2022-1136, -1186

United States Court of Appeals for the Federal Circuit

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

Plaintiffs-Appellants,

v.

MEDICAL COMPONENTS, INC.,

Defendant-Cross-Appellant.

Appeal from the United States District Court for the District of Utah in No. 2:12-cv-00032-RJS (Hon. Robert J. Shelby, Judge)

BRIEF OF AMICUS CURIAE ANGIODYNAMICS, INC. IN SUPPORT OF DEFENDANT-CROSS-APPELLANT URGING AFFIRMANCE

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2022-1136, - 1186

Short Case Caption C.R. Bard, Inc. v. Medical Components, Inc.

Filing Party/Entity AngioDynamics, Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

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

Date: 03/25/2022

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.		BlackRock, Inc.

☐ 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).

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

C.R. Bard, Inc. et al. v. Medical Components, Inc. No. 2:17-cv-00754-HCN-DAO	Bard Peripheral Vascular, Inc. v. AngioDynamics, Inc. No. 1:15-cv-00218-JFB-SRF	C.R. Bard, Inc. et al. v. Smiths Medical ASD, Inc. No. 1:20-cv-01543-CFC
C.R. Bard, Inc. et al. v. AngioDynamics, Inc. No. 1:20-cv-01544-CFC	C.R. Bard, Inc. et al. v. AngioDynamics, Inc. No. 1:21-cv-00349-CFC	

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

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STATEMENT OF IDENTITY AND INTEREST OF AMICUS CURIAE

AngioDynamics, Inc.'s ("AngioDynamics") interest in this case stems from its involvement in litigation related to U.S. Patent Nos. 7,785,302, 7,959,615, and 7,947,022, and other Bard patents directed to nearly identical subject matter. In particular, AngioDynamics is a defendant in the following proceedings, which it believes will be impacted by this appeal:

(i) *C.R. Bard, Inc. v. AngioDynamics*, *Inc.*, C.A. No. 20-1544-CFC (D. Del.), in which Bard asserts the 7,785,302, 7,959,615, and 7,947,022 Patents;

(ii) *C.R. Bard, Inc. v. AngioDynamics*, *Inc.*, C.A. No. 15-218-JFB (D. Del.), in which Bard asserts three patents directed to nearly identical subject matter; and

(iii) *C.R. Bard, Inc. v. AngioDynamics*, *Inc.*, C. A. No. 21-349-CFC (D. Del.), in which Bard asserts three additional patents directed to nearly identical subject matter, two of which claim priority to the same application that led to U.S. Patent Nos. 7,785,302, 7,959,615, and 7,947,022.

IDENTIFICATION UNDER RULE 29(a)(4)(E)(i)-(iii)

AngioDynamics's counsel, Danielle V. Tully, John T. Moehringer, Michael B. Powell, and John T. Augelli, authored AngioDynamics's amicus curiae brief submitted herewith. Only the amicus curiae, AngioDynamics, paid for the preparation of this brief. No other party or other party's counsel contributed money that was intended to fund preparation and/or submission of this brief.

IDENTIFICATION UNDER RULE 29(a)(2)

The parties have consented to the filing of this amicus brief in support of Defendant-Cross-Appellant Medical Components, Inc., in email correspondence dated March 23, 2022 with counsel for C.R. Bard, Inc., Lauren Martin, and dated March 22, 2022 with counsel for Medical Components, Inc., Mark Gibb and Alfred Zaher.

INTRODUCTION

Amicus Curiae, AngioDynamics, Inc. ("AngioDynamics"), submits this brief in support of Cross-Appellant Medical Components, Inc. ("MedComp"). The district court correctly held Bard's claims ineligible under 35 U.S.C. § 101, and its decision should be affirmed.

First, the district court properly applied *Alice*'s two-step inquiry to invalidate the claims as patent ineligible. At step one, the district court properly applied this Court's precedent, including *Secured Mail Solutions LLC v. Universal Wilde, Inc.*, 873 F.3d 905 (Fed. Cir. 2017), in holding that the claims are directed to the abstract idea of communicating information. *See infra* Section I.A. At step two, the district court properly relied on a developed record—including publicly available references and Bard's own admissions—when determining that there is no inventive concept. Nothing the district court cited is "obscure." And every cited reference comes from the relevant field: implantable medical devices. *See infra* Section I.B. The district court also properly considered the means by which the information is conveyed as part of its *Alice* analysis, rightly rejecting that conveying information with radiopaque identifiers or shape could salvage the claims. Section I.C.

Second, Bard misreads *C.R. Bard, Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372 (Fed. Cir. 2020) ("*AngioDynamics*"), which addressed a different factual record and

different legal issues. That case does not provide the safe harbor Bard seeks. Instead, *AngioDynamics* confirms that the identifier limitations here are printed matter. As such, those limitations cannot provide the inventive concept at *Alice* step two under this Court's jurisprudence. *See infra* Part II.

