Nos. 22-1136, 22-1186

In the 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.

Appeals from the United States District Court
for the District of Utah, No. 2:12-cv-00032-RJS.
The Honorable **Robert J. Shelby**, Judge Presiding.

BRIEF OF AMICUS CURIAE SMITHS MEDICAL ASD, INC. IN SUPPORT OF DEFENDANT-CROSS-APPELLANT AND AFFIRMANCE

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2022-1136, 22-1186

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

Filing Party/Entity Smiths Medical ASD, Inc.

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

Date: 03/25/2022

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Name: Jeffrey N. Costakos

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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.	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	☑ None/Not Applicable	☐ None/Not Applicable
Smiths Medical ASD, Inc.		Smiths Medical Group Ltd.
		Smiths Medical 2020 Ltd.
		ICU Medical Bidco Ltd
		ICU Medical, 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).

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C.R. Bard, Inc., et al. v. Medical Components, Inc., C.A. No. 2:17-cv-00754-HCN-DAO (D. Utah)	C.R. Bard, Inc. et al. v. Smiths Medical ASD, Inc., C.A. No. 20-1543-CFC (D. Del.)	C.R. Bard, Inc. et al. v. AngioDynamics, Inc., C.A. No. 20-1544-CFC (D. Del.)

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FORM 9. Certificate of Interest Additional Page

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Smiths Medical ASD, Inc. ("Smiths"), a corporation incorporated under the laws of the State of Delaware with a principal place of business located at 6000 Nathan Lane North, Plymouth, Minnesota 55442. Smiths has an interest in the appeal because Smiths is the Defendant in *C.R. Bard, Inc. et al. v. Smiths Medical ASD, Inc*., C.A. No. 20-1543-CFC (D. Del.), where claims 5-9 of U.S. Patent No. 7,785,302 and claims 1, 2, 6, 8, and 9 of U.S. Patent No. 7,947,022 have been asserted against Smiths.

[1] Pursuant to Federal Rule of Appellate Procedure 29(a), all parties have consented to the filing of this brief. This brief was not authored in whole or in part by a party or a party's counsel. No monetary contribution to the preparation or submission of this brief was made by any person or entity other than the amicus curiae or its counsel.

SUMMARY

The claims at issue in this appeal recite a prior art access port having a radiopaque alphanumeric label. The District Court properly found that these claims were not patent eligible because the focus of the patented advance was printed matter. The District Court also correctly found the claims patent ineligible because they failed the two-step *Alice* test.

The District Court's thorough and well-reasoned decision should be affirmed in its entirety. Chief Judge Shelby applied correct legal standards for the printed matter doctrine and invalidity under 35 U.S.C. § 101. This Court should affirm the District Court's grant of summary judgment for Defendant-Cross-Appellant Medical Components, Inc. ("MedComp") finding that claims 1, 3-8 and 10 of U.S. Patent No. 7,785,302 ("the '302 patent") and claims 1, 3, 5, 8-10, 12 and 14 of U.S. Patent No. 7,947,022 ("the '022 patent") are invalid.

ARGUMENT

The District Court's painstaking analysis of claims 1, 3-8 and 10 of the '302 patent and claims 1, 3, 5, 8-10, 12 and 14 of the '022 patent (collectively, "the asserted claims") cuts no corners. Rather, the District Court took all of the necessary steps to come to the correct conclusion that the asserted claims are subject to the printed matter doctrine and are invalid because they are directed to ineligible subject matter. Bard's disagreement with Judge Shelby's approach suggests Bard would

have Judge Shelby bypass the framework developed by this Court, but that would be error. Instead Judge Shelby applied the framework in its entirety to render his correct decision.

First, he analyzed whether the asserted claims were subject to the printed matter doctrine. Second, he applied the framework this Court set forth in *AngioDynamics* specific to the intersection of the printed matter doctrine and unpatentability under §101. *C R Bard Inc. v. AngioDynamics, Inc.*, 979 F.3d 1372, 1376 (Fed. Cir. 2020) ("*AngioDynamics*"). And third, Judge Shelby performed the two-step analysis under *Alice* to render his decision that the asserted claims are invalid.

While the District Court applied the *AngioDynamics* framework as appropriate, the District Court was not precluded from finding the asserted claims invalid in view of the *AngioDynamics* decision. Bard makes a conclusory declaration that *AngioDynamics* "controls," but that is not true. MedComp was not a party to *AngioDynamics* and the evidence and arguments in front of the District Court differed from those in *AngioDynamics*. *AngioDynamics* is distinguishable, as explained below. But even if it were not, it is not controlling here.

