ray"), Angio.Br.38 (Port-A-Cath: "perceivable on the x-ray"). AngioDynamics thus effectively concedes that the anticipation JMOL cannot survive against the limitations this Court gave patentable weight.

AngioDynamics also bases anticipation on another misconception cutting across all prior-art ports—that "any attribute of a port, such as its shape or suture holes, could be a radiographic marker." *E.g.*, Angio.Br.23-24, 32, 39 (citing Appx105(col.25:35-46,63-67); Appx19326-19336). This argument is doubly flawed. First, neither Bard's patents nor its provisional application says that. Rather, they describe "identification features" generally, which span a range of attributes observed "visually, by palpation, ultrasonically, radiographically, etc." Appx105(col.25:35-46,63-67); Appx19326-19336 (similar). For example, the provisional application describes a port with a quadrilateral shape and two concave

sides to allow the port to be identified by palpation (touch) after implantation. Appx19333-19334(¶¶67-68), Appx19361. AngioDynamics wrongly equates descriptions of that and other identifiable features with descriptions of *radiographic* identifiable features, the relevant subset of features claimed here. Second, and regardless, AngioDynamics wrongly assumes that just because some physical attributes *could* be a radiographic marker (i.e., a radiographic "indicium") for some ports depending on the arrangement and configuration, a reasonable jury could *only* conclude that any x-ray-visible attribute of any port is a claimed radiographic marker regardless of arrangement and configuration. *E.g.*, Angio.Br.23-24, 39; Appx105(col.25:35-41,63-67). Nothing compelled the jury to draw that inference.

These cross-cutting failures in AngioDynamics's invalidity challenge, which the district court embraced, are another independent basis to reverse or vacate on anticipation.

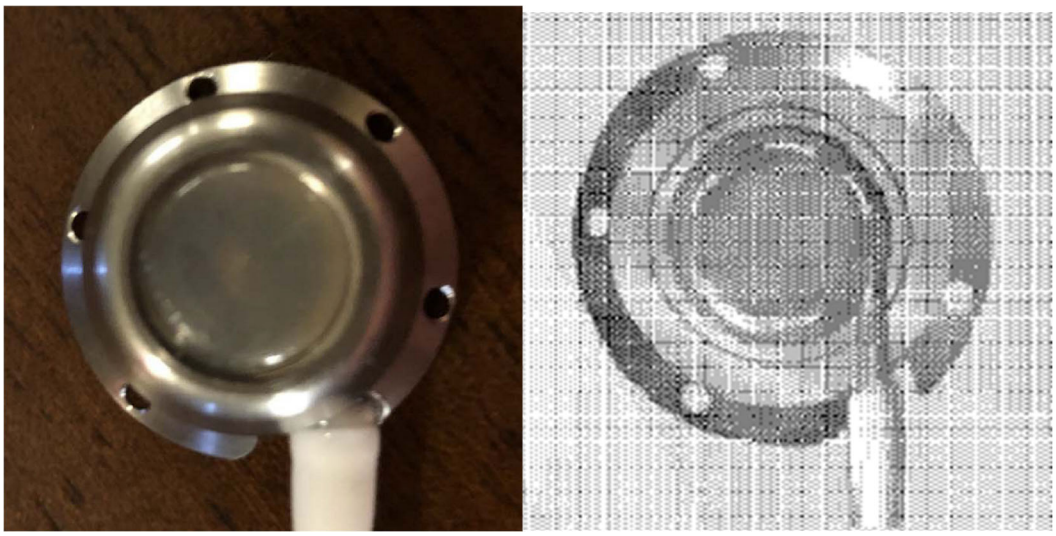
#### *b. AngioDynamics reargues facts about each prior-art port and fails to show the jury was compelled to find anticipation*

##### *i. Vortex*

***Not identifiable.*** AngioDynamics asserts that "[u]ncontroverted 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." Angio.Br.36. But AngioDynamics never addresses Bard's expert testimony

contesting those very points. Bard.Br.45-46; Appx5520-5521, Appx5789, Appx5931-5932.