The district court's well-reasoned analysis correctly applied the law to undisputed facts and should be affirmed.

STATEMENT OF FACTS

This appeal stems from a case Bard brought against MedComp in January 2012—not the one it brought against AngioDynamics in 2015 that resulted in the *AngioDynamics* decision. As the district court recognized, the record and legal issues are different. *See* Appx25 (differentiating the Federal Circuit's printed matter decisions from the general *Alice* framework, and then performing a reasoned eligibility analysis under *Alice*).

In this case, the district court entered summary judgment in favor of MedComp, ruling that the asserted claims are ineligible under Section 101. *See* Appx40. The district court held that the asserted claims are "directed to the ineligible abstract idea of communicating information and lack an inventive concept." Appx40. In doing so, the district court rejected Bard's argument that the asserted patents were eligible under *AngioDynamics*. *See* Appx35-36.

ARGUMENT

I. THE DISTRICT COURT FAITHFULLY APPLIED FEDERAL CIRCUIT PRECEDENT TO A DEVELOPED RECORD; ITS DECISION SHOULD BE AFFIRMED.

Unlike the district court in *AngioDynamics*, the district court here performed a full two-step *Alice* analysis. The district court also considered a significantly more developed record than the one in *AngioDynamics*, including multiple prior art references, Bard's admissions that it did not invent radiopaque identifiers, and Bard's admissions that adding radiopaque identifiers to ports would be trivial.

At *Alice* step one, the district court correctly applied *Secured Mail* to conclude that the claims are directed to an abstract idea. *See* Appx30-32. It also correctly applied this Court's precedent in holding that the inclusion of physical components cannot render abstract claims patent eligible. Appx31-32; *see ChargePoint, Inc. v. Sema-Connect, Inc*., 920 F.3d 759, 769 (Fed. Cir. 2019). Thus, the district court properly held that the claims are directed to an abstract idea. *See infra* Section I.A.

At *Alice* step two, the district court correctly determined that the claimed identification features—radiopaque identifiers and shape—were well-understood, routine, and conventional based on an undisputed record. Bard attacks the record as obscure and unrelated to ports, but both challenges lack legal support. Bard also argues that the means used to convey information—radiopaque identifiers and

shape—is somehow inventive. But both "means" are well-understood, routine, and conventional ways of communicating information about implantable medical devices. And the district court correctly found that neither could provide an inventive concept. *See* Appx28 & n.137 (citing *King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) (holding the means by which information is conveyed does not impact the printed matter analysis)). *See infra* Section I.B.

Bard is wrong that the district court erroneously created a four-step analysis when considering ineligibility. *See* AppBr29. Instead, the district court properly analyzed the claims to determine that the identification limitations were unpatentable printed matter, tracking the printed matter analysis in *AngioDynamics*. *See* Appx7-29. The district court then performed a two-step *Alice* analysis—something the district court in *AngioDynamics* did not do. *See* Appx29-40; *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014). Thus, rather than create a novel four-part test, the district court performed two separate inquiries: first printed matter, then *Alice*.

A. THE DISTRICT COURT CORRECTLY CONCLUDED THAT THE CLAIMS ARE DIRECTED TO THE ABSTRACT IDEA OF COMMUNICATING INFORMATION.

At *Alice* step one, the district court first looked to the claims and specification to determine that the claims are directed to the abstract idea of "using a specific

identifier . . . to communicate information." Appx30. This abstract idea is akin to the abstract idea in *Secured Mail*—a case the district court analyzed and applied faithfully to the asserted claims. *See* Appx30-32. Consistent with precedent, the district court correctly held that the inclusion of physical components—including "traditionally used" access ports and old identifiers (*i.e.*, radiopaque identifiers and shape)—did not save the claims from abstractness. *See* Appx31.

1. The District Court Correctly Looked At The Claimed Advance To Determine What The Claims Are "Directed To."

In determining whether claims are "directed to" an abstract idea, the district court looked at the claimed advance over the prior art—here, communicating information that the ports are power-injectable using an identifier. *See* Appx31; *ChargePoint*, 920 F.3d at 767. Bard's suggestion that this approach "import[ed] . . . a novelty analysis" into the inquiry is wrong. AppBr34. As this Court held in *Simio*, step one looks to "what the patent asserts to be the focus of the claimed advance over the prior art." *Simio, LLC v. Flexsim Software Prods., Inc.*, 983 F.3d 1353, 1359 (Fed. Cir. 2020). That is where the district court began.

The district court then analogized the claims to *Secured Mail*, which also concerned claims directed to communicating information using an identifier. *See* Appx30-31. Specifically, the *Secured Mail* claims recited "methods whereby a

sender ***affixes an identifier***[1] on the outer surface of a mail object . . . before the mail object is sent." *Secured Mail*, 873 F.3d at 907. The claims were not directed to an improvement in computer functionality, a new barcode, or a new method for scanning or generating the barcodes. They were instead directed to the abstract idea of "communicating information about a mail object." *Id.* at 910-11.