I. THE FINDING OF SUBJECT MATTER ELIGIBILITY IN *ANGIODYNAMICS* IS NOT CONTROLLING IN THIS CASE

Bard's lead argument on appeal is that "[t]his Court's *AngioDynamics* decision is controlling and indistinguishable." Bard's Opening Brief ("Bard Br.") at

23. That is not correct. While it is certainly true that the *legal holding* in *AngioDynamics* is controlling, that does not mean that the finding of subject matter eligibility is controlling. Although Bard does not really articulate a basis for its argument, it appears to conflate doctrines of preclusion and precedent to conclude that the finding of subject matter eligibility in *AngioDynamics* is somehow applicable to and binding on MedComp.

Of course, MedComp was not a party to the *AngioDynamics* case, so the decision is not binding under doctrines of issue or claim preclusion. *See In re Trans Tex. Holdings Corp.*, 498 F.3d 1290, 1297-8 (Fed. Cir. 2007) ("We have never applied issue preclusion against a non-party to the first action."); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 329 (1971); *see also Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 327 n.7 (1979) ("It is a violation of due process for a judgment to be binding on a litigant who was not a party or a privy and therefore has never had an opportunity to be heard.").

Nor is the *finding* of subject matter eligibility controlling under some other doctrine. While this Court has applied the doctrine of *stare decisis* to give weight to its prior claim constructions involving different parties, *see Ottah v. Fiat Chrysler*, 884 F.3d 1135, 1139-1140 (Fed. Cir. 2018), that rationale has not been applied to a patent eligibility ruling, particularly one involving different patents and different parties. This Court's finding that AngioDynamics had not proved patent ineligibility

on summary judgment in *AngioDynamics* should not be controlling in this case. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 n.3 (Fed. Cir. 1988) ("Accordingly, a court's decision upholding a patent's validity is not ordinarily binding on another challenge to the patent's validity, in either the courts or the PTO."); *Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 710 (Fed. Cir. 1983) ("We also add, as stated earlier, that the prior holding of validity is not necessarily inconsistent with the subsequent holding of invalidity. In one action, the defendants did not overcome the statutory presumption of validity; in the other they did. The difference in result could be attributable to many neutral facts: e.g., different prior art references or different records.").

This conclusion is particularly appropriate here. As Judge Shelby stated, the evidence and argument in front of him were not the same as those in front of the *AngioDynamics* court. Appx00028 n.138. Judge Shelby specifically noted that he examined a different record, including substantial evidence that radiopaque markers were routine and conventional. Indeed, Judge Shelby recognized Bard admitted in a related case that "Bard did not invent radiopaque markings on subcutaneous medical devices for identification by x-ray or other imaging." Appx00037.

The patents here are also different. In *AngioDynamics*, the claims included specific limitations that described flow rates and pressures present during power injection, for example, requiring that the implanted access port be "suitable for

flowing fluid at a rate of at least 1 milliliter per second through the access port and for accommodating a pressure within the cavity of at least 35 psi." *See AngioDynamics*, 979 F.3d at 1376. By contrast, none of the asserted claims set out limitations to specific flow rates or pressures such that the port is capable for power injection. Indeed, nowhere in the '302 or '022 patents is there any description of what a power injectable port is other than the circular description that it "may be injected and pressurized by mechanical assistance (e.g., a so-called power injectable port)," what pressures and flow rates it must be able to handle, or that the radiopaque alphanumeric message must describe the capabilities the port, other than indicating that the assembly is power injectable. Appx00110 at 1:42-47; Appx00114-00115 at 12:56-14:21; Appx00171 at 3:21-18; Appx00177 at 15:11-16:44. This difference in the claims is significant. Besides the fact that the specific requirements in terms of flow rate and pressure capacity for power injection are not adequately described in the '302 or '022 patent specifications, the lack of these claim limitations further demonstrates that the claims, taken as a whole, are only directed at the content of the radiopaque alphanumeric message, i.e. "the assembly is power injectable."