Nor does AngioDynamics have an answer for its own internal documents, which admit that the SmartPort initially had "no indicators that could identify it as CT compatible" or identify any other port functionality. Appx24817; *see* Appx25469; Appx25635; Appx25692 (customer complaints about lack of "identifiable" features). Plus, AngioDynamics never disputes the Vortex port looks identical to AngioDynamics's original power-injectable SmartPort, with the same round shape, suture holes, and tangential outlet stem (Vortex on left; original SmartPort on right):



Appx31094; Appx25423 (both cropped/rotated). Given these undisputed similarities in ports with differing functionalities and AngioDynamics's own admissions that this design lacked a "means … to identify" (Appx24942), the jury reasonably found that Vortex's common attributes are not the claimed radiographic

markers. Nothing about that finding depends on the claims being "a moving target," as AngioDynamics argues. Angio.Br.36. Rather, the jury simply found that generic attributes like a round shape and suture holes are not "radiographically discernible" features that can "be used to distinguish or identify the device or its functionality," which this Court required AngioDynamics to prove for anticipation. *Bard*, 979 F.3d at 1385.

***Not power-injectable.*** In repeating its mantra about supposedly "[u]ncontroverted evidence" of Vortex's power-injectability at the claimed flow rate and cavity pressure, AngioDynamics again overlooks contrary evidence and testimony. Appx5931; Appx24210; Appx5498-5500; Appx29231-29264. For example, AngioDynamics says its witness produced a supposedly "unchallenged" lab notebook purportedly showing power-injection testing on Vortex. Angio.Br.33-34. But that same witness admitted AngioDynamics told its customers that the FDA required "extensive" material changes to Vortex before it could be marketed as power-injectable, ultimately leading AngioDynamics to rename and rebrand the redesigned port the "SmartPort." Appx5518-5520. Rather than dispute that those extensive changes were required, AngioDynamics says "[o]nly Vortex matters," not SmartPort. Angio.Br.34-35. But based on those conceded changes, a jury could reasonably find that the prior-art Vortex port was not power-injectable at the required flow rate and cavity pressure.

AngioDynamics also points to FDA filings attesting to "no changes" between Vortex and SmartPort. Angio.Br.35. But Bard's witness explained that such FDA statements merely mean a port "operates using the same general principle, which means you're flowing fluid through a system and it's under the skin." Appx4761-4762 (explaining similar statements). The jury reasonably credited that testimony rather than drawing AngioDynamics's preferred inference.

For similar reasons, AngioDynamics wrongly accuses Bard of "twist[ing] its claims" by treating the same FDA-testing evidence differently for infringement and invalidity. Angio.Br.35-36 (alteration/citation omitted). But the testing evidence was not the same. AngioDynamics tried unsuccessfully to elicit testimony that FDA testing was performed on a prior-art Vortex port; Dr. Clark disagreed, explaining that although AngioDynamics used "an internal designation number" for the Vortex family in its filings, the tested port was actually a non-prior art "SmartPort." Appx5050-5053.

### *ii. Port-A-Cath*

***Not identifiable.*** AngioDynamics concedes that, for a jury to find for it, the jury would have needed to find that a generic square shape and standard suture holes are a radiographic marker that can identify the port or its functionality:

Angio.Br.38-39 (cropped; citing Appx29545). But AngioDynamics never explains what would have compelled the jury to so find. That was not the only reasonable finding, especially given Bard's contrary evidence, including that Bard rejected a square-shaped port after testing. Appx4539; Appx5936-5937; Appx27422. While AngioDynamics says Dr. Clark admitted "a 'square shape' *could* be a radiographic marker," that equivocal statement did not compel the jury to find that the Port-A-Cath's square shape was such a marker. Angio.Br.38-39 (citing Appx5061; emphasis added).