As the district court recognized, "[t]he Federal Circuit explicitly held in *Secured Mail* that the process of communicating information using a marking or identifier that ***does not functionally improve any aspect of the underlying object*** or identification process is an abstract idea not directed to patent eligible subject matter." Appx32 (citing *Secured Mail*, 873 F.3d at 910-11). So too here.

Bard's claims "require[] the use of an identifier to communicate information about the power injectability of the underlying port and provide[] no functional improvement to the port itself or the X-ray technology used to view the radiopaque identifiers[.]" Appx32. Indeed, this Court recognized that power-injectable ports long existed in the art—a finding the district court recognized as well. *See AngioDynamics*, 979 F.3d at 1375, 1384; *see also* Appx36. And the record on appeal includes Bard's admissions that it did not invent the use of radiopaque identifiers or come up with the idea to include them on ports. *See* Appx36-37; Appx2452.

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[1] All emphasis added unless otherwise noted.

Secured Mail is no outlier. This Court recently determined that claims directed to an "identification structure" on a lock were not patent eligible when they did not recite any "technical specifications or concrete improvements" to the lock. *Travel Sentry, Inc. v. Tropp*, No. 2021-1908, 2022 WL 443202, at *1 (Fed. Cir. Feb. 14, 2022) (per curium). Thus, the district court correctly relied on *Secured Mail* in holding the claims are directed to an abstract idea. *See* Appx30-32.

Bard attempts "to shift the focus away from the stated purpose of the asserted claims—***identifying*** power-injectable ports subsequent to implantation—to the purported novelty of power-injectable ports." Appx27. Like the district court, this Court should refuse to "countenance this argument." Appx27. As the district court explained, "the core of each of the asserted claims . . . is the basic idea of using" either a radiopaque identifier or concave sides (a shape) to convey information about a port's power-injection capability. Appx27. The claims are devoid of any structure that makes the claimed port power-injectable. *See* Appx31. And the claims are not about creating a new or improved identification feature. *See* Appx31.

In analyzing the specification, the district court explained that "the sole motivation of the patents at issue is providing some type of identifiable feature that communicates information about the underlying access port." Appx26. But the specification never says what an "identifiable feature" is. Why? Because the claims only require the communication of information, not any specific or improved

structure for conveying that information. Thus, the claims are "directed to" the abstract idea of communicating information at step one.

2. The District Court Correctly Recognized That Physical Components Cannot Make Abstract Claims Patent Eligible.

Bard's arguments that its claims are directed to a "machine" and that the district court discounted "claimed structural features" is unavailing. AppBr31-33 (citing Appx30-31, Appx26). The claims are not directed to any improved machine or improved port structure. *See* Appx31. They recite nothing beyond the generic port structure common to all ports—a body, reservoir, septum, and outlet—and vaguely defined identifiers. *See* Appx27.

Bard's argument also ignores Supreme Court precedent. *Alice* step one does not turn on whether the claims recite physical components. It is instead about whether the claims are "directed to" patent eligible subject matter. *Alice*, 573 U.S. at 217. Indeed, Bard's logic invites the Court to create a loophole: a patentee could insulate claims directed to an abstract idea from *Alice* simply by reciting conventional components. The Supreme Court has expressly cautioned against such drafting gamesmanship. *See id.* at 224. And it has rejected the rote reliance on the machine-or-transformation test for this reason. *See Bilski v. Kappos*, 561 U.S. 593, 604 (2010).

This Court has also declined to create such a loophole. *See ChargePoint*, 920 F.3d at 769. The *ChargePoint* claims included controllers and transceivers for the purposes of turning on and off electricity to charge electric vehicles. *Id.* at 766. But the alleged improvement was the abstract idea itself, and "the broad claim language would cover any mechanism for implementing" the abstract idea using the claimed physical components. *Id.* at 770. So too here. The claimed advance is the abstract idea of communicating information about a port's intended use. *See supra* Section I.A.1. And the recitation of generic, old physical port components—like the physical charging components in *ChargePoint*—cannot save the claims from abstractness.

Yu v. Apple Inc., 1 F.4th 1040 (Fed. Cir. 2021), and *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020), follow this principle. In *Yu*, this Court rejected the argument that the "asserted advance in the claims"—a "particular configuration of lenses and image sensors"—made the claims non-abstract at step one. *Yu*, 1 F.4th at 1044. The claims were not ***directed to*** an improved physical camera, even though they contained physical camera components. *Id.* at 1044-45. "Even a specification full of technical details about a physical invention may nonetheless conclude with claims that claim nothing more than the broad law or abstract idea underlying the claims." *Id.* at 1044 (quoting *ChargePoint*, 920 F.3d at 769). Likewise, in *American Axle*, the recitation of physical tuning liners was insufficient at step one. *See Am. Axle*, 967 F.3d at

1294-95. The claims were directed to an application of Hooke's Law rather than an improved physical product. *See id.*

Thus, the mere recitation of physical components cannot save the claims at step one, and this Court should decline Bard's invitation to revisit settled law.