Additionally, as will be explained further herein, Judge Shelby examined an issue not considered in *AngioDynamics*, i.e. whether the claims were directed to the abstract idea of communicating information as considered in *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 909 (Fed. Cir. 2017). Indeed, the Federal

Circuit in *AngioDynamics* limited its review to the basis for the trial court's opinion—that those claims were ineligible as being "directed solely to non-functional printed matter." *See AngioDynamics*, 979 F.3d at 1383. And in reversing on this narrow legal question, the Federal Circuit did not examine other ways the claims could be ineligible, such as for claiming the abstract idea of "communicating information about the power injectability of the underlying port" via a well-understood "typical access port made up of conventional features" incorporating "a radiopaque identifier into the port for the purpose of conveying its suitability for power injection." Appx00032, Appx00037.

II. THE PRINTED MATTER DOCTRINE APPLIES

The District Court correctly recognized that the printed matter doctrine applied to the asserted claims. At bottom, the asserted claims simply recite a prior art device with a visible label. This is fundamentally indistinguishable from the labeled meat found patent ineligible in *In re McKee*, 64 F.2d 379, 380 (C.C.P.A. 1933), or the labeled prior art drug found patent ineligible in *AstraZeneca LP v. Apotex, Inc*., 633 F.3d 1042, 1064-65 (Fed. Cir. 2010).

Under Federal Circuit precedent, the printed matter doctrine applies where "a [patent] limitation claims (a) printed matter that (b) is not functionally or structurally related to the physical substrate holding the printed matter." *In re Distefano*, 808 F.3d 845, 848 (Fed. Cir. 2015). The District Court applied this two-step analysis and

found the printed matter doctrine applied to the asserted claims directed to a venous access port assembly having radiopaque alphanumeric characters, markings, messages or identification features that are observable under x-ray that convey, identify or indicate the port is power injectable. *See* Appx00018-00023.

A. The Claim Limitations in Question Are Directed to Printed Matter

The District Court performed a thorough analysis to determine whether the claim limitations in question were directed to the content of the information.[2] *Praxair Distrib., Inc. v. Mallinckrodt Hosp. Products IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018) ("A claim limitation is directed to printed matter if it is 'directed to the content of information.'"). In its analysis, the District Court evaluated the claim limitations "radiopaque markings" from the '302 patent and "radiopaque identification feature" from the '022 patent. Appx00018. Both were described as "identification feature[s]," "which are observable on X-ray following subcutaneous implantation, to convey to a medical practitioner that the access port is power injectable." *Id.*

Chief Judge Shelby determined, based on the language of the claims and Bard's statements that the identification features were "directed to and claim the

[2] The District Court noted, "because the parties had agreed that the asserted claims included printed matter, [this Court's] analysis at the first step was limited." Appx00016 (citing *AngioDynamics*, 979 F.3d at 1381).

content of the information that a subcutaneously implanted port is suitable for power injection." Appx00020. Thus, his finding that the identification features in question are printed matter because their "sole function is to convey the information that the port is power injectable" comports with this Court's holdings. *E.g.*, *AstraZeneca LP*, 633 F.3d at 1064-65; *Praxair*, 890 F.3d at 1032.

B. The Claimed Markings Do Not Have a Functional Relation to the Substrate

Having established that the claims are directed to printed matter, the District Court's inquiry turned to whether the printed matter has a functional or structural relationship to the substrate. *Distefano*, 808 F.3d at 851. This prong examines "whether the printed matter merely informs people of the claimed invention, or whether it instead interacts with the other elements of the claim to create a new functionality in a claimed device or to cause a specific action in a claimed process." *AngioDynamics*, 979 F.3d at 1381. "Where the printed matter is not functionally related to the substrate" it "will not distinguish the invention from the prior art." *See In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983).

There was no real controversy that the information conveyed by the claimed markers did not provide new functionality to the port, nor did Bard argue any such functional relationship. Appx00020; *see also AngioDynamics*, 979 F.3d at 1382 ("A conclusion that mere identification of a device's own functionality is sufficient to constitute new functionality for purposes of the printed matter doctrine would

eviscerate our established case law that 'simply adding new instructions to a known product' does not create a functional relationship.").

Judge Shelby's finding that the identification features are not entitled to patentable weight because "the printed matter does not change how the port works once it is implanted, it does not affect whether the port is capable of power injection, and it does not interrelate with the port to produce a new and useful product" also comports with this Court's holdings. Appx00021 ("the printed matter in no way depends on the [port], and the [port] does not depend on the printed matter. All that the printed matter does is [add a subcutaneous identified to] an existing product." quoting *In re Ngai,* 367 F.3d 1336, 1339 (Fed. Cir. 2004)); *AngioDynamics,* 979 F.3d at 1382 ("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.").