***Not power-injectable.*** AngioDynamics at most identifies factual disputes about Port-A-Cath's power-injectability, disputes the jury reasonable resolved against AngioDynamics. Angio.Br.37-38. AngioDynamics mainly points to Gebauer. Angio.Br.37-38 (citing Appx28344-28346). But Bard showed why the jury reasonably rejected that argument, including because Gebauer reported successful power injection only at cavity pressure "under 35 psi"; AngioDynamics's

expert admitted that the "max pressure" for Port-A-Cath "is 15 psi"; and Gebauer "d[id] not recommend routine use of port systems for contrast injection." Appx5845-5846; Appx5914, Appx5917-5918, Appx5858-5860. AngioDynamics calls these "irrelevancies and distractions" because Gebauer says no ports ruptured or had catastrophic failure. Angio.Br.38. But the jury was not required to find that any port that avoids catastrophic failure under pressure is "structured for power injection" as required by Bard's claims. And AngioDynamics has no support for asserting that only flow rate matters because Bard's claims "equate cavity pressures of 35 psi with flow rates of 1 mL/s." Angio.Br.38. Indeed, the patent gives an example where a pressure of roughly 35 psi is achieved only at flow rate of 5 mL/s, contradicting AngioDynamics's purported equation. Appx64. Regardless, the claims recite flow rate and cavity pressure as two separate requirements; they do not equate them. Appx107-108(col.30:51-31:6).

### *iii. Adult Titanium Port*

***Not identifiable.*** AngioDynamics gives no reason to disturb the jury's verdict on the Adult Titanium Port either. It says its expert gave "uncontroverted, unimpeached" testimony about pattern recognition that would have allowed practitioners to use a circular shape and suture holes as identifying radiographic features. Angio.Br.32. But Bard's expert controverted that testimony: "[a]s a practicing radiologist," he would not "be able to conclude anything about the port"

from an x-ray. Appx5920-5925. Other than its flawed arguments that any perceivable attribute suffices, AngioDynamics has no response.

***Not power-injectable.*** Again rearguing evidence the jury was not required to credit, AngioDynamics asks the Court to overlook evidence favoring Bard and credit evidence AngioDynamics prefers. Angio.Br.27-31. But Bard's lead inventor addressed that evidence, including testing of the Adult Titanium Port, explaining that "sometime[s] it would pass and sometimes it would fail." Appx4508-4509. Skilled artisans would not consider such a port "structured for power injection," meaning the port never embodied the claims (Appx4485, Appx4508-4509, Appx4516)—not, as AngioDynamics suggests, that it "sometimes" did (Angio.Br.29). At least, the jury was entitled to so find. That testimony was corroborated by evidence that Bard changed the Adult Titanium Port to create the PowerPort. Appx4511-4512, Appx4658-4759; Appx5928. Although AngioDynamics belittles the changes (Angio.Br.28), that evidence supports inferring that the Adult Titanium Port was not power-injectable. AngioDynamics itself admitted pre-litigation that Bard's PowerPort (and not the earlier Adult Titanium Port) was "the first power injectable port." Appx25583.

AngioDynamics points to Bard's FDA filing and internal documents to argue the Adult Titanium Port is the "same" as Bard's power-injectable PowerPort. Angio.Br.27-31. But the jury heard and reasonably rejected those assertions,

including because Bard's FDA filings focused on showing substantial equivalency for regulatory purposes, which is different from an infringement or invalidity analysis. Appx4760-4761; *supra* p. 27. AngioDynamics likewise continues its flawed reliance on testimony and evidence about power-injecting Adult Titanium port at an unspecified flow rate and cavity pressure, none of which compels finding anticipation of the specifically claimed flow rate and cavity pressure. Angio.Br.29-30. And AngioDynamics wrongly says Bard "ignores Herts, an independent study from 2001." Angio.Br.30-31. Bard addressed Herts, another reference that says nothing about the cavity pressure used. Bard.Br.56. As Bard's witness explained, Herts "used slower flow rates," took measures to stay under a 25 psi "pressure limit," and reported "much, much, much worse" imaging." Appx5905-5908.