B. THE ASSERTED CLAIMS DO NOT RECITE AN INVENTIVE CONCEPT.

At *Alice* step two, the district court correctly determined that the claims recite no inventive concept. *See* Appx33-40. The only possible inventive concept in the claims is the radiopaque identifiers and port shape. *See* Appx28. But the court correctly concluded that both were well-understood, routine, and conventional based on a well-developed record (*see* Appx36; Appx39). *See infra* Section I.B.1.

Bard acknowledges the large body of evidence relied on by the district court showing conventionality of the identifiers. *See* AppBr45-46. Yet Bard urges this Court to ignore this proof, arguing that it is both "obscure" and irrelevant to the identification of port properties. *See* AppBr45-47. Both arguments ignore settled law. *See infra* Section I.B.2.

The district court properly analyzed the '615 Patent, concluding that identification via shape cannot be inventive. *See* Appx39-40. The district court declined to import the idea of palpation from the specification into the claims, and this Court should as well. *See infra* Section I.B.3.

In asking this Court to reject the district court's careful application of this Court's precedent, Bard also urges this Court to follow a non-controlling district court case. But that district court case is not on appeal, and its record is not subject to review here. *See infra* Section I.B.4.

As the district court correctly held, the *means* of communicating information—whether by a radiopaque identifier or shape—cannot be inventive. The focus of the claims is on informational content. And using radiopaque identifiers and shapes to convey information is well-understood, routine, and conventional. *See infra* Section I.C.

1. The District Court Relied On A Fulsome Record When Finding That The Claimed Identification Features Were Well-Understood, Routine, And Conventional.

"Patent eligibility has in many cases been resolved on motions to dismiss or summary judgment" when no disputed facts exist at step two. *See Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018). The district court's "factual determinations are reviewed for clear error." *Ameranth, Inc. v. Domino's Pizza, LLC*, 792 F. App'x 780, 782 (Fed. Cir. 2019) (nonprecedential).

The district court properly focused on the claimed identification features at step two. As the district court explained, "[t]he claims are not directed to an improvement in port technology—the port will function in exactly the same manner

whether the identifier is present or not[.]" Appx31. The claims are not directed to an improvement in identification. *See* Appx31. And conveying information about power-injectability is printed matter. *See* Appx20-21. Thus, the district court properly analyzed whether radiopaque identifiers and shapes were well-understood, routine, and conventional—finding the largely undisputed record dispositive on this point. *See* Appx32; Appx36; Appx39-40.

a. The Record Established That The Radiopaque Identifiers In The '302 and '022 Patents Were Well-Understood, Routine, And Conventional.

The district court correctly found that the radiopaque identification features fail to provide an inventive concept. *See* Appx37. The district court relied on multiple prior art references and admissions from Bard, including sworn statements made to the USPTO and representations in a related case (*see* Appx34-37; *see also* MedCompBr15-16):

- Bard's admissions in the Declaration of Kenneth Eliasen (the "Eliasen Declaration") (Appx2853-2869);
- Bard's admissions about radiopaque identifiers in a 2001 news bulletin in Medical Industry Week (the "2001 Bard Bulletin") (Appx2524);
- Bard's admission in the related case before Judge Nielson that "Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging" (Appx2452);

- A 1995 article, *Implantable Cardioverter-Defibrillators: Implications for the Nonelectrophysiologist*, Sergio L. Pinski, MD and Richard G. Trohman, MD, ANNALS OF INTERNAL MEDICINE, Vol. 122, No. 10 ("Pinski") (Appx2526-2533);

- A 2003 article, *Radiopaque Imprinting Enables Alternative to Angioplasty: Markings on fabric substrate of device allow precise positioning*, reprinted from MEDICAL PRODUCT MANUFACTURING NEWS, April 2003 ("Medical Product Manufacturing News") (Appx2534);

- A 1996 article, G. McKillop & J. H. Reid, *Retained surgical swab misinterpreted as epicardial pacing wire on chest x ray*, HEART, 75(4), 342 (1996) ("McKillop") (Appx2535);

- A 2000 article, K.A.Wolfson, L.L. Seeger, B.M. Kadell, & J.J. Eckardt, *Imaging of surgical paraphernalia: what belongs in the patient and what does not*, RADIOGRAPHICS, 20(6), 1665-1673 (2000) ("Wolfson") (Appx2536-2544);

- A 2003 article, A.R. O'Connor, F.V. Coakley, M.V. Meng, & S. Eberhardt, Imaging of retained surgical sponges in the abdomen and pelvis, AMERICAN JOURNAL OF ROENTGENOLOGY, 180(2), 481-489 (2003) ("O'Connor") (Appx2545-2553).