III. THE DISTRICT COURT PROPERLY APPLIED THE *ANGIODYNAMICS* FRAMEWORK

The District Court properly applied the framework this Court articulated in *AngioDynamics* "that a claim may be found patent ineligible under §101 on the grounds that it is directed to solely non-functional printed matter and the claim contains no additional inventive concept." *AngioDynamics*, 979 F.3d 1383.

A. The Asserted Claims Are Solely Directed Toward Alphanumeric Radiopaque Markings

As set forth in *AngioDynamics*, Judge Shelby began the analysis examining whether the asserted claims were "[1] directed solely to non-functional printed matter." Appx00025 (quoting *AngioDynamics*, 979 F.3d at 1383). Judge Shelby correctly concluded that the asserted claims are "directed solely to non-functional printed matter" or in other words, that the "sole feature of alleged novelty" was directed to alphanumeric radiopaque markings indicating that a port is power injectable. Appx00025-00027. Claim 8 of the '302 patent is representative of how the printed matter is the sole feature of the alleged novelty:

> 8. A venous access port assembly for implantation into a patient, comprising:
>
> a housing and a needle-penetrable septum together defining a reservoir, and,
>
> the housing including an outlet and a radiopaque alphanumeric message observable through interaction with X-rays subsequent to subcutaneous implantation of the assembly into the patient, the radiopaque alphanumeric message identifying the venous access port assembly as suitable for power injection.

Appx00115 at 14:1-10. The specification adds context to the focus of the asserted claims. The specification makes clear that the described conventional port structure was a "typical" construction, and explains that "once an access port is implanted, it may be difficult to determine the model, style, or design of the access port." Appx00025-00026, Appx00109 at 1:20-24, 48-57, Appx00170 at 1:24-28, 52-61.

From this, Judge Shelby correctly determined that "[i]t is clear from this language that the sole motivation of the patents at issue is providing some type of identifiable feature that communicates information about the underlying access port," and ultimately, "the core of each of the asserted claims at issue here is the basic idea of using a specific type of identifier to convey information that a port is capable of power injection." Appx00026-00027. There is no other claimed novelty or improvement over the prior art other than the radiopaque identifier, i.e. the printed matter. Thus, the claims are directed solely to non-functional printed matter because the "sole feature of alleged novelty" is the alphanumeric radiopaque identifier indicating the port as capable of power injection.

The *AngioDynamics* decision cannot be read, as Bard suggests and Judge Shelby rejected, to imply that claims "directed ***solely*** to non-functional printed matter" must ***only*** contain printed matter with no other claim elements or limitations whatsoever, even if the only other elements were well-understood, routine, and conventional. *See* Bard Br. at 19-20. Indeed, claims that have been deemed unpatentable under the printed matter doctrine in other cases before the Federal Circuit have specifically contained elements or limitations that were not *solely* directed to printed matter, but nonetheless were still patent ineligible because the remaining elements were well-understood, routine, and conventional. For example,

claims have been invalidated that included not just printed matter, but also a physical composition:

> 29. A kit for treating respiratory diseases, the kit comprising (a) a budesonide composition in a sealed container, the composition containing 0.05 mg to 15 mg budesonide and a solvent, and (b) a label indicating administration by nebulization in a continuing regimen at a frequency of not more than once per day.

AstraZeneca LP, 633 F.3d at 1048 (affirming the district court's holding that "the kit claims are invalid, ***finding the claimed budesonide composition and suspension were known in the prior art*** and that the instructions in the claimed label are non-statutory subject matter and therefore not entitled to patentable weight."); *see also In re Ngai,* 367 F.3d 1336, 1337-38 (Fed. Cir. 2004). Likewise, in *McKee*, this Court's predecessor found "the marking of meat for [the purpose of identification] does not come within the purview of the patent statute." *McKee*, 64 F.2d at 379. As here, the claim did not solely recite printed matter—it also recited the substrate, the cut of meat. But the court still found the claim patent ineligible. Nor is *AngioDynamics* inconsistent with these holdings. *See AngioDynamics*, 979 F.3d at 1381-2 (citing *AstraZeneca*, 633 F.3d at 1065). Indeed, it is difficult to conceive of an example of claim language that would literally be directed ***solely*** to printed matter without any other limitations whatsoever.