***3. The verdict on the method claim is further supported***

AngioDynamics cannot overcome the district court's additional independent flaws in invalidating Bard's asserted method claim. For that claim, AngioDynamics failed to identify any single reference disclosing or showing practice of every claimed step. Bard.Br.55-57.

AngioDynamics responds by trying to read out the claimed step of "identifying the indicating radiographic feature" on the x-ray. Angio.Br.39-41. It says that is just a "mental step" "not entitled patentable weight." Angio.Br.39-40.

There is no rule that anything labeled as a mental step is unpatentable printed matter, nor did AngioDynamics press for such a rule in the prior appeal, which resolved the parties' printed-matter dispute. This Court's printed matter decision affected only the requirement of "a radiographic feature indicating that the access port is suitable for flowing fluid at a rate of at least 1 milliliter per second." Appx223-224(col.30:58-31:4). The Court was clear about the reach of its decision: "the content of the information conveyed by the claimed markers—i.e. that the claimed access ports are suitable for injection at the claimed pressure and flow rate—is printed matter not entitled to patentable weight." *Bard*, 979 F.3d at 1382. Thus, in Bard's method claim, nothing relieved AngioDynamics of otherwise showing every step of the claimed method was disclosed or practiced, including the identifying step.

AngioDynamics falls far short of showing the jury had no choice but to find anticipation. Instead, as with its other anticipation arguments, AngioDynamics changes the target and addresses whether the prior art discloses "visualizing the port" on an x-ray. Angio.Br.41 (prior art shows "port visualization"; taking scans "to visualize the implanted port"). But Bard's claim is more specific than generally "visualizing" the port: it requires "identifying the indicating radiographic feature on the x-ray." Appx223-224(col.30:58-31:4). The jury was not required to find that merely x-raying a port sufficed to expressly disclose that limitation, and AngioDynamics rightly disclaims any inherency theory. Angio.Br.41.

AngioDynamics's only other response is to attack another strawman argument: "that Angio must show actual use of the claimed method in the prior art." Angio.Br.40. But Bard acknowledged that anticipation could be shown with "clear and convincing evidence *either* that a single reference discloses every claimed step *or* that someone actually practiced every step." Bard.Br.55 (emphasis added). There was no evidence of either. If AngioDynamics now disclaims reliance on actual practice, its main district-court theory, that only underscores the errors in the district court's decision. Regardless, the jury reasonably found no anticipation under either a disclosure or actual-performance theory.

### C. The Court Should Also Reverse Or Vacate Because No Allegedly Anticipatory Port Includes A Radiographic Letter

AngioDynamics hardly responds to yet another independent basis for relief on claims 5 and 12 of the '417 patent and claim 3 of the '478 patent. Those claims include a more specific requirement than just a "radiographic marker"; they require that the marker be a "radiographic letter." Appx108(col.31:16-17,col.31:27-49); Appx224(col.31:8-9). No proffered prior-art port included a radiographic letter. The district court erred when it belatedly adopted a new claim construction reading that requirement out of the claims, which at least requires vacatur and a remand.

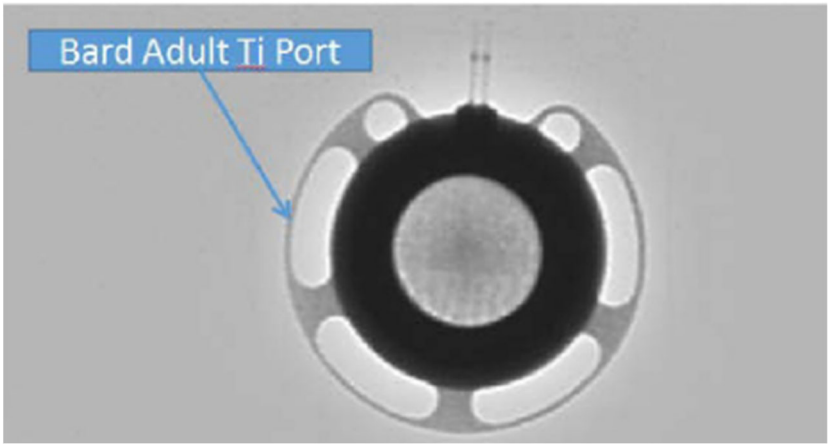
AngioDynamics makes the bald assertion that "[l]etters are a canonical example of printed matter." Angio.Br.25. But the claim limitation here is not "letters," much less the content of any message conveyed by them. Rather, the