Bard fails to present any contrary evidence and does not identify a clear error in the district court's reliance on this evidence in finding no inventive concept. *Cf. Ameranth*, 792 F. App'x at 788 (affirming district court's grant of summary judgment of ineligibility where patentee's declarations on inventiveness did not save the claims at step two). Instead, Bard attempts to equate this record to the record in *AngioDynamics*. *See* AppBr43-44. But the *AngioDynamics* trial court relied on none of this evidence. After *sua sponte* raising patent ineligibility at the end of Bard's case-in-chief, the trial court granted JMOL ***before*** AngioDynamics put on its

invalidity case. *See AngioDynamics*, 979 F.3d at 1377-78. By contrast, the district court here reviewed a developed record at step two, including these references and party admissions. *See* Appx33-37. Thus, this record should be considered undisputed, and Bard's reliance on *AngioDynamics* is misplaced.

Bard's admissions in the Eliasen Declaration (Appx2853-2869), the 2001 Bard Bulletin (Appx2524), and before Judge Nielson (Appx2452) are alone sufficient to support a finding of no inventive concept. *See Berkheimer*, 881 F.3d at 1370 (finding admissions that certain features "existed for years before [the] patent" supported a finding of no inventive concept at step two).

Bard submitted the Eliasen Declaration during the prosecution of its 11/368,954 Application[2] in an effort to provoke an interference with MedComp's 11/725,287 Application. *See* Appx2853-2869. Bard succeeded—both in provoking the interference and during the interference itself. *See* Appx869-894; Appx2871-2873. Bard cannot now take a position contrary to those set out in the Eliasen Declaration. *See Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1360 (Fed. Cir. 2017) (applying judicial estoppel to arguments made during "proceedings before the PTO").

[2] Bard's application eventually granted as U.S. Patent No. 7,785,302, one of the patents at issue here.

As Bard explains in the Eliasen Declaration, at the time of the '302 Patent, "placement of a radiopaque marking on a surface of the housing base" was "obvious to a person of ordinary skill in the art" and "would have only involved ordinary creativity on behalf of the designer." Appx2858-2859 ¶ 27; *see also* Appx2859 at ¶ 29. The district court correctly relied on this testimony at step two.[3]

Echoing the Eliasen Declaration, the 2001 Bard Bulletin states that a new stent released by Bard at the time included "radiopaque marker technology" that "greatly improve[d] radiopacity, allowing for better stent visualization, pre- and post-placement." Appx2524. The district court also properly relied on this admission, which is contained in a prior art reference Bard distributed to the industry. *See* Appx34-35 & n.174.

On top of all this, Bard represented in a related case that it did not invent the use of radiopaque identifiers on implantable medical devices for identification purposes. *See* Appx2452. Again, the district court was right to rely on this evidence. *See* Appx36-37 & n.183.

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[3] In addition to the paragraphs the district court relied on, Mr. Eliasen also testified that the housing base was an obvious location for radiopaque identifiers because it has the "largest outside surface" and "requires relatively simple manufacturing processes . . . as evidenced by the fact that nearly every port has a lot number and/or company logo printed, embossed, engraved, etc. on the bottom of the housing base[.]" Appx2862 ¶ 38. Going further, Mr. Eliasen concluded that a POSA "would have immediately thought to put the radiopaque markings on the housing base." Appx2862 ¶ 38.

The other references considered by the court, including medical journals and the like, also establish that these radiopaque identifiers and shape identifiers were routine and conventional. Pinski describes the need to identify a defibrillator model radiographically. *See* Appx2526-2533; Appx35 & n.176. Medical Product Manufacturing News discusses a new arterial implantable device imprinted with radiopaque ink for easy tracking and placement by medical practitioners. *See* Appx2534; Appx35 & n.176. This article also describes that there was "a growing interest in the use of radiopaque inks in the medical field[.]" Appx2534. And McKillop describes incorporating radiopaque identifiers in surgical swabs and sponges to increase the likelihood that they will be detected by medical professionals. *See* Appx2535; Appx35 & n.176.

Given this largely uncontested record, the district court rightly concluded that the use of radiopaque identifiers in the medical field was well-understood, routine, and conventional. *See* Appx36. This conclusion does not conflict with *AngioDynamics.* As the district court recognized, the "evidence and arguments" here "are considerably different" than in *AngioDynamics*. Appx36. Indeed, the district court "[did] not have before it the same record AngioDynamics[] generated[,]" (Appx36), because trial ended before AngioDynamics could put on its affirmative case.

b. The Record Also Established That The Shape Identification Feature In The '615 Patent Was Well-Understood, Routine, And Conventional.

The district court also correctly determined that the claims of the '615 Patent do not recite an inventive concept because using "shape to convey information is not a new concept." Appx40. Simply put, identifying items by their shape is a basic human activity. For example, an octagonal sign on a roadway is universally recognized as a stop sign and a red cross represents medical personnel or facilities. Yet shape is the only potential inventive concept Bard has for the '615 Patent.