Moreover, MedComp correctly identifies that "directed solely to non-functional printed matter" must be read in context of the printed matter cases that

came before and were relied on by *AngioDynamics*, and is more properly described as "the sole feature of the alleged novelty" is directed to printed matter. *See* MedComp Response Brief ("MedComp Br.") at 38-39; *see AngioDynamics*, 979 F.3d at 1383 (quoting *In re McKee*, 75 F.2d 991, 992 (C.C.P.A. 1935)) ("where the printed matter, irrespective of the material upon which it is printed, ***is the sole feature of alleged novelty***, it does not come within the purview of the statute, as it is merely an abstract idea, and, as such, not patentable.") (emphasis added). This language makes clear that the claims can contain other limitations, but the sole feature of the alleged novelty must be directed to the printed matter.

The prosecution history of the patents-in-suit further demonstrates that the sole focus of Bard's invention was the radiopaque alphanumeric markings. For example, the claims of the '302 patent were allowed over the Inamed Health BioEnterics© LAP-BAND® "Adjustable Gastric Banding System" ("LAP-BAND") only after the claims were amended to recite an alphanumeric feature that identified the port as specifically power injectable. Appx01042, Appx01098-01104. The Examiner cited the LAP-BAND as having all the features of the claimed port, including "a radiopaque feature (a single dot) that conveys information indicative of an attribute of the assembly when an X-ray of the patient is taken after implantation so that a practitioner can be advised after implantation by the information indicative of an attribute of the assembly (to distinguish it from other ports. . .)." Appx01042.

The Examiner also stated that "[i]t would be well within the level of ordinary skill to use an alphanumeric message in the place of the single dot, to convey a different message or to distinguish a different port differently." Appx01044. The inventor's claimed advance did not reside in the claimed use of a radiographic marker nor in the port's structural characteristics or functional capability. Rather, the claimed advance lay in the use of the alphanumeric marking to convey the identity of the port as power injectable.

Following the Examiner's rejection, an interview occurred after which the Applicant amended the claims "to include the alphanumeric radiopaque feature, as well as further describing the port and the attribute as being power injectable." *See* Appx01059. The claims were allowed based on the addition of this printed matter, i.e., "because the prior art of record fails to disclose either singly or in combination the claimed device of an implantable access port that has a radiopaque alphanumeric message to indicate that this port is specifically power injectable." Appx01102. The record is indisputable, therefore, that the "focus of the claimed advance over the prior art," *AngioDynamics*, 979 F.3d at 1382, was the use of radiopaque alphanumeric features.

It makes no difference that the alphanumeric features are "radiopaque." That is no different from a claim reciting that the printed matter be "visible" or "capable of detection." In an implanted device, the only way to see printed matter is to make

it visible under x-ray. Just as claims directed to printed matter would not become patent eligible by specifying that the printed matter is machine readable as a barcode or QR code—*Secured Mail*, 873 F.3d at 909—so too a claim directed to printed matter does not become patent eligible by reciting that the printed matter is visible under x-ray. The District Court thus properly held that the asserted claims are directed solely to non-functional printed matter.

B. When Printed Matter Is Removed, the Asserted Claims Recite Routine and Conventional Elements

Having determined that the claims were solely directed to non-functional printed matter, Judge Shelby assessed whether "[2] the claim contains no additional inventive concept." Appx00025. Based on the substantial record, Judge Shelby correctly determined that the asserted claims do not contain any inventive concept insofar as they are directed to the use of (1) radiographic markers, (2) on known medical devices, (3) that are visible on X-ray, or (4) that are alphanumeric characters. These elements were well-known, routine, and conventional.

Moreover, Judge Shelby properly rejected Bard's argument that its patent claims are directed to the power injectability of the port. Appx00027 ("Bard's argument 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. The court will not countenance this argument."). Indeed, the Federal Circuit acknowledged that "[a]s of 2005, vascular

access ports were not specifically approved by the FDA for use with power injection" however, "certain medical providers were using existing ports for power injection. . . ." *See AngioDynamics*, 979 F.3d at 1375. Moreover, the use of the alphanumeric radiographic markings in the "ordered combination" of claimed elements was not an inventive concept. *See AngioDynamics*, 979 F.3d at 1382. Whether considered individually or ordered, after the printed matter is set aside, all that exists is an identification of a well-known port assembly and a conventional alphanumeric radiopaque marking applied to that assembly.