limitation requires a specific type of "radiographic marker": a "radiographic letter." Appx108(col.31:16-17,col.31:27-49); Appx224(col.31:8-9). And AngioDynamics concedes that radiographic markers carry patentable weight. Angio.Br.23-24. Rightly so, because radiographic markers, like radiographic letters, are the patentable "means by which the information is conveyed," not the unpatentable "content of the information conveyed." *Bard*, 979 F.3d at 1381-82, 1384. AngioDynamics wrongly accuses Bard of previously saying otherwise; Bard said the same thing: "'the information conveyed by the radiographic letters and separated features is printed matter.'" Appx50001 (citation/emphasis omitted).

The decisions AngioDynamics cites contradict its position and instead show a claim requirement for a letter cannot be ignored. *Xiao* expressly compared the requirement that a claimed lock have "alphabetical position-labels" against prior-art locks "bearing letters"; only the requirement of conveying a specific "wild-card" message was printed matter carrying no patentable weight. *In re Xiao* 462 F. App'x 947, 950 (Fed. Cir. 2011). *Marco* similarly compared a claimed die with markings against prior-art "markings on a typical die"; only the "information" each marking "communicates" was printed matter lacking patentable weight. *In re Marco Guldenaar Holding*, 911 F.3d 1157, 1161 (Fed. Cir. 2018). More recently, this Court rejected an argument like AngioDynamics's and held that a requirement for "encrypted communications" was not printed matter: "the fact that there is a

communication itself is not content; content is what the communication actually says." *IOENGINE v. Ingenico*, No. 21-1227, Slip op. 10-11 (Fed. Cir. May 3, 2024). These decisions match the Court's prior decision here, requiring at least vacatur given the district court's contrary construction. *SimpleAir v. Sony Ericsson*, 820 F.3d 419, 425 (Fed. Cir. 2016).[2]

The Court can also reverse outright. AngioDynamics's only attempt to address anticipation under the proper construction is to assert that the Adult Titanium Port includes radiographic letters based on the below x-ray image taken of a non-implanted port under undisputedly unsafe settings:




Appx25813. Nothing about that unrepresentative image compelled the jury to find anticipation or shows a lack of substantial evidence for the jury's presumed finding of no radiographic letters. Bard.Br.57-58.

[2] AngioDynamics cites district-court decisions that never mention radiographic letters or that have been vacated for not applying this Court's prior decision. Angio.Br.25 n1.

Finally, AngioDynamics wrongly asserts the jury cannot be presumed to have found a lack of radiographic letters because the jury was instructed to give letters no patentable weight. Angio.Br.25. That instruction does not help AngioDynamics given the jury's no-anticipation finding. To make that finding, the jury had to find the prior art lacked a radiographic marker of any kind, including radiographic letters; so the jury is presumed to have found a lack of radiographic letters.

* * * * *

For all these reasons, the anticipation judgment should again be reversed or vacated.

## CONCLUSION

The invalidity judgments should be reversed or vacated.

Dated: May 6, 2024

Respectfully submitted,

/s/ Deanne E. Maynard

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## CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally-spaced typeface and includes 6,969 words, excluding the parts of the filing exempted by the Rules.

Dated: May 6, 2024 /s/ Deanne E. Maynard

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