The record before the district court confirms that this idea cannot be inventive. As the district court explained, "articles and charts from medical journals dating between 1969 to 2019" showed that using shape to convey information about a medical device was routine at the time of invention. Appx39-40 & n.193. These references included:

- Lt. Col. William H. Walter, III, USAF, MC, and Nanette K. Wenger, MD, *Radiographic Identification of Commonly Used Implanted Pacemakers*, THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 281, No. 22, pp. 1230-3131 (1969) (Appx2554-2555);
- Lt. Col. William H. Walter, III, MC, USAF, *Radiographic Identification of Commonly Used Pulse Generators - 1970*, THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, Vol. 215, No. 12, pp. 1974-75 (1970) (Appx2556-2557);
- "*Artificial intelligence can improve X-ray identification of pacemakers in emergencies,*" sourced from Imperial College

> London and published in SCIENCEDAILY, available at https://www.sciencedaily.com/releases/2019/03/190327142013.htm (Appx2558-2560).

Both Walter articles recognize the benefits of using shape to identify the brand and type of implantable pacemakers. *See* Appx2554-2557. In fact, each brand of pacemaker had its own distinctive and identifying shape, as shown in the diagram from the 1969 article, reproduced below (Appx2554):

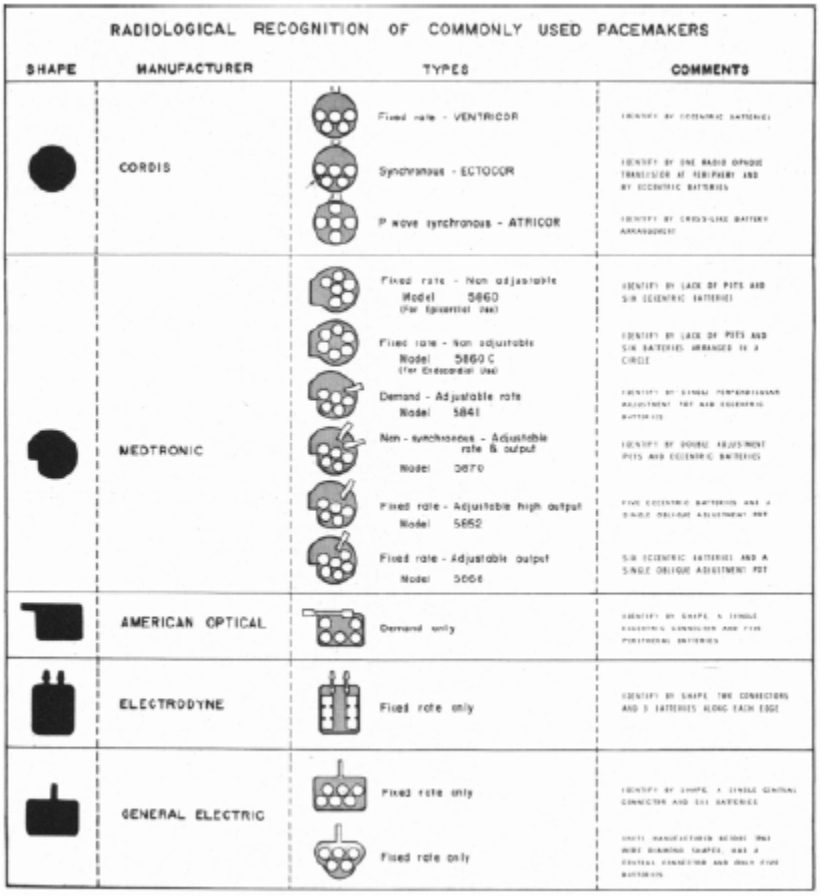

FIGURE 1. *Shapes and Characteristics of Five Pacemaker Units.*

The Imperial College London article describes a "new artificial intelligence software" that could improve on the conventional, "slow and out-dated" practice of

using a "flowchart contain[ing] a series of shapes and circuit board components of different pacemakers designed to help clinicians identify the make and model of a patient's pacemaker." Appx2558-2559; *see also* MedCompBr18.

And once again, Bard admitted that the use of shapes to communicate information about a medical device was well-known in the art. Appx2859 ¶ 28. Mr. Eliasen swore to the USPTO that Jones, another prior art Bard patent, taught "two locators [that] can have distinguishable shape[s] or markings (e.g., holes or projections)." Appx2859 ¶ 28. Bard cannot take a contrary position here. *See Aylus*, 856 F.3d at 1360. Thus, like with radiopaque identifiers, the record shows that shape identification features were well-understood, routine, and conventional.

2. Bard's Arguments About "Obscure" References Are Unpersuasive And Its Attempt To Narrow The Scope Of The Step Two Inquiry Fails.

Rather than confront its own admissions or the merits of any reference, Bard denigrates the district court's references as "obscure" and unrelated to access ports. *See* AppBr45-47.

In Bard's view, the district court could only rely on prior art if it met some unknown standard for notoriety. But Bard does not contest the availability and accessibility of any reference. All the references here are from professional medical

journals or industry sources. And Bard does not argue that the district court improperly relied on its own admissions.