The prosecution history likewise shows the lack of an inventive concept, and Judge Shelby correctly determined that Bard's use of this radiopaque marking was not inventive. Indeed, in an interference that Bard provoked during prosecution of the '302 patent, Bard and Bard's expert, Kenneth Eliasen, acknowledged that:

(a) U.S. Patent No. 6,287,293 to Jones filed September 28, 1999 disclosed a radiopaque marking on the surface of the housing of a venous access port (Appx01007-01008);

(b) U.S. Patent No. 5,203,777 to Lee filed March 19, 1992 "is directed to a radiopaque marking system for a device meant to be inserted into a human body and imaged under an X-ray source" and that "[t]he marking system can be used to ascertain the radial orientation for the device" (Appx01009); and

(c) U.S. Patent No. 4,863,470 to Carter filed September 24, 1987 "teaches incorporating a radiopaque identification marker including alphanumeric characters into a prosthesis." Appx01015-01016.

See also Appx01002-01018. These statements from the intrinsic record demonstrate that alphanumeric radiopaque markings were routinely used to identify characteristics of medical devices.

IV. THE DISTRICT COURT PROPERLY APPLIED *ALICE* AND FOUND THE ASSERTED CLAIMS INVALID

Separate from what Judge Shelby referred to as the *AngioDynamics* framework, the District Court also analyzed the claims under the standard two-step *Alice* framework and correctly found the asserted claims were invalid.

A. Judge Shelby Was Correct—the Asserted Claims Are Directed to the Abstract Idea of Communicating Information under *Alice* Step One

Judge Shelby correctly identified that the asserted claims are directed to abstract idea of communicating information, specifically holding:

> Because each asserted claim at issue here requires the use of an identifier ***to communicate information about the power injectability of the underlying port*** and provides no functional improvement to the port itself or the X-ray technology used to view the radiopaque identifiers, the court finds the claims are directed to an abstract idea.

Appx00032 (emphasis added). In reaching this conclusion, Judge Shelby analogized the claims before him to those from this Court's 2017 decision in *Secured Mail*, 873

F.3d at 909. There, "[a]ll the patents involve[d] methods whereby a sender affixes an identifier [an Intelligent Mail Barcode, a QR code, or a Personalized URL] on the outer surface of a mail object (e.g. envelope or package) before the mail object is sent. *Id*. at 907; Appx00030. Because the claims were "not directed to a new barcode format, an improved method of generating or scanning barcodes, or similar improvements in computer functionality" and were likewise "not directed to specific details of the barcode or the equipment for generating and processing it," the Federal Circuit concluded that "the claims embrace the abstract idea of using a marking affixed to the outside of a mail object to communicate information about the mail object, i.e., the sender, recipient, and contents of the mail object." *Secured Mail*, 873 F.3d at 910-11.

The asserted claims are directed to the same abstract idea, namely "an identification feature that is incorporated into the underlying access port, which then communicates information about the port's capability to withstand power injection." Appx00031. A barcode affixed to mail communicating information about that mail is an abstract idea, even though the barcode itself is a technology that increases the efficiency of the process. *Secured Mail*, 873 F.3d at 910 ("The fact that an identifier can be used to make a process more efficient, however, does not necessarily render an abstract idea less abstract."). Applying the same reasoning to the asserted claims, a radiopaque alphanumeric message that simply communicates information about

the port it is affixed to is equally abstract. This is true, even if the radiopaque alphanumeric message makes injecting into the power-injectable port more efficient, for example, by allowing a medical practitioner to identify a port as power injectable after implantation without having to perform an operation to physically verify the port is power injectable or otherwise take time to look into the patient's medical records to see if the implanted port is power-injectable. Thus, even though the radiopaque alphanumeric message identifier might make the process of verifying the power injectability of the port more efficient, that alone does not "render the abstract idea less abstract." *Id*.