Bard further argues that the district court could only consider references that specifically describe access ports. This is contrary to law. *Cf. Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1327 (Fed. Cir. 2020) (holding that limiting the abstract idea to a particular environment is insufficient). Access ports—like pacemakers, catheters, and breast implants—are implantable medical devices. The need to identify them arises because they are implanted, not because they are any particular type of device.

a. The Court Relied On Bard's Own Admissions And Publicly Available Medical Journals And Industry Sources.

Bard completely ignores its own admissions. In fact, Bard never mentions the Eliasen Declaration in its opening brief, despite it being a focus of the district court's analysis. *See* Appx34 & n.173 (citing Appx2858-2859 ¶ 27).

Bard instead homes in on the prior art, taking issue with what it refers to as MedComp's "vague reference to patent prior art," and citing *Exergen* as support. AppBr45. But the "obscure reference" in *Exergen* was "a ***single copy*** of a thesis written in German and located in a German university library." *Exergen Corp. v. Kaz USA, Inc.*, 725 F. App'x 959, 965 (Fed. Cir. 2018) (nonprecedential). By that

metric, the multiple references here could hardly be "obscure." None are in a foreign language, single copies, or accessible only from a single foreign university library. *See id.*; *cf. GoPro, Inc. v. Contour IP Holding LLC*, 908 F.3d 690, 693 (Fed. Cir. 2018) ("[E]ven relatively obscure documents qualify as prior art so long as the relevant public has a means of accessing them."). Instead, they are all from widely available professional medical journals or industry sources. Thus, Bard's "obscurity" argument should be rejected.

b. The Relevant Field Includes Implantable Medical Devices.

Bard also tries to disqualify the prior art through a box-drawing exercise designed to limit the district court's discretion. According to Bard, the district court could have only considered "whether radiopaque markers used for identification of port properties was well-known or routine[,]" because the district court had no discretion to consider non-port references. AppBr47 (emphasis omitted). But Bard cites no case that would support such a narrowed approach to *Alice* step two. Instead, the step two inquiry focuses on the relevant "industry," *Alice*, 573 U.S. at 225, and "field," *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 73 (2012). Under this Supreme Court precedent, the district court properly considered all prior art in the relevant industry and field: implantable medical devices.

Bard cites *BASCOM*, *Amdocs*, and *Berkheimer* to argue that the district court's step two analysis of radiopaque identifiers and shape should have been more narrowly focused on art about the "identification of port properties." *See* AppBr47; AppBr52. None of these cases stand for this proposition. In *BASCOM Global Internet Service, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341, 1351 (Fed. Cir. 2016), this Court determined that installing a filtering tool at a specific location provided an inventive concept because it "improve[d] the performance of the computer itself." And in *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, the claims recited generic components that worked "together in a distributed manner . . . to achieve an improvement in computer functionality." 841 F.3d 1288, 1301 (Fed. Cir. 2016). Bard's reliance on *Berkheimer* is completely misplaced. *See* AppBr52. *Berkheimer* explains that at step two courts should consider the art in the relevant field and industry—which is exactly what the district court did. *See Berkheimer*, 881 F.3d at 1368 (stating that at step two a court may decide "whether the claim element or claimed combination is well-understood, routine, conventional to a skilled artisan in the relevant field").

Ultimately, Bard's argument boils down to a contention that the information conveyed by the identification features is an inventive concept. But, as explained in Section I.C, this is printed matter, which cannot provide the inventive concept at step

two. *See In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157, 1161-62 (Fed. Cir. 2018).

3. For The '615 Patent, The District Court Correctly Refused To Import Unclaimed Details From The Specification.

Bard criticizes the district court for not reading a limitation from the specification into the claims of the '615 Patent. AppBr50 (citing Appx39). While the specification describes multiple ways to perceive the shape—such as by touch or by sight—***none are claimed***. *Compare* Appx216 at 4:17-26, *with* Appx220-221. Moreover, the claims do not define *how* the shape—*i.e.* concave sides—allows a practitioner to determine that the port is power injectable. Instead, the claims recite only that the shape "identif[ies] the access port as being power injectable." Appx221, Claim 8. Indeed, Bard does not contest this point. *See* AppBr51.

Bard argues that the "specification's disclosure of palpating the port to feel a particular port shape is within the scope of the claims." AppBr51. The district court properly rejected this attempt to import details from the specification, relying on *Two-Way Media Ltd. v. Comcast Cable Communications, LLC*, 874 F.3d 1329, 1338 (Fed. Cir. 2017). *See* Appx39 & n.191-92. There, this Court explained that the alleged "inventive concept must be evident in the claims." *Two-Way Media*, 874 F.3d at 1338. But the alleged inventive concept—"scalable architecture"—was present only in the specification. *Id.* Similarly here, the specification describes

palpation, but the claims do not recite any particular method of identification—*e.g.*, palpation.