Judge Shelby correctly analogized to *Secured Mail* in stating that the asserted claims are not directed to an improvement in port technology, nor to improvements in x-ray technology or improvements to visibility of radiopaque markers, nor even describe in detail the x-ray technology used or how the radiopaque identifiers are generated. Appx00030-00032. These are the exact same issues identified in *Secured Mail* that led the Federal Circuit to conclude it is an abstract idea to use "a marking affixed to the outside of a mail object to communicate information about the mail object, i.e., the sender, recipient, and contents of the mail object." *Secured Mail*, 873 F.3d at 911. The analogy is strikingly apt in that the markings in *Secured Mail* could help identify otherwise imperceptible information, such as the contents of the mail *inside of its packaging*, by using a reception device capable of scanning the message

and retrieving information. *Id*. at 908-911. This is directly analogous to the alphanumeric radiopaque markings in the asserted claims that can likewise identify otherwise imperceptible information, such as whether a port is power injectable *underneath a patient's skin*, by using an x-ray scanning device capable of scanning the port and displaying alphanumeric information. *See id*. Indeed, the abstract idea from *Secured Mail* can be rewritten to directly read on the claims of the '302 and '022 patents as follows, "a marking affixed to the outside of a [port assembly] to communicate information about the [port assembly], i.e., [that it is power injectable]." *Id*. (notations added). Judge Shelby correctly concluded that the claims of the '302 and '022 patents are directed to the abstract idea of communicating information, applying this Court's reasoning in *Secured Mail*.

B. Judge Shelby Was Correct—the Asserted Claims Do Not Contain an Inventive Concept under *Alice* Step Two

As described above, the claims just recite routine and conventional aspects including (1) radiographic markers, (2) on medical devices, (3) that are visible on X-ray, or (4) that are alphanumeric characters. Whether considered alone, or in an ordered combination, the claimed elements of the patents-in-suit do not recite any additional inventive concept under step two of *Alice*. The record before Judge Shelby demonstrates that these steps were routine and conventional.

The "inventive concept" analysis examines "whether the claim limitations ***other than the invention's use of the ineligible concept*** to which it was directed

were well-understood, routine, and conventional." *BSG Tech LLC v. Buyseasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018) (emphasis added). In other words, "we examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed ineligible subject matter into a patent-eligible application." *AngioDynamics*, 979 F.3d at 1382. Once the printed matter—alphanumeric markings conveying the port is power injectable—is set aside, all that remains are well-known features of venous access ports and the routine and conventional use of radiographic markers to convey information about the device. There is nothing about these elements individually, or in an ordered combination, that constitute an inventive concept under *Alice*. Appx00032-00040.

Judge Shelby correctly determined that the asserted claims do not contain an inventive concept under *Alice* step two. Because the specification for the '302 and '022 patents describe how an identifiable feature may be observed via x-ray imaging indicating that the port is power injectable, Judge Shelby analyzed the claims "more microscopically to determine whether they capture the stated improvements." Appx00033-00034 (citing *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016); *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018)). No parties dispute that the "alleged improvements to port identification are captured" in the claims, but rather the dispute revolves around whether the use of

radiopaque identifiers on implanted medical devices was well-understood, routine, and conventional. Appx00034.

The record presented to Judge Shelby included substantial evidence that using radiopaque identifiers on implanted medical devices was well-understood, routine, and conventional. This included evidence from Bard's own representations and products, including a Bard engineer stating "that placement of a radiopaque marking on the surface of a port 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'" and Bard's self-expanding nitinol biliary stent implantable product which "included radiopaque marker technology to allow for better visualization following placement of the stent within a patient." Appx00034-00035. The record also included articles from medical journals discussing the wide use of radiographic markers on implanted medical devices for years before Bard's patents. *Id*.

Bard failed to contravene this substantial record, or make any representations that radiopaque markers on implanted medical devices were not well-known and routine. *See also* MedComp Br. At 32-33. And Judge Shelby specifically identified that the substantial record before him was not the same record that was before the *AngioDynamics* court. Appx00036 ("this court does not have before it the same record *AngioDynamics* []. The evidence and arguments submitted here by MedComp are considerably different."). Judge Shelby correctly applied the law, and based on

the substantial record presented to him, properly concluded "the use of a radiopaque identifier to convey information is not an inventive concept" both individually and as an ordered combination "that transforms the claims into a patent-eligible application." Appx00037.

CONCLUSION

For the foregoing reasons, this Court should affirm the District Court's grant of summary judgment for Defendant-Cross-Appellant Medical Components, Inc. that claims 1, 3-8 and 10 of U.S. Patent No. 7,785,302, claims 1, 3, 5, 8-10, 12 and 14 of U.S. Patent No. 7,947,022 are invalid under 35 U.S.C. § 101.

Dated: March 25, 2022

Respectfully submitted,

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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, 2022-1186

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

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