At any rate, Bard cannot credibly argue that palpation is a novel approach to identification of an implantable medical device. Identifying objects via palpation is fundamental human activity—as anyone looking for an object in a dark room would know.

Bard cites *ChargePoint* and *Universal Secure Registry* but neither case supports its attempt to read in limitations. *See* AppBr50. The opposite is true: *ChargePoint* explains that "the specification cannot be used to import details from the specification if those details are not claimed." *ChargePoint*, 920 F.3d at 769 (reasoning that, like here, the only possible inventive concept was the abstract idea itself). And in *Universal Secure Registry*, this Court refused to read in limitations from the specification. *Universal Secure Registry LLC v. Apple Inc.*, 10 F.4th 1342, 1353 (Fed. Cir. Aug. 26, 2021). As Bard acknowledges, this Court instead ***confirmed*** the lack of an inventive concept in the claims based on the specification. *See* AppBr50 (citing Appx39).

4. Judge Nielson's Opinion Is Not Precedent.

Bard relies on another district judge's opinion to argue that the record here is insufficient. *See* AppBr44. But that case is not before this Court, its record is not

subject to review here, and it has no precedential effect. Bard's arguments that this Court should follow Judge Nielson's lead thus carry no weight.

C. THE DISTRICT COURT CORRECTLY CONSIDERED THE MEANS BY WHICH THE INFORMATION IS CONVEYED IN ITS *ALICE* ANALYSIS.

Bard argues that the means for conveying information must be considered as part of the *Alice* analysis. *See* AppBr35. This is exactly what the district court did. In analyzing the claims and the specification, the district court held that the "sole motivation" of the claims is "some type of identifiable feature that communicates information about the underlying access port." Appx26-28 & n.137 (citing *King*, 616 F.3d at 1279, and *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004) (per curium)). The district court then determined that the claimed means for conveying the information—the identifiable features—are well-understood, routine, and conventional. *See* Appx32-40.

With respect to the '022 and '302 Patents, the "means" is an alphanumeric radiopaque identifier. In the '615 Patent, the "means" is shape. Bard argues that these identification features are "technological means for conveying information." AppBr36. But whether something is "technological" is not the relevant inquiry. Instead, courts must consider whether these limitations provide the "something more" demanded at step two. *Alice*, 573 U.S. at 217. As the district court found,

they do not. *See* Appx36; Appx39-40. Moreover, Bard's argument about technological means amounts to an attempt to "limit the abstract idea to a particular environment," which is insufficient under *Alice*. *Ericsson*, 955 F.3d at 1327.

The policy reasons underlying the district court's opinion make sense. The claimed access ports are old. The claimed means for identifying them are old. Power injection is old. Bard cannot take these conventional devices and techniques out of the public domain by adding new information. *See Guldenaar*, 911 F.3d at 1161.

II. THE DISTRICT COURT CORRECTLY DETERMINED CERTAIN CLAIM ELEMENTS ARE PRINTED MATTER.

Claim limitations that convey information with no functional relationship to the claimed invention are printed matter and are not given patentable weight. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018). The district court correctly performed this two-part test.

In *AngioDynamics*, this Court recognized that the "claims contain printed matter that is not functionally related to the remaining elements of the claims." *AngioDynamics*, 979 F.3d at 1381. This Court held that "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." *Id.* at 1382. Bard argues that there is no material distinction

between the claims here and those in *AngioDynamics*. *See* AppBr2. Thus, there should be no dispute that the following limitations are printed matter:

- "the housing base including radiopaque alphanumeric characters that convey to a practitioner that the venous access port assembly is power injectable when an x-ray of the patient is taken after implantation[,]" (Appx114, Claim 1);
- "the at least one radiopaque identification feature including one or more alphanumeric characters identifying the access port as a power injectable port[,]" (Appx177, Claim 1); and
- "at least one structural feature of the access port identifying the access port as being power injectable[,]" (Appx221, Claim 8).

As the district court held, these "claim limitations . . . are printed matter not entitled to patentable weight." Appx21; *see* Appx18 (identifying "'radiopaque markings' ('302 Patent), 'radiopaque identification feature' ('022 Patent), and 'structural feature of the access port identifying the access port as being power injectable' ('615 Patent)" as the claim limitations in question). And since these limitations are printed matter, they cannot provide an inventive concept at step two of *Alice*. *See Guldenaar*, 911 F.3d at 1161-62.

Yet this printed matter is the only idea Bard has pointed to throughout its brief as its inventive concept. The district court thus correctly recognized that Bard is foreclosed from distinguishing its claims on this basis. *See* Appx20 ("[T]he claim limitations in question are directed to and claim the content of the information that a subcutaneously implanted port is suitable for power injection.").

The district court's printed matter decision should be affirmed.

CONCLUSION

This Court should affirm the district court's well-reasoned analysis that the claims are ineligible under Section 101.

March 25, 2022

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2022-1136, -1186

Short Case Caption: C.R. Bard, Inc. v. Medical Components, Inc.